CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 6 **CX/FH 19/51/6-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD HYGIENE

Fifty-first Session

Cleveland, Ohio, United States of America, 4 - 8 November 2019

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

Comments at Step 3 in reply to CL 2019/70 -FH

Comments of Argentina, Brazil, Canada, Chile, Colombia, Egypt, Gambia, Guatemala, Honduras, India, Iraq, Japan, Morocco, New Zealand, Nicaragua, Peru, Thailand, Uruguay, the United States of America, Collagen Casings Trade Association (CCTA), FoodDrinkEurope, International Accreditation Forum (IAF), International Dairy Federation (IDF/FIL) and International Organization for Standardization (ISO)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2019/70-FH issued in August 2019. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as **Annex I** and are presented in table format.

ANNEX I

GENERAL COMMENT	MEMBER/OBSERVER
1. Translation: throughout the entire document, the following words should be replaced: • **guarantee** should be replaced with **contribute** when referring to the Health Authority, or **ensure**, as the case may be. • **vigilar** by **monitorear** [in Spanish - Translator's note: the second suggested replacement does not affect the English.] 2. We support the redrafting of paragraph 4 as it has the same approach for FBOs that do not have enough experience to conduct a hazard analysis, that they may use external sources to determine if the GHPs are sufficient for addressing food safety. 3. We support adopting the definition of Hazard as shown in the Procedural Manual, which includes the condition of the food as a hazard to be considered. 4. We accept the redrafting of paragraph 121 regarding WATER, taking into account that if the new work on Water is accepted, its content should be simpler. ***5.*** We propose reordering the paragraphs and sections to improve the flow and readability as follows: put ***Definitions*** before ***General Principles*** following ***Introduction and food hazard control,*** the sections ***Skills and training***, and ***Personal Hygiene.*** We suggest putting the ***Transport*** section before***Product information and consumer awareness.*** 6. We agree with incorporating Diagrams 1, 2, 3 and 4 as they are clear and useful.	**Argentina**
General comment (para. 7 of the summary of discussions): Canada agrees with the clarification proposed by the co-chairs. General comment (para. 9 of the summary of discussions): Canada has no specific preference (keep or delete) the proposed definitions. General comment (para. 13 of the summary of discussions): Canada would support the proposal of the co-chairs and the EWG to re-order the sections in Chapter 1 as proposed. Alternatively if consensus cannot be reached on the new order, we would support the current order of the document but with the definitions before the general principles. General comment (para. 14 of the summary of discussions): Canada would support keeping “allergen specifications” in the title of section 7.2.3. Recognizing that this is still under study by FAO/WHO, however, some FBOs may already be using specifications for allergens (e.g., absence of a specific allergen) and therefore CCFH could keep the concept of allergen specifications while the work continues.	**Canada**
Egypt appreciates the work done by the eWG, with the following comments: 1- in section 2.2; kindly clarify the meaning flexibility, with examples for permissible ranges to be implemented. 2- in section 3.11; replace the statement with "Establish verification procedures"	**Egypt**
we are agree with PROPOSED DRAFT REVISION of the CXC 1-1969.	**Iraq**
1. Morocco thanks the Chair and the Co-Chairs for overseeing the revision of CXC 1-1969. Morocco supports the reorganization of the draft into two chapters 1 (GHPs) and 2 (HACCP) and appreciates the efforts made to clarify, in the document, that the application of GHPs alone can be sufficient for producing safe food without needing to apply HACCP, and the adoption of the principle of flexibility for small businesses. 2. On the other hand, Morocco is concerned by the adoption of certain steps of the HACCP system during the application of GHPs (product description, process description, monitoring, verification). 3. Morocco proposes to provide more details about the practical arrangements to decide that a GHP requires more attention.	**Morocco**
New Zealand would like to thank The United Kingdom, and Co-Chairs France, Ghana, India, Mexico and the United States of America along with the electronic Working Group for the progression that this document has made. This is a very important revision of the General Principles of Food Hygiene and its HACCP Annex and plays a major part in underpinning food hygiene and food safety worldwide, including trade negotiations. New Zealand would like to submit the following comments to assist further agreement on this document: General comments: Overall this document is progressing well towards finalisation. However further consideration should be given to ensuring clarification as to	**New Zealand**

whether the HACCP plan is intended to cover application of the HACCP principles when no CCP is determined as well as where one or more CCPs are determined. At present it reads as though the HACCP plan is only for where there are 1 or more CCPs addressing the significant hazards identified. The easiest solution is that the HACCP plan covers both scenarios, i.e. amend the definition of HACCP plan to include where significant hazards (if any are present), are addressed. That would enable a hazard analysis and CCP determination to also be part of the HACCP plan without any significant hazards and resultant CCP(s) being identified. The HACCP system also would then apply to both scenarios, and would undergo review periodically to check whether changes are needed within the HACCP Plan. New Zealand would like to see validation not only covered under Principle 3 in association with Critical Limits but also elaborated further in a new section after current Section 3.12 entitled 3.13 Initial Implementation. This would then cover off validation of measureable entities other than process parameters associated with critical limits, such as any relevant performance criteria and/or final product criteria for the hazard/food combination. Specific comments on the draft text presented Paragraph Comment Rationale Definitions Contaminant The Contaminant definition in GPFH is not consistent with General Standard for Contaminants and Toxins in Food and Feed CODEX STAN 193-1995 and Codex Alimentarius Commission Procedural Manual. Definitions Controll Controll Spelling error Definitions Good Hygienic Practices (GHPs) Fundamental measures and conditions applied at any step within the food chain specifically for the production, manufacturing, preparation, retail and food service operation of that ensure safe and suitable food. The steps within the food chain are not needed. Definitions HACCP plan Documentation or set of documents prepared in accordance with the principles of HACCP to ensure control of significant hazards, if any, in the food business Expand to allow for both 1) hazard analysis with no significant hazards identified and therefore no CCPs as well as 2) where significant hazards are identified and CCPs are determined. Primary Production Para 25 Production programmes such as “quality assurance programmes”…… NZ would like to see Quality Assurance programmes also mentioned elsewhere, as referred to, in the Summary of Discussion para 19. Could the Co-chairs please clarify why it was decided not to widen the scope of application of Quality Assurance programmes to the food chain as a whole and as appropriate, and include within the Introduction of the Document? Para 34 The surfaces of walls, partitions and floors should be made of impervious materials that are resistant to cracking, pitting, easy to clean and, where necessary, disinfect; Recommendation to expand on ‘impervious’ to comment also on durability. Para 48 Adequate and, where necessary, separate facilities for the safe and hygienic storage of food products including suspect or non-conforming product, food ingredients, food packaging materials and non-food chemicals (including cleaning materials, lubricants, fuels), should be provided. Storage should allow for segregation for the manufacturing of raw and cooked foods or allergenic and non-allergenic food Add “suspect or non-conforming product” to ensure consistency with the later sections of the document. Need to be able to hold removed or returned product Para 49 Bullet 3. • enable food to be effectively protected from contamination and including allergen cross-contact during storage, Alter to be	

clear that allergen cross contact is a type of contamination rather than something different. Para 51 another sentence to be added at end Any methods of identification for containers (or contents of the containers) should not introduce a source of contamination and identification should be removed and refreshed as appropriate. In process containers are often labelled during process e.g. in batching, or during the process. Methods to identify these in process ingredients often involve labelling in some form. Multiple labels can cause confusion and certain labelling practices can potentially introduce hazards. Para 53 Add new last sentence Where appropriate, monitoring equipment should be calibrated to ensure that temperatures of food processes are accurate. Such calibrations should be regularly checked and maintained with appropriate records kept. To ensure that the calibrated equipment is checked and maintained as required Para 66 Separate cleaning equipment and utensils, suitably designated should be used for different hygiene zone, e.g. food and non-food contact surfaces, and where separation of equipment required, e.g. handling allergens Clarify advice separate cleaning equipment and utensils when handling allergens Para 72 New 2nd bullet •the cleaning equipment to be used; The procedure should include what equipment should be used Para 79 Where necessary, experts should be consulted for advice on appropriate landscaping plants for use if needed. Delete this sentence as planting near to processing areas attracts pests. Para 97 last bullet Food packaging material used and any packaging standards met Useful information for product description Para 101 Properly disposing of affected product that is not acceptable to market, with confirmation and evidence of disposal Evidence of proper disposal to confirm action Para 113 Raw, unprocessed food, where not considered ready-to-eat and which could be a source of contamination, should be separated from ready-to-eat foods, either physically or by time…… Raw un processed food may also be considered ready-to-eat. Para 115 For example, where the likelihood of product contamination is high, access to processing areas should be via a properly designed from a changing facility designed to minimise contamination from external factors, e.g. with hand washing/sanitiser, boot wash, red line procedures as appropriate Explain what is meant by properly designed changing facility Para 125 last sentence The General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) applies particularly for food service and consumers. The reference is limited in its application to food service and consumers Para 127 last sentence Information for FBOs should be clearly distinguishable from consumer information, particularly on food labels. The General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) applies The General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) particularly applies here and should be referenced here Chapter TWO Para 135 Last sentence In addition, the application of HACCP systems can aid review inspection by competent authorities and promote…. This activity is most often a review by competent authorities rather than an inspection Para 138 Last sentence HACCP application will not be effective without prior implementation of prerequisite programmes including GHPs Delete as covered in first sentence of this paragraph Para 140 Second sentence The intent of the HACCP system is to focus control at Critical Control Points (CCPs), if any. By adding “if any” into this sentence it also allows coverage of hazard analysis where no CCPs have been identified. Para 150	

First sentence …the description may be influenced by external information, e.g. from the competent authority, on should also include ways in which consumers are known to use the product other than those intended by the FBO Competent authorities could collect this sort of information and provide feedback to the FBO. Otherwise, it seems impractical to expect FBOs to know this outside their business. Para 153 Fourth sentence Hazards should be specific, e.g. ….. It would be more helpful to have an example of specificity for each category of hazard, i.e. biological, chemical as well as physical. Lack of specificity for biological and chemical hazards is often seen. Para 155 3rd bullet point The likelihood and severity of adverse health effects associated with the hazards in the food in the absence of control9, typo Para 155 7th bullet point The intended use and/or probability of product mishandling by potential consumers ….. Point of clarification: What are the boundaries around this as it sits outside the FBO responsibilities? Isn't this information more likely to come through to a particular food sector from the competent authority where a known problem exists? Para 156 Unintended use and the difficulties in finding this information out. See also Para 155 above Para 158 Last sentence In other instances, specific control measures will need to be applied Control measures are specific for CCPs Para 159 Last sentence 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; while such a heat treatment can also control both Salmonella and E. coli O157:H7 that present a hazard in raw meat when they are also present as hazards in the food. More accurate wording to reflect the food that is being mentioned and also S and E don't present a hazard; rather they could also be hazards in this food. Delete "raw meat". Para 161 Second bullet Determine whether a control measure at a step is used in combination with a control measure at another step to control the same hazard to an acceptable level; if so, both steps should be considered as CCPs. Include "to an acceptable level" as this is the primary reason that a CCP (s) exists. Para 164 Second to last sentence …… such as a pump setting or application of the correct label with appropriate allergen information Delete as this is not a critical limit. It does not change the status of the hazard at all and would be considered GHP for allergen management Para 165 Critical limits for control measures at each CCP should be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level of properly implemented10. Typo Para 168 4th Sentence Critical limits that are observable, such as a pump setting or applying the correct label with appropriate allergen information are rarely monitored continuously. Delete as this is not a critical limit. It does not change the status of the hazard at all and would be considered GHP for allergen management New section (before current 3.13): Initial implementation Suggested wording to start discussion: Initial implementation of the HACCP plan by the FBO may mean that other measureable criteria need validation besides the Critical Limits to ensure that the final food product meets all specifications. This would particularly apply when performance criteria (e.g. log reduction of a pathogen) and/or final product criteria (e.g. 100cfu L. monocytogenes in RTE food that does not support growth in the final product), are required to be met for the food in its final form. Validation is further described in the Guidelines for the Validation of Food Safety Control	

Measures (CXG 69 – 2008). New Zealand suggests that this would meet further expectations for validation within a HACCP plan. Besides validating the critical limits (already covered), there may be performance criteria (e.g. log reduction of a pathogen) and/or final product criteria to be validated (e.g. 100cfu L. monocytogenes in ready-to eat-food that does not support growth in the final product), both separate validations to that done for process parameters (CLs) at CCPs. Annex 1 Title: Comparison of GHP and CCP control measures GHPs and control measures at CCPs Amend title and first column to reflect control measures for both GHP and CCPs as they both have control measures, e.g. preventative control measures particularly for GHP Diagram 2 New Question 3: Is the identified hazard significant in this product at this step? Does this potential hazard need to be addressed in the HACCP plan? Proposed new question is clearer about why the hazard needs to be addressed and therefore is more useful to the user. This new question also merges nicely into Q5 which is also about the significant hazard being reduced to an acceptable level.	
Nicaragua thanks the eWG for the development of this document.	**Nicaragua**
1. Requirements in all Sections of Chapter One may not be feasible for all types of food business operators. For example, the primary producer with limited resources may only be able to follow the requirements in Section 2 Primary Production. In some cases, following Section 2 may be enough to provide safety and suitability to consumers. For the other sections, e.g. Sections 7.1.1 Product description 7.1.2 Process description, and 7.1.3 Consideration of the effectiveness of GHPs, the primary producers might not be able to do so since the detail is more complex as they are part of HACCP system. Also, the requirements in Sections 3, 4, 5 and 6 are more appropriate for the food business operators at downstream of the supply chain such as packing house, food manufacturer, etc. Thus, the requirement for primary producer should only focus on Section 2 Primary Production. 2. Also, the issues which were widely discussed and agreed upon in CCFH49 and CCFH50 should not be reopened unless it is really necessary to do so. To reopen the previously discussed issues will delay the progress of the Drafting process.	**Thailand**
We have noticed on many occasions the word “should” in English is translated as “debe” and not as “debería.” We suggest adding that what applies “must be based on scientific evidence, when appropriate.”	**Uruguay**
The United States was one of several co-chairs for the development of this document. We appreciate all the input received from the other co-chairs and the working group members. We hope that this document can be finalized at CCFH51. We continue to support the need to pay additional attention to some GHPs because of their impact on food safety and think this is an important aspect in updating the General Principles of Food Hygiene. The document does not specify when a GHP requires additional attention, thus providing the needed flexibility for food business operators, given the diversity of food businesses for which these GHPs are applicable. There continues to be concern about text that would indicate all food businesses need to conduct a hazard analysis. We concur with the approach agreed to by CCFH that all FBOs need to “be aware” of the hazards associated with their operation and controls for these hazards that are applicable to their business, as noted in paragraph 4. The EWG has tried to explain that FBOs that are not able to conduct a hazard analysis can become aware of hazards and can control them by following appropriate food safety practices in information from competent authorities, academia, trade associations, etc., since these food safety practices are based on knowledge of hazards and their control. The discussion of validation in this document is limited to validation of critical limits. We agree that validation of critical limits is key to a successful HACCP plan. We have previously stated, however, that we do not support removing validation from Principle 6. The validity of HACCP plans also involves identifying the correct hazards and control measures, determining the appropriate frequency of monitoring, and determining that the HACCP plan overall is scientifically and technically sound, which go beyond validation of critical limits. Periodic comprehensive review of the HACCP system is needed to confirm that the HACCP plan and its implementation are still valid. This is captured in paragraph 180 as part of verification. We see this comprehensive review as “obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome” – the definition of validation. We believe that validation also includes obtaining evidence in operation during the initial implementation of the HACCP system to show that control can be achieved consistently under production conditions. This is captured in paragraph 176 as part of verification. Thus, it seems likely that there is agreement on the activities needed for verification and validation, but there are differences in whether people consider an activity to be verification or validation. We look forward to the discussions on this at CCFH51.	**USA**
Overall, the IAF Working Group on Food considers this most recent draft a significant improvement. The EWG and the co-chairs should be	**IAF**

congratulated. We appreciate the opportunity to comment on the current draft.	
On behalf of ISO TC 34 Sc 17 AG 3: Many thanks to the CCFH working group. We appreciate the current document as a major step forward. Although we have got quite a number of comments, we trust they will be welcomed as a contribution to the further improvement of the document. We are looking forward to a fruitful meeting in Cleveland in November. 1st ISO comment to the "summary of discussion" 9. Over the two drafts, the definitions have been refined by the EWG, including proposals to delete definitions for 'acceptable level', 'competent authority' and 'Food Business Operator', but input from CCFH is requested on whether these terms should be deleted. ISO comment: ISO supports the definitions to be included. 2nd ISO comment to the "summary of discussion" 15. During CCFH50, there was lengthy discussion about whether 'validated' should be added to Principle 3 and removed from Principle 6. The consensus was that it should be retained in Principle 6. The Co-chairs discussed this point again following further comments received via the EWG and agreed with the rationale that critical limits could not be set until they had been validated, and that therefore it was logical to include 'validated' within Principle 3. 'Validated' should be removed from Principle 6 as this principle focusses on the verification process, although it is acknowledged that some countries consider validation is part of verification in step 11. The EWG supports further discussion on this topic at the PWG prior to CCFH51 to reach a consensus. ISO comment 2: Validation should be included in principle 1, 2 or 3. Since validation refers to the capability of control measures and critical limits can only be established once validation is completed. Validation is addressed inconsistently throughout the document as follows: Para. 165. Validation of critical limits Para. 175. Validation of control measures Para. 176: Validation based on collection of data during operating conditions Para. 182: Validation of critical limits Annex 1: Validation of control measures Consequently, we support: Chapter One - General Principles (v) on page 6: Control measures that are essential to achieve an acceptable level of food safety, should be scientifically validated.	**ISO**

SPECIFIC COMMENTS	**MEMBER / OBSERVER AND RATIONALE**
PROPOSED DRAFT REVISION OF THE GENERAL PRINCIPLES OF FOOD HYGIENE(CXC 1-1969)	
INTRODUCTION	
INTRODUCTION	**FoodDrinkEurope** We would like to thank the eWG for the significant improvement made to the draft. The structure of the document is not very clear and could be improved. We suggest adding a table of contents, putting page breaks before new sections and changing font/style of headlines to facilitate reading
International food trade and the flow of travellers are increasing, ~~bringing~~ entailing important social and economic benefits.	**Colombia**
This document outlines the general principles that should be understood and followed by FBOs at all stages of the food chain and that provide a basis for competent authorities to oversee food safety and suitability… While it is the FBOs' responsibility to provide safe food, for some FBOs this may be as	**Canada** We suggest adding a reference to the guidance in question (https://www.who.int/foodsafety/areas_work/food-

simple as ensuring that the WHO 5 keys for Safer ~~Food~~ Food[add a footnote with a link to the relevant WHO guidance] are adequately implemented…	hygiene/5keys/en/), as done for other technical guidance quoted in the text elsewhere.
This document outlines the general principles that should be understood and followed by FBOs at all stages of the food chain and that provide a basis for competent authorities to oversee food safety and suitability… While it is the FBOs' responsibility to provide safe food, for some ~~FBOs~~ FBOs, such as street vendors, this may be as simple as ensuring that the WHO 5 keys for Safer Food are adequately implemented…	**Brazil** Rationale: Since the five keys cannot be taken as a single control measure for any FBO, the example inserted helps to understand the type of establishment that could use this approach.
This document outlines the general principles that should be understood and followed by FBOs at all stages of the food chain and that provide a basis for competent authorities to oversee food safety and suitability. Taking into account the stage in the food chain, the nature of the product, the ~~relevant~~ possible contaminants, and whether the ~~relevant~~ possible contaminants adversely affect safety, suitability or both, these principles will enable food businesses to develop their own food hygiene practices and necessary food safety control measures, while complying with requirements set by competent authorities.	**Colombia**
FBOs need to be aware of hazards that may affect their food. FBOs need to understand the consequences of these hazards for consumer health and should ensure that they are properly managed. Good Hygiene Practices (GHPs) are the foundation of any effective control of hazards associated with their businesses. For some FBOs effective implementation of GHPs will be sufficient to address food safety. Ideally this would be determined through conducting a hazard analysis in relation to the risk of the type of food and the volume produced and determining how to control identified hazards...	**Chile**
FBOs need to be aware of hazards that may affect their food. FBOs need to understand the consequences of these hazards for consumer health and should ensure that they are properly managed. Good Hygiene Practices (GHPs) are the foundation of any effective control of hazards associated with their businesses…	**Gambia** CCFH50 agreed on para 4 as follows: "FBOs need to be aware of hazards that may affect their food. FBOs need to understand the consequences of these hazards for consumer health and should ensure that they are properly managed. Good Hygiene Practices (GHPs) are the basis of any effective control of hazards associated with their businesses. For some FBOs effective implementation of GHPs will be sufficient to address food safety." Position: The Gambia recommends to retain the original text for para.4 as agreed at CCFH50. Rationale: The amended text suggest that GHP cannot be sufficient to ensure safe food and contradicts the decision of CCFH50 relating to Para. 4. The implementation of GHP to provide safe food does not ideally require conducting Hazard analysis.
FBOs need to be aware of hazards that may affect their food. FBOs need to understand the consequences of these hazards for consumer health and should ensure that they are properly managed. Good Hygiene Practices (GHPs) are the foundation of any effective control of hazards associated with their businesses. For some FBOs effective implementation of GHPs will be sufficient to address food safety.- N~~Ideally this would be determined through conducting a hazard analysis and determining how to control identified hazards. However, not~~ ot all FBOs have the expertise to do this. If the FBO is not able to conduct a hazard analysis, the FBO may rely on information on appropriate food safety practices from external sources such as that provided by competent authorities, academia	**Thailand** Despite the clarification of the co-chairs about the intention of the added text in para 4, the text should be clear to avoid misunderstanding. It should be clear that not all FBOs need or have ability to do hazard analysis.

or other competent bodies (e.g. trade associations or professional societies) that has been based on the identification of relevant hazards and controls...	
FBOs need to be aware of hazards that may affect their food. FBOs need to understand the consequences of these hazards for consumer health and should ensure that they are properly managed…	**Morocco** Morocco proposes keeping the original text for paragraph 4, as agreed at CCFH50. (CCFH50 approved paragraph 4 as follows: "FBOs need to be aware of any potential hazards that may affect their food. FBOs need to understand the consequences of these hazards for consumer health, and should ensure that they are properly managed. GHPs are the basis of any effective control of hazards associated with their businesses. For some Food Business Operators effective implementation of GHPs will be sufficient to address food safety. ") Rationale: The amended text suggests that GHPs cannot be sufficient to ensure food safety and contradicts the decision of CCFH50 relating to Para. 4.
For some GHPs, based on safety concerns with the food, greater ~~attention~~ emphasis on the properly implementation monitoring may be needed to provide safe food…	**Chile** use greater attention could lead to the other be considered of less attention, when all GHP has same relevance for food safety, is just some of them more emphasis should be given to the control, verification, register and monitoring--
For some GHPs, based on safety concerns with the food, greater attention may be needed to provide safe food. For example, the cleaning of equipment and surfaces which come into contact with ready-to-eat food should warrant greater ~~attention, through frequency of application, monitoring and verification,~~ attention than other areas such as the cleaning of walls and ceilings, because if food contact surfaces are not properly cleaned, this could lead to direct contamination of food. Greater attention may include a higher frequency of application, of monitoring and of verification.	**ISO**
In some circumstances, the implementation of GHPs may not be sufficient to ensure food safety due to the complexity of the food operation and/or specific hazards associated with the product or process, technological advances (e.g. extending shelf-life through modified atmosphere packaging) or end use of the product (e.g. products destined for a special dietary purpose). In such cases, when there are significant hazards identified through hazard analysis, ~~Hazard Analysis and Critical Control Point (HACCP) principles~~ control measures at CCPs should be applied.	**FoodDrinkEurope** The last sentence suggests that hazard analysis comes before HACCP, in contradiction with principle 1 described in Chapter 2: hazard analysis is part of HACCP system.
In some circumstances, the implementation of GHPs may not be sufficient to ensure food safety due to the complexity of the food operation and/or specific hazards associated with the product or process, technological advances (e.g. extending shelf-life through modified atmosphere packaging) or end use of the product (e.g. products destined for a special dietary purpose). In such cases, when there are significant hazards identified through hazard analysis, ~~Hazard Analysis and Critical Control Point (HACCP) principles~~ they should be ~~applied~~addressed in HACCP plan.	**Brazil** Rationale: As hazard identification is part of the first principle of HACCP, it makes no sense to establish that only after hazard identification will the principles be applied.
.Chapter One of this document describes prerequisite programmes including GHPs, which are the basis of all food hygiene systems to support the production of safe and suitable food. Chapter Two describes HACCP. HACCP principles can be applied throughout the food chain from primary production to final consumption and their implementation should be guided by scientific evidence of risks to human health.. For FBOs that apply HACCP, the GHPs specified in Chapter one constitute	**ISO** Use this part to clarify the relation between PRPs, GHPs and HACCP.

part of the prerequisite programmes to the HACCP system in place. The table in Annex 1 provides examples of the application and a comparison of GHPs and control measures at Critical Control Points (CCPs).~~should be guided by scientific evidence of risks to human health. The table in Annex 1 provides examples of the application and a comparison of GHPs and control measures at Critical Control Points (CCPs).~~	
OBJECTIVES	
clarify the relationship between PRPs, GHPs and HACCP; and	**ISO**
Provide the basis on which sector and product-specific codes of practice can be established. [Translator's note: change does not affect the English]	**Colombia**
USO	
General	
The text indicates where such questions are likely to arise by using the phrases “where necessary” and “where appropriate.” In deciding whether a requirement is necessary or appropriate, an evaluation of the potential harmful effects to consumers should be made, taking into account any relevant knowledge of the operation and hazards, including available scientific information. This approach allows the requirements in this document to be flexibly and ~~sensibly~~ ***judiciously*** applied with a proper regard for the overall objectives of producing food which is safe and suitable for consumption.	**Argentina**
The text indicates where such questions are likely to arise by using the phrases “where necessary” and “where appropriate”. In deciding whether a ~~requirement~~ measure is necessary or appropriate, an evaluation of the potential harmful effects to consumers should be made, taking into account any relevant knowledge of the operation and hazards, including available scientific information. This approach allows the ~~requirements~~ measures in this document to be flexibly and sensibly applied with a proper regard for the overall objectives of producing food which is safe and suitable for consumption…	**Brazil** Rationale: Replace requirement for measure, requirement by definition means something that you must do, or something you need. Requirements are not flexible.
The text indicates where such questions are likely to arise by using the phrases “where necessary” and “where appropriate.” [Translator's note: change does not affect the English]	**Honduras**
The text indicates where such questions are likely to arise by using the phrases “where necessary” and “where appropriate.” In deciding whether a requirement is necessary or appropriate, an evaluation of the potential harmful effects to consumers should be made, taking into account any relevant knowledge of the operation and hazards, including available scientific information. This approach allows the requirements in this document to be flexibly and sensibly applied with a ~~proper~~ regard for the overall objectives of producing food which is safe and suitable for consumption.	**Colombia**
Roles of Competent Authorities, Food Business Operators, and Consumers	
Competent authorities are responsible for deciding how these general principles are best applied through legislation, regulation or guidance to: - Protect consumers from illness, injury, or death caused by consumption of ***unsafe*** food;	**Argentina**
Protect consumers from illness, injury, or death caused by consumption of **unsafe** food;	**Honduras**
~~support FBOs to~~ Verify FBOs implement an effective control system to ensure food is safe and suitable for consumption;	**Chile** It´s not the responsibility of the authorities to support or help FBO implement.
develop, implement and verify processes that provide food that is safe and suitable for its intended	**Morocco**

use;	Add at the end of the first bullet point: "and conduct withdrawals and/or recalls when the product presents a hazard for the consumer."
Ensure personnel are competent as appropriate to their job activities; [Translator's note: change does not affect the English]	**Colombia**
ensure that consumers have clear and easily ~~understood~~ understandable information to enable them to identify the presence of food allergens, protect their food from contamination, and prevent the growth/survival of foodborne pathogens by storing, handling and preparing food correctly.	**FoodDrinkEurope**
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~~ pathogenic microorganisms by storing, handling and preparing food correctly.	**Colombia**
Consumers should play their role by following relevant guidance and instructions for food handling, preparation, and storage and applying appropriate food hygiene measures. [Translator's note: change does not affect the English]	**Colombia**
GENERAL PRINCIPLES	
(i) Food safety and suitability should be controlled using a ***validated*** science-based preventive approach, for example a food hygiene system. GHPs should ensure that food is produced and handled in an environment that minimizes the presence of contaminants. (iv) Depending on the nature of the food ~~**food**~~ ***processing*** process, and the potential for adverse health effects, to control hazards it may be sufficient to apply GHPs, including, as appropriate, some that require more attention than others, as they have a greater impact on food safety. If not, a combination of GHPs and ~~**control measures at CCPs**~~ ***the HACCP system*** should be applied.	**Argentina**
Each FBO should be aware of the hazards associated with the activities of its processes such as raw materials and other ingredients, the production or preparation process, and the environment in which the food is produced and/or handled.	**IDF/FIL** Current wording will require that FBOs that are not manufacturers (e.g. transporters, retailers etc.) will have to be aware of hazards associated with food manufacture. This may be too much to expect. It is sufficient that e.g. a transporter is aware of the hazards associated with handling of food. The suggested addition will take care of this.
Each FBO should be aware of and clearly identify the hazards associated with the raw materials and other ingredients, the production or preparation process, and the environment in which the food is produced and/or handled.	**Colombia**
Depending on the nature of the food, food process, and the potential for adverse health effects, to control hazards it may be sufficient to apply GHPs, including, as appropriate, some that require more attention than others, as they have a greater impact on food safety. ~~If not,~~ When the appliaction of GHPs is not sufficient a combination of GHPs and control measures at CCPs should be applied.	**ISO**
Depending on the nature of the food, food process, and the potential for adverse health effects, to control hazards it may be sufficient to apply GHPs, including, as appropriate, some that require more attention than others, as they have a greater impact on food safety. ~~If not~~When the application of GHPs is not sufficient , a combination of GHPs and control measures at CCPs should be applied.	**Japan** To improve clarity.
Control measures that are essential to achieve an acceptable level of ~~food safety,~~ consumer protection should be scientifically validated[1].	**USA** The change would make the terminology consistent with that in the Guidelines for the Validation of Food Safety Control Measures (CXG 69-2008).

~~The~~ As appropiate the application of control measures should be subject to ~~monitoring,~~ monitoring and corrective ~~actions~~action to detect and correct deviations, ~~verification,~~ and to verification and documentation~~, as appropriate~~.	**ISO** A frequent mistake in the application of HACCP is that FBOs regard deviation (high temperature due to broken down coolong) as a hazard. Next to the control of hazards through control measures, the HACCP system should focus on the control of deviations through the application of monitoring and corrective action.
Food hygiene systems should be reviewed to determine if modifications are needed. This should be done periodically and whenever there is a significant change that could impact the potential hazards and/or the control measures (e.g. new process, new ingredient, new product, new equipment) associated with the food ~~business)~~business.	**Canada** Remove the parenthesis at the end of the sentence.
Food hygiene systems should be reviewed to determine if modifications are needed. This should be done periodically and whenever there is a significant change that could impact the potential hazards and/or the control measures (e.g. new process, new ingredient, new product, new equipment) associated with the food ~~business)~~business.	**USA** The parenthetical statement ends after “equipment.”
Food hygiene systems should be reviewed to determine if modifications are needed. This should be done periodically and whenever there is a significant change that could impact the potential hazards and/or the control measures (e.g. new process, new ingredient, new product, new equipment) associated with the food business). [Translator's note: change does not affect the English]	**Colombia**
Appropriate communication about the food and food process, should be maintained among all relevant parties to ensure food safety and suitability across the entire food chain. As apporpiate, consumers should be made aware that despite the efforts of FBOs, due to the inevitable (natural) presence of a hazard, some products can be unsafe for vulnerable consumers.	**ISO**
Appropriate communication about the food and food process, should be maintained among all relevant parties to ensure food safety and suitability across the entire food chain. It should be stated as a general requirement that consumers should be made aware that despite the efforts of FBOs due to the inevitable presence of hazards some products can be unsafe for consumption for vulnerable groups.	**ISO** ISO comment: The phrase in 118 “Where cross-contact cannot be prevented despite well-implemented controls, consumers should be informed”, does not apply to allergens only. There are other examples. Despite well-implemented controls fish bones might still be present in filleted fish, pathogens might be present in products made from raw milk or raw meat and levels of mercury can be found in types of fish that are therefore unfit for consumption by pregnant or breastfeeding women.
Management Commitment to Food Safety	
Management Commitment to Food Safety	**Gambia** Issue – General Principles, Para.16: Exclusion of the term ‘Culture’ from the title “management commitment to food safety culture” Position: The Gambia recommends retention of the term ‘culture” in the title so that the title reads “Management Commitment and Food Safety Culture” Rationale: The text in Para. 16 elaborates on the distinct roles of personnel and management in ensuring the establishment and

	maintenance of food safety culture. Since food safety culture is an important emerging concept in food safety management, it is appropriate that it is captured and its role recognised. Issue - Definitions: Inclusion of the definition "food safety culture" in light of the proposed change in the title from "management Commitment to food safety" to "management commitment and food safety culture" Position: The Gambia proposes the definition of "Food Safety culture" as "the attitude, values, norms beliefs and behaviours that a particular group of people share about food safety. It include visible and invisible attributes and is reflected in the actions of role players" Rationale: The term "Food Safety culture" needs to be defined to provide uniform interpretation and understanding. Issue – Definitions: Definition for FBO. Position: The Gambia recommends the modification of the definition of FBO to read "A person or entity responsible for operating a business at any step in the food chain." Rationale: The current definition for FBO is narrow and must be expanded to include an entity, as is the case in the food laws in most jurisdictions.
Management Commitment to Food Safety	**Morocco** keep the term "culture" in the title so that the title reads "Management Commitment and Food Safety Culture." Rationale: the text in Para. 16 lists the distinct roles of personnel and management in ensuring the establishment and maintenance of food safety culture. Given that food safety culture is an important emerging concept in food safety management, it is appropriate that it is included and its role recognized.
~~Fundamental~~ Food business managers should be committed to ~~the successful functioning~~ food safety. This can be done through a number of ~~any~~ activities, including incorporating food ~~hygiene system is~~ safety into the ~~establishment and maintenance~~ overall objectives of ~~an appropriate~~ the food ~~safety culture acknowledging~~ business and communicating the importance of ~~human behaviour in providing~~ producing safe ~~and suitable~~ food~~. The following elements are important in cultivating a positive~~, as fundamental to the success of any food ~~safety culture:~~hygiene system.	**Thailand** We think that the wording provided in CRD2 of CCFH50 gives more flexibility to small holder farmers and SMEs than the current text.
~~Commitment of the management and all personnel to the production and handling of safe food;~~	**Thailand**
Commitment of the management and all other personnel to the production and handling of safe food;	**USA** "Personnel" includes management.
~~Leadership to set the right direction and to engage all personnel in food safety practices;~~	**Thailand**
~~Awareness of the importance of food hygiene by all personnel in the business;~~	**Thailand**
~~Open and clear communication among all personnel in the business, including communication of deviations and expectations; and~~	**Thailand**

~~The availability of sufficient resources to ensure the effective functioning of the food hygiene system.~~	**Thailand**
Verifying that controls are carried out and working and that documentation ~~is~~ is kept up to date;	**Colombia**
DEFINITIONS	
DEFINITIONS	**Nicaragua** Nicaragua suggests listing the definitions in alphabetical order.
DEFINITIONS	**Uruguay** Uruguay believes that definitions are always good to have. We agree with keeping the definitions of “acceptable level,” “competent authority” and “food business operator."
~~**[Competent Authority:** the official body authorized by the government with the control of food hygiene, including setting and enforcing regulatory food safety requirements.]~~	**Argentina** Rationale: We suggest striking this as it is already defined in other documents.
~~**Acceptable level:** A level of hazard in a food at or below which the food is safe according to its intended use.~~	**Japan** We propose to delete this definition. The term is self-explanatory and we do not see the necessity to define this.
Acceptable level: A level of hazard in a food at or below which the food is generally accepted to be safe according to its intended use.	**FoodDrinkEurope** Definition of ‘acceptable level’ assumes that it is possible to be definitive on the safety of a food based on a level.
Acceptable level : A level of hazard in a food at or below which the food is safe according to its intended use.	**Morocco** Morocco proposes to keep the definitions.
Acceptable ~~level~~ limit: A level of hazard in a food at or below which the food is safe according to its intended use.	**Nicaragua** Nicaragua proposes replacing the term to avoid redundancy.
Acceptable level: A level of hazard in a food at or below which the food is safe according to its intended use.	**Guatemala** Guatemala proposes adding the following to the current definition of Acceptable Level: “Such acceptable level must be validated by a hazard analysis or with scientific evidence to support it.”
~~**Competent Authority:** The official body authorized by the government with the control of food hygiene, including setting and enforcing regulatory food safety requirements.~~	**Japan** We propose to delete this definition. Competent Authority is a common term used in various Codex texts without causing any confusion and we believe that a new definition would offer no value. Also, in the 26th CCGP, it was agreed that there was no merit in having a general definition of the term "competent authority" (para. 63, AINORM 10/33/33).
Competent authority: The official body authorized by the government with the control of food hygiene, including setting and enforcing regulatory food safety requirements.	**Morocco** Morocco proposes keeping this definition. Rationale: the terms are used in the text and therefore must be defined to ensure consistent understanding.
Competent Authority: The official body authorized by the government with the control of food hygiene, including setting and enforcing regulatory food safety requirements.	**Guatemala** Guatemala proposes: “The official body responsible for verifying that FBOs have implemented required hygiene controls for food safety. It is also responsible for controlling the regulatory requirements for food safety.
~~**Controll**~~**Control:**	**Canada**

	Remove the typo.
Controll:	**Brazil** Rationale: editorial
~~Controll~~Control:	**FoodDrinkEurope**
~~Controll~~Control:	**USA**
Controll:	**CCTA** Controll or Control ?
Corrective action: Any action taken when a deviation occurs in order to re-establish control, determine the disposition of the affected product if any and ~~minimize~~ avoid reoccurrence of the deviation.	**Chile** a corrective action should avoid the re ocurrence, because if not correct the problem, then the system and the PCC should be revised.
Corrective action: Any action taken when a deviation occurs in order to re-establish control, determine the disposition of the affected product if any and minimize reoccurrence of the deviation.	**Morocco** Add “and determine the origin of the deviation.”
Critical Control Point (CCP): A step at which a control measure or control measures, essential to control a significant hazard, is/are applied in a HACCP system.	**IDF/FIL** Needed for clarity that “control measures” and not just “measures” control hazards. Note that the definition of GHP uses the term “measures”. Without the suggested change, GHP will be included in the definition of CCP which is confusing
Critical Control Point (CCP): A step at which a control measure or measures, essential to control a significant hazard, is/are applied in an HACCP system.	**Guatemala** [Translator's note: change does not affect the English]
Critical limit: A criterion which separates acceptability from ~~unacceptability.~~ unacceptability of a control measure at a CCP.	**FoodDrinkEurope** Make definition of critical limit specific to control measures at CCPs
Critical limit: A criterion which separates acceptability from unacceptability.	**Honduras** We suggest adopting the definition from 9CFR 417 of Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard
Flow diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of food.	**Morocco** Replace the term “Flow diagram” with “Manufacturing diagram.”
~~**Food business operator (FBO):** A person(s) responsible for operating a business at any step in the food chain.~~	**Japan** We propose to delete this definition. The term has already been used in various Codex texts without causing any problem
Food business operator: A person(s) responsible for operating a business at any step in the food chain.	**Morocco** - Morocco proposes keeping this definition. Rationale: the terms are used in the text and therefore must be defined to ensure consistent understanding. - Amend the definition as follows: “A person(s) or entity responsible for operating a business at any step in the food chain. Rationale: The current definition is narrow and must be expanded

	to include an entity, as that is the case in food laws in the majority of jurisdictions.
Food business operator (FBO): A person(s) responsible for operating a business at any step in the food chain.	**Guatemala** Guatemala proposes that the definition of Food Handler from the original document is kept in the definitions. CAC-RCP1-1969. Food Handler: Any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements. The justification for this request is to avoid confusion that could arise from interpreting that a Food Business Operator (FBO) is the same as a Handler or Operator.
Food hygiene system: The application of GHPs or a combination of prerequisite programmes, and control at CCPs, as appropriate, that when taken as a whole, ensures that food is safe and suitable for its intended use.	**IDF/FIL** Current wording does not include food hygiene systems solely based on GHPs
Food hygiene system: The combination of prerequisite programmes, and control measures at CCPs, as appropriate, that when taken as a whole, ensures that food is safe and suitable for its intended use.	**FoodDrinkEurope**
Good Hygiene Practices (GHPs): Fundamental measures and conditions applied at any step ~~within~~ of the food chain to ensure~~specifically for~~ the production, manufacturing, ~~preparation, retail~~ and ~~food service operation~~ preparation of safe and suitable food.	**Canada** The modified text for the definition of GHP no longer works grammatically (“for the production, (…) retail and food service operation of safe and suitable food” ?) – see suggested edits.
Good Hygiene Practices (GHPs): Fundamental measures and conditions to provide safe and suitable food and applied at any step within the food chain specifically for the production, manufacturing, preparation, retail and food service ~~operation of safe and suitable food~~operation.	**ISO**
Good Hygiene Practices (GHPs): Fundamental measures and conditions applied at any step within the food chain specifically for the production, manufacturing, preparation, retail and food service operation of safe and suitable food.	**Honduras** [Translator's note: change does not affect the English]
Good Hygiene Practices (GHPs): Fundamental measures and conditions applied at any step within the food chain specifically for the production, manufacturing, preparation, retail and food service operation of safe and suitable food.	**Guatemala** Guatemala proposes deleting “retail” as it could cause confusion. We propose: “....sales, food service operation, and supply of safe and suitable food.”
~~**HACCP Plan**~~**HACCP:** a system which identifies, evaluates, and controls hazards which are significant for food safety through implementation of control measures at identified critical control points. **HACCP Plan:** Documentation or set of documents, prepared in accordance with the principles of HACCP to ensure control of significant hazards in the food business.	**Japan** We propose to keep the original definition of "HACCP" instead of creating a new definition "HACCP System". In the draft document, the word HACCP alone is used in a different sense from "HACCP System" (e.g., the principles of HACCP, the application of HACCP), and also the concept of "system" is already contained in the term "HACCP".
HACCP System: The development of a HACCP plan and the implementation of the procedures in accordance with that plan.	**IAF** HACCP system – The draft includes a clarification of the difference between ‘HACCP” and “HACCP Plan” by adding the word “system” to “HACCP”. This is an important clarification. HACCP System: The development of a HACCP plan and the

	implementation of the procedures in accordance with that plan. It is proposed that the draft be further clarified to differentiate between a “HACCP System” and a “HACCP-based System”. Such clarification would provide clarity not only within the draft but would assist other stakeholders clarify the use of “HACCP-based” within their benchmarking and certification programs that are based on the Codex GPFH. The current GPFH draft raises the practicality of small and less developed FBOs “adapt[ing] a generic HACCP plan provided by the competent authority, academia or other competent bodies (e.g. trade or industry associations) to the specific site circumstances” (para 135) in several places (paras: 137, 147, 157) and at times refers to this approach as a “HACCP-based system” (para 137) or as “Generic HACCP- based tools and guidance documents” (para 157). This concept was included in ISO 22000:2005 as “externally developed combinations of control measures”. It was revised and broadened in ISO 22000:2018 as follows: 7.1.5 Externally developed elements of the food safety management system When an organization establishes, maintains, updates and continually improves its FSMS by using externally developed elements of a FSMS, including PRPs, the hazard analysis and the hazard control plan (8.5.4), the organization shall ensure that the provided elements are: a) developed in conformance with requirements of this document; b) applicable to the sites, processes and products of the organization; c) specifically adapted to the processes and products of the organization by the food safety team; d) implemented, maintained and updated as required by this document; e) retained as documented information. The criteria a) to e) are similar to those sketched in the paragraphs of the draft cited above. Proposed NEW Definition of HACCP-based System: HACCP-based System: The implementation of PRPs, including GHPs, and control measures based on a generic hazard analysis conducted by a competent external body (e.g. competent authority, academia, trade or industry association), appropriate to the products and processes of the FBO and [adapted or tailored] by the FBO to its operations.
~~**HACCP System:** The development of a HACCP plan and the implementation of the procedures in accordance with that plan.~~	**Japan** We propose to keep the original definition of "HACCP" instead of

	creating a new definition "HACCP System". In the draft document, the word HACCP alone is used in a different sense from "HACCP System" (e.g., the principles of HACCP, the application of HACCP), and also the concept of "system" is already contained in the term "HACCP".
Hazard: A biological, chemical or physical agent**, or condition of,** food with the potential to cause an adverse health effect.	**Argentina** Rationale: to be consistent with the definition in the Procedural Manual
Hazard: A biological, chemical or physical agent in food with the potential to cause an adverse health effect.	**Morocco** Morocco supports deleting the term “condition of” in the definition of “hazard.” Rationale: the expression “condition of” is not easily understood in the current application of the HACCP system. Moreover, it is difficult to provide a control measure.. As a correlative amendment to the definition of “hazard” in the Codex Procedural Manual, Morocco supports the recommendation to refer the matter to CCGP so that it considers reexamining the definition of “hazard” in the Procedural Manual.
Hazard analysis: The process of collecting and evaluating information on hazards identified in the raw material, the environment, in the process or in the food, and conditions leading to their presence to decide whether or not these are significant hazards.	**ISO**
Hazard analysis: The process of collecting and evaluating information on hazards identified in raw materials, the environment, in the process or in the food, and conditions leading to their presence to decide whether or not these are significant hazards. ,	**Japan** Hazards in raw materials should also be included.
Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is ~~under control.~~being implemented.	**Colombia**
Primary Production: Those steps in the food chain up to and including storage ~~and~~ and, where appropriate, transport of outputs of farming. This would include growing crops, raising fish and animals, and the harvesting of plants, animals or animal ~~by-products~~ products from a farm or their natural habitat.	**Thailand** 1. Our study shows that transport of outputs of farming is not always the responsibility of the primary producers since the collectors, packers, or customers are in control of this process. 2. We would like to seek a clarification about the words ‘animal by products’. In this context, it should be “animal products” which is referred to edible product e.g. milk, honey, etc., specifically from primary producer.
Primary production: Those steps in the food chain up to and including storage and transport of outputs of farming. This would include growing crops, raising fish and animals, and the harvesting of plants, animals or animal by-products from a farm or their natural habitat.	**Morocco** Morocco proposes the following definition: Primary product: any grown, gathered or harvested agricultural product intended for human consumption, any product obtained from animals such as milk, honey and eggs, and products from hunting, fishing and gathering of wildlife species that are sold, as is, without the use of any specific preparation systems for their preservation other than refrigeration
Primary Production: Those steps in the food chain ~~up to and including~~ and outputs of farming,	**Uruguay**

including storage and transport of ~~outputs of farming~~their products. This would include growing crops, raising fish and animals, and the harvesting of plants, animals or animal by-products from a farm or their natural habitat.	
Prerequisite programme: Programmes including Good Hygiene Practices, Good Agricultural Practices and Good Manufacturing Practices, as well as other practices and procedures such as training and traceability, that establish the basic environmental and operating conditions that set the foundation for implementation of a HACCP system.	**IAF** b) Prerequisite Programmes and GHPs The current draft, to some degree, has clarified the committee's differentiation between "prerequisite programmes" (PRPs) and "good hygiene practices" (GHPs). For example, the definitions clearly identify GHPs as a subset of PRPs and PRPs and control measures as the basis for a "food hygiene system". However, the definition of a GHP is virtually the same as that for a PRP. PRPs – "Programmes including Good Hygiene Practices, Good Agricultural Practices and Good Manufacturing Practices, as well as other practices and procedures such as training and traceability, that establish the basic environmental and operating conditions that set the foundation for implementation of a HACCP system. " GHPs – "Fundamental measures and conditions applied at any step within the food chain specifically for the production, manufacturing, preparation, retail and food service operation of safe and suitable food." It is recommended that a review of the full text be undertaken to ensure that these closely related concepts (PRPs and GHPs) are used appropriately and clarified.
Prerequisite programme: Programmes including Good Hygiene Practices, Good Agricultural Practices and Good Manufacturing Practices, as well as other practices and procedures ~~such as training and traceability,~~ that establish the basic environmental and operating conditions that set the foundation for implementation of a HACCP system.	**FoodDrinkEurope** Example of other types of PRPs is not appropriate.
Step: A point, procedure, operation or stage in the food chain, ~~including raw materials,~~ from primary production to final consumption.	**Uruguay** Strike "including raw materials" as it is not a specific step in the food chain.
Monitoring: The application of methods, procedures, tests and other evaluations to determine whether a control measure is operating as intended. **Verification:** The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine whether a control measure ~~is or~~ has been ~~operating as intended~~effective.	**FoodDrinkEurope** We need a definition for monitoring. It seems it has been captured into the definition of verification
CHAPTER ONE	
GOOD HYGIENE PRACTICES	
Section 1: INTRODUCTION AND CONTROL OF FOOD HAZARDS	
Control of water quality – minimizes the presence of many potential hazards (e.g., biological, chemical, physical); [Translator's note: change does not affect the English]	**Colombia**
Control of faecal contamination – minimizes the potential for contamination with many foodborne pathogens such as **e.g.,** Salmonella, *Campylobacter*, Yersinia, pathogenic strains of E. coli;	**Honduras**

Control of food handler practices and hygiene – prevents many potential ~~communicable~~ diseases that could be foodborne; and	**Colombia**
Control of food contact surfaces by cleaning ~~—~~and disinfecting~~–~~ removes bacterial contaminants, including foodborne pathogens, and allergens.	**USA** Although we recognize that disinfection is not applicable to allergens, disinfection is needed to remove bacterial contaminants on food contact surfaces, and cleaning alone is inadequate.
Control of food contact surfaces by cleaning – ~~removes~~ **reduces allergens and** bacterial contaminants, including foodborne pathogens~~, and allergens~~.	**Honduras**
Control of food contact surfaces by cleaning – removes ~~bacterial~~ contaminants, ~~including foodborne pathogens~~, and allergens.	**Colombia**
After consideration of the conditions and activities in the business, it may be determined that GHPs alone may be sufficient to manage the hazards. However, it may also be determined that it is necessary to place greater attention on some GHPs that are particularly important for food safety (e.g. ~~increased stringency of~~ more thorough cleaning of a mincer for producing minced meat for raw or lightly cooked consumption compared to equipment used for producing meat to be cooked prior to consumption; increased monitoring and/or verification of cleaning and disinfection of food contact surfaces).	**USA** Commenters seem confused by the term “increased stringency.”
After consideration of the conditions and activities in the business, it may be determined that GHPs alone may be sufficient to manage the hazards. However, it may also be determined that it is necessary to place greater attention on some GHPs that are particularly important for food safety (e.g. increased stringency of cleaning of a mincer for producing minced meat for raw or lightly cooked consumption compared to equipment used for producing meat to be cooked prior to consumption; increased monitoring ~~and/or~~ and verification of disinfection of food contact surfaces).	**Colombia**
Hazards that occur or are present at levels such that GHP procedures are not sufficient to provide safe food should be managed by an appropriate combination of control measures that are capable of preventing occurrence of hazards or removing or reducing them to an acceptable level. The control measures can be identified in one or more steps throughout the production process. In the case in which significant hazards are identified that need to be controlled after the implementation of GHPs, it will be necessary to ~~develop and~~ implement a HACCP system (see Chapter 2). Development of a HACCP ~~system~~ plan may identify the need for changes in processing parameters, in processing steps, in manufacturing technology, in end product characteristics, in method of distribution, in the intended use or in the GHPs applied.	**Canada** To be consistent with our definitions of HACCP plan and HACCP system.
Hazards that occur or are present at levels such that GHP procedures are not sufficient to provide safe food should be managed by an appropriate combination of control measures that are capable of preventing occurrence of hazards or ~~removing~~ eliminating or reducing them to an acceptable level. The control measures can be identified in one or more steps throughout the production process…	**Canada** For consistency - the word “eliminate” rather than “remove” is used throughout the document for “hazards”.
Hazards that occur or are present at levels such that GHP procedures are not sufficient to provide safe food should be managed by an appropriate combination of control measures that are capable of preventing occurrence of hazards or removing or reducing them to an acceptable level…Development of a HACCP system may identify the need for changes in processing parameters, in processing steps, in manufacturing technology, in end product characteristics, in method of distribution, in the intended use or in the GHPs applied. The applicable GHPs should constitute an integrated part of the	**IDF/FIL** This addition will provide clarity to the difference between GHP and PRP, as outlined in their respective definitions.

prerequisite program founding the HACCCP system in place.	
Hazards that occur or are present at levels such that GHP procedures are not sufficient to provide safe food should be managed by an appropriate combination of control measures that are capable of preventing occurrence of hazards or ~~removing~~ eliminating or reducing them to an acceptable level…	**ISO**
Hazards that occur or are present at levels such that GHP procedures are not sufficient to provide safe food should be managed by an appropriate combination of control measures that are capable of preventing occurrence of hazards or ~~removing~~ eliminate or reducing them to an acceptable level…	**Brazil** Rationale: For consistency.
Hazards that occur or are present at levels such that GHP procedures are not sufficient to provide safe food should be managed by an appropriate combination of control measures that are capable of preventing occurrence of hazards or removing or reducing them to an acceptable level. … ~~Development of a HACCP system may identify the need for changes in processing parameters, in processing steps, in manufacturing technology, in end product characteristics, in method of distribution, in the intended use or in the GHPs applied.~~	**USA** This is more appropriate in the HACCP Chapter.
SECTION 2: PRIMARY PRODUCTION	
The types of activities involved in primary production may make eliminating or reducing some hazards difficult. However, ~~by applying Good Agricultural Practices (GAPs) and/or GHPs~~through the application of good practices programmes at primary production, steps can be taken to minimize the occurrence and levels of hazards in the food chain, e.g. at milking for dairy production, steps taken in the hygienic production of eggs, or the controls on irrigation water used for growing salad crops. Not all provisions apply for all primary production situations and consideration will need to be given by the FBO on the appropriateness of the measures to be taken.	**India** We propose this inclusion, since it will not be appropriate to restrict such activities to GAP only whereas other practices like best aquaculture practices etc will also be included under primary production.
The **different** types of activities involved in primary production may make eliminating or reducing some hazards difficult. However, by applying good ~~Agricultural Practices (GAPs)~~ ***farming practices*** and/or GHPs, steps can be taken to minimize the occurrence and levels of hazards in the food chain, e.g., at milking for dairy production, steps taken in the hygienic production of eggs, or the controls on irrigation water used for growing salad crops. Not all provisions apply for all primary production situations and consideration will need to be given by the FBO on the appropriateness of the measures to be taken.	**Argentina** Farming practices involve both livestock as well as agricultural activities.
The types of activities involved in primary production may make eliminating or reducing some hazards difficult. However, by applying Good Agricultural Practices (GAPs), **good animal husbandry practices,** and/or GHPs, steps can be taken to minimize the occurrence and levels of hazards in the food chain, e.g. at milking for dairy production, steps taken in the hygienic production of eggs, or the controls on irrigation water used for growing salad crops.	**Honduras**
The types of activities involved in primary production may ~~make~~ affect eliminating or reducing some hazards ~~difficult~~ .	**Colombia**
Production programmes such as “quality assurance programmes” ~~which achieve specific food safety goals are becoming an important part of primary production and~~ can be considered by FBOs as an additional resource in the management of their primary production activities.	**Thailand** Quality assurance programme is another mean to manage the food safety in primary production. However, the food safety goal specified in this paragraph is not very clear. Without the phrase, farmers will be easier to follow this recommendation.
Production programmes such as “quality assurance programmes” which achieve specific food safety goals are becoming an important part of primary production and can be considered by FBOs as an additional resource in the management of their primary production activities.	**Japan** We would like to ask for the clarification about what exactly "quality assurance programmes" is supposed to mean.
2.2 Hygienic Production	

Producers should as far as practicable implement measures to: • Manage waste and store harmful substances appropriately. [Translator's note: change does not affect the English]	**Argentina**
Control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect the suitability of the product (e.g., ~~observe the withdrawal period and grace period of veterinary drugs and pesticides, respectively, keeping records where applicable).~~ **control zoonotic diseases,** observe the withdrawal period and grace period of veterinary drugs and pesticides, respectively, keeping records where applicable).	**Honduras**
2.3 Handling, Storage and Transport	
Protect food from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling (e.g. sorting, grading, washing), storage and transport. Care should be taken to prevent deterioration and spoilage through **applying** appropriate measures, which may include controlling temperature, humidity, and/or other controls.	**Argentina**
2.4 Cleaning, Maintenance and Personnel Hygiene	
An appropriate degree of personal hygiene is maintained to ensure personnel are not a source of contamination (e.g. by human faeces). [Translator's note: change does not affect the English]	**Colombia**
SECTION 3: ESTABLISHMENT - DESIGN OF FACILITIES AND EQUIPMENT	
There are sufficient and appropriate washroom facilities for personnel. [Translator's note: change does not affect the English]	**Argentina** Attention to good hygienic design and construction, appropriate location, and the provision of adequate facilities is necessary to enable contaminants to be effectively controlled.
SECTION 3: ESTABLISHMENT - DESIGN OF FACILITIES AND EQUIPMENT	**Colombia** Depending on the nature of the operations and the associated risks, premises, equipment and facilities should be located, designed and constructed to ensure that: • Contamination is minimized; Attention to good hygienic design and construction, appropriate location, and the provision of adequate facilities is necessary to enable contaminants to be effectively controlled, thus ensuring food safety.
3.1.2 Design and layout of food establishment	
Areas having different levels of hygiene control (e.g. the raw material and finished product areas) should be separated to minimize cross-contamination through measures such as physical separation (e.g. walls, partitions) and/or location (e.g. distance), traffic flow (e.g. one-directional production flow), airflow, ~~and~~ or separation in time, with suitable cleaning and disinfection between uses.	**IDF/FIL** Separation in time is an alternative to other ways of separation. Replace “and” with “or.
3.1.3 Internal structures and fittings	
Work surfaces that come into direct contact with food should be in sound condition, durable, and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and to disinfectants under normal operating conditions. [Translator's note: change does not affect the English]	**Honduras**
Internal structures and fittings (smooth, non-toxic , easy-to clean, and non-absorbent surface), except for specific ones having their own characteristics, e.g., floors and their supporting structures,	**Peru** The characteristics of internal structures and fittings (smooth,

baseboards, concave walls.	non-toxic , easy-to clean, and non-absorbent surface) should be generalized, except for specific ones having their own characteristics, e.g., floors and their supporting structures, baseboards, concave walls.
The surfaces of walls, partitions and floors should be made of impervious materials that are rodent-resistant, easy to clean and, where necessary, should be disinfected; Ceilings, supporting structures (beams, trusses) and overhead fixtures (e.g. lighting) should be constructed to be shatterproof where appropriate, and finished to minimize the build-up of dirt and condensation and the shedding of particles;	**Peru** The building's interior materials must be such as to reduce or prevent cross-contamination by pests. It is included to minimize the build-up of dirt and condensation and the shedding of particles.
Work surfaces, fittings, utensils and equipment that come into direct contact with food should be in sound condition, durable, and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and to disinfectants under normal operating conditions.	**Peru** We include these to minimize the build-up of dirt and condensation.
3.1.4 Temporary/mobile food establishments and vending machines	**Honduras** We request clarification on the relevance of including this section in view of the challenges to regulate and implement them in developing countries.
Establishments and structures covered here include market stalls, street vending vehicles, vending machines and temporary premises such as tents and marquees. [Translator's note: change does not affect the English]	**Honduras**
Establishments and structures covered here include market stalls, ~~street vending vehicles,~~, ~~vending machines and temporary premises such as tents and marquees.~~	**Peru** These establishments REQUIRE THEIR OWN STUDY to establish specific regulations, as they cannot meet the requirements of this standard due to their characteristics.
3.2.1 Drainage and waste disposal	**Morocco** Add the term “facilities” to the title for better understanding. The amended title will be as follows: “Drainage and waste disposal facilities”
3.2.1 Drainage ~~**and waste disposal facilities**~~**and** proper **waste** management	**Honduras**
3.2.1 Drainage and ~~**waste disposal facilities**~~proper **waste disposal** management	**Honduras**
Adequate drainage and waste disposal systems and facilities should be provided and well-maintained. They should be designed and constructed so that the likelihood of contaminating food or the water supply is avoided. For plumbing, steps should be taken to prevent backflow, cross-connections, and backup of sewer gases. [Translator's note: change does not affect the English] It is important that drainage does not flow from highly contaminated areas (such as toilets or raw production areas) to areas where finished food is exposed to the environment.	**Colombia**
Waste should be collected, disposed of by trained personnel and, where appropriate, disposal records maintained. The waste ~~disposal~~ **drainage and proper management** 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.	**Honduras**
Containers used to hold hazardous substances prior to disposal should be identified and, where	**Gambia**

appropriate, be lockable to prevent intentional or accidental contamination of food.	Position: The Gambia recommends the revision of the paragraph as follows: Hazardous waste should be disposed of by specially trained personnel. Containers used to hold hazardous substances prior to disposal should be identified and, where appropriate, be lockable to prevent intentional or accidental contamination of food. Rationale: There should be a distinction between normal and hazardous waste. Hazardous waste generated in the food processing area poses high risk to the public if not handled appropriately. Hence the need for such personnel to be trained.
3.2.2 Cleaning facilities	
Adequate, suitably designated facilities should be provided for cleaning utensils and equipment. Such facilities should have an adequate supply of hot and/or cold water, where required. A separate cleaning area should be provided for tools and equipment from highly contaminated areas like toilets, drainage and waste disposal areas. ~~Facilities~~ Where appropriate, facilities for washing food should be separate from facilities for cleaning utensils and equipment, and separate sinks should be available for hand washing and food washing.	**Japan** Some flexibilities should be considered e.g. for very small FBOs or street vendors. In such cases, sinks could be used for multipurpose but safety should be ensured by e.g. cleaning and disinfecting the sink after each use.
Adequate, suitably designated facilities should be provided for cleaning utensils and equipment. Such facilities should have an adequate supply of hot and/or cold water, where required. A separate cleaning area should be provided for tools and equipment from highly contaminated areas like toilets, drainage and **proper** waste **management** ~~disposal~~ areas. Facilities for washing food should be separate from facilities for cleaning utensils and equipment, and separate sinks should be available for hand washing and food washing.	**Honduras**
Adequate, suitably designated facilities should be provided for cleaning utensils and equipment. Such facilities should have an adequate supply of hot and/or cold water, where required. A separate cleaning area should be provided for tools and equipment from highly contaminated areas like toilets, drainage and waste disposal areas. Facilities for washing food should be separate from facilities for cleaning utensils and equipment, and separate sinks should be available for hand washing and food washing.	**Peru** We include these to minimize cross-contamination.
3.2.3 Personnel hygiene facilities and toilets	
Adequate washing and toilet facilities should be available so that an appropriate degree of personal hygiene can be maintained and to avoid personnel contaminating food…	**Morocco** Add “and sufficient.” The sentence will be: “Adequate and sufficient washing and toilet facilities should be available so that an appropriate degree of personal hygiene can be maintained....”
Adequate means of washing and drying hands, including soap (preferably liquid soap), wash basins and, where appropriate, a supply of hot and cold (or suitably temperature controlled) water; [Translator's note: change does not affect the English]	**Colombia**
hand washing basins of an appropriate hygienic design, ideally with taps not operated by ~~hands; where this is not possible, appropriate measures~~ hands to minimize contamination from the taps should be in place; and	**Thailand** Taps not operated by hands in food establishments at downstream of the supply chain such as packing house, food manufacturer, etc. is now very common. The addition of another appropriate measures might cause confusion to the FBOs.
suitable changing facilities for personnel~~.~~, if required.	**India** To bring more clarity, since changing facilities may not be

	required in all types of food businesses.
3.2.4 Temperature	**Morocco** Add the term “facilities” to the title for better understanding and harmonization. The amended title will be as follows: “Temperature control facilities”
Depending on the nature of the food operations undertaken, adequate facilities should be available for heating, cooling, cooking, refrigerating and freezing food, for storing refrigerated or frozen foods, systems for holding prepared foods and, when necessary, controlling ambient temperatures to ensure the safety and suitability of food.	**Peru** According to the WHO, barrier temperatures must be maintained to minimize microorganism growth by not providing temperatures for this to occur, in order to ensure food safety and suitability.
3.2.5 Air quality and ventilation	**Morocco** Add the term “system” to the title and delete “Air Quality.” The title is as follows “Ventilation system”
3.2.6 Lighting	**Morocco** Add the term “system” to the title. The amended title will be as follows: “ Lighting system”
3.2.7 Storage	**Morocco** Add the term “facilities” to the title. The amended title will be as follows: “Storage facilities”
Adequate and, where necessary, separate facilities for the safe and hygienic storage of food products, food ingredients, food packaging materials and non-food chemicals (including cleaning materials, lubricants, fuels), should be provided. Storage should allow for segregation ~~for the manufacturing~~ of raw and cooked foods or allergenic and non-allergenic food.	**Canada** These extra words should have probably been deleted when the text was edited.
3.3.2 Food control and monitoring equipment	
Equipment used to cook, heat, cool, store or freeze food and systems for holding prepared foods should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and to maintain food temperatures effectively.	**Peru** To ensure the established temperature parameters for prepared foods and ensure safety and suitability.
Such equipment should also be designed to allow temperatures to be monitored, where necessary, and controlled. Where appropriate, ~~monitoring equipment~~ the measuring device used should be calibrated ~~to ensure~~ to verify that temperatures of food processes are accurate.	**Honduras**
SECTION 4: TRAINING AND COMPETENCE	
	IAF c) Competence The emphasis in the current draft on the concept of “competence” is supported. It could be strengthened by two additions – the inclusion of a definition and changes to the text in the discussion of “management commitment”. Proposed definition – ISO uses the following definition of “competence” which has been included in ISO 22000:2018. “3.4 competence ability to apply knowledge and skills to achieve intended results” Proposed revision of text in para. 17, 4th bullet: “Ensuring that personnel are competent and that the appropriate training and supervision are in place for personnel;”

	FoodDrinkEurope This section is not at the right place, we suggest moving it between Section 6 – Personal hygiene and Section 7 – Control of operation
	Japan Training and competence is relevant to both GHP and HACCP, and we propose to move this part to introduction part, after "Management Commitment to Food Safety".
	Honduras Adequate hygiene training, and/or instruction and supervision of all people involved in food-related activities assist in ensuring the safety of food and its suitability for consumption.
4.1 Awareness and Responsibilities **[Translator's note: change does not affect the English]**	**Uruguay** The document in English has “Awareness” in the title and the paragraph text. We recommend keeping the previous version of the title in Spanish. “Awareness and responsibilities” and within the paragraph: “All personnel should be aware of their role...”
Food hygiene training is fundamentally important to the food business. All personnel should be aware of their role and responsibility in protecting food from contamination or deterioration. [Translator's note: change does not affect the English] Personnel should have the knowledge and skills necessary to enable them to handle food hygienically. Those who handle cleaning chemicals or other potentially hazardous chemicals should be instructed in proper use to prevent contamination of food.	**Uruguay**
4.2 Training Programmes **55bis. Personnel handling food should be instructed and/or educated in food hygiene matters commensurate with their work activity**	**IDF/FIL** Suggest highlighting that training is targeted to the needs of each person.
the good hygiene practices applicable to the food business~~.~~;	**Canada** Remove the period and replace with semicolon.
Periodic assessments of the effectiveness of training and instruction programmes should be made, as well as routine supervision and verification to ensure that procedures are being carried out effectively. Personnel tasked to ~~monitor the equipment used~~ perform any activity in food control should be trained adequately to ensure that they are competent to perform their tasks and are aware of the impact of their tasks on the safety and suitability of the food.	**Japan** Too specific and narrow. Not only personnel tasked to monitor the equipment but also personnel tasked to perform any activity in food control should be trained.
4.4 Refresher Training **[Translator's note: change does not affect the English]**	**Colombia**
5.1 MAINTENANCE AND CLEANING **5.1.1 GENERAL**	**Colombia** Proper maintenance of physical facilities;
Prevent contamination of food, such as from pests, metal shards, flaking plaster, debris, chemicals, wood, plastic, glass, paper, among others.	**Colombia**
Cleaning should remove food residues and dirt which may be a source of contamination, including cross-contact allergens. The cleaning methods and materials necessary will depend on the nature of the food business, the food type and the surface to be cleaned. Disinfection may be necessary after cleaning, especially for food contact surfaces.	**FoodDrinkEurope** Removal of allergens to be limited to those not desired

5.1.2 Cleaning and disinfection methods and procedures	
Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, and vacuum cleaning (or other methods that avoid the use of water), and chemical methods using solutions of detergents, alkalis or acids. Dry cleaning or other appropriate methods for removing and collecting residues and debris may be needed in some operations and/or food processing areas ~~where~~ as water increases the likelihood of microbiological contamination. Care should be taken to ensure cleaning procedures do not lead to contamination of food, e.g. spray from pressure washing can spread contamination from dirty areas, such as floors and drains, over a wide area and contaminate food contact surfaces or exposed food.	**IDF/FIL** Water always increases microbiological contamination. Replace "where" with "as".
Removing **of** gross visible debris ~~from~~ **on** surfaces;	**Honduras**
applying an appropriate detergent solution to loosen ~~soil~~soil and biofilm; and	**IDF/FIL** One of the important objectives of wet cleaning is to control biofilm.
5.1.3 ~~Monitoring of Effectiveness~~"Monitoring and verification"	**FoodDrinkEurope** This sub-section covers concepts of monitoring and verification. We suggest to re-title: "Monitoring and verification"
Application of cleaning and disinfection procedures should be monitored ~~for effectiveness~~ and periodically verified by means such as visual inspections and audits to ensure the procedures have been applied ~~properly~~properly and are effective. The type of monitoring will depend on the nature of the procedures, but could include pH, water temperature, conductivity, cleaning agent concentration, disinfectant concentration, and other parameters important to ensure the cleaning and disinfection programme is being implemented as designed and verify its effectiveness.	**FoodDrinkEurope** It seems that there is a confusion of the concepts monitoring and verification
Microorganisms can sometimes develop resistance to disinfecting agents and the food production environment can change over time; however, microorganisms are unlikely to develop resistance if recommended cleaning and disinfection procedures are explicitly followed. Periodic review with disinfectant manufacturers/suppliers, where feasible, should be conducted to help ensure the disinfectants used are effective and appropriate~~. Rotation of the disinfectants could be considered to ensure inactivation of different types of microorganisms (e.g., bacteria and fungi).~~	**Canada** We suggest removing or rewording this statement as it is causing confusion. The disinfectants used should be appropriate for the targeted micro-organisms at all times, and this statement suggests otherwise.
Microorganisms can sometimes develop resistance to disinfecting agents and the food production environment can change over time; however, microorganisms are unlikely to develop resistance if recommended cleaning and disinfection procedures are explicitly followed. Periodic review with disinfectant manufacturers/suppliers, where feasible, should be conducted to help ensure the disinfectants used are effective and appropriate. Rotation of the disinfectants could be considered to ensure inactivation of different types of ~~microorganisms (e~~microorganisms~~.g., bacteria and fungi).~~	**Brazil** Rationale: The example gives the idea that disinfectants used for bacteria and fungi should be alternated temporarily, for example, i.e., one month only effective fungal disinfectant is used and next month effective bacterial disinfectant.
While effectiveness of cleaning and disinfecting agents and instructions for use are validated by their manufacturers, measures should be taken for sampling and testing the environment and food contact surfaces (e.g. protein and allergen test swabs, or microbiological testing for indicator organisms) to help verify that cleaning and disinfection programmes are effective and being applied properly. Microbiological sampling and testing may not be appropriate in all cases and an alternative approach might include observation of cleaning and disinfection procedures including the correct disinfectant concentration, to achieve the necessary results and to make sure protocols are being followed. Cleaning and disinfection and maintenance procedures should be regularly reviewed and adapted to reflect any changes in circumstances and documented as appropriate.	**Colombia**

[Translator's note: change does not affect the English]	
5.3.1 General	**FoodDrinkEurope** Remove “General” headline
SECTION 6: PERSONAL HYGIENE	
6.1 Health Status	
Personnel known or suspected to be ill or carrying a disease likely to be transmitted through food should not enter any food handling area if there is a likelihood of their contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management.	**Gambia** Position: All food handlers should periodically undergo medical screening as appropriate to prevent contamination of food. Personnel known or suspected to be ill or carrying a disease likely to be transmitted through food should not enter any food handling area if there is a likelihood of their contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management. Rationale: To ensure that food safety is not compromised through transmission of infectious pathogens from unhealthy food handlers to the food or food processing environment.
Personnel known or suspected to be ill or carrying a disease likely to be transmitted through food should not enter any food handling area if there is a likelihood of their contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management	**Morocco** Add the following sentence: “All food handlers should undergo periodic medical examinations to prevent contamination of food.” Personnel known or suspected to be ill or carrying a disease likely to be transmitted through food should not enter any food handling area if there is a likelihood of their contaminating food.. Any person so affected should immediately report illness or symptoms of illness to the management. Rationale: Regular medical screening is required to prevent the contamination of food by infectious pathogens carried by ill handlers.
6.3 Personal Cleanliness	
In order not to contaminate food, personnel should wash hands with soap that is verified as effective, and water and rinse and dry them in a manner that does not recontaminate the hands. Hand sanitizers that are verified as effective should not replace hand washing and should be used only after hands have been washed.	**Peru** We are including this to minimize cross-contamination.
In order not to contaminate food, personnel should wash hands with soap and water and rinse and dry them in a manner that does not recontaminate the hands, e.g., with a single-use paper towel. Hand sanitizers should not replace hand washing and should be used only after hands have been washed.	**USA** Clarification to provide an example of “in a manner that does not recontaminate the hands.”
6.4 Personal Behaviour	**Morocco** Personnel Behaviour
Smoking or vaping~~;~~ **(use of electronic cigarettes)**	**Honduras**
6.5 Visitors and other persons from outside the establishment	
Personal ~~effects~~ **objects** such as jewellery, watches, pins or other items such as false nails/eye lashes should not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.	**Honduras**

SECTION 7: CONTROL OF OPERATION	
	FoodDrinkEurope This section is confusing as there are elements that concern the HACCP system that are already addressed in chapter 2 (clauses 96, 97, 98, 99). We suggest to remove clauses 96 to 99. They are already addressed in chapter 2. We suggest to re-order the sub-sections as follows: 7.1 Control of inputs 7.1.1 Incoming materials (clause 119) 7.1.2 Packaging (clause 120) 7.1.3 Water (clause 121) 7.2 Control of contamination 7.2.1 Microbiological contamination (clauses 112 to 115) 7.2.2 Physical contamination (clause 116) 7.2.3 Chemical contamination (clause 117) 7.2.4 Allergen management (clause 118) 7.3 Process control 7.3.1 Monitoring of process (clauses 100-102) 7.3.2 Time and temperature control (clauses 106-108) 7.3.3 Specific process steps (clauses 109 & 110) 7.4 Verification 7.4.1 Microbiological, physical, chemical and allergen specifications (clause 111) 7.4.2 Verification (clause 103 & 104) 7.5 Recall procedures – removal from the market of unsafe food (clauses 123 & 124) 7.6 Documentation and records (clause 122)
	Honduras Formulating design requirements with respect to raw materials and other ingredients, composition/formulation, production, processing, distribution, and consumer use to be met as appropriate to the food business;
Control of operation is achieved by having an appropriate food hygiene system in place. The following section describes practices that can assist in the identification and application of appropriate controls, as well as activities that should take place to ensure the operation is under control.	**Gambia** The use of the term “food hygiene system” which implies the use of both GHP and HACCP to be applied where GHP may be sufficient. Position: Since chapter (1) deals with GHP, The Gambia proposes to replace “Food Hygiene System” with “Good Hygiene Practices”. The paragraph will read as follows: Control of operation is achieved by having an appropriate food hygiene practices system in place. The following section describes practices that can assist in the identification and application of appropriate controls, as well as activities that should take place to ensure the operation is under control.

	Rationale: Food Hygiene System is a combination of pre-requisite programmes and HACCP as per the definition. However GHP on its own can be used in the control of operation to ensure food safety.
7.1 Description of products and processes	**Morocco** Morocco proposes amending the paragraphs listed below to reflect requirements relating to GHPs and to reconsider this wording (Certain steps used in the application of HACCP standards (paragraphs 96, 97, 98, 100, 101, 102, 103 and 104) (product description, process description, surveillance and verification were introduced into the application of GHPs). Rationale: There is some confusion about the introduction of certain steps of the HACCP system into the application of GHPs. For example, corrective actions focused on the product are taken when the GHP monitoring results reveal a deviation; and according to the same principle as the one used for application of the HACCP system (product segregation, assessment of its safety and suitability, etc).
An FBO that is producing, storing or otherwise handling food should have a description of the food. Products may be described individually or in groups in a manner ~~that does not~~provided that they ~~compromise the awareness of~~clearly identify hazards or other factors such as suitability of the products for the purpose intended. Any grouping of food products should be based on them having similar inputs and ingredients, product characteristics (such as pH, water activity (aw)), process steps and/or intended purpose.	**Colombia**
7.1.3 Consideration of the effectiveness of GHPs	
Having considered the product and process descriptions, an FBO should determine (using information relevant to hazards and controls from various sources as appropriate) whether the GHPs and other programmes they have in place are sufficient to address food safety and suitability or if some GHPs need greater attention. For example, a cooked meat slicer may require specific and more frequent cleaning to prevent the build-up of Listeria spp. on its meat contact surfaces, or a conveyor belt used in direct contact with the food, such as in sandwich production, may require an increased frequency of cleaning or a specific cleaning programme. When such increased attention on GHPs is insufficient to ensure food safety, it will be necessary to implement a HACCP system (Chapter 2). 99a. In specific cases, vulnerable groups of the population (e.g. institutional catering and consumers with food allergies), may have to be considered. Where foods are being produced specifically for a vulnerable population, it may be necessary to pay greater attention to some GHPs, increased frequency of monitoring including corrective actions, verification of the effectiviness by testing products, or conduct other activities to provide a high level of assurance that the food is safe for the vulnerable population.	**ISO** The text below is part of 150 in Chapter two on HACCP, it is however a typical GHP approach. The text should be Chapter 1 – for instance as a new paragraph following para. 99, i.e. under the heading “Consideration of the effectiveness of GHPs” In specific cases, vulnerable groups of the population, e.g. institutional catering, may have to be considered. Where foods are being produced specifically for a vulnerable population, it may be necessary to pay greater attention to some GHPs, enhance process controls, monitor control measures more frequently, verify controls are effective by testing products, or conduct other activities to provide a high level of assurance that the food is safe for the vulnerable population.
Having considered the product and process descriptions, an FBO should determine (using information relevant to hazards and controls from various sources as appropriate) whether the GHPs and other programmes they have in place are sufficient to address food safety and suitability or if some GHPs need greater attention. For example, a cooked meat slicer may require specific and more frequent cleaning to prevent the build-up of ~~Listeria~~ *Listeria* spp. on its meat contact surfaces, or a conveyor	**Brazil** Rationale: Editorial: Italic for scientific name.

belt used in direct contact with the food, such as in sandwich production, may require an increased frequency of cleaning or a specific cleaning programme. When such increased attention on GHPs is insufficient to ensure food safety, it will be necessary to implement a HACCP system (Chapter 2).	
7.1.4 Monitoring of process	
7.1.4 Monitoring ~~of process~~ and corrective action	**ISO**
The FBO should monitor the hygienic procedures and practices as relevant to the business and as applicable to the hazard being controlled. Procedures could include defining methods of monitoring (including defining responsible ~~personnel, frequency~~ personnel and ~~sampling regime~~ frequency if applicable) and monitoring records to be kept. The frequency of monitoring should be appropriate to ensure consistent process control.	**ISO** ISO comment: Monitoring is an observations or measurements of control parameters to assess control measures relative to their critical limits. Sampling is a-typical as monitoring; sampling is typical as verification to assess products relative to the acceptable levels for a hazard. We should not provide sampling as an example for monitoring.
7.1.~~6~~ 5 Verification	**Canada** Correct the section number.
The FBO should undertake verification activities as relevant to the business, to check that GHP procedures have been implemented effectively, monitoring is ~~occurring~~executed, where planned, and that appropriate corrective actions are taken when requirements are not met. Examples of verification activities could include the following, as appropriate:	**ISO**
The FBO should undertake verification activities as relevant to the business, to check that GHP procedures have been implemented effectively, monitoring is ~~occurring~~conducted, where planned, and that appropriate corrective actions are taken when requirements are not met. Examples of verification activities could include the following, as appropriate:	**Japan**
~~assessment of the efficacy of cleaning.~~	**India** “Assessment of efficacy” should be a part of validation and should not be included under verification.
assessment of the efficacy of cleaning~~.~~. sampling and analysis	**ISO** add ampling and analysis after last bullet.
7.2 KEY ASPECTS OF FOOD HYGIENE SYSTEMS	
Some key aspects of food hygiene systems could be considered ~~as control measures applied at CCPs~~ in the HACCP system.In a HACCP system, some GHPs - like cooking, cooling, metal detection and sieves - could be identified as control measures at CCPs	**ISO**
Some key aspects of food hygiene systems could be considered as control measures applied at CCPs in the HACCP system.	**ISO** This phrase can be more specific and thus clarify the relation between GHP and HACCP.
Some key aspects of ~~food hygiene systems~~ GHPs could be considered as control measures applied at CCPs in the HACCP system.	**Gambia** Rationale: Food Hygiene System implies the use of both GHP and HACCP. However, the section has been dedicated to GHPs hence this should be reflected appropriately in the text.
Some key aspects of food hygiene systems ~~could~~ should be included in the HACCP system. Some GHPs - like cooking, cooling, metal detection and sieves - should be considered as control measures ~~applied~~ at CCPs in the HACCP system.	**ISO** this phrase can be more specific and thus clarify the relation between GHP and HACCP.
Some key aspects of food hygiene ~~systems~~ systems, e.g. heat treatment and cooling, could be	**Japan**

considered as control measures applied at CCPs in the HACCP system.	To improve clarity.
7.2.1 Time and temperature control	
Inadequate time and temperature control, e.g. during cooking, cooling, processing and storage, are among the most common failures of ~~process~~ operational control. These allow survival or growth of microorganisms that may cause foodborne illness or food spoilage. Systems should be in place to ensure that temperature is controlled effectively where it impacts the safety and suitability of food and that ~~processes~~ operations are conducted without undue delay.	**India** The term "process control" is not used anywhere in the document and has understanding as that in ISO standards and therefore should not be mentioned here.
Inadequate time and temperature control, e.g. during cooking, cooling, processing and storage, are among the most common failures of process control. These allow survival or growth of microorganisms that may cause foodborne illness or food spoilage. Systems should be in place to ensure that temperature is controlled effectively where it impacts the safety and suitability of ~~food and that processes are conducted without undue delay~~food. Corrective actions shall be taken in case deviations impact the safety and suitability of food.	**ISO** Unclear wording… what is meant by processes are conducted without undue delay? It is not always necessary or appropriate to conduct processes without undue delay. It depends on the likelihood of hazard occurrence or proliferation between two steps. It is more appropriate to require that corrective action must be taken if planned storage conditions for intermediate products are not adhered to.
the nature of the food, e.g. its ~~aw~~water activier (aw), pH, and likely initial level and types of microorganisms, such as pathogenic and spoilage microflora;	**IDF/FIL** aw should be spelled out.
~~The nature of the food, e.g. its aw, pH, and likely initial level and types of microorganisms, such as pathogenic and spoilage microflora;~~The nature of the food, e.g. its aw, pH, and likely initial level and types of **pathogenic** microorganisms, such as pathogenic and spoilage microflora;	**Honduras**
how the product is intended to be used, e.g. further cooking/processing or ready-to-eat~~.~~. 107bis When relevant, estimating shelf-life of a food should be based on: • The potential and rate of chemical and microbiological deterioration, taking into account o The likelihood of microorganisms being present in the food, o The microbial growth potential in and on the food, and o The storage conditions, as labelled • Reasonable foreseeable conditions to which the food may be submitted after having left the step of manufacture	**IDF/FIL** Consider a new paragraph on establishing shelf-life. As para. 107 is currently worded, shelf-life is not a variable. Actual shelf-life may differ from intended shelf-life.
7.2.3 Microbiological , physical, chemical and allergen specifications	
There are many individual processing steps for specific foods which contribute to the production of safe and suitable food products. These vary depending on the product and can include key steps such as cooking, chilling, freezing, drying and packaging.	**Uruguay** The wording in the English document is different: "There are many individual processing steps for specific foods which contribute to the production of safe and suitable food products." This translation needs to be improved.
Where microbiological, physical, chemical and allergen specifications are used for food safety or suitability, such specifications should be based on sound scientific principles and state, where appropriate, sampling parameters, analytical methods, acceptable limits and monitoring procedures. Specifications should meet or exceed regulatory standards, when available. Specifications can help ensure that raw materials and other ingredients are fit for purpose and contaminants have been minimized.	**Canada** Additional wording proposed to ensure regulatory standards are considered.

7.2.4 Microbiological contamination	
In some food operations, access to processing areas may need to be restricted or controlled for food safety purposes. For example, where the likelihood of product contamination is high, access to processing areas should be via a properly designed changing facility. Personnel may be required to put on clean protective clothing (which may be of a differentiating colour from that worn in other parts of the facility), including head and beard ~~covering,~~ covering and footwear, and to wash their hands.	**USA**
7.2.7 Allergen Management **Footnote 5 – see the Code of Practice on Allergen Management for Food Business Operators (being developed)**	
~~See the *Code of Practice on Allergen Management for Food Business Operators* (being developed).~~	**Thailand** we would like to ask for a clarification about the appropriateness in referring to the Code of Practice on Allergen Management for Food Business Operators. To our knowledge, the Code is the requirement in addition to CXC 1-1969. Its use should depend on the risk related to each business.
Systems should be in place to take into account the allergenic nature of some foods. Presence of allergens, e.g. tree nuts, milk, eggs, crustacea, fish, peanuts, soybeans and wheat and other cereals containing gluten and their derivatives (not an inclusive list; allergens of concern differ among countries and populations), should be identified in raw materials, other ingredients and products… It should be stated as a general requirement that consumers should be made aware that despite the efforts of FBOs due to the inevitable presence of hazards some products can be unsafe for consumption for vulnerable groups.	**ISO** The phrase "Where cross-contact cannot be prevented despite well-implemented controls, consumers should be informed", does not apply to allergens only. There are other examples. Despite well-implemented controls fish bones might still be present in filleted fish, pathogens might be present in products made from raw milk or raw meat and levels of mercury can be found in types of fish that are therefore unfit for consumption by pregnant or breastfeeding women. - See the ISO proposed text in 99a.
~~Systems~~ Having determined the risk of allergen cross-contact, system should be in place to take into account the allergenic nature of some foods. Presence of allergens, e.g. tree nuts, milk, eggs, crustacea, fish, peanuts, soybeans and wheat and other cereals containing gluten and their derivatives (not an inclusive list; allergens of concern differ among countries and populations), should be identified in raw materials, other ingredients and products…	**Thailand** Not all FBOs have the same risk of allergen cross-contact. Some FBOs such as warehouse of pre-packaged food, rice mill, etc. has very low risk of allergen cross-contact. The added Code of Practice on Allergen Management for Food Business Operators is very detail. The use of the Code should depend on the risk of each FBO.
7.2.7 Allergen Management [4]	**Honduras** We suggest making the paragraph on addressing the Code of Practice on Allergen Management for Food Business Operators (being developed) explicit. And not as a footnote.
7.2.8 ~~**Incoming Materials**~~Raw materials and other ingredients	**Honduras**
7.2.8 ~~**Incoming materials**~~**Inputs**	**Uruguay**
[7.3 Water	
Water, as well as ice and steam made from water, should be fit for its intended purpose based on a risk-based approach [here we would add the footnote to the FAO/WHO report when it is available]. They should not cause contamination of food. Water and ice should be stored and handled in a manner that does not result in their becoming contaminated, and the generation of steam that will contact food should not result in its contamination. Water that is not fit for use in contact with food (e.g., water for fire control and for steam that will not directly contact food) should have a separate	**IDF/FIL** Reword to ensure that reuse of water for cleaning is covered. Membrane filtration is a commonly used recovery technology to generate water

system that does not connect with or allow reflux into the system for water that will contact food. Water recirculated for reuse and water recovered from ~~processing of~~ food processing operations by evaporation or filtration should be treated where necessary to ensure that the water does not compromise the safety and suitability of food.	
Water, as well as ice and steam made from water, should be fit for its intended purpose based on a risk-based ~~approach [here we would add the footnote to the FAO/WHO report when it is available]~~approach. They should not cause contamination of food. Water and ice should be stored and handled in a manner that does not result in their becoming contaminated, and the generation of steam that will contact food should not result in its contamination. Water that is not fit for use in contact with food ~~(e.g., water for fire control and for steam that will not directly contact food)~~ should have a separate system that does not connect with or allow reflux into the system for water that will contact food. Water recirculated for reuse and water recovered from processing of food by evaporation should be treated where necessary to ensure that the water does not compromise the safety and suitability of food.	**Brazil** Rationale: In this paragraph it would be better to refer to the water document that will still be approved as new work (agenda item 9). As the title of the document has not yet been agreed, we suggest leaving the paragraph without references. The examples are unnecessary for understanding the context.
Water, as well as ice and steam made from water, should be fit for its intended purpose based on a risk-based ~~approach [here we would add the footnote to the FAO/WHO report when it is available]. They should not cause contamination of food. Water and ice should be stored and handled in a manner that does not result in their becoming contaminated, and the generation of steam that will contact food should not result in its contamination. Water that is not fit for use in contact with food (e.g., water for fire control and for steam that will not directly contact food) should have a separate system that does not connect with or allow reflux into the system for water that will contact food. Water recirculated for reuse and water recovered from processing of food by evaporation should be treated where necessary to ensure that the water does not compromise the safety and suitability of food.~~approach[x]. They should not cause contamination of food. Water and ice should be stored and handled in a manner that does not result in their becoming contaminated, and the generation of steam that will contact food should not result in its contamination. Water that is not fit for use in contact with food (e.g., some water used for fire control and for steam that will not directly contact food) should have a separate system that does not connect with or allow reflux into the system for water that will contact food. Water recirculated for reuse and water recovered from processing of food by evaporation should be treated where necessary to ensure that the water does not compromise the safety and suitability of food.	**USA** Footnote X: Safety and Quality of Water used in Food Processing. FAO/WHO, 2019. The report is now available; the paragraph is consistent with the recommendations in the report that Codex documents need to include greater emphasis on a risk-based approach to safe water use and reuse and that in Codex texts a risk-based approach to safe water sourcing and use that is fit for purpose should be articulated. We also suggest qualifying the example of water that is not fit for use in food, since in many cases the same water is used for food and non-food uses; the fact that the water is used for fire control, etc. does not necessarily make it not fit for use in food.
[~~7~~7.3 Water	**Nicaragua** Nicaragua supports the proposed text.
Water, as well as ice and steam made from water, should be fit for its intended purpose based on a risk-based approach [here we would add the footnote to the FAO/WHO report when it is available]. They should not cause contamination of food. Water and ice should be stored and handled in a manner that does not result in their becoming contaminated, and the generation of steam that will contact food should not result in its contamination. Water that is not fit for use in contact with food (e.g., water for fire control and for steam that will not directly contact food) should have a separate system that does not connect with or allow reflux into the system for water that will contact food. Water recirculated for reuse and water recovered from processing of food by evaporation should be treated where necessary to ensure that the water does not compromise the safety and suitability of food.]	**Nicaragua**
Water, as well as ice and steam made from water, should be fit for its intended purpose based on a	**Uruguay**

risk-based approach [here we would add the footnote to the FAO/WHO report when it is available]. They should not cause contamination of food. Water and ice should be stored and handled in a manner that does not result in their becoming contaminated, and the generation of steam that will contact food should not result in its contamination. Water that is not fit for use in contact with food (e.g., water for fire control and for steam that will not directly contact food) should have a separate system that does not connect with or allow reflux into the system for water that will contact food. Water recirculated for reuse and water recovered from processing of food by evaporation should be treated where necessary to ensure that the water does not compromise the safety and suitability of food.]	In addition to the FAO/WHO report, a discussion document was recently presented to the CCFH: "Discussion paper on principles for the safe use of water in food processing". Uruguay also suggests waiting for the developments of this document and its impact on the issue of water in the CCFH and the corresponding documents, such as this one.
7.5 Recall Procedures - removal from the market of unsafe food	
~~FBOs should ensure effective procedures are in place to respond to deviations from the food hygiene system. Deviations should be assessed for the impact on food safety or suitability. Procedures should enable the comprehensive, rapid and effective removal from the market by the involved FBO(s) and/or return to the FBO by the consumers of any food that may pose a risk to public health.~~ FBOs should ensure effective procedures are in place to respond to a non-conformity in the food hygiene system. A non-conformity should be assessed for the impact on food safety or suitability.Procedures should enable the comprehensive, rapid and effective removal from the market by the involved FBO(s) and/or return to the FBO by the consumers of any food that may pose a risk to public health. Where a product has been recalled because of the likely presence of hazards that may represent an immediate health risk, other products which are produced under similar conditions which may also present a hazard to public health should be evaluated for safety and may need to be recalled. The need for public warnings and reporting to the relevant competent authority should be considered where product may have reached consumers and when return of product to the FBO is advisable. Recall procedures should be documented, maintained, and modified where necessary based on the findings of periodic field trials.	**ISO** According to the definitions "deviation" is failure to meet a critical limit or to follow a GHP procedure. This definition does not relate to "deviations from the hygiene system". Since the hygiene system contains more than critical limits or GHP procedures, the word "deviation" should not be used in relation to the hygiene system.
Provision should be made for removed or returned products to be held under secure conditions until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to reduce the hazard to acceptable levels, where permitted by the competent authority. The cause, extent and result of a recall should be retained as documented information.	**Japan** For clarification.
FBOs should ensure effective procedures are in place to respond to deviations from the food hygiene system. Deviations should be assessed for the impact on food safety or suitability. Procedures should enable the comprehensive, rapid and effective removal from the market by the involved FBO(s) and/or return to the FBO by the consumers of any food that may pose a risk to public health. Where a product has been recalled because of the likely presence of hazards that may represent an immediate health risk, other products which are produced under similar conditions which may also present a hazard to public health should be evaluated for safety and may need to be recalled. ~~The need for public warnings and reporting to the relevant competent authority should be considered where product may have reached consumers and when return of product to the FBO is advisable. Recall procedures should be documented, maintained, and modified where necessary based on the findings of periodic field trials.~~**Communication mechanisms between the FBOs and competent authorities** should be considered regarding the need to issue public alerts and inform the competent authority when the product as reached consumers and when it is advisable to return the product to the FBO. Recall procedures should be documented, maintained, and modified where necessary based on the	**Honduras** We suggest referencing CXG19-1995 and CXG 25-1997.

findings of periodic field trials.	
SECTION 8: PRODUCT INFORMATION AND CONSUMER AWARENESS [Translator's note: change does not affect the English]	**Uruguay**
8.1 Lot Identification and Traceability	
Lot identification or other identification strategies are essential in product recall and also help effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. [Translator's note: change does not affect the English] The General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) applies.	**Argentina** CXS 1-1985 refers to permanently.
8.2 Product Information	
All food products should be accompanied by or bear adequate information to enable the next ~~person/FBO~~ user and consumer in the food chain to handle, prepare, display, store, and/or use the product safely and correctly. Information for FBOs should be clearly distinguishable from consumer information, particularly on food labels.	**Gambia** Rationale: For consistency with paragraph 150 and uniform interpretation.
All food products should be accompanied by or bear adequate information to enable the next person/FBO in the food chain to handle, prepare, display, store, and/or use the product safely and correctly. ~~Information for FBOs should be clearly distinguishable from consumer information, particularly on food labels.~~	**Japan** We are not sure why the information for FBOs should be distinguished from consumer information, and propose to delete this sentence.
All food products should be accompanied by or bear adequate information to enable the next person/FBO in the food chain to handle, prepare, display, store, and/or use the product safely and correctly. Information for FBOs should be clearly distinguishable from consumer information, particularly on food labels.	**Morocco** Morocco proposes replacing the term “person” with the term “next user or consumer in the food chain.” The text will be as follows: “All food products should be accompanied by or bear adequate information to enable the next user or next user or consumer in the food chain to handle, prepare, display, store, and/or use the product safely and correctly. Information for economic operators should be clearly distinguishable from consumer information, particularly on food labels. Rationale: for consistency with paragraph 150 and uniform interpretation.
CHAPTER TWO	
HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION	
INTRODUCTION	
The first section of this Chapter sets out the seven principles of the Hazard Analysis and Critical Control Point (HACCP) system. The second section provides general guidance for the application of the HACCP system and the third section describes its application in 12 successive steps (Diagram 1), while recognizing that the details of application may vary and a more flexible approach to application may be appropriate depending on the circumstances and the capabilities of the food business operation. The HACCP system, which is science-based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on control measures for significant hazards along the food chain, rather than relying mainly on end-product testing. Development of a HACCP system may identify the need for changes in processing parameters, in processing steps, in manufacturing technology, in end product characteristics, in method of	**USA** The sentence is more appropriate in this Chapter and paragraph than its original location in Chapter One on Good Hygiene Practices.

distribution, in the intended use or in the GHPs applied. Any HACCP system should be capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.	
HACCP principles can be considered throughout the food chain from primary production to final consumption, and their implementation should be guided by scientific evidence of risks to human health. Although it is not always feasible to apply HACCP at primary production, some of the principles can be applied and may be incorporated into good practices programmes, such as Good Agricultural Practice ~~programmes~~programmes etc.. It is recognised that implementation of HACCP may be challenging for some businesses. However, HACCP principles can be applied flexibly in individual operations, and businesses may use external resources (e.g. consultants) or adapt a generic HACCP plan provided by the competent authority, academia or other competent bodies (e.g. trade or industry associations) to the specific site circumstances. As well as enhancing food safety, implementation of HACCP can provide other significant benefits, such as more efficient processes based on a thorough analysis of capability, more effective use of resources by focusing on critical areas, and fewer recalls through identification of problems before product is released. In addition, the application of HACCP systems can aid inspection by competent authorities and promote international trade by increasing confidence in food safety.	**India** Primary also cover aquaculture practices and many more. Therefore it will not be appropriate to restrict such activities to GAP only whereas other practices like best aquaculture practices etc are also included under primary production.
The successful application of HACCP requires the commitment and involvement of management and other personnel and the knowledge and/or training in its application for the particular type of food business. A multi-disciplinary approach is strongly recommended; this multi-disciplinary approach should be appropriate to the food business operation and may include, for example, expertise in primary production, agronomy, veterinary health, microbiology, public health, food technology, environmental health, chemistry and engineering, according to the particular application. The application of HACCP is the system of choice to achieve food safety.	**USA** These fields are important and provide unique and valuable knowledge, especially for food businesses in the primary production area.
The first section of this Chapter sets out the seven principles of the Hazard Analysis and Critical Control Point (HACCP) system. The second section provides general guidance for the application of the HACCP system and the third section describes its application in 12 successive steps (Diagram 1), while recognizing that the details of application may vary and a more flexible approach to application may be appropriate depending on the circumstances and the capabilities of the food business operation. The HACCP system, which is science-based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on control measures for significant hazards along the food chain, rather than relying mainly on end-product testing. Any HACCP system ~~should~~ must be capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.	**Colombia**
HACCP principles can be considered throughout the food chain from primary production to final consumption, and their implementation ~~should~~ must be guided by scientific evidence of risks to human health. Although it is not always feasible to apply HACCP at primary production, some of the principles can be applied and may be incorporated into Good Agricultural Practice programmes. It is recognised that implementation of HACCP may be challenging for some businesses. However, HACCP principles can be applied flexibly in individual operations, and businesses may use external resources (e.g. consultants) or adapt a generic HACCP plan provided by the competent authority, academia or other competent bodies (e.g. trade or industry associations) to the specific site	**Colombia**

circumstances. As well as enhancing food safety, implementation of HACCP can provide other significant benefits, such as more efficient processes based on a thorough analysis of capability, more effective use of resources by focusing on critical areas, and fewer recalls through identification of problems before product is released. In addition, the application of HACCP systems can aid inspection by competent authorities and promote international trade by increasing confidence in food safety.	
The successful application of HACCP requires the commitment and involvement of management and personnel and the knowledge and/or training in its application for the particular type of food business. A multi-disciplinary approach is strongly recommended; this multi-disciplinary approach ~~should~~ must be appropriate to the food business operation and may include, for example, expertise in primary production, microbiology, public health, food technology, environmental health, chemistry and engineering, according to the particular application. The application of HACCP is the system of choice to achieve food safety.	**Colombia**
Barriers to the application of HACCP in small and less developed businesses (SLDBs) have been acknowledged and flexible approaches to the implementation of HACCP in such businesses[6] are available and encouraged. Some approaches may provide ways to adapt the HACCP approach to assist competent authorities in supporting SLDBs, for example, development of a HACCP-based system which is consistent with the seven principles of HACCP but does not conform to the layout or steps described in this chapter, e.g. recording only non-compliance monitoring results instead of every monitoring result to reduce unnecessary burden of record keeping for certain types of FBOs.	**Guatemala** Guatemala suggests adding the following to paragraph 137: “It is the competent authority's responsibility to determine if an FBO can be considered an SLDB so that it may have more flexible guidelines applied than those set forth in this document.”
SECTION 1: PRINCIPLES OF THE HACCP SYSTEM	**Honduras** We suggest including a final paragraph to compile the guidelines on validating the HACCP and the safety system control measures referenced in the CAC/GL 69-2008 document.
PRINCIPLE 3	
Establish ~~validated~~ critical limits.	**Brazil** Rationale: It will not always be necessary to validate the critical limit internally. Sometimes the critical limit is scientifically validated from a recognized source and will be simply be assumed by the FBOs
PRINCIPLE 5	
Establish the corrective actions to be taken when monitoring indicates ~~that~~ a ~~particular CCP is not under control.~~ deviation from a critical limits at a CCP.	**ISO** proposal for consistent language: a loss of control at a CCP is defined as a deviation and the purpose of monitoring is to detect deviation. According to the definitions "Loss of control" is a broader concept than "a deviation".
Establish the corrective actions to be taken when monitoring indicates that a deviation from a critical limit at a particular ~~CCP is not under control~~CCP.	**Japan** To improve clarity.
PRINCIPLE 6	
	Gambia Issue – Section 1: Principles of HACCP System – Principle 6. The inclusion of validation in HACCP Principle 6 Position: The Gambia supports the inclusion of validation in

	HACCP Principle 6 to read as follows: Conduct validation and establish procedures for verification to confirm that the HACCP system is working effectively. Rationale: Validation is applicable in the whole HACCP system just like verification.
~~Establish~~ Validate the HACCP plan and the establish procedures for verification to confirm that the HACCP system is working effectively.	**Brazil** Rationale: Thus, it is understood that the validation and verification are distinct procedures and the chronological order for its realization, being the verification performed after validation.
Establish procedures for verification to confirm that the HACCP system is working effectively.	**Morocco** Morocco supports the inclusion of "HACCP validation" in Principle 6 as follows: Conduct validation and verification procedures to confirm that the HACCP system is working effectively. Rationale: Validation is applicable for the entire HACCP system just like verification.
Establish procedures for verification to confirm that the HACCP system is working effectively. [Translator's note: change does not affect the English]	**Honduras**
Establish procedures for verification to confirm that the HACCP system is working effectively. [Translator's note: change does not affect the English]	**Colombia**
2.1 Introduction	
A HACCP approach should be customized to each food business. Hazards, CCPs, critical limits, CCP monitoring, CCP corrective actions and verification activities can be distinctive for a particular situation and those identified in a Codex Code of Practice or other appropriate guidelines might not be the only ones identified for a specific application or might be of a different nature.	**Gambia** Issue - para. 141 Inclusion of "control measure" in Position: The Gambia recommends the inclusion of the phrase "control measure" in para 141. The sentence should read as follows: A HACCP approach should be customized to each food business. Hazards, CCPs, critical limits, CCP monitoring, control measure, CCP corrective actions and verification activities can be distinctive for a particular situation and those identified for a specific application or might be of a different nature. Rationale: To emphasize that "control measures" applied by different FBOs may be distinctive depending on the operations of the FBO.
Prior to application of a HACCP system by any FBO in the food chain, that FBO should have in place prerequisite programmes, including GHPs established in accordance with Chapter One of this document, the appropriate product and sector-specific Codex Codes of Practice, and in accordance with relevant food safety requirements set by competent authorities. Prerequisite programmes ~~should~~ must be well-established, fully operational and verified, where possible, in order to facilitate the successful application and implementation of the HACCP system. HACCP application will not be effective without prior implementation of prerequisite programmes including GHPs.	**Colombia**
2.2 Flexibility for small and/or less developed food businesses	
The application of the HACCP principles to develop an effective HACCP system should be the responsibility of each individual business. However, it is recognised by competent authorities and FBOs that there may be obstacles that hinder the effective application of the HACCP principles by	**IDF/FIL** The intent is that flexibility should not impact negatively on food safety. The current wording implies that there is "a correct

individual businesses. This is particularly relevant in small and/or less developed businesses. While it is recognized that flexibility appropriate to the business is important when applying HACCP, all seven principles should be considered in developing the HACCP system. This flexibility should take into account the nature of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints, as well as the risk associated with the produced food. ~~The~~ Applying such flexibility is not intended to ~~reduce CCPs~~ impact negatively on the efficacy of the HACCP system and should not endanger food safety.	number of CCPs", which is not always the case. Rewording of this sentence is necessary.
The application of the HACCP principles to develop an effective HACCP system should be the responsibility of each individual business. However, it is recognised by competent authorities and FBOs that there may be obstacles that hinder the effective application of the HACCP principles by individual businesses. This is particularly relevant in small and/or less developed businesses. While it is recognized that flexibility appropriate to the business is important when applying HACCP, all seven principles should be considered in developing the HACCP system. This flexibility should take into account the nature of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints, as well as the risk associated with the produced food. The flexibility is not intended to reduce CCPs and should not endanger food safety.	**Gambia** Issue - Para. 143. Flexibility for small and/or less developed food businesses Position: To aid in the utility of the document, The Gambia recommends the inclusion of other examples of activities that can be considered as "flexible" apart from documentation.
The application of the HACCP principles to develop an effective HACCP system should be the responsibility of each individual business. However, it is recognised by competent authorities and FBOs that there may be obstacles that hinder the effective application of the HACCP principles by individual businesses. This is particularly relevant in small and/or less developed businesses. While it is recognized that flexibility appropriate to the business is important when applying HACCP, all seven principles should be considered in developing the HACCP system. This flexibility should take into account the nature of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints, as well as the risk associated with the produced food. The flexibility is not intended to simply reduce the number of CCPs and should not endanger food safety.	**Japan** For clarity. The original text is not clear whether "reduce CCP" means reducing the number of CCPs or reducing the intensity of control measures applied at CCPs.
The application of the HACCP principles to develop an effective HACCP system should be the responsibility of each individual business. However, it is recognised by competent authorities and FBOs that there may be obstacles that hinder the effective application of the HACCP principles by individual businesses. This is particularly relevant in small and/or less developed businesses. While it is recognized that flexibility appropriate to the business is important when applying HACCP, all seven principles should be considered in developing the HACCP system. This flexibility should take into account the nature of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints, as well as the risk associated with the produced food. The flexibility is not intended to reduce CCPs and should not endanger food safety.	**Morocco** Morocco proposes the inclusion of other examples of activities that can be considered as "flexible" apart from documentation. Rationale: For better understanding of flexibility.
Small and/or less developed businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP system. In such situations, expert advice should be obtained from other sources, which may include trade and industry associations, independent experts and competent authorities. HACCP literature and especially sector-specific HACCP guides (HACCP based systems - see 137 and 157) can be valuable. HACCP guidance developed by experts relevant to the process or type of operation may provide a useful tool for businesses in designing and implementing a HACCP plan. Where businesses are using expertly developed HACCP guidance, it is essential that it is specific to the foods and/or processes under consideration[7]. A comprehensive explanation of the basis for the HACCP plan should be provided to	**ISO**

the FBO. The FBO is ultimately responsible for the HACCP system and the production of safe food.	
The HACCP system ~~should~~ must be reviewed periodically and whenever there is a significant change that could impact the potential hazards and/or the control measures (e.g. new process, new ingredient, new product, new equipment) associated with the food business.	**Colombia**
The application of the ~~HACCP~~ hazard analysis critical control point principles to develop an effective HACCP system should be the responsibility of each individual business. However, it is recognised by competent authorities and FBOs that there may be obstacles that hinder the effective application of the HACCP principles by individual businesses. While it is recognized that flexibility appropriate to the business is important when applying HACCP, all seven principles ~~should~~ must be considered in developing the HACCP system. This flexibility ~~should~~ must take into account the nature of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints, as well as the risk associated with the produced food. The flexibility is not intended to reduce CCPs and ~~should~~ must not endanger food safety.	**Colombia**
SECTION 3: APPLICATION **THE APPLICATION OF HACCP PRINCIPLES CONSISTS OF THE FOLLOWING TASKS AS IDENTIFIED IN THE LOGICAL SEQUENCE FOR APPLICATION OF HACCP (DIAGRAM 1).**	**Honduras** We suggest including this paragraph in Section 3, which is in the Codex document. The application of HACCP principles consists of the following tasks as identified in the Logical Sequence for Application of HACCP (Diagram 1).
3.2 Describe product (Step 2)	
A full description of the product should be developed, including relevant safety information such as composition (i.e. ingredients), physical/chemical characteristics (e.g. a_w, pH, preservatives, allergens), processing methods/technologies (heat-treatment, freezing, drying, brining, smoking, etc.), packaging, durability/shelf life, storage conditions and method of distribution. Within businesses with multiple products, it may be effective to group products with similar characteristics and processing steps for the purpose of development of the HACCP plan. ~~Any limits relevant to the food product already established for hazards should be considered and accounted for in the HACCP plan, e.g. limits for food additives, regulatory microbiological criteria, maximum allowed veterinary medicines residues, and times and temperatures for heat treatments prescribed by competent authorities.~~	**USA** The paragraph is about describing the product, not about limits on hazards.
3.1 ~~Assemble HACCP Team and Identify Scope (Step 1)~~Form **an HACCP Team and Identify Scope (Step 1)**	**Honduras** We suggest considering to change the word “assemble” with “form” to be consistent with the concepts found in the existing document and the description in the paragraph.
The FBO should ensure that the appropriate knowledge and expertise are available for the development of an effective HACCP system. This may be achieved by assembling a multidisciplinary team responsible for different activities within the operation, e.g. production, maintenance, quality control, cleaning and disinfection. The HACCP team is responsible for developing the HACCP plan.	**Colombia**
The HACCP team ~~should~~ must identify the scope of the HACCP system and applicable prerequisite programmes. The scope ~~should~~ must describe which food products and processes are covered.	**Colombia**
3.3 Identify intended use and users (Step 3)	
Describe the use intended by the FBO and the expected uses of the product by the next user in the food chain or the consumer (they are the end user); the description should also include ways in which consumers are known to use the product other than those intended by the FBO. In specific cases,	**Argentina**

vulnerable groups of the population, e.g. institutional catering ***in institutional food services***, may have to be considered. Where foods are being produced specifically for a vulnerable population, it may be necessary to pay greater attention to some GHPs, enhance process controls, monitor control measures more frequently, verify controls are effective by testing products, or conduct other activities to provide a high level of assurance that the food is safe for the vulnerable population.	
Describe the use intended by the FBO and the expected uses of the product by the next user in the food chain or the consumer (they are the end user); the description ~~should~~ must also include ways in which consumers are known to use the product other than those intended by the FBO. In specific cases, vulnerable groups of the population, e.g. institutional catering, may have to be considered. Where foods are being produced specifically for a vulnerable population, it may be necessary to pay greater attention to some GHPs, enhance process controls, monitor control measures more frequently, verify controls are effective by testing products, or conduct other activities to provide a high level of assurance that the food is safe for the vulnerable population.	**Colombia**
Describe the use intended by the FBO and the expected uses of the product by the next user in the food chain or the consumer (they are the end user); the description should also include ways in which consumers are known to use the product other than those intended by the FBO. In specific cases, vulnerable groups of the population, e.g. institutional catering, may have to be considered. Where foods are being produced specifically for a vulnerable population, it may be necessary to pay greater attention to some GHPs, enhance ~~process~~ operation controls, monitor control measures more frequently, verify controls are effective by testing products, or conduct other activities to provide a high level of assurance that the food is safe for the vulnerable population.	**India** The term “process control” is not used anywhere in the document and has understanding as that in ISO standards and therefore should not be mentioned here.
Describe the use intended by the FBO and the expected uses of the product by the next user in the food chain or the consumer (they are the end user); the description should also include ways in which consumers are known to use the product other than those intended by the FBO. ~~In specific cases, vulnerable groups of the population, e.g. institutional catering, may have to be considered. Where foods are being produced specifically for a vulnerable population, it may be necessary to pay greater attention to some GHPs, enhance process controls, monitor control measures more frequently, verify controls are effective by testing products, or conduct other activities to provide a high level of assurance that the food is safe for the vulnerable population.~~	**ISO** The text below is written as a GHP and – unless reworded to fit into Chapter 2 – should be relocated to Chapter 1 – for instance as a new paragraph following para. 99, i.e. under the heading “Consideration of the effectiveness of GHPs” In specific cases, vulnerable groups of the population, e.g. institutional catering, may have to be considered. Where foods are being produced specifically for a vulnerable population, it may be necessary to pay greater attention to some GHPs, enhance process controls, monitor control measures more frequently, verify controls are effective by testing products, or conduct other activities to provide a high level of assurance that the food is safe for the vulnerable population.
3.4 Construct flow diagram (Step 4)	
	Japan Cross reference should be made to Chapter 1, Section 7.1.1.
“…….. Flow diagrams should, as appropriate, include but not be limited to the following: - Any outsourced**/subcontracted** processes	**Argentina**
A flow diagram that covers all steps in the production of a specific product, including any applicable rework, should be constructed. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. The flow diagram should indicate all inputs, including those of ingredients and food contact ~~materials~~materials (e.g., packaging), water and air if	**Canada** For clarification: does the reference to “inputs…including those of food contact materials…” - refer to “packaging”? If so, see suggested edit, if not please clarify.

relevant. Complex manufacturing operations can be broken down into smaller, more manageable modules and multiple flow diagrams that link together can be developed. The flow diagrams should be used when conducting the hazard analysis as a basis for evaluating the possible occurrence, increase, decrease or introduction of hazards. Flow diagrams should be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. Flow diagrams should, as appropriate, include but not be limited to the following:	
A full description of the product ~~should~~ must be developed, including relevant safety information such as composition (i.e. ingredients), physical/chemical characteristics (e.g. a_w, pH, preservatives, allergens), processing methods/technologies (heat-treatment, freezing, drying, brining, smoking, etc.), packaging, durability/shelf life, storage conditions and method of distribution. Within businesses with multiple products, it may be effective to group products with similar characteristics and processing steps for the purpose of development of the HACCP plan. Any limits relevant to the food product already established for hazards ~~should~~ must be considered and accounted for in the HACCP plan, e.g. limits for food additives, regulatory microbiological criteria, maximum allowed veterinary medicines residues, and times and temperatures for heat treatments prescribed by competent authorities.	**Colombia**
A flow diagram that covers all steps in the production of a specific product, including any applicable rework, ~~should~~ must be constructed. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. The flow diagram ~~should~~ must indicate all inputs, including those of ingredients and food contact materials, water and air if relevant. Complex manufacturing operations can be broken down into smaller, more manageable modules and multiple flow diagrams that link together can be developed. The flow diagrams ~~should~~ must be used when conducting the hazard analysis as a basis for evaluating the possible occurrence, increase, decrease or introduction of hazards. Flow diagrams ~~should~~ must be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. Flow diagrams ~~should~~ must, as appropriate, include but not be limited to the following:	**Colombia**
3.5 On-site confirmation of flow diagram (Step 5)	
3.5 On-site ~~confirmation~~ verification of flow diagram (Step 5) Steps should be taken to confirm the processing activities against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The ~~confirmation~~ verification of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.	**IDF/FIL** The term “verification” is commonly used for such exercise.
Steps ~~should~~ must be taken to confirm the processing activities against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the flow diagram ~~should~~ must be performed by a person or persons with sufficient knowledge of the processing operation.	**Colombia**
	Japan Cross reference should be made to Chapter 1, Section 7.1.2.
3.6 List all hazards that are likely to occur and associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards (Step 6/ Principle 1)	
The hazard analysis can be simplified by breaking down complex manufacturing operations and analysing steps in the multiple flow diagrams described in **step** 4 [Translator's note: change does not affect the English] 156. The hazard analysis should consider not only the intended use, but also any known unintended	**Argentina**

use (e.g. a soup mix intended to be mixed with water and cooked but known to commonly be used without a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan. (See Diagram 2 for an example of a hazard analysis worksheet.). ***It must also be considered whether a food may be a choking hazard for consumers, depending on the size, shape and texture of the food.***	
Hazard analysis consists of identifying potential hazards and evaluating these hazards to determine which of them are significant for the specific food business operation. An example of a hazard analysis worksheet is provided at Diagram 2. The HACCP team should ~~list~~ identify and document all food safety hazards that are associated with the raw materials and other ingredients, the product, the production or preparation process, and the environment in which the food is produced and/or handled *. The HACCP team shall determine for which of these hazards control measures are required and shall identify the steps where these hazards ~~reasonably likely~~ can be prevented, eliminated or reduced to ~~occur at~~ acceptable levels. The HACCP team shall assess each step (including all inputs into that step) according to the scope of the food business operation~~. Hazards should be specific, e.g. metal fragments, and the source or reason for presence should be described, e.g. metal from broken blades after chopping. The hazard analysis can be simplified by breaking down complex manufacturing operations and analysing steps in the multiple flow diagrams described in step 4.~~	**ISO** ISO comment: We recommend that prior to the assessment of their process steps, FBOs make a list of hazards that they should be looking for. See General Principles (iii) on page 6 and ISO 22000 8.5.2.2.1
hazards associated with producing or processing the type of food, including its ingredients and process steps (e.g. from surveys or sampling and testing of hazards in the food chain, from recalls, from information in the scientific literature or from epidemiological data); • the nature of the hazards, such as their source/origin, ability to multiply in the food, deteriorate and produce toxins	**IDF/FIL** add important aspects of hazard analysis.
the likelihood of occurrence of hazards, taking into consideration prerequisite programs, in the absence of additional control~~;~~; • Identified acceptable levels of hazards in the food (e.g. based on regulation, intended use and experience)	**IDF/FIL** An important aspect of hazard analysis is an assessment of whether identified acceptable levels are met. A prerequisite for such assessment is that acceptable levels are identified. [(The acceptable level in the end-product should be determined on the basis of: ■ End-product specifications (for example, max. levels and other criteria) specified by regulatory authorities ■ Specifications required for bulk food by the next step in the food chain ■ Scientific literature and professional experience]
3.6 ~~**List all hazards that are likely to occur and associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards (Step 6/ Principle 1))**~~Identify a list of **all hazards that are likely to occur and associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards (Step 6/ Principle 1)**	**Honduras** We suggest considering to change the verb “list” for “identify” to be consistent with the concepts in the current document and with the paragraph description.
Hazard analysis consists of identifying potential hazards and evaluating these hazards to determine which of them are significant for the specific food business operation. An example of a hazard analysis worksheet is provided at Diagram 2. The HACCP team ~~should~~ must list all of the hazards reasonably likely to occur at each step (including all inputs into that step) according to the scope of the food business operation. Hazards ~~should~~ must be specific, e.g. metal fragments, and the source	**Colombia**

or reason for presence ~~should~~ must be described, e.g. metal from broken blades after chopping. The hazard analysis can be simplified by breaking down complex manufacturing operations and analysing steps in the multiple flow diagrams described in step 4.	
The HACCP team ~~should~~ must next evaluate the hazards to identify which of these ~~hazards~~may be present~~are such~~ and that their prevention, elimination, or reduction to acceptable levels is essential to the production of safe food (i.e., determine the significant hazards that have to be addressed in the HACCP plan).	**Colombia**
survival or multiplication of pathogenic ~~microorganisms~~microorganisms after production;	**IDF/FIL** Suggest putting emphasis on considering growth potential during shelf-life
the intended use and/or probability of reasonably foreseeable product mishandling by potential consumers that could render the food unsafe; and,	**IDF/FIL** The proposed qualification is commonly used in food safety texts *Category : TECHNICAL*
The hazard analysis should consider not only the intended use, but also any ~~known~~ reasonably foreseeable unintended use (e.g. a soup mix intended to be mixed with water and cooked but known to commonly be used without a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan. (See Diagram 2 for an example of a hazard analysis worksheet.)	**IDF/FIL** The proposed qualification is commonly used in food safety texts
The hazard analysis should consider not only the intended use, but also any ~~known unintended~~ reasonably foreseeable use (e.g. a soup mix intended to be mixed with water and cooked but known to commonly be used without a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan. (See Diagram 2 for an example of a hazard analysis worksheet.)	**Brazil** Rationale: Some uses may not be as predictable for FBOs.
The hazard analysis should consider not only the intended use, but also any known unintended use (e.g. a soup mix intended to be mixed with water and cooked but known to commonly be used without a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan. ~~(See Diagram 2 for an example of a hazard analysis worksheet.)~~	**USA** The second sentence in paragraph 153 provides this information ("An example of a hazard analysis worksheet is provided at Diagram 2.").
The hazard analysis should consider not only the intended use, but also any known unintended use (e.g. a soup mix intended to be mixed with water and cooked but known to commonly be used without a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan. (See Diagram 2 for an example of a hazard analysis worksheet.)	**Uruguay** Uruguay considers that this paragraph requires further discussion, as it is not possible to predict "known unintended use."
The hazard analysis ~~should~~ must consider not only the intended use, but also any known unintended use (e.g. a soup mix intended to be mixed with water and cooked but known to commonly be used without a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan. (See Diagram 2 for an example of a hazard analysis worksheet.)	**Colombia**
Hazards which are such that their prevention, elimination or reduction to acceptable levels is essential to the production of safe food (because they are reasonably likely to occur in the absence of control and reasonably likely to cause illness or injury if present) should be identified as significant and controlled by measures designed to ~~prevent or eliminate~~ control these ~~hazards or reduce them to an acceptable level~~hazards. In some cases, this may be achieved with the application of good hygiene practices, some of which may target a specific hazard (for example, cleaning equipment to control contamination of ready-to-eat foods with Listeria monocytogenes or to prevent food allergens being transferred from one food to another food that does not contain that allergen). In other instances,	**IDF/FIL** Alignment with the definition of "significant hazard". Simplification of the text. "Control" is a more comprehensive term. The text striked out is implicit in the term "control measure".

control measures will need to be applied within the process, e.g. at critical control points.	
Hazards which are such that their prevention, elimination or reduction to acceptable levels is essential to the production of safe food (because they are reasonably likely to occur in the absence of control and reasonably likely to cause illness or injury if present) should be identified and controlled by measures designed to prevent or eliminate these hazards or reduce them to an acceptable level. In some cases, this may be achieved with the application of good hygiene practices, some of which may target a specific hazard (for example, cleaning equipment to control contamination of ready-to-eat foods with ~~Listeria monocytogenes~~ *Listeria monocytogenes* or to prevent food allergens being transferred from one food to another food that does not contain that allergen). In other instances, control measures will need to be applied within the process, e.g. at critical control points.	**USA**
Hazards which are such that their prevention, elimination or reduction to acceptable levels is essential to the production of safe food (because they are reasonably likely to occur in the absence of control and reasonably likely to cause illness or injury if present) ~~should~~ must be identified and controlled by measures designed to prevent or eliminate these hazards or reduce them to an acceptable level. In some cases, this may be achieved with the application of good hygiene practices, some of which may target a specific hazard (for example, cleaning equipment to control contamination of ready-to-eat foods with Listeria monocytogenes or to prevent food allergens being transferred from one food to another food that does not contain that allergen). In other instances, control measures will need to be applied within the process, e.g. at critical control points.	**Colombia**
Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specified control measure. For example, to control L. monocytogenes, a heat treatment may be needed to kill the organism in the food and cleaning and disinfection may be needed to prevent transfer from the processing environment; while a heat treatment can control both Salmonella and E. coli O157:H7 that present a hazard in raw meat.	**IDF/FIL** "More than one control measure may be required to control a specific hazard ": Although this statement is correct it should be noted that it conflicts with the identification of a CCP using the decision tree in Diagram 3. See our comments to that diagram.
Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specified control measure. For example, to control ~~L. monocytogenes~~*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; while a heat treatment can control both ~~Salmonella~~ *Salmonella* and ~~E. coli~~ *E. coli* O157:H7 that present a hazard in raw meat.	**Japan**
Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specified control measure. For example, to control ~~L. monocytogenes~~*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; while a heat treatment can control both ~~Salmonella~~ *Salmonella* and ~~E. coli O157:H7~~ *E. coli O157:H7* that present a hazard in raw meat.	**USA**
Consideration ~~should~~ must be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specified control measure. For example, to control L. monocytogenes, a heat treatment may be needed to kill the organism in the food and cleaning and disinfection may be needed to prevent transfer from the processing environment; while a heat	**Colombia**

treatment can control both Salmonella and E. coli O157:H7 that present a hazard in raw meat.	
3.7 Determine the Critical Control Points (Step 7/ Principle 2)	
	Japan Cross reference should be made to Chapter 1, Section 7.1.2.
The FBO ~~should~~ must consider which among the available control measures listed during step 6, Principle 1 should be applied at a CCP. Critical Control points are to be determined only for hazards identified as significant as of the result of a hazard analysis. CCPs are established at steps where control is essential and where a loss of control could result in the production of a potentially unsafe food. The control measures at CCPs ~~should~~ must result in an acceptable level of the hazard being controlled. There may be more than one CCP in a process at which control is applied to address the same hazard (e.g. the cook step may be the CCP for killing the vegetative cells of a pathogenic spore-former, but the cooling step may be a CCP to prevent germination and growth of the spores). Similarly, a CCP may control more than one hazard (e.g. cooking can be a CCP that addresses several microbial pathogens). Determining whether or not the step at which a control measure is applied is a CCP in the HACCP system can be helped by using a decision tree (for example see diagram 3). A decision tree ~~should~~ must be flexible, given whether it is for use in production, slaughter, processing, storage, distribution or other processes Other approaches such as expert consultation may be used.	**Colombia**
The FBO should consider which among the available control measures listed during step 6, Principle 1 should be applied at a CCP. More than one control measures may be necessary at a CCP. Critical Control points are to be determined only for hazards identified as significant as of the result of a hazard analysis. CCPs are established at steps where control is essential and where a loss of control could result in the production of a potentially unsafe food. The control measures at CCPs should result in an acceptable level of the hazard being controlled. There may be more than one CCP in a process at which control is applied to address the same hazard (e.g. the cook step may be the CCP for killing the vegetative cells of a pathogenic spore-former, but the cooling step may be a CCP to prevent germination and growth of the spores). Similarly, a CCP may control more than one hazard (e.g. cooking can be a CCP that addresses several microbial pathogens). Determining whether or not the step at which a control measure is applied is a CCP in the HACCP system can be helped by using a decision tree (for example see diagram 3). A decision tree should be flexible, given whether it is for use in production, slaughter, processing, storage, distribution or other processes. Other approaches such as expert consultation may be used.	**IDF/FIL** Addition of useful information.
The FBO should consider which among the available control measures listed during step 6, Principle 1 should be applied at a CCP. Critical Control points are to be determined only for hazards identified as significant as of the result of a hazard analysis. CCPs are established at steps where control is essential and where a ~~loss of control~~ deviation could result in the production of a potentially unsafe food. The control measures at CCPs should result in an acceptable level of the hazard being controlled. There may be more than one CCP in a process at which control is applied to address the same hazard (e.g. the cook step may be the CCP for killing the vegetative cells of a pathogenic spore-former, but the cooling step may be a CCP to prevent germination and growth of the spores). Similarly, a CCP may control more than one hazard (e.g. cooking can be a CCP that addresses several microbial pathogens). Determining whether or not the step at which a control measure is applied is a CCP in the HACCP system can be helped by using a decision tree (for example see diagram 3). A decision tree should be flexible, given whether it is for use in production, slaughter,	**ISO** a loss of control at a CCP has a specific definition: it is defined as a deviation.

processing, storage, distribution or other processes. Other approaches such as expert consultation may be used.	
If the control measure can be used at the step being analysed, but can also be used later in the process, or there is another control measure for the hazard at a later step, the step being analysed should not be considered as a CCP. (As a general rule, the CCP should be the last step where the control measure can be effective for controlling the hazard).	**Canada** With regards to the statement "(As a general rule, the CCP should be the last step where the control measure can be effective for controlling the hazard)", this statement is debatable – if kept, a short rationale/explanation should accompany it.
If the control measure can be used at the step being analysed, but can also be used later or earlier in the process, or there is another control measure for the hazard at a ~~later~~ another step, the step being analysed should not be considered as a CCP. ~~(As~~ (When proliferation of a ~~general rule~~hazard can occur during processing, the CCP should be the last step where the control measure can be effective for controlling the hazard).	**IDF/FIL** This statement is not entirely true. CCP can be defined earlier in process, e.g. when removing hazards that do not proliferate later in the process. Any location of a CCP is acceptable if the combination of control measures show that hazards are in control. For example, the production of cream cheese may include 3 heat treatments, the first (milk pasteurization) being the CCP (elimination of zoonotic hazards from the milk) whereas the two other heat treatments mainly have a technological impact on the cheese and an effect on any spoilage bacteria from post contamination. In this scenario, the heat treatment that is the most decisive for food safety, is the milk pasteurization because early treatment prevents growth of zoonotic pathogens during subsequent process steps. If the CCP was located at the end of the processing, the traditional PO of heat treatments (5-6 log reductions) may not be sufficient. We suggest including the option of locating the CCP at other steps – not only later steps.
To identify a CCP, whether using a decision tree or other approach, the following ~~should~~ must be considered:	**Colombia**
Determine whether a control measure at a step is used in combination with a control measure at another step to control the same hazard; if so, both steps ~~should~~ must be considered as CCPs.	**Colombia**
If no control measures ~~exist~~ are implemented at any step for an identified significant hazard, then the product or process should be modified. If in a particular process or for a particular product, a hazard cannot be prevented, eliminated or reduce to acceptable levels, users and/or consumers of the product should be informed so when applicable they can apply control measures or they can avoid to use the product.	**ISO** Some hazard cannot be controlled or cannot be controlled fully: e.g. 1) allergens that are of natural origin cannot be prevented, eliminated or reduced to acceptable levels, 2) pathogens in raw ready to eat product cannot always be prevented. see also propsed text at principle(viii)
Establish validated critical limits for each CCP (Step 8/ Principle 3)	**Thailand** The detail of validation now only appears in Section 3.8 (para 164-166) which is only related to the validation of critical limits. Consequently, the validation of all elements of HACCP plan as a whole before implementation is left out.]The mentioned activity is now mixed with verification procedures in Section 3.11 (para 175-

	180). Thus, we are of the opinion that the detail about validation of all elements of HACCP plan as a whole before implementation should be clearly separated from verification.
Establish ~~validated~~ critical limits for each CCP (Step 8/ Principle 3)	**Brazil**
If the control measure cannot be used at this step, then this step ~~should~~ must not be considered as a CCP for the significant hazard.	**Colombia**
Critical limits are values that establish whether a CCP is in control, and in doing so they can be used to separate acceptable products from unacceptable ones. These critical limits should be measurable or observable. In some cases, more than one parameter could have a critical limit designated at a particular step (e.g. heat treatments commonly include critical limits for both time and temperature). Criteria often used include minimum and/or maximum values for critical parameters associated with the control measure such as measurements of temperature, time, moisture level, pH, aw, available chlorine, contact time, conveyor belt speed, viscosity, conductance, flow rate, or, where appropriate, parameters that can be observed, such as a pump setting or application of the correct label with appropriate allergen information. A deviation from the critical limit ~~non-conformance~~ indicates that it is likely that unsafe food has been produced.	**Canada** The term “non-conformance” is only used this one time in the whole document – we recommend using the term “deviation” for consistency with the terminology used in the rest of the document.
Critical limits are values that establish whether a CCP is in control, and in doing so they can be used to separate acceptable products from unacceptable ones. These critical limits should be measurable or observable. In some cases, more than one parameter could have a critical limit designated at a particular step (e.g. heat treatments commonly include critical limits for both time and temperature). Criteria often used include minimum and/or maximum values for critical parameters associated with the control measure such as measurements of temperature, time, moisture level, pH, aw, available chlorine, contact time, conveyor belt speed, viscosity, conductance, flow rate, or, where appropriate, parameters that can be observed, such as a pump setting or application of the correct label with appropriate allergen information. ~~A critical limit non-conformance indicates that it is likely that unsafe food has been produced.~~	**ISO**
Critical limits are values that establish whether a CCP is in control, and ~~in doing~~ so they ~~can be used~~ define the correct application and performance of a control measure. A deviation to ~~separate~~ a critical limit indicates that it is likely that the hazard is present in excess of it’s acceptable ~~products from unacceptable ones~~level and thus that unsafe food has been produced. ~~These critical~~ Critical limits should be measurable or observable. In some cases, more than one parameter could have a critical limit designated at a particular step (e.g. heat treatments commonly include critical limits for both time and temperature). Criteria often used include minimum and/or maximum values for critical parameters associated with the control measure such as measurements of temperature, time, moisture level, pH, aw, available chlorine, contact time, conveyor belt speed, viscosity, conductance, flow rate, or, where appropriate, parameters that can be observed, such as a pump setting or application of the correct label with appropriate allergen information. A critical limit non-conformance indicates that it is likely that unsafe food has been produced.	**ISO** In our view it is important to make a clear distinction between “acceptable levels” and “critical limits”. Acceptable level are related to maximum levels of a hazard in a certain product: they define whether a product is safe or unsafe. Critical limits are related to one or more parameters at a control measure. Critical limits define the correct application of a control measure. When all parameters of all control measures in a certain process of a certain product are within their critical limits this implies that hazards will be within acceptable levels and thus that products are safe. Our statement here above is supported by CX/FH 19/51/6 Chapter Two - 171: When critical limits at CCPs are monitored continuously and a deviation occurs, any product being produced at the time the deviation occurs is potentially unsafe. The phrase “A critical limit non-conformance” is inconsistent wording, according to the definitions we should refer to this as a deviation.

Critical limits are values that establish whether a CCP is in control, and in doing so they can be used to separate acceptable products from unacceptable ones. These critical limits should be measurable or observable. In some cases, more than one parameter could have a critical limit designated at a particular step (e.g. heat treatments commonly include critical limits for both time and temperature). Criteria often used include minimum and/or maximum values for critical parameters associated with the control measure such as measurements of temperature, time, moisture level, pH, aw, available chlorine, contact time, conveyor belt speed, viscosity, conductance, flow rate, or, where appropriate, parameters that can be observed, such as a pump setting or application of the correct label with appropriate allergen information. A critical limit non-conformance indicates that it is likely that unsafe food has been produced. 164bis: Any limits relevant to the food product already established for hazards should be considered and accounted for in the HACCP plan, e.g. limits for food additives, regulatory microbiological criteria, maximum allowed veterinary drug residues, and times and temperatures for heat treatments prescribed by competent authorities.	**USA** Moved from paragraph 149. Veterinary drug residues is more consistent with Codex terminology.
If the control measure can be used at the step being analysed, but can also be used later in the process, or there is another control measure for the hazard at a later step, the step being analysed ~~should~~ must not be considered as a CCP. (As a general rule, the CCP ~~should~~ must be the last step where the control measure can be effective for controlling the hazard).	**Colombia**
Critical limits for control measures at each CCP should be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented[9]. Validation of control measures and their critical limits is performed during the development of the HACCP plan and could include a review of scientific literature, using mathematical models, conducting validation studies, and/or using guidance developed by authoritative sources. when this alternatives are used a verification of the capability by the FBO to implement this measures in a proper way is recommended, when FBOs may not always need to commission studies themselves to validate critical limits. These could be based on existing literature, regulations or guidance from competent authorities, or studies carried out by a third party e.g. studies conducted by an equipment manufacturer to determine the appropriate time, temperature and bed depth for dry roasting tree nuts. Validation of control measures is further described more fully in the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69 – 2008).	**Chile** Due to the size or other aspects not always validated measures from literature function in the same way in every scenario.
Critical limits for control measures at each CCP should be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented[9]…	**IDF/FIL** This text is broader than validating critical limits As the heading of section 3.8 relates to critical limits, we suggest including a separate section on validation and moving this text to that section (e.g. a new section with its own heading "3.11bis Validation of control measures" See later comment.
Critical limits for control measures at each CCP should be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented[9]. ~~Validation of control measures and their critical limits is performed during the development of the HACCP plan and could include a review of scientific literature, using mathematical models, conducting validation studies, and/or using guidance developed by authoritative sources. FBOs may not always need to commission studies themselves to validate critical limits. These could~~	**Brazil**

~~be based on existing literature, regulations or guidance from~~ competent authorities, or studies carried ~~out by a third party e.g. studies conducted by an equipment manufacturer to determine the appropriate time, temperature and bed depth for dry roasting tree nuts. Validation of control measures is further described more fully in the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69 – 2008).~~	
Critical limits for control measures at each CCP should be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented[9]… Validation of control measures is ~~further~~ described more fully in the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69 – 2008).	**USA** The terms “further” and “more fully” are duplicative.
Critical limits are values that establish whether a CCP is in control, and in doing so they can be used to separate acceptable products from unacceptable ones. These critical limits should be measurable or observable. A critical limit **deviation that is in** non-conformance indicates that it is likely that unsafe food has been produced.	**Honduras** We suggest including deviation taking into account that the concept in this document's definitions refers specifically to critical limits.
Critical limits are values that establish whether a CCP is in control, and in doing so they can be used to separate acceptable products from unacceptable ones. These critical limits ~~should~~ must be measurable or observable. In some cases, more than one parameter could have a critical limit designated at a particular step (e.g. heat treatments commonly include critical limits for both time and temperature).	**Colombia**
Critical limits for control measures at each CCP ~~should~~ must be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented. Validation of control measures and their critical limits is performed during the development of the HACCP plan and could include a review of scientific literature, using mathematical models, conducting validation studies, and/or using guidance developed by authoritative sources. FBOs may not always need to commission studies themselves to validate critical limits. These could be based on existing literature, regulations or guidance from competent authorities, or studies carried out by a third party e.g. studies conducted by an equipment manufacturer to determine the appropriate time, temperature and bed depth for dry roasting tree nuts. ~~Validation of control measures is further described more fully in the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69 – 2008).~~	**Colombia**
~~Where HACCP guidance developed by experts, instead of the HACCP team, has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration.~~	**Brazil** Rationale: For consistency, Brazil suggests that validation be included in a later item, relating to all stages.
3.9 Establish a monitoring system for each CCP (Step 9/ Principle 4)	
Monitoring of CCPs is the scheduled measurement or observation at a CCP relative to its critical limits. The monitoring procedures ~~should~~ must be able to detect loss of control at the CCP. Further, the monitoring method and frequency ~~should~~ must be capable of timely detection of any failure to remain within critical limits, to allow timely isolation and evaluation of the product. Where possible, process adjustments ~~should~~ must be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs.	**Colombia**
Monitoring of CCPs is the scheduled measurement or observation at a CCP relative to its critical limits. The monitoring procedures should be able to detect ~~loss of control~~ a deviation at the CCP. Further, the monitoring method and frequency should be capable of timely detection of any failure to	**ISO** a loss of control at a CCP has a specific definition: it is defined as a deviation.

remain within critical limits, to allow timely isolation and evaluation of the product. Where possible, process adjustments should be made when monitoring results indicate a trend towards ~~loss of control~~ a deviation at a CCP. The adjustments should be taken before a deviation occurs.	
Where possible, monitoring of CCPs ~~should~~ must be continuous. Monitoring of measurable critical limits such as processing time and temperature can often be monitored continuously. Other measurable critical limits such as moisture level and preservative concentration cannot be monitored continuously. Critical limits that are observable, such as a pump setting or applying the correct label with appropriate allergen information are rarely monitored continuously. If monitoring is not continuous, then the frequency of monitoring ~~should~~ must be sufficient to ensure to the extent possible the critical limit has been met and limit the amount of product impacted by a deviation. Monitoring procedures for CCPs ~~should~~ must be capable of timely detection of a deviation from the critical limit to allow isolation of the affected products. Physical and chemical measurements are usually preferred to microbiological testing because physical and chemical tests can be done rapidly and can often indicate the control of microbial hazards associated with the product and/or the process.	**Colombia**
Where possible, monitoring of CCPs should be continuous. Monitoring of measurable critical limits such as ~~processing~~ combinations of time and temperature employed in processing can often be monitored continuously…	**India** To avoid usage of new term and make the statement more generic.
Where possible, monitoring of CCPs should be continuous. Monitoring of measurable critical limits such as processing time and temperature can often be monitored continuously. Other measurable critical limits such as moisture level and preservative concentration cannot be monitored continuously. Critical limits that are observable, such as a pump setting or applying the correct label with appropriate allergen information are rarely monitored continuously. If monitoring is not continuous, then the frequency of monitoring should be sufficient to ensure to the extent possible the critical limit has been met and limit the amount of product impacted by a deviation. Monitoring procedures for CCPs should be capable of timely detection of a deviation from the critical limit to allow isolation of the affected products. Physical and chemical measurements are usually preferred to microbiological testing because physical and chemical tests can be done rapidly and can often indicate the control of microbial hazards associated with the product and/or the process.	**Honduras** We suggest adding this paragraph at the end. Physical and chemical measurements are usually preferred to microbiological testing because physical and chemical tests can be done rapidly and often are related to surveillance activities while the control of microbial hazards are associated with the product, the process, verification and/or validation.
Where possible, monitoring of CCPs should be continuous. Monitoring of measurable critical limits such as processing time and temperature can often be monitored continuously. Other measurable critical limits such as ~~moisture level~~ pH and ~~preservative concentration~~ a_w cannot be monitored continuously. Critical limits that are observable, such as a pump setting or applying the correct label with appropriate allergen information are rarely monitored continuously...	**Japan** To be consistent with the examples in the comparison table in Annex 1.
~~Where possible, monitoring of~~ WMonitoring procedures for CCPs should be ~~continuous~~capable of timely detection of a deviation from the critical limit to allow isolation of the affected products. Monitoring of measurable critical limits such as processing time and temperature can often be monitored continuously, whereas other control measures cannot. ~~Other measurable critical limits such as moisture level~~ The method and ~~preservative concentration cannot be monitored continuously. Critical limits that are observable~~frequency of monitoring of CCPs should take into account the nature of the deviation, ~~such as~~ (temporally or permanent e.g. a ~~pump setting~~ drop in temperature drop or ~~applying~~ a broken sieve) and the ~~correct label with appropriate allergen information are rarely monitored continuously~~speed of their occurrence (rapid drop in temperature at pasteurisation or slow temperature rise in cooled storage). If monitoring is not continuous, then corrective actions shall	**ISO** • The main principle is the timely detection and correction of a deviation, which should be stated first. • It may be a problem that specific measures are listed as CCPs, in particular moisture levels, preservative concentration, applying correct label, allergen information). These are typically managed as PRPs or GHPs with greater attention. As regards reference to allergen information as a CCP – see our comment to para. 118. • A more generic wording is preferred (see proposed text

include all products produced after the ~~frequency~~ latest positive results of ~~monitoring should be sufficient to ensure to the extent possible the critical limit has been met and limit the amount of product impacted by a deviation~~monitoring. Monitoring ~~procedures for CCPs should be capable~~ of ~~timely detection of a deviation from the critical limit to allow isolation of the affected products. Physical and chemical measurements are usually preferred to microbiological testing because~~ physical and chemical ~~tests~~ parameters can be done rapidly and can often indicate the control of microbial hazards associated with the product and/or the process. In addition to monitoring, microbiological testing can be done to verify the safety of the product.	below) • Monitoring is an observations or measurements of control parameters to assess control measures relative to their critical limits. Sampling is a-typical as monitoring; sampling is typical as verification to assess products relative to the acceptable levels for a hazard. We should not provide sampling as an example for monitoring
~~Where possible, monitoring of~~ Monitoring procedures for CCPs should be ~~continuous~~capable of timely detection of a deviation from the critical limit to allow isolation of the affected products. Monitoring of measurable critical limits such as processing time and temperature can often be monitored continuously~~. Other measurable critical limits such as moisture level and preservative concentration cannot be monitored continuously. Critical limits that are observable~~, ~~such as a pump setting or applying the correct label with appropriate allergen information are rarely monitored continuously~~whereas other control measures cannot. ~~If monitoring is not continuous, then the~~ The method and frequency of monitoring ~~should be sufficient to ensure to the extent possible the critical limit has been met and limit the amount~~ of ~~product impacted by a deviation. Monitoring procedures for~~ CCPs should ~~be capable of timely detection of a deviation from~~ take into account the ~~critical limit to allow isolation~~ nature of the ~~affected products~~deviation, (temporally or permanent e.g. ~~Physical~~ a drop in temperature drop or a broken sieve) and ~~chemical measurements are usually preferred to microbiological testing because physical and chemical tests can be done rapidly and can often indicate~~ the ~~control~~ speed of ~~microbial hazards associated with~~ their occurrence (rapid drop in temperature at pasteurisation or slow temperature rise in cooled storage). If monitoring is not continuous, then corrective actions shall include all products produced after the ~~product and/or the process~~latest positive results of monitorings.	**ISO** Monitoring is an observations or measurements of control parameters to assess control measures relative to their critical limits. Sampling is a-typical as monitoring; sampling is typical as verification to assess products relative to the acceptable levels for a hazard. We should not provide sampling as an example for monitoring. The main principle is the timely detection and correction of a deviation, which should be stated first. • It may be a problem that specific measures are listed as CCPs, in particular moisture levels, preservative concentration, applying correct label, allergen information). These are typically managed as PRPs or GHPs with greater attention. As regards reference to allergen information as a CCP – see our comment to para. 118. • A more generic wording is preferred (see proposed text below)
Where possible, monitoring of CCPs should be continuous. Monitoring of measurable critical limits such as processing time and temperature can often be monitored continuously. Other measurable critical limits such as moisture level and preservative concentration cannot be monitored continuously. Critical limits that are observable, such as a pump setting or applying the correct label with appropriate allergen information are rarely monitored continuously. If monitoring is not continuous, then the frequency of monitoring should be sufficient to ensure to the extent possible the critical limit has been met and limit the amount of product impacted by a deviation. ~~Monitoring procedures for CCPs should be capable of timely detection of a deviation from the critical limit to allow isolation of the affected products.~~ Physical and chemical measurements are usually preferred to microbiological testing because physical and chemical tests can be done rapidly and can often indicate the control of microbial hazards associated with the product and/or the process.	**USA** This says essentially the same thing as a sentence in paragraph 167 (“Further, the monitoring method and frequency should be capable of timely detection of any failure to remain within critical limits, to allow timely isolation and evaluation of the product.”).
The personnel doing the monitoring ~~should~~ must be instructed on appropriate steps to take when monitoring indicates the need to take action. Data derived from monitoring ~~should~~ must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.	**Colombia**
All records and documents associated with monitoring CCPs ~~should~~ must be signed ~~or initialled~~ by the person performing the monitoring.	**Colombia**
The personnel doing the monitoring should be instructed on appropriate steps to take when monitoring indicates a deviation that requires corective action. the need to take action. Data derived	**ISO**

from monitoring should be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.	
The personnel doing the monitoring should be instructed on appropriate steps to take when monitoring indicates the ~~need to take action~~deviation. Data derived from monitoring should be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.	**Japan** To be consistent with para. 171.
Where HACCP guidance developed by experts, instead of the HACCP team, has been used to establish the critical limits, care ~~should~~ must be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration.	**Colombia**
3.10 ESTABLISH CORRECTIVE ACTIONS (STEP 10/ PRINCIPLE 5)	
	Canada Remove the caps in the title for consistency with the other sections.
Specific written corrective actions ~~should~~ must be developed for each CCP in the HACCP system in order to effectively respond to deviations when they occur. When critical limits at CCPs are monitored continuously and a deviation occurs, any product being produced at the time the deviation occurs is potentially unsafe. When a deviation in meeting a critical limit occurs and monitoring was not continuous, then the FBO ~~should~~ must determine what product may have been impacted by the deviation.	**Colombia**
Specific written corrective actions should be developed for each CCP in the HACCP system in order to effectively respond to deviations when they occur. When critical limits at CCPs are monitored continuously and a deviation occurs, any product being produced at the time the deviation occurs is potentially unsafe. When a deviation in meeting a critical limit occurs and monitoring was not continuous, then the FBO should determine ~~what~~ which lots of product may have been impacted by the deviation.	**USA**
The corrective actions taken when a deviation occurs ~~should~~ must ensure that the CCP has been brought under control and food that is potentially unsafe is handled appropriately and does not reach consumers. Actions taken ~~should~~ must include segregating the affected product and analysing its safety to ensure proper disposal.	**Colombia**
The corrective actions taken when a deviation occurs should ensure that the CCP has been brought ~~under control~~ within critcal limits and food that is potentially unsafe is handled appropriately and does not reach consumers. Actions taken should include segregating the affected product and analysing its safety to ensure proper disposal.	**ISO**
The corrective actions taken when a deviation occurs should ensure that the CCP has been brought ~~under control~~ within the critical limit and food that is potentially unsafe is handled appropriately and does not reach consumers. Actions taken should include segregating the affected product and analysing its safety to ensure proper disposal.	**Japan** For clarity.
External experts may be needed to conduct evaluations of the safety of products when a deviation occurs. In some cases, the evaluation may indicate that the product is safe and can be released. In other cases, it may be determined that the product could be reprocessed (e.g. pasteurized) or the product could be diverted to another use. In other situations, the product may need to be destroyed (e.g. contamination with Staphylococcus enterotoxin). A root cause analysis ~~should~~ must be conducted where possible to identify and correct the source of the deviation in order to minimize the	**Colombia**

potential for the deviation to reoccur. A root cause analysis could identify a reason for the deviation that limits or expands the amount of product impacted by a deviation.	
Details of the corrective actions, including the cause of the deviation and product disposal procedures, ~~should~~ must be documented in the HACCP records. Periodic review of corrective actions ~~should~~ must be undertaken to identify trends and to ensure corrective actions are effective.	**Colombia**
3.11 Establish and verification procedures (Step 11/Principle 6)	
3.11 Establish ~~and~~ verification procedures (Step 11/ Principle 6)	**Canada** Remove a word that remains from track changes.
3.11 Establish and verification procedures (Step 11/ Principle 6) **Validation should also be included under Principle 6. We also propose retaining the paragraphs related to validation under this Step/Principle.**	**India** Validation is not restricted to critical Limits alone. The control measures and the HACCP system as a whole needs to be validated. Validation is for effectiveness. Thus having it at Principle 6 is more appropriate. Validation is also done while developing the system, after implementation too, while verification is done only after implementation. Hence, proposed to retain it under Principle 6.
3.11 ~~Establish~~ HACCP plan validation and Establish verification procedures (Step 11/ Principle 6)	**Brazil**
Establish validation and verification procedures (Step 11 and Principle 6) [Translator's note: change does not affect the English]	**Peru** The text on validation must be included before verification as that last step is performed afterwards and allows for determining if the HACCP is effective and suitable.
Procedures should be established to confirm that the HACCP system is working effectively. These include procedures to verify that the HACCP plan is being followed and controlling hazards on an ongoing basis~~, as well as procedures that show the control measures are capable of controlling the hazards as intended.~~ Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur.	**Canada** The last statement in this paragraph pertains to validation (see definition: “Obtaining evidence that a control measure (…) is capable of controlling the hazard to a specified outcome”), not verification.
Procedures should be established to confirm that the HACCP system is working effectively. These include procedures to verify that the HACCP plan is being followed and controlling hazards on an ongoing basis, as well as procedures that show the control measures are ~~capable of~~ effectively controlling the hazards as intended. Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur.	**ISO** Assessment of capability is done through validation which assesses the control of hazards. Verification assesses the effectivity of control measures that includes the control of hazards as well as the control of deviations through monitoring and corrective actions.
An FBO that is producing, storing or otherwise handling food should have a description of the food. Products may be described individually or in groups in a manner that does not compromise the ~~awareness~~ ***perception*** of hazards or other factors such as suitability of the products for the purpose intended. Any grouping of food products should be based on them having similar inputs and ingredients, product characteristics (such as pH, water activity (aw)), process steps and/or intended purpose.	**Argentina**
Procedures should be established to confirm that the HACCP system is working effectively. These include procedures to verify that the HACCP plan is being followed and controlling hazards on an ongoing basis, as well as procedures that show the control measures are capable of controlling the hazards as intended. Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur.	**Brazil**

175a. Firstly, Validation of the HACCP plan is required: hazards identified, critical control points, critical limits, control measures, frequency and type of monitoring of CCPs, corrective actions, frequency and type of verification and the type of information to be recorded. 175b. Validation could include a review of scientific literature, using mathematical models, conducting validation studies, and/or using guidance developed by authoritative sources. 175c. Validation of control measures and their critical limits is performed during the development of the HACCP plan. FBOs may not always need to commission studies themselves to validate critical limits. These could be based on existing literature, regulations or guidance from competent authorites, or studies carried out by a third party e.g. studies conducted by an equipment manufacturer to determine the appropriate time, temperature and bed depth for dry roasting tree nuts. Validation of control measures is further described more fully in the Guidelines for the Validation of Food Safety Control Measures (CXG 69-2008). 175d. Where HACCP guidance developed by experts, instead of the HACCP team, has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration. 175e. After Validation, procedures should be established to confirm that the HACCP system is working effectively. These include procedures to verify that the HACCP plan is being followed and controlling hazards on an ongoing basis, as well as procedures taht show the control measures are capable of controlling the hazards as intended. Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur.	
Procedures ~~should~~ must be established to confirm that the HACCP system is working effectively. These include procedures to verify that the HACCP plan is being followed and controlling hazards on an ongoing basis, as well as procedures that show the control measures are capable of controlling the hazards as intended. Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur.	**Colombia**
During the initial implementation of the HACCP system and after verification procedures have been established, evidence ~~should~~ must be obtained in operation to verify that control can be achieved consistently under production conditions.	**Colombia**
Verification activities ~~should~~ must be performed on an ongoing basis to ensure the HACCP system functions as intended and continues to operate effectively. Verification, which includes observations, auditing (internal and external), calibration, sampling and testing, and records review, can be used to determine if the HACCP system is working correctly and as planned. Examples of verification activities include:	**Colombia**
Verification should include a comprehensive review (e.g. reanalysis or an audit) of the HACCP system periodically, as appropriate, or when changes occur, to confirm the efficacy of all elements of the HACCP system. This review of the HACCP system should confirm that the appropriate significant hazards have been identified, that control measures and critical limits are adequate to control the hazards, that monitoring, and verification activities are occurring in accordance with the plan and are capable of identifying deviations, and that corrective actions are appropriate for deviations that have occurred. This review can be carried out by individuals within a food business or by external experts. 3.11BIS VALIDATION (STEP 12/ PRINCIPLE 3) 180bis. Validation of control measures and their critical limits is performed during the development of	**IDF/FIL** As suggested in our comment to paragraph 165, we recommend addressing validation in a separate section. The suggested para 180bis is a copy paste of the text in para. 165, whereas the text in para. 180bisbis have been reinstated, as it was removed from the previous version of this document (para. 170 of the version dated 28 May 2019).

the HACCP plan and could include a review of scientific literature, using mathematical models, conducting validation studies, and/or using guidance developed by authoritative sources. FBOs may not always need to commission studies themselves to validate critical limits. These could be based on existing literature, regulations or guidance from competent authorities, or studies carried out by a third party e.g. studies conducted by an equipment manufacturer to determine the appropriate time, temperature and bed depth for dry roasting tree nuts. Validation of control measures is further described more fully in the Guidelines for the Validation of Food Safety Control Measures (CXG 69 – 2008). 181bisbis In addition to obtaining the evidence that the combination of control measures are capable of controlling the hazard, validation also includes obtaining evidence in operation during the initial implementation of the HACCP system to show that control can be achieved consistently under production conditions.	
Verification should include a comprehensive review (e.g. reanalysis or an audit) of the HACCP system periodically, as appropriate, or when changes occur, to confirm the efficacy of all elements of the HACCP system. This review of the HACCP system should confirm that the appropriate significant hazards have been identified, that control measures and critical limits are adequate to control the hazards, that ~~monitoring, and verification~~ monitoring activities are ~~occurring~~ executed in accordance with the plan and are capable of identifying deviations, and that corrective actions are appropriate for deviations that have occurred. The review also includes confirmation that various verification activities has been executed as intended.This review can be carried out by individuals within a food business or by external experts.	**ISO** Monitoring should be capable of detecting deviation - verification does not. Verification can detect a loss of control which is a broader concept then detection of a deviation by monitoring. And … verification cannot include review of verification
Verification should include a comprehensive review (e.g. reanalysis or an audit) of the HACCP system periodically, as appropriate, or when changes occur, to confirm the efficacy of all elements of the HACCP system. This review of the HACCP system should confirm that the appropriate significant hazards have been identified, that control measures and critical limits are adequate to control the hazards, that ~~monitoring, and verification~~ monitoring activities are occurring in accordance with the plan and are capable of identifying deviations, and that corrective actions are appropriate for deviations that have occurred, and that verification activities are conducted in accordance with the plan. This review can be carried out by individuals within a food business or by external experts.	**Japan** To avoid confusion. The original text would read like verification activities are capable of identifying deviations.
Verification should include a comprehensive review (e.g. reanalysis or an audit) of the HACCP system periodically, as appropriate, or when changes occur, to confirm the efficacy of all elements of the HACCP system… 180b. Any change in the production process requires an automatic revision of the HACCP plan and its subsequent validation. Likewise, any change in the HACCP plan, even without changing the production process, such as changing a control measure or a corrective measure, requires further validation.	**Brazil** Rationale : The validation item should include, in addition to critical limit validation, the validation of the HACCP plan as a whole. Therefore, paragraphs have been rearranged / rewritten to include this requirement.
Verification ~~should~~ must 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.	**Colombia**
The frequency of verification activities ~~should~~ must be sufficient to confirm that the HACCP system is working effectively. Verification of the implementation of control measures ~~should~~ must be conducted with sufficient frequency to determine that the HACCP plan is being implemented properly.	**Colombia**

Verification ~~should~~ must include a comprehensive review (e.g. reanalysis or an audit) of the HACCP system periodically, as appropriate, or when changes occur, to confirm the efficacy of all elements of the HACCP system. This review of the HACCP system ~~should~~ must confirm that the appropriate significant hazards have been identified, that control measures and critical limits are adequate to control the hazards, that monitoring, and verification activities are occurring in accordance with the plan and are capable of identifying deviations, and that corrective actions are appropriate for deviations that have occurred. This review can be carried out by individuals within a food business or by external experts.	**Colombia**
Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures ~~should~~ must be documented. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained. Expertly developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilized as part of the documentation, provided that those materials reflect the specific food operations of the business.	**Colombia**
validation of critical limits and control measures and	**IDF/FIL** Consistency with other parts of the text
Annex 1 - Comparison of GHPs and control measures at CCPs ***in an HACCP system*** with examples.	**Argentina**
Annex 1 - Comparison of GHPs and control measures at CCPs with examples. **Title of first column: Prerequisite programs, including GHPsunder that colum for scope: General conditions and activities that for maintaining hygiene, including creating the environment (inside and outside the food business) so as to ensure production of safe and suitable food, . and that set the foundation for implementation of a HACCP system.**	**IDF/FIL** It was not possible to insert changes directly in the table so proposed chanegs are summarized here. For consistency with the rest of the document and the defitnition of PHPs.
~~**Annex 1 - Comparison of GHPs and control measures at CCPs with examples.**~~**Annex 1 - Comparison of GHPs and control measures at CCPs with examples.** **1st ISO comment to Annex 1.** **Scope - right column** **Specific to production process steps and a product or group of products and necessary to eliminate or reduce to acceptable level a hazard determined as significant by the hazard analysis.** ISO comment: According to the decision tree and to the definitions of a CCP and of control measure this phrase should also include the prevention of a hazard. Proposed wording: Specific to production process steps and a product or group of products and necessary to prevent, eliminate or reduce to acceptable level a hazard determined as significant by the hazard analysis. **2nd ISO comment to Annex 1.** Annex 1 - when identified - right column After a hazard analysis has been completed, for each hazard identified as significant, control measures are established at steps (CCPs) where a loss of control would result in the production of a potentially unsafe food	**ISO**

ISO comment: a loss of control at a CCP is defined as “deviation”. Proposed wording: After a hazard analysis has been completed, for each hazard identified as significant, control measures are established at steps (CCPs) where their absence or a deviation would result in the production of a potentially unsafe food **3rd ISO comment to Annex 1.** Annex 1 left column: Validation of the effectiveness of the measure ISO comment: Validation assesses the capability of control measures, the effectiveness is assessed through verification. Proposed wording Validation of the capability of the measure **4th ISO comment to Annex 1.** Annex 1 right column: Critical limits which separate acceptable products from unacceptable at CCPs: ISO Comment: critical limits do not define acceptable product, they define the correct application of a control measure. It is important to make a distinction between “acceptable levels” and “critical limits”. Acceptable level are related to maximum levels of a hazard in a certain product: they define whether a product is safe or unsafe. Critical limits are related to one or more parameters at a control measure. Critical limits define the correct application of a control measure. When all parameters of all control measures in a certain process of a certain product are within their critical limits this implies that hazards will be within acceptable levels and thus that products are safe. Proposed wording: Critical limits which separate acceptable application from unacceptable application of control measures at CCPs: **5th ISO comment to Annex 1.** ISO comment: Within a HACCP system next to the control of hazards with control measures we should also focus on control of deviations with monitoring and corrective actions. We suggest to include a row after critical limit on deviations Proposed wording: First column: Deviation Second column Deviations may require an evaluation of the impact on safety of the product (e.g. whether the cleaning of complex equipment such as meat slicers is adequate). Third column: A deviation to a critical limit indicates that it is likely that the hazard is present in excess of it’s	

acceptable levels and thus that unsafe food has been produced.	
Annex 1 - Comparison of GHPs and control measures at CCPs with examples.	**Brazil** Control measures applied at CCPs in a HACCP system - Criteria: Critical limits which separate acceptable products from unacceptable at CCPs: • measurable (e.g. time, temperature, pH, aw), or • observable (e.g. ice covering product).
Annex 1 - Comparison of GHPs and control measures at CCPs with examples.	**Brazil** Rationale: For Brazil, the first example is measurable because the indicator is speed, the time it takes to travel a distance.
Training of personnel in food businesses, government and academia in HACCP principles and applications is an essential element for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures ~~should~~ must be developed which define the tasks of the operating personnel in charge of each Critical Control Point. Training programmes ~~should~~ must be designed to address the concepts at a level appropriate for the knowledge and skill level of the personnel being trained. Training programmes ~~should~~ must be reviewed periodically and updated where necessary. Re-training may be needed as part of corrective actions for some deviations.	**Colombia**
Annexe 1 – Comparison of GHPs and control measures at CCPs with examples	**Morocco** Morocco supports the table in Annex 1, because it will facilitate understanding and implementation of document requirements.
Annex 1 - Comparison of GHPs and control measures at CCPs with examples.	**Honduras** We suggest expanding the guidelines to clearly differentiate the GHPs from the control measures applied at CCPs. The current table does not provide practical and easy-to-understand instructions that guide FBOs that do not implement HACCP and have little knowledge of the system to identify the differences, and that facilitate designing an HACCP plan.
Annex 1 - Comparison of GHPs and control measures at CCPs with examples.	**Uruguay** Validation of the effectiveness of the control measure *Technical comment: All information used as a reference must have scientific basis to support it, including information provided by the product or equipment manufacturers.
Annex 1 - Comparison of GHPs and control measures at CCPs with examples.	**Colombia** Annex 1 - Comparison of GHPs and control measures at CCPs with examples. Validation of the effectiveness of the measure GHP When necessary, and in general, … manufacturer. The FBOs must be able to demonstrate they can follow manufacturers' instructions.

	Validation of the effectiveness of the measure Validation should be carried out (Guidelines for the Validation of Food Safety Control Measures CXG 69-2008)
Diagram 1 – Logic Sequence for Application of HACCP	**Japan** We propose the following modifications to Step 6 for clarity: List all Potential Hazards Conduct a Hazard Analysis and identify significant hazards Consider Control Measures against significant hazards
Diagram 1 – Logic Sequence for Application of HACCP	**Brazil** 3 Identify Intended Use and reasonably foreseeable use
Diagram 1 – Logic Sequence for Application of HACCP	**Brazil** Rationale: For consistency with change suggested in paragraph 156.
Diagram 1 – Logic Sequence for Application of HACCP	**USA** Revise step 8 as follows: Establish Validated Critical Limits for each CCP. This is for consistency with the revised Principle 3.
Diagram 2 – Example of Hazard Analysis Worksheet	**Japan** We propose to make the following modification to the last part of (3): (3) Does this potential hazard need to be addressed in the HACCP plan (i.e. significant hazard)?
Diagram 2 – Example of Hazard Analysis Worksheet	**Thailand** The Questions listed in the Worksheet of Diagram 2 should be correlated with the Questions appeared in Diagram 1.
Diagram 2 – Example of Hazard Analysis Worksheet	**Brazil** (3) Does this potential hazard is a significant hazard and needs to be addressed in the HACCP Plan?
Diagram 2 – Example of Hazard Analysis Worksheet	**Brazil** Rationale: If the hazard must be contained in the HACCP plan, this is considered a significant hazard. The amendment gives more clarity when using terminology in chapters 1 and 2.
	Honduras In box 6 Identification of the possible hazards. Conduct a hazard analysis. Consider control measures.
Diagram 2 – Example of Hazard Analysis Worksheet	**Nicaragua** Nicaragua proposes inserting a column to identify if the step is a CCP or not.
Diagram 2 – Example of Hazard Analysis Worksheet	**Honduras** We suggest putting another type of example that really describes the hazard analysis, according to section 3.6, paragraphs 155 - 157, as it needs descriptions such as for associated hazards, the likelihood of severity, among others.

Diagram 3 – Example of Decision Tree to Identify CCPs	**Canada** We suggest expanding the title of this diagram as it covers more than the identification of CCPs. Diagram 3 – "Example of Decision Tree to Identify if a hazard is controlled by a GHP or a CCP" or “Example of a decision tree to determine how a hazard is controlled”
Diagram 3 – Example of Decision Tree to Identify CCPs	**Peru** GHPs are part of the prerequisites, since the prerequisite programs include good manufacturing practices as well as other practices and procedures such as training and traceability, that form the foundation for applying an HACCP system. See the flow chart.
Diagram 3 – Example of Decision Tree to Identify CCPs	**FoodDrinkEurope** There is a missing arrow from Q3 to ‘Yes’ What if ‘No’ on Q5? Loop to Q2b if NO on Q5.
Diagram 3 – Example of Decision Tree to Identify CCPs	**Chile** On the Q1 Prerequisite programmes should be replaced by GHP.
Diagram 3 – Example of Decision Tree to Identify CCPs	**IDF/FIL** Comment 1 to Question 1: The decision tree is designed to be applied at each process step. However, many PRPS/GHPs are not applied at process steps, but elsewhere in the facilities. Therefore, it does not make sence to include the part that addresses the nature of the GHPs. The effect of GHPs that are subject to additional attention is implicit in answering Q1. Consequently, the text in box Q1b should be replaced by a statement as follows. The Prerequisite Programmes are sufficient to control the hazard. Alternatively, an approach where NO to Q1 leads to a Q1b that asks whether modification to the procedure/practice of a GHP (e.g. monitoring frequency) will result in sufficient control of the hazard. • Answering YES to this question would then turn the user back to Q1 (a loop similar to Q2b). • Answering NO to this question will lead the user to Q2 Comment 2 to Question 1: Refer to hazards (in plural) as more than one hazard are often present in a process step Comment to Question 3: An arrow linking Q2 to the YES-box is missing Comment to Question 5: Replace “a subsequent step” with “another step” – see our comments to para. 161
Diagram 3 – Example of Decision Tree to Identify CCPs	**ISO** 1st ISO Comment to diagram 3 -Decision tree

	Delete Q 1 - do not include GHPs in the HACCP decision tree. As ISO 22000 representatives we support the statement “the application of HACCP is the system of choice to achieve food safety” (CX/FH 19/51/6 Chapter Two 136). At same time we also realise that major parts of the global food supply chain - small and less developed businesses in particular - rely on the application of GHPs. In this light, we support the concept of “GHPs that require greater attention”. However, for FBOs that choose or are mandated to apply HACCP, we think that these “GHPs that require greater attention” should be addressed in their HACCP plan. In CX/FH 19/51/6, control measures that are typically applied at CCPs - like cooking, cooling, metal detection, sieves and x-ray detectors - are included in Chapter One on GHPs; following this approach these typical CCPs will have to be deleted from the already established HACCP plans of many FBOs worldwide. This approach will offer no support for the further appreciation, acceptance and improvement of the HACCP system. In this Q1 approach the HACCP system will only be there for advanced, exotic or innovative control measures that or not covered by GHPs in chapter one. We think that FBOs that apply HACCP should consider “GHPs that require greater attention” as control measures. In doing so, the HACCP system will truly be the system of choice and as the system that provides consistent and verifiable control beyond that achieved by GHPs (Chapter Two 140). Basically in CX/FH 19/51/6 as in CAC/RCP 1-1969, Rev 4 - 2003, there is no practical difference between the application of PRPs or of HACCP except for the fundamental aspect that HACCP includes hazard analysis to provide the rationale for the application of control measures (including GHPs that requires greater attention), monitoring and corrective actions. Our statement here above is supported by CX/FH 19/51/6 Chapter One 7.2 - 105: Some key aspects of food hygiene systems could be considered as control measures applied at CCPs in the HACCP system. Our statement is supported/illustrated by the control of allergens with GHPs in chapter 1 7.2.7 (118) and as control measures / CCPs in chapter 2 3.8 (164) and 3.9 (168). 2nd ISO comment to Diagram 3 - Example of Decision Tree Q 3 and Q 5 The decision tree is designed to be applied at each process step. However, many PRPS/GHPs and/or control measures are not applied at process steps, but elsewhere in the facilities (like separation of product containing natural allergens - environmental

	cleaning or high care production room to prevent contamination with Listeria monocytogenes) and/or many apply at several steps (a FBO that does refrigerated transport and distribution will have different steps at which the same control measure - cooling - applies). We suggest to focus on the control measures rather than on steps. Since "a step" has or very broad definition - a step = a point, procedure operation or stage - we propose for Q3 and Q5 to replace "a step" with "a control measure" which is defined more specific. This replacement will bring questions Q3 and Q5 in alignment with Q2 (do control measures exist) and will bring more emphasis on "what" needs to be monitored (the application of a control measure) at a CCP rather than on "where" (the step) it needs to be monitored. 3rd ISO comment to diagram 3 Decision tree In Q3 and Q5 the decision tree uses the phrase "to prevent, to reduce or to eliminate the likely occurrence of a hazard to an acceptable level". The definition of a control measure uses the phrase "to prevent or eliminate a hazard or reduce to an acceptable level". "To prevent, to reduce or to eliminate the likely occurrence of a hazard" is not the same as "to prevent, to reduce or to eliminate a hazard". Q3 and Q5 should use the same phrasing as in the definition for a control measure. Proposed wording: Q3. Is this control measure specifically designed to prevent, eliminate, or reduce a hazard to an acceptable level? Q5. Will a subsequent control measure eliminate the identified hazard or reduce it to an acceptable level?
Diagram 3 – Example of Decision Tree to Identify CCPs	**Honduras** We request clarification on the concept of GHPs that "need greater attention." The document does not provide practical guidelines on managing these types of GHPs and the decision tree does not clarify or provide guidelines on the final decision the FBO must make. We suggest striking it from this diagram. It could be useful to include another diagram where it outlines what is described in paragraph 99. When such increased attention on GHPs is insufficient to ensure food safety, it will be necessary to implement a HACCP system (Chapter 2). In other words, clarify that in case of identifying a GHP that needs more attention, it requires implementing an HACCP plan.

Diagram 4 – Example of a HACCP Worksheet	
Critical Control Points (CCPs)	**Nicaragua** Nicaragua proposes adding the word “step” to the description of the column for better understanding.