



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD HYGIENE
Forty-eighth Session**

Los Angeles, California, United States of America, 7 - 11 November 2016

**Comments on the
Proposed Draft Revision of the General Principles of Food Hygiene and its HACCP Annex**

Comments Submitted by:

Argentina, Brazil, Canada, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Japan, Malaysia, Mexico, Nicaragua, New Zealand, Paraguay, Switzerland, Uruguay, United States of America, FAO, IDF, IFU, SSAFE

ARGENTINA

Argentina appreciates the opportunity to submit these comments and thanks the electronic Working Group for its work on this draft.

General Comments

1. Argentina suggests a work scheme so that the comments made in all languages can be shared and discussed by all participating countries to have an effective exchange.
2. Argentina feels that the reasons for including the concept "suitability" into this document are not clear.
3. Argentina believes that this phase of work, and not for inclusion in the draft, should provide examples that demonstrate the need for including these new concepts that have been proposed for inclusion in this document (real time CCP monitoring, critical criterion).

Argentina would appreciate a more thorough discussion on the new approach for "CCP Type B" (which does not use real time measurements or a critical limit). The use of examples could help clarify the newly proposed concept (it's not clear if it's necessary or not).

4. The concept of "hazard control measures" is confusing. It begs discussion of whether the CCPs will still be determined based on the traditional methodology (decision-making tree: Was the phase specifically designed to reduce the potential presence of a hazard? Won't the potential presence be reduced to an acceptable level in a subsequent phase?) As long as this methodology remains in place, we agree to calling the control measures applied to CCPs "hazard control measures."

5. Critical criterion: We suggest not introducing the concept "critical criterion," as it contradicts the definition of CCPs, which maintains that they must be measurable.

"Critical criterion": We feel a more thorough discussion is necessary for this concept, which isn't clear yet. The use of examples could help clarify the newly proposed concept.

6. Regarding the question of the most appropriate way to describe the HACCP system, when choosing between the option relating to a 'two-phase process' (underlining that GHPs are to be designed before the HACCP plan is established) vs. a 'two-component' process (meaning that GHPs and HACCP can be designed at the same time), Argentina chooses the first. However, it needs to be clear that not all cases need/require the application of HACCPs. Argentina suggests as a new option: *two processes*.

7. Argentina believes that the new definitions should be incorporated once they are included in the document.

8. Special attention should be paid to the translation into Spanish of the English "should," as the meaning changes depending on whether "debe" or "debería" is used. To clarify, in the case of the HACCP principles, "debe" should be used instead of "debería."

9. Argentina would like to know if the *Notes* to the definitions will be incorporated into the final document.

Specific CommentsINTRODUCTION

Paragraph 1. Option B: People have the right to expect the food they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury are at best unpleasant; at worst, they can be fatal. [*Translator's note: change does not apply to the English*] But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation. [*Translator's note: change does not apply to the English*] Food spoilage is ~~wasteful, costly~~ economically wasteful and can adversely affect trade and consumer confidence.

International food trade, and foreign travel, are increasing, bringing important social and economic benefits. But this also makes the spread of illness around the world easier. Eating habits too, have undergone major change in many countries over the last two decades and new food production, preparation and distribution techniques have developed to reflect this. Effective hygiene control, therefore, is vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage. Everyone, including ~~farmers and growers~~ primary producers, ~~manufacturers~~ and processors, food handlers and consumers, has a responsibility to assure that food is safe and suitable for consumption.

These General Principles lay a firm foundation for ~~ensuring~~ providing food hygiene and should be used in conjunction with each specific code of hygienic practice, where appropriate, and the guidelines on microbiological criteria.

The controls described in this General Principles document are internationally recognized as essential to ensure the safety and suitability of food for consumption. The General Principles are commended to Governments, food business operators (including ~~individual~~ primary producers, ~~manufacturers~~ processors, food service operators and retailers) and consumers alike.]

Comment: We suggest this option with the changes made.

Paragraph 2. Option A: [This document shows how food safety and food suitability can be enhanced throughout the food chain from primary production to the final consumer, including manufacturing and distribution. To achieve this goal, each business establishes its own control system taking into account its specific requirements and domestic regulations.]

Comment: We suggest this option with the addition made.

Paragraph 4. The application of appropriate GHPs in food businesses provides a sanitary environment that supports the production of safe and suitable food. [*Translator's note: change does not affect the English*]

Paragraph 5. 5. The second section will describe the *Hazard Analysis and Critical Control Point System for Food Safety (HACCP)*.

HACCP application will not be effective without prior implementation of GHPs.

- HACCP is a preventive approach that aims to enhance food safety where this is appropriate and feasible, by improving the control of hazards over that achieved by the GHPs.
- HACCP accomplishes this with the help of hazard control measures applied at critical control points (CCPs).
- HACCP may not be applicable to all type of food businesses, in particular at the stages of primary production. However, the principles of HACCP can be applied to certain activities related to primary production [e.g. administration of veterinary drugs].
- HACCP requires specific knowledge and skills.

Paragraph 7. The document could be applied from primary production to the final consumer and provides a foundational structure for other, more specific, codes applicable to particular food sectors. Such specific codes and guidelines should be read in conjunction with this document.

Paragraph 11. Governments should decide how best they should apply these general principles through legislation, regulation and guidance to:

- protect consumers adequately from illness or injury caused by food; policies need to consider the vulnerability of the population, or of different groups within the population;
- ~~provide assurance~~ provide an effective system to ensure that food is suitable for human consumption;

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

- develop and implement processes that provide food that is safe and suitable for consumption;

- ~~ensure that~~ provide consumers ~~have~~ with clear and easily-understood information including ingredient content, by way of labelling and other appropriate means, to enable them to protect their food from contamination and prevent the growth/survival of foodborne pathogens by storing, handling and preparing it correctly; and
- maintain confidence in internationally traded food.

Basic principles for a food safety control system.

- i) The recommended way to maximize food safety and suitability is a two [~~phase/component~~] preventive approach. (See General Comment No. 6)
- ii) The implementation of GHPs is the first [~~phase/component~~], of the design of a food safety control system. (See General Comment No. 6)
- iii) GHPs should ensure that food is produced in a sanitary environment and reduce the ~~burden~~ presence of contaminants, whether hazardous or not.
- iv) GHPs are a prerequisite to the implementation of a HACCP system, because they provide the foundation for a HACCP system to be effective.
- v) The application of GHPs should be subject, where appropriate, to monitoring, verification and documentation.
- vii) The implementation of HACCP, where needed and feasible, is the second [~~phase/component~~] of the design of an effective food safety control system. (See General Comment No. 6)
- vii) HACCP should identify all hazards associated with the production process and its environment, and specify the significant ones that should be controlled because they can occur at an unacceptable level. [*Translator's note: change does not apply to the English*]
- viii) HACCP should determine validated hazard control measures that are essential to increase the level of food safety. [*Translator's note: change does not apply to the English*]
- ix) The application of hazard control measures should be subject to monitoring, verification and documentation. [*Translator's note: change does not apply to the English*]
- x) Changes in the food business, e.g. new process, new ingredient, new product, new equipment, should lead to a review of both GHPs and the HACCP plan to determine if modifications are needed. [*Translator's note: change does not apply to the English*]

Comment: For points vii, viii, ix, and x, the "should" in English should be translated as "debe," since the HACCP principles are mandatory. We suggest finding an alternative so that the English can keep this meaning.

Paragraph 15.

Contaminant: Any biological or chemical agent, or other objectionable matter *or physical object (i.e. foreign matter or other substances)* not intentionally added to food that may compromise food safety or suitability.

Comment: This differs from the definition in the Codex Procedural Manual: "Contaminant - Any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter."

Environment: The surroundings of the food and processing equipment within the establishment, including air but excluding humans.

Comment: We suggest reviewing this as the document moves forward.

~~Food safety:~~ (See General Comment No. 2)

~~Good Hygienic Practices Prerequisite programs aiming specifically at food hygiene, applied in the establishment.~~ Food hygiene All conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

Comment: Source: FAO, WHO guidelines for governments on the application of the HACCP system in small or less-developed food businesses.

Corrective action: Any action on the process or environment to be taken when the results of monitoring at the CCP indicate a loss of control.

~~Option A (based on ISO 9000)~~

~~Corrective action [Action on the process or the environment to eliminate the cause of a detected nonconformity and to prevent its recurrence.]~~

~~Correction [Action to eliminate a detected nonconformity.]~~

~~Option B (US)~~

~~Corrective action [Any action taken when a deviation occurs to correct the problem, to segregate and evaluate any food impacted by the deviation and determine appropriate disposition of the food, and to identify the cause of the problem and reduce the likelihood it will reoccur.]~~

~~Correction: [An action taken in lieu of corrective actions to identify and correct a problem when a deviation does not impact the safety of the food (e.g. recleaning insanitary equipment before production begins).]~~

~~Comment: We suggest a new definition~~

~~Critical criterion A criterion that separates acceptability from unacceptability with respect to the safety of the food.~~

~~Comment: (See General Comment No. 5)~~

~~Critical limit A criterion that separates acceptability from unacceptability. A numeric value characterizing the critical criterion of a measurable parameter that can be monitored in a timely manner. NOTE 1: A critical limit relates to a measurement, of e.g. time, temperature, pH, water activity, pressure. NOTE 2: When a hazard control measure is the combination of more than one action, there may be several critical limits that must be complied together, e.g. for temperature and time, pH and water activity. Rationale for the two above definitions: The original definition was: "Critical limit. A criterion that separates acceptability from unacceptability". A critical limit is a characteristic of a hazard control measure that can be monitored timely. Yet, for hazard control measures that cannot be timely monitored, various types of criteria have to be used; hence, a wide definition is given for "Critical criterion" and a narrow one for "Critical limit."~~

~~Critical limit: A criterion that separates acceptability from unacceptability.~~

~~Comment: (See General Comment No. 5)~~

~~Deviation Failure to meet a critical limit criterion.~~

~~Comment: (See General Comment No. 5)~~

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

~~Comment: Argentina suggest including the definition if it is to be considered within the document.~~

BRAZIL

Brazil would like to thank the opportunity to comment the Proposed Draft Revision of the General Principles of Food Hygiene.

Regarding the recommendations, we inform the following:

a) Consider the proposed draft as presented in Appendix I. In particular, specific attention should be paid to the approach proposed for the differential management of CCPs, depending on the type of monitoring which is available in a given context;

Paragraph 1: Option B

Paragraph 2: Option B

b) Pursue the revision of CAC/RCP 1-1969 with an approach consistent with the one that has been implemented to date, and to establish an EWG to that effect. In order to allow an effective and inclusive work to achieve this goal in a timely manner, the prospective EWG should use modern technologies, *i.e.* work through the Codex Alimentarius bulletin board www.forum.codex-alimentarius.net. A complementary system using massive mailing should also be considered. A specific attention should be paid to the question of an effective translation system and its costs for the hosting(s) member country(ies) or organization(s);

It is strongly recommended that the work is also conducted in a complementary system using mass mailing.

c) Regarding the amendments and revisions in Appendix I, should pay attention to:

- The appropriateness of an introductory paragraph to the General Introduction section, with the scope to explain the importance of the standard CAC/RCP 1-1969 and to provide general information regarding the international context it is part of;

Option B

- Determining if the concepts of 'GHP-based control measures' and 'HACCP-based control measures', which have been recently used in Codex documents, could be appropriate for the revision of CAC/RCP 1-1969.

The concepts of 'GHP-based control measures' and 'HACCP-based control measures' used in specific documents should be incorporated in this general document and their relation to the concept of critical criterion should be clarified.

- The need for additional definitions, including: Potential hazard; Food business operator (FBO); Operational Prerequisite Program.

We agree with the need of the definition for food business operator. We also agree with the definition of prerequisite programs inserted and there is no need to add a definition for potential hazard.

- The improvement of proposed or existing definitions, including: Environment, Food safety and Food suitability, Primary production.

We agreed that there is need to improve the definition of food suitability.

-The deletion of 'condition of' in the definition of Hazard

We suggest the following definition:

Hazard: a biological, chemical, physical agent or intrinsic condition of the food with the potential to cause an adverse health effect.

Rationale: With the presence of the note, the term "or condition of" can be eliminated without defining lose all its meaning. However, if the note was deleted from the document, the condition of the food, which is intrinsic and can constitute a hazard is not contemplated.

-The deletion of 'eliminate' from the definition of CCP.

We agree with the removal of the term "eliminate" from the definition of CCP.

- To consider the exact meaning of the terms 'Corrective action' and 'Correction' and to agree on related definitions.

Option A with modifications

Corrective Action: Action based on the production system, focusing on measures in the process or the environment with the main purpose of eliminating the cause of the deviation detected and prevent a recurrence. Eventually corrective action may contemplate the correction.

Correction: focal action and limited to eliminate the deviation detected and its consequences, where appropriate, in food or the environment.

With respect to the document text, we suggest the following amendments:

INTRODUCTION

Paragraph 1: Option B

Paragraph 2: Option B

OBJECTIVES

Paragraph 6:

- provide a guidance that may be needed for specific codes for sectors of the food chain, processes, or commodities to amplify the hygiene **and safety** requirements specific to those areas.

SCOPE

Paragraph 7:

This document provides a framework for producing foods that are safe and suitable for human consumption by setting out necessary hygiene **and safety** conditions and applying, where appropriate, enhanced control measures at certain production steps. The document is intended for use by food business operators and countries³, as appropriate.

BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM

Paragraph 13:

(i) The recommended way to maximize food safety and suitability is a two [~~phase~~/**component**] preventive approach.

DEFINITIONS

We suggest that the term 'critical criterion' is replaced by 'pre defined criteria'

Rationale: The term "critical criterion", leads to possible direct and exclusive links with the HACCP and can cause misunderstandings to the document, since it can be directly linked to the HACCP, even with the resolution, expected parameters mensuraveise and countable. With the change proposed term, it keeps the intended meaning, without naming leading to misinterpretation of the term. Thus the proposed term does not lose the desired effect and may be used in HACCP or GMP without misinterpretation or without raising doubts about the term and its application.

CANADA

Canada would like to congratulate the chairs of the electronic working group for preparing this document for discussion.

General Comments

We think that the document is a good starting point but some of the major issues will need to be discussed, for example, in regards to bullet 8 of the "Work of the EWG" section in the beginning of the document, Canada has concerns that the approach taken, particularly around CCPs, does not follow previous recommendations made to, and adopted by the committee. The discussion paper presented at the last CCFH stated that there was "*almost unanimity that the current definition of CCP should remain unchanged*", and that clarity should be provided around some key hygiene controls sometimes misinterpreted as CCPs, to "*prevent the inappropriate proliferations of CCPs*" (CX/FH 15/47/9, para. 8). Yet, the WG is now proposing two types of CCPs, type A where critical limits can be defined and type B where critical limits cannot be defined. In the case of "Type B" CCPs ("*in case of deviation, a decision has to be made about the fate of the lot...*"), we have concerns that this is a step backwards when end-product, lot-by-lot testing, has to be performed rather than using a preventative approach advocated by HACCP.

Canada has concerns that redefining CCPs and acceptability at CCPs will confuse more than clarify the intent of HACCP, and that will lead to more CCPs, therefore weakening the HACCP system.

Canada recommends that the WG continues its work by focusing its efforts on the revision of the figures and diagrams in the HACCP annex, and finding examples to illustrate the concepts of hazard analysis, CCP determination, critical limits, monitoring, etc. This approach, which was previously recommended in the report of the June 2014 Majvik HACCP colloquium, will help reach consensus on the clarifications needed in the text and definitions, and facilitate the work ahead.

Specific comments:

Introduction

1. Canada prefers Option B as the context is better laid out and provides better readability.
2. Canada prefers Option B with the following minor changes:

[This ~~Introduction~~ **document** will outline the general principles that should be understood and followed by food businesses **operators** and help governments to establish appropriate oversight. It ~~will then define~~ **also includes definitions for** specific terms and expressions applicable to the document:]

Rationale: We would recommend changing the term introduction to document as it is the entire document that this section is referring to. For consistency use, the expression "food business operators" should be used when referring to industry.

3. The first section will describe Good Hygienic Practices for Food Safety and Suitability (GHPs). GHPs are the basis of any food safety control system:

- GHPs are ~~part of~~ prerequisite programs which should always be implemented in any operating food business.

~~GHPs, in general, only need basic knowledge and skills.~~

Rationale: Minor wording changes to facilitate reading and the text should be in line with the definition of GHPs for consistency. We propose deleting bullet 4, due to redundancy with bullet 3.

4. The application of ~~appropriate~~ **relevant** GHPs in food businesses **should** provides a sanitary environment that supports the production of safe and suitable food.

Rationale: We are not quite sure what constitutes "appropriate". The term "relevant" may be better.

5. The second section will describe the Hazard Analysis and Critical Control Point System for Food Safety (HACCP).

- HACCP accomplishes this **food safety** with the help of **hazard identification, evaluation, and** hazard control measures applied at critical control points (CCPs).

Rationale: Bullet 3 above is ambiguous. We recommend rewording the sentence to provide clarity.

OBJECTIVES

6. The General Principles of Food Hygiene for Food Suitability and Safety: Good Hygienic Practices (GHPs) and Hazard Analysis and Critical Control Point System (HACCP) aims to:

- ~~identify the good hygienic practices~~ **Provide guidance on the application of good hygienic practices** applicable throughout the food chain (including primary production through to the final consumer) to provide food that is safe and suitable for human consumption;

Rationale: This document will not identify good hygienic practices but will provide guidance on the application of GHP.

SCOPE

7. This document provides a framework for producing foods that are safe and suitable for human consumption by setting out necessary hygiene conditions and applying, where appropriate, enhanced control measures at certain production steps **throughout the food chain**. The document is intended for use by food business operators, and countries³, as appropriate.

Rationale: We recommend adding “throughout the food chain” to make it more complete statement.

USE

General

8. ~~The document provides a foundational structure for other, more specific, codes applicable to particular food sectors. Such specific codes and guidelines should be read in conjunction with this document.~~

9. Each section in this document states both the objectives to be achieved and the rationale behind those objectives in terms of the safety and suitability of food. There will ~~inevitably~~ be situations where some of the specific requirements contained in this document are not applicable. The fundamental question in every case is “what is necessary and appropriate on the grounds of the safety and suitability of food for consumption?”

10. The text indicates where such questions are likely to arise by using the phrases “where necessary” and “where appropriate”. In practice, this means that, although the requirement is generally appropriate and reasonable, there will ~~nevertheless~~ be some situations where it is neither necessary nor appropriate on the grounds of food safety and suitability. In deciding whether a requirement is necessary or appropriate, an assessment of the risk should be made. This approach allows the requirements in this document to be flexibly and sensibly applied with a proper regard for the overall objectives of producing food which is safe and suitable for consumption. In so doing it takes into account the wide diversity of food processing practices and varying degrees of risk involved in producing food.

Rationale: We propose removing section 8 as it is already covered in the objectives. The rest of the changes in 9 and 10 are editorial to improve readability.

Roles of Governments, food business operators, and consumers

11. Governments should decide how best they should apply these general principles through legislation, regulation and guidance to:

- provide assurance that food is **safe and** suitable for human consumption;

Rationale: For consistency, the term safety should be used in the second bullet point.

BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM

(i) The recommended way to maximize food safety and suitability is a two [~~phase/~~component] preventive approach.

Rationale: Canada supports the use of component. We are also proposing editorial changes to clarify the meaning of the text below.

(ii) The ~~implementation~~ **identification** of GHPs is the first [~~phase/~~component], of the design of a food safety control system.

(iii) GHPs should ensure that food is produced in a sanitary environment and reduce the ~~burden of~~

level of contaminants, ~~whether hazardous or not.~~

- (iv) GHPs are a prerequisite to the implementation of a HACCP system, because they provide the foundation for a HACCP system to be effective.
- (v) The application of GHPs should be subject, where appropriate, to monitoring, verification and documentation.
- (vi) The implementation of HACCP, where needed and feasible, is the second ~~phase/~~component] of the design of an effective food safety control system.
- (vii) HACCP should identify all hazards associated with the production process and its environment, and specify **how** the significant ones ~~that should be controlled because they can occur at an unacceptable level.~~
- (viii) HACCP **system** should ~~determine~~ **identify** validated hazard control measures that are essential to ~~increase~~ **achieve an acceptable** the level of food safety.

DEFINITIONS

Canada has suggestions to improve the definitions, as follows:

Definitions applying within the whole document

Contaminant Any biological or chemical ~~agent, or other objectionable matter or physical object~~ **agent** (i.e. foreign matter or other substances) not intentionally added to food that may compromise food safety or suitability.

Rationale: In order to maintain consistency the text should be in-line with the definition for hazard.

Disinfection The reduction, by means of chemical agents and/or physical methods, of the number of microorganisms **in the environment** to a level that does not compromise food safety or suitability.

Rationale: Canada supports the original definition of disinfection.

Environment The **food and non-food contact surfaces** ~~surroundings of the food and processing equipment within the establishment, including air but excluding humans.~~

Rationale: The term air is difficult to include here. Air cannot be disinfected. It is not clear if the environment refers to the plant environment or the surroundings outside the plant. We think it should refer to inside the plant environment.

Food handler Any person who directly handles packaged or unpackaged food, **uses** food equipment and utensils, or **works on** food contact surfaces and is therefore expected to comply with food hygiene requirements.

Rationale: Editorial comments for ease of reading.

~~**Prerequisite programs** Procedures and actions taken to maintain hygienic conditions throughout the food chain, that provide the foundation for the HACCP system.~~

Rationale: This definition is redundant to GHPs. However, we suggest to add the following text in the GHP definition "...that provide the foundation for the HACCP system".

Primary production ~~These~~ The first steps in the food chain ~~up to and including,~~ for example, *raising of animals, growing and harvesting crops, slaughter, milking, fishing,* **and transport to slaughter.**

Rationale: We believe that the transportation to slaughter should be included. Please see CCFH47 page 31. The Salmonella document flowchart for beef has "transportation to slaughter" in primary production.

Definitions specific to the HACCP system

Option B (US)

Corrective action [Any action taken when a deviation occurs to correct the problem, to segregate and evaluate any food impacted by the deviation and determine appropriate disposition of the food, and to identify the cause of the problem and reduce the likelihood it will reoccur.]

Correction: [An action taken in lieu of corrective actions to identify and correct a problem when a deviation does not impact the safety of the food (e.g. recleaning insanitary equipment before production begins).]

Comment: Canada supports option B. However, we do not see the need for defining the term correction. As it seems redundant, we suggest to delete it.

Critical criterion A criterion that separates acceptability from unacceptability with respect to the safety of the food.

Comment: We do not understand the difference between criterion and limit. We believe that the limit is what determines acceptability. We would recommend replacing critical criterion with critical control parameter (defined as follows: A parameter that needs to be measured to assess if a CCP is under control). In order to understand the difference, we need examples of critical criterion that are not critical limits.

Deviation Failure to meet a critical ~~limit~~ ~~criterion~~.

Comment: Canada recommends retaining the term limit as it is more appropriate and less confusing.

Monitoring The act of conducting a planned sequence of observations or measurements of hazard control measure ~~parameters~~ ~~criteria~~ to assess whether **a CCP** the measure is **under** in control.

Comment: Canada recommends the retention of the original definition.

Significant hazard A hazard identified by the hazard analysis as having to be controlled.

Comment: We find this definition confusing. It seems self-explanatory and it is already defined in the definition of hazard analysis.

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

Comment: We disagree with the deletion since we find this definition useful.

COLOMBIA

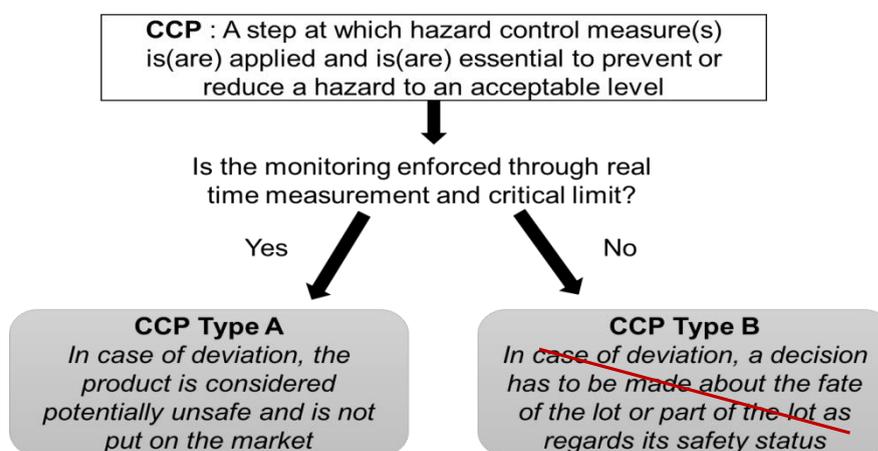
Colombia is pleased to present the following comments on the "Proposed Draft Revision of the General Principles of Food Hygiene" at Step 3, sent by the Secretariat of the Codex Alimentarius Commission.

We reference the Spanish version of document CX/FH 16/48/5.

I. Diagram Paragraph 8

Colombia recommends withdrawing the proposal for CCP "Type B," because the monitoring is not performed in real time. The description for "Type B" is a requirement that food businesses must fulfill as part of their food hygiene practices [for Colombia, *Buenas Prácticas de Manufactura* (Good Manufacturing Practices)].

Proposal:



II. Paragraph 18.

For Colombia, Option A is not applicable because it is based on using proposed types A and B to monitor CCPs. Therefore, a more thorough revision of the purpose of amending the HACCP annex to CAC/RCP 1-1969 is required.

We also recommend distributing the documents that will be discussed by the EWG by e-mail, since Colombia does not have access to the forum at: www.forum.codex-alimentarius.net.

Proposal: b) Continue with the revision of CAC/RCP 1-1969 using an approach that is consistent with the one implemented to date and establish an EWG for this purpose. In order to enable effective and inclusive work to achieve this goal in a timely manner, ~~the prospective EWG should use modern technologies, i.e., work through the Codex Alimentarius discussion forum www.forum.codex-alimentarius.net.~~ a complementary system to send mass e-mails should also be considered. Special attention should be given to the use of an effective translation system and its cost for the host member country(ies) or organization(s).

III. Introduction, Paragraph 1

We recommend including Option B in the introduction section of the document as it focuses more on the content addressed in the proposed draft on food safety and the implementation of food safety assurance systems.

Proposal: Option B:

[People have the right to expect the food they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury are at best unpleasant; at worst, they can be fatal. But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.

International food trade and foreign travel are increasing, bringing important social and economic benefits. But this also makes the spread of illness around the world easier. Eating habits too, have undergone major change in many countries over the last two decades and new food production, preparation and distribution techniques have developed to reflect this. Effective hygiene control, therefore, is vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage. Everyone, including farmers and growers, manufacturers and processors, food handlers and consumers, has a responsibility to assure that food is safe and suitable for consumption.

These General Principles lay a firm foundation for ensuring food hygiene and should be used in conjunction with each specific code of hygienic practice, where appropriate, and the guidelines on microbiological criteria.

The controls described in this General Principles document are internationally recognized as essential to ensure the safety and suitability of food for consumption. The General Principles are commended to Governments, food business operators (including individual primary producers, manufacturers, processors, food service operators and retailers) and consumers alike.]

IV. Paragraph 11.

It is important that consumers have confidence not only in the products intended for export, but also in the domestic products, considering that this is part of each country's public health policy.

Proposal: Include the following paragraph:

"-Maintain confidence in the food offered to consumers in their country."

V. Paragraph 12.

It is important that confidence extends not only to export-type products but also to domestic products, given that this issue is part of each country's public health policies.

Proposal: "-Maintain confidence in **domestically** and internationally-traded foods."

VI. Definitions.

The proposal in Option B clearly differentiates "corrective action" from "correction."

Proposal: Include Option B:

"Corrective action": [Any action taken when a deviation occurs to correct the problem, to segregate and evaluate any food impacted by the deviation and determine appropriate disposition of the food, and to identify the cause of the problem and reduce the likelihood it will reoccur.]

"Correction": [Any action taken in lieu of a corrective action to identify and correct a problem when a deviation does not impact food safety (e.g., recleaning insanitary equipment before production begins).]

COSTA RICA

INTRODUCTION

Costa Rica would like to thank the electronic working group for its work and appreciates the opportunity to submit the following comments.

General comments:

Costa Rica is in favor of keeping the current introduction to the document. As such, it supports Option B.

Rationale: the wording is clearer, more easily understood, and less redundant with some terms.

Specific comments:

1. Par. 13:

If the most appropriate way to describe the HACCP system relates to a 'two-phase process' (underlining that GHPs are to be designed before the HACCP plan is established) vs. a 'two-component' process (meaning that GHPs and HACCP can be designed at the same time).

Costa Rica supports the opinion that an HACCP system is a two-phase process. This clearly indicates that, in order to have a valid HACCP plan, the GHPs must be implemented.

2. Appendix 1, Par. 3, subparagraph 4: GHPs, in general, only need basic knowledge and skills.

Costa Rica believes that his concept is not completely true and that it is not clear to what the phrase "basic skills" refers.

For Costa Rica, part of the process for applying the GHPs is the cleaning and disinfection of equipment and facilities. As such, the knowledge the operator must have for real hygiene is quite specialized for an effective outcome. Furthermore, pest control – which many times is performed by company staff – requires specialized training. Based on the foregoing, Costa Rica suggests the following wording:

GHPs, in general, require basic knowledge and skills; some activities may require some specialization.

3. Appendix 1, Par. 5, subparagraph 1: HACCP application will not be effective without prior implementation of GHPs.

Costa Rica submits that this wording is confusing. We suggest the following:

HACCP application will not be effective without prior implementation of GHPs, which would read as follows:

HACCP application is effective with prior implementation of GHPs.

4. Chart in Par. 8.

Costa Rica requests clarification on the technical ground for establishing the CCP Type B classification.

It would also be important to include examples to facilitate understanding of the proposal and to distinguish between the terms 'monitoring' and 'verification'. It is difficult to understand the difference in the new classification proposal, given that there are monitoring activities whose results are not obtained in real time.

5. Paragraph 13. **BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM**

Costa Rica proposes amendments to the following subparagraphs:

i) The recommended way to maximize food safety and suitability is a two [~~phase/component~~] preventive approach

ii) The implementation of GHPs is the first [~~phase/component~~], of the design of a food safety control system

vi) The implementation of HACCP, where needed and feasible, is the second [~~phase/component~~] of the design of an effective food safety control system

6. Par. 15

Costa Rica does not support the inclusion of the definition of 'Critical criterion'.

Rationale: the current definition of critical limit is correct.

7. Regarding corrective action and correction, Option A is clearer.

Rationale: the option is clearer and more compatible with other management systems.

CUBA

In response to document CX/FH 16/48/5 **Proposed Draft Revision of the General Principles of Food Hygiene**, Cuba wishes to submit the following comments:

GENERAL COMMENTS

1. The document is very explicit concerning monitoring in accordance with the CCPs, whose concept we support.

2. The Working Group suggested that Point 13 requires further discussion. Cuba believes that Point 13 is very clear and supports the proposed options.

II. SPECIFIC COMMENTS

1. Regarding the title of the draft presented by the Working Group, it is our understanding is more encompassing than the proposed title for the **GENERAL PRINCIPLES OF FOOD HYGIENE FOR FOOD SAFETY AND SUITABILITY: GOOD HYGIENIC PRACTICES (GHPS) AND HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM (HACCP)**
2. Cuba, having examined the text of Appendix 1 and its introduction, supports Option B for paragraph 1, as we feel it is clearer and more explanatory.
3. For paragraph 2, we support Option A and all the other points and recommendations.
4. Regarding the objectives and point 2 of paragraph 6, we propose replacing “**enhance food safety**” with “**enhance product safety**,” as we cannot measure levels of food safety, but perhaps we can refer to product units being safe or not.

Regarding the **BASIC PRINCIPLES OF A FOOD SAFETY CONTROL SYSTEM**, in our opinion the term Food Safety Control ~~System~~ is far more comprehensive and encompasses 5 elements. This document only references the principles of food hygiene control, which are indispensable for implementing of this document. Therefore, we suggest eliminating the word and leaving the heading as **Basic Principles for Food Safety Control**.

5. Regarding the definitions specific to the HACCP system, we support Option B put forward by the US on correct action and correction, as the concepts are clearer. We support all the other proposals put forth in the draft.

DOMINICAN REPUBLIC

Dominican Republic appreciates the opportunity to submit comments as requested, on the working paper CX/FH 16/48/5 Proposed Draft Revision of the General Principles of Food Hygiene, slated to be discussed at the 48th Session of the CCFH. It would also like to recognize the efforts of the eWG, chaired by France and co-chaired by Chile, United States, Ghana, and India in drafting the document.

I) *Specific comments:*

INTRODUCTION

Sub-heading 1

We support the paragraphs proposed in Option B and suggest the following specific amendments to the first paragraph of Option B.

*“People have the right to expect the food they eat to be safe and suitable for human consumption. Foodborne illness and foodborne injury are at best unpleasant; at worst, they can fatal. But, there are also other consequences. Outbreaks of foodborne illnesses can ~~damage~~ **be harmful** to trade and tourism and lead to loss of earning, unemployment and ~~litigation~~ **disputes**. Food spoilage is wasteful, costly and ~~may~~ **adversely affects** trade and consumer confidence.”*

Rationale: In our opinion the proposed changes render the text clearer and more precise.

Sub-heading 2

We suggest adopting a new Option C:

*[This document shows how food safety and suitability can be enhanced throughout the food chain, from primary production to the final consumer, including manufacturing and distribution, **and should assist governments in establishing appropriate control mechanisms**. To achieve this goal, each business establishes its own control system taking into account its specific requirements.]*

Rationale: It is our opinion that Option A is a better approach with this addition and for this reason we have defined it as Option C under this new proposal.

We approve of sub-headings 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12 as they stand.

Under sub-heading 13, we support the following points:

- I) *The recommended way to maximize food safety and suitability is a two [~~phase/component~~] preventive approach.*
- II) *The implementation of BHPs is the first [~~phase/component~~] approach of the design of a food safety control system.*
- VI) *The implementation of HACCP, where needed and feasible, is the second [~~phase/component~~] approach of the design of a food safety control system.*

Rationale: The term phase is used in the HACCP system: "A point, procedure, operation or stage in the food chain, including raw materials, from primary production to final consumption."

In sub-heading 15, we support Option A for the definition of Corrective Action:

[Action on the process of the environment to eliminate the cause of a detected nonconformity and to prevent its recurrence.]

Rationale: We support this option as it is based on ISO 9000.

ECUADOR

i) Specific comments:

Introduction

Ecuador prefers number 1 of Option B and suggests the following amendment to the paragraph below:

(...) Foodborne illness and foodborne injury ~~are at best unpleasant; at worst they can be fatal~~ **can be harmful to consumer health and can be fatal.**

Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment, and litigation. ~~adversely affecting consumer confidence. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.~~

The export and import international of food products and **tourism** and foreign travel are increasing, bringing important social and economic benefits. But this also makes the spread of illness around the world easier.

Everyone, from primary production to the end consumer, including manufacturing and distribution, including farmers and growers, manufacturers and processors, food handlers and consumers, has a responsibility to assure that food is safe and suitable for consumption.

Ecuador supports number 1, Option A.

- We recommend striking the following text from number 3 of the Introduction: GHPs, in general, only need basic knowledge and skills
- Ecuador deems it necessary to specify whether food business operators include from primary production to the end consumer; if this is not the case it contradicts the objectives of the proposed draft.
- Regarding the definition of Corrective Action, Ecuador agrees with Option A and requests the inclusion of the definition of Nonconformity.
- Ecuador suggest that the basic principles for a suitability system be included, as the document only refers to a food safety control system. Given that they are two different terms, there should be basic principles for each one.

(i) General comments:

Ecuador intends to approve and endorse the document, taking into consideration the comments made above. This is important for Ecuador, as we are currently working on a set of standards in line with the General Principles of Food Hygiene and the HACCP. The purpose is for food businesses to ensure that their products are safe and suitable for human consumption, which will promote domestic and international demand.

EL SALVADOR

General Comments:

Use the terms "food business" and "food business operators" consistently and systematically, to facilitate understanding of the text. We recommend defining these terms.

The translation for the English "should" should be "*debería*" in Spanish.

Specific Comments:

INTRODUCTION

- Paragraph 1. Regarding the introductory paragraph: El Salvador believes Option A is more appropriate, given that it explains the importance of the standard CAC/RCP 1-1969 and provides general information regarding the international context it is part of.
- Paragraph 2. We support Option A.

- Paragraph 3, bullet 4: GHPs, in general, ~~only~~ need basic knowledge and skills.
- Paragraph 4. The application of appropriate GHPs in food businesses provides a sanitary environment that supports the **chain of** production of safe and suitable food.
- Paragraph 5, bullet 1: HACCP application will not be effective without prior implementation of GHPs.
- Bullet 2: HACCP is a preventive approach that aims to ~~enhance~~ **ensure** food safety where this is appropriate and feasible, by improving the control of hazards ~~over~~ that achieved by the GHPs.
- Bullet 4: HACCP may not be applicable to all type of food businesses, in particular at the stages of primary production. However, the principles of HACCP can be applied to certain activities related to primary production [e.g. administration of veterinary drugs].
- Bullet 5: HACCP requires specific knowledge and skills. [Translator's note: change does not affect the English]

USE

General Aspects

- Paragraph 10. ... In so doing it takes into account the wide diversity of food ~~processing~~ **chain** practices and varying degrees of risk involved in producing food.

Roles of Governments, food business operators, and consumers

- Paragraph 13. Consumers should recognize their **responsible** role by following relevant instructions **provided for their consumption** and applying appropriate food hygiene measures.

BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM

- i) The recommended way to maximize food safety and suitability is a two [~~phase/component~~] preventive approach.
- ii) The implementation of GHPs is the first [~~phase/component~~], of the design of a food safety control system.
Rationale: application of the HACCP requires a prerequisite program, ergo a two-phase process is needed.
- v) The application of GHPs should be subject, ~~where appropriate,~~ to monitoring, verification and documentation.
- vii) The implementation of HACCP, where needed and feasible, is the second [~~phase/component~~] of the design of an effective food safety control system.
- viii) HACCP should determine validated hazard control measures that are essential to ~~increase~~ **ensure** the ~~level of~~ food safety.

DEFINITIONS

Definitions applying to the whole document

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

Rationale: keep "or condition of," because it should consider the various conditions to which the food is subjected.

Definitions specific to the HACCP system

We support Option A (based on ISO 9000):

- Corrective action: [Translator's note: change does not affect the English] [Action on the process or the environment to eliminate the cause of a detected nonconformity and to prevent its recurrence.]
- Correction: [Action to eliminate a detected nonconformity.]

We support the CCP proposal:

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

DEFINITIONS

Definitions applying to the whole document

-Cleaning: **Prerequisite to disinfection to remove foreign matter (physical, chemical, and biological) present in food and processing areas and on surfaces, equipment, and utensils.** ~~The removal of soil, food residue, dirt, grease or other objectionable matter.~~

-Contaminant: Any biological, chemical ~~or other objectionable matter~~ or *physical object (i.e. foreign matter or other substances)* not intentionally added to food that may compromise food safety or suitability.

This definition could include contaminants intentionally added, as part of the "Food Defense."

-Contamination: ~~The introduction of~~ **Occurrence** of a contaminant in food or food environment.

-Disinfection: **A process to reduce** ~~The reduction,~~ by means of chemical agents and/or physical methods, of the number of **pathogenic** microorganisms to a level that does not compromise food safety or suitability.

-Environment: *The **handling area surroundings** of the food, **machinery** and processing equipment within the establishment, including air, **humidity, and temperature.** but excluding humans.*

This definition is not very clear because of the use of the term "surroundings," which could be interpreted several ways.

-Establishment: Any building or area in which food is handled and the surroundings under the control of the same management. [Translator's note: the change does not affect the English version.]

-Food handler: Any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and ~~is therefore expected to~~ **who must** comply with food hygiene requirements

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

-Food safety: ~~Assurance~~ **Condition** that food will not cause harm to the consumer. ~~when it is prepared and/or eaten according to its intended use~~

-Food suitability: ~~Assurance that food is acceptable for human consumption according to its intended use.~~

We believe that the term that could be included is "Food integrity" (Safety, health, and quality).

-Good Hygienic Practices: *Prerequisite programs **on the conditions and measures necessary** aiming specifically at **to ensure** food hygiene, applied in the establishment.*

- Prerequisite programs: ***Prior** procedures and actions taken to maintain hygienic conditions throughout the food chain, that ~~provide the foundation~~ **are essential** for the HACCP system.*

Definitions specific to the HACCP system

HACCP plan: A document prepared in accordance with the principles of HACCP *that describes the actions to be taken* to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration. [Translator's note: change does not affect the English version.]

Monitoring: ~~The act of conducting~~ A planned sequence of observations, or measurements, **and registries** of hazard control measure ~~parameters~~ *criteria* to assess whether a ~~CCP~~ *the measure* is ~~under~~ *in control functions* effectively. [SIC]

GUATEMALA

Background:

In Guatemala, Ministerial Agreement 1126-2002 decides that it is the Vice Minister of Agricultural Health and Regulation's Department of Food Safety, which falls under the Ministry of Agriculture, Livestock and Food, that will represent the Codex Focal Point.

Agenda Item 4: Proposed Draft Revision of the General Principles of Food Hygiene (CAC/RCP 1-1969) and its Annex: Hazard Analysis and Critical Control Points (HACCP) System - Guidelines for its Application (Annex to the HACCP).

Guatemala thanks the eWG, presided over by France, Chile, United States, Ghana, and India, for preparing the document and for its efforts in coordinating and drafting it.

GENERAL COMMENTS: Guatemala supports El Salvador's proposal on using the term "food business" to facilitate understanding of the text.

The translation for the English "should" needs to be "debería" in Spanish.

Guatemala does not agree with the use of the term SAFETY AND SUITABILITY in the title and other paragraphs in the document, given that they are different terms and should not be used simultaneously. A

product could be suitable, but not safe, or vice versa. (Safety: a concept that refers to the existence and control of hazards associated with products for human consumption, through the ingestion of food and medicines, such that they do not cause harm to consumer health.)

Suitability: n. Appropriateness for a particular person, purpose, or situation.) [*Translator's note: the definition differs in English and Spanish. This definition is taken from Oxford*]

The use of the term 'suitable' is not appropriate when referring to food in which 'safety' is being determined, given that if a food is safe, this is synonymous with a person being able to consume it without any risk to his/her health (a raw potato may be safe, but it is not suitable for consumption in its raw state).

SPECIFIC COMMENTS:

Paragraph 1: Guatemala finds Option B to be more relevant, as it provides a better, real description of safety and refers to the ETAS and harm to human health.

Paragraph 2: Guatemala finds Option B to be more relevant, given that businesses are currently responsible for preparing their own products. Thus, they should work with governments and competent authorities on the matter.

Paragraph 3, bullet 4: 'GHPs, in general, **only** need basic knowledge and skills.'

Paragraph 5, bullet 1: HACCP application will not be effective without prior implementation of GHPs. [*Translator's note: change does not affect the English*]

Paragraph 5, bullet 2: Guatemala supports El Salvador's description that "HACCP is a preventive approach that aims to **enhance ensure** food safety where this is appropriate and feasible, by improving the control of hazards over that achieved by the GHPs."

Paragraph 5, bullet 5: Guatemala supports El Salvador's description that "HACCP requires specific knowledge and skills." [*Translator's note: change does not affect the English*]

OBJECTIVES

Paragraph 6, bullet 2: recommend an HACCP-based approach as a means to **enhance ensure** food safety. (A food is either safe or not; as such the term 'enhance' does not fit here).

GENERAL ASPECTS:

Paragraph 9: Each section in this document states both the objectives to be achieved and the rationale behind those objectives in terms of the safety **and suitability** of food. There will inevitably..... The fundamental question in every case is "what is necessary and appropriate on the grounds of the safety **and suitability** of food for consumption?"

Paragraph 10:, there will nevertheless be some situations where it is neither necessary nor appropriate on the grounds of food safety **and suitability**.....

In so doing it takes into account the wide diversity of food **preparation** practices and varying degrees of risk involved in **its** production.

Roles of Governments, food business operators, and consumers

Paragraph 11, bullet 2: provide assurance that food is **suitable for human consumption** safe.

Paragraph 12, bullet 1: develop and implement processes that provide **assurance that** food that is safe **and suitable for consumption**.

Paragraph 13: Consumers should recognize their **responsible** role by following relevant instructions and applying appropriate food hygiene measures.

BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM

i) The recommended way to **maximize provide assurance of** food safety **and suitability** is a two [phase/**component**] preventive approach. (Safety is not negotiable and, thus, cannot be maximized or minimized. A product is either safe or not.)

ii) The implementation of GHPs is the first [phase/**component**], of the design of a food safety control system.

v) The application of GHPs should be subject, ~~where appropriate~~, to monitoring, verification and documentation.

vii) The implementation of HACCP, where needed and feasible, is the second [phase/**component**] of the design of an effective food safety control system.

viii) HACCP should determine validated hazard control measures that are essential to **increase the level of guarantee** food safety.

x) Modifications should be documented and, ~~when necessary~~, validated.

DEFINITIONS

Definitions applying within the whole document

(the terms should be in alphabetical order for ease of use and term search)

Contaminant Any biological ~~or~~ **chemical, or physical** agent, ~~or other objectionable matter or physical object~~ (i.e. foreign matter or other substances) not intentionally added to food that may compromise food safety ~~or suitability~~.

Contamination The introduction or occurrence of **a one or several** contaminants in food or food environment.

Disinfection.....to a level that does not compromise food safety **or suitability**

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

Food safety Assurance that food will not cause harm to the consumer when it is **prepared and/or** eaten ~~according to its intended use~~.

~~**Food suitability** Assurance that food is acceptable for human consumption according to its intended use.~~

Good Hygienic Practices Prerequisite programs aiming specifically at food hygiene, applied in the establishment. **This is part of the HACCP requirements.**

Definitions specific to the HACCP system:

Guatemala supports Option A (based on ISO 9000)

Corrective action [Action on the process or the environment to eliminate the cause of a detected nonconformity and to prevent its recurrence.] [*Translator's note: change does not affect the English*]

Correction [Action to eliminate a detected nonconformity.]

Guatemala supports the CCP proposal.

Critical Control Point (CCP) A step at which hazard control measure(s) is(are) ~~can be~~ applied and is(are) essential to prevent ~~or eliminate~~ reduce a hazard ~~or reduce it~~ to an acceptable level.

Deviation Failure to meet a critical **criteria limit**.

JAPAN

The Government of Japan is pleased to submit the following comments on the Proposed Draft Revision of the General Principles of Food Hygiene for consideration at the forthcoming 48th Session of the Codex Committee on Food Hygiene.

General Comments

- The Committee should discuss the structure/outline of the whole document first since some sections (e.g., INTRODUCTION) need to be drafted in consideration with the structure/outline of this document.
- Japan would like to request that the following points be clarified before we start actual discussion on the sections of "Basic Principles for a Food Safety Control System" and "Definitions":
 - In the proposed draft, it seems that the concept of so-called "Operational Prerequisite Programs (OPRP)" (defined in ISO22000) is included in CCP (as CCP Type B). Is this correct?
 - If this is the case, we believe that OPRPs should be considered as a continuation of GHPs/PRPs rather than as CCPs, and incorporating OPRPs in CCPs implicitly should be confusing to the users of this document who are familiar with the current CCP approach, and even familiar with ISO22000 .
 - And, to begin with, if we are to introduce "OPRP" into this document, we need to discuss its necessity first, as this is the new concept to the Codex GPFH and HACCP.

Until these points are fully clarified, it would be difficult to discuss the definitions of certain terms (e.g., Hazard control measures, CCP), which are dependent on the fundamental direction of this document.

- Aside from the discussion whether OPRPs can be incorporated in CCPs, Japan agrees with adopting a wide variety of CCPs. To adopt a wide variety of CCPs in this document, we would like to propose that: i) the original definition of "Critical limit" be kept, instead of introducing a new term "Critical criterion", and ii) an

explanation that critical limit should not be limited to the numeric parameter monitored timely be described in the HACCP part of this document, not in the section of “DEFINITIONS”.

- As mentioned above, it would be difficult to discuss the definitions of certain terms (e.g., Hazard control measures, CCP) before the three points in the 2nd bullet are fully clarified. The titles of the subsections “Definitions applying within the whole document” and “Definitions specific to the HACCP system” should be put in square bracket until those are clarified.

Specific Comments

Title:

GENERAL PRINCIPLES OF FOOD HYGIENE ~~FOR FOOD SAFETY AND SUITABILITY: GOOD HYGIENIC PRACTICES (GHPS) AND HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM-~~ (HACCP)

Rationale: From the definition of “food hygiene”, it is obvious that this document is for food suitability and safety, therefore redundant as the title.

Para 1-2: Japan proposes to put them in square brackets to be discussed later.

Rationale: Refer to the General Comments. We should determine the fate of these paragraphs after the discussion on the structure of the new document.

Para 3-4:

3. The first section will describe Good Hygienic Practices for Food Safety and Suitability (GHPs). GHPs are the basis of any food safety control system:

- **The application of appropriate GHPs in food businesses provides a sanitary environment that supports the production of safe and suitable food.**

- GHPs are aimed at preventing or reducing the level of contaminants so that the suitability of the end product as well its safety will not be compromised.

- GHPs are part of prerequisite programs which should always be implemented in any operating food business.

- All employees should be trained in GHPs as appropriate to their job activities; it is important that food handlers have basic knowledge of the impact GHPs can have on the safety and suitability of food.

- ~~GHPs, in general, only need basic knowledge and skills.~~

4. ~~The application of appropriate GHPs in food businesses provides a sanitary environment that supports the production of safe and suitable food.~~

Rationale: Para 4 should be transferred as the first bullet point under the para 3, because it is not an independent point, rather it is related to para 3.

We propose to delete the last bullet point, because, i) this point should not be compared with the last bullet of para 5, ii) not always true, and iii) not necessary.

Para 5, last bullet:

- ~~HACCP requires specific knowledge and skills.~~

Rationale: We propose to delete the last bullet point, because, i) this point should not be compared with the last bullet of para 3, and ii) not necessary.

BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM:

i. The recommended way to maximize food safety and suitability is a two [~~phase~~/component] preventive approach.

ii. The implementation of GHPs is the first [~~phase~~/component], of the design of a food safety control system.

Rationale: Japan proposes to use “component” throughout this document. If we use “Phase”, it might give a wrong message that “GHP comes first, then next CCP”.

iii. GHPs should ensure that food is produced in a sanitary environment and reduce the ~~burden~~ **introduction, presence and accumulation** of contaminants, whether hazardous or not.

Rationale: The term “burden” is too broad, and could cause confusions among readers.

iv. GHPs are **a part of** a prerequisite to the implementation of a HACCP system, because they provide the foundation for a HACCP system to be effective.

Rationale: to be consistent with 2nd bullet point under the para 3. There are other PRPs (e.g. Good Agriculture Practice, Good Veterinary Practice)

vi. The implementation of HACCP, ~~where needed and feasible~~, is the second [phase/component] of the design of an effective food safety control system.

Rationale: The difference and relation between GHPs and HACCP are described in this section. The necessity, feasibility and applicability of HACCP should be described in other sections.

vii. HACCP should identify all hazards associated with **the ingredients**, the production process and its environment, and specify the significant ones that should be controlled because they can occur at an unacceptable level.

Rationale: Ingredients, especially raw ingredients, often contain significant food safety hazards that must be controlled through HACCP, therefore it should be clearly spelled out.

Para 15:

{Definitions applying within the whole document}

Rationale: Refer to the General Comments.

Good Hygienic Practices ~~Prerequisite programs~~ **Practice** aiming specifically at food hygiene, applied in the establishment

Or . **A part of p** ~~Prerequisite programs~~ aiming specifically at food hygiene, applied in the establishment

Rationale: GHP is a part of PrP, but GHP is not equal to PrP.

Hazard

Japan supports the deletions of “, or conditions of”.

Rationale: The Committee should consider the proposal of the amendment of the “hazard” definition in the Codex Procedural Manual when needed, in accordance with the Guide to the Procedure for the Amendment and Revision of Codex Standards and Related Texts.

~~Definitions specific to the HACCP system~~

Rationale: Refer to the General Comments.

Corrective action

We prefer the definition of “Corrective action” in the Option B.

Option A (based on ISO 9000)

~~**Corrective action** [Action on the process or the environment to eliminate the cause of a detected nonconformity and to prevent its recurrence.]~~

~~**Correction** [Action to eliminate a detected nonconformity.]~~

Option B (US)

Corrective action [Any action taken when a deviation occurs to correct the problem, to segregate and evaluate any food impacted by the deviation and determine appropriate disposition of the food, and to identify the cause of the problem and reduce the likelihood it will reoccur.]

~~**Correction:** [An action taken in lieu of corrective actions to identify and correct a problem when a deviation does not impact the safety of the food (e.g. recleaning insanitary equipment before production begins).]~~

Rationale: Corrective action should include two components: i) identification of the cause of failure and remove it and fix the process, and ii) identify and remove the affected products. The definition of the Option B “Corrective action” covers both aspects in one term.

For the term “Correction”, the current text [.....when a deviation does not impact the safety of the food] is contradictory to the definitions of “Deviation (Failure to meet a critical criterion)” and “Critical criterion (a criterion that separates acceptability from unacceptability with respect to the safety of the food.)” in the current draft.

~~**Critical criterion** A criterion that separates acceptability from unacceptability with respect to the safety of the food.~~

Critical limit ~~A criterion that separates acceptability from unacceptability. A numeric value characterizing the critical criterion of a measurable parameter that can be monitored in a timely manner.~~

Rationale: Please refer to the General Comments.

The definitions of the following terms should be put in square brackets.

Rationale: Please refer to the General Comments.

[**Critical Control Point (CCP)** A step at which *hazard control measure(s) is(are) can be applied and is(are) essential to prevent or eliminate reduce a hazard or reduce it to an acceptable level.*]

[**HACCP plan** A document prepared in accordance with the principles of HACCP *that describes the actions to be taken to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration*]

[**Hazard control measure** Any action that can be used *to address a significant hazard present in a food or the environment or occurring during the production process, to ensure its level in food does not exceed an acceptable level.*]

[**Monitoring** The act of conducting a planned sequence of observations or measurements of *hazard control measure parameters criteria to assess whether a CCP the measure is under in control.*]

[**Significant hazard** A hazard identified by the hazard analysis as *having to be controlled.*]

[**Validation** Obtaining evidence that ~~the elements of the HACCP plan are effective~~ *a hazard control measure or combination of hazard control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.*]

[**Verification** The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine ~~compliance with the HACCP plan~~ *whether a hazard control measure is or has been operating as intended.*]

MALAYSIA

Malaysia would like to congratulate members of the electronic Working Group chaired by France and co-chaired by Chile, Ghana, India and the United States of America on the progress of the document.

Malaysia would like to offer our comments as follows:

INTRODUCTION

Para 1:

Malaysia prefers Option B as an introduction of this document. However, we would like to adopt the last two sentences in Option A to become the third para in Option B. This is to reflect the Good Hygienic Practices (GHP) and Hazard Analysis and Critical Control Point (HACCP) as stated in the new title of the document. Therefore, Option B will read as follows:

"People have the right to expect the food they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury are at best unpleasant; at worst, they can be fatal. But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.

International food trade, and foreign travel, are increasing, bringing important social and economic benefits. But this also makes the spread of illness around the world easier. Eating habits too, have undergone major change in many countries over the last two decades and new food production, preparation and distribution techniques have developed to reflect this. Effective hygiene control, therefore, is vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage. Everyone, including farmers and growers, manufacturers and processors, food handlers and consumers, has a responsibility to assure that food is safe and suitable for consumption.

Effective safe food practices including Good Hygienic Practices (GHP) and application of Hazard Analysis and Critical Control Point (HACCP) System are therefore essential in avoiding the adverse human health of unsafe and unsuitable food. Such a two phase/component approach will also provide assurance of the safety and suitability of food, adequately protect consumers from illness or injury caused by food and maintain consumer confidence.

These General Principles lay a firm foundation for ensuring food hygiene and should be used in conjunction with each specific code of hygienic practice, where appropriate, and the guidelines on microbiological criteria.

The controls described in this General Principles document are internationally recognized as essential to

ensure the safety and suitability of food for consumption. The General Principles are commended to Governments, food business operators (including individual primary producers, manufacturers, processors, food service operators and retailers) and consumers alike."

Para 2:

Malaysia prefers Option A but with an amendment. In view that the term "food chain" already covers primary production to the final consumer, we propose to delete the term "including manufacturing and distribution" from the first sentence. We also would like to delete the second sentence as the word "goal" is not clearly defined. Therefore, the para would read as follows:

"This document shows how food safety and food suitability can be enhanced throughout the food chain from primary production to the final consumer, including manufacturing and distribution. To achieve this goal, each business establishes its own control system taking into account its specific requirements."

Para 3 (third bullet):

Malaysia is of the view that food handlers should have basic knowledge and understand the impact of GHPs on food safety and suitability. Therefore, we propose that the third bullet in para 3 would read as follows:

"- All employees should be trained in GHPs as appropriate to their job activities; it is important that food handlers have basic knowledge **and understanding** of the impact GHPs can have on the safety and suitability of food."

Para 5 (fourth bullet):

Malaysia is of the view that the example for certain activities related to primary production may not be necessary to be listed and proposes to delete the phrase in brackets. Therefore, the fourth bullet in para 5 would read as follows:

"HACCP may not be applicable to all type of food businesses, in particular at the stages of primary production. However, the principles of HACCP can be applied to certain activities related to primary production [e.g. administration of veterinary drugs],".

Para 5 (fifth bullet):

Malaysia is of the view that for HACCP to be implemented effectively, the knowledge and skills on hazard control measures acquired through training and work experience and how to control them is essential. Therefore, the fifth bullet in para 5 would read as follows:

"- HACCP requires **food businesses to have** specific knowledge and skills **on hazard control measures to be applied at critical control points (CCPs)**."

SCOPE

Para 7:

Malaysia is of the view that the first sentence in para 7 should be strengthened by inserting the word "and additional" before the words "control measure at certain production steps". Therefore, the first sentence in para 7 would read as follows:

"?. This document provides a framework for producing foods that are safe and suitable for human consumption by setting out necessary hygiene conditions and applying, where appropriate, enhanced **and additional** control measures at certain production steps."

Roles of Governments, food business operators and consumers

Para 11 (second bullet)

Malaysia is of the view that the word "safe" should be inserted after the word "food is" to be consistent with the new title and scope of this general principles. Therefore, the second bullet in para 11 would read as follows:

"- Provide assurance that food is **safe and** suitable for human consumption;".

Para 12 (second bullet)

Malaysia is of the view that as the requirements of ingredient content and labelling are covered under Codex General Standard for the Labelling of Prepackaged Food, thus the words ingredient content and labelling should not be covered under these general principles. Therefore, the second bullet in para 12 would read as follows:

"- ensure that consumers have clear and easily-understood information including ingredient content, by way of labelling and other appropriate means, to enable them to protect their food from contamination

and prevent the growth/survival of foodborne pathogens by storing, handling and preparing it correctly; and".

BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM

Para (vii)

Malaysia proposes to substitute the word "ones" with the word "hazards" for better understanding. Therefore, para (vii) would read as follows:

"(vii) HACCP should identify all hazards associated with the production process and its environment, and specify the significant ~~ones~~ **hazards** that should be controlled because they can occur at an unacceptable level."

Para (viii) and (ix)

Malaysia proposes to insert the word "significant" to differentiate between all hazards and significant hazards, as only significant hazards require control measures under HACCP. Therefore, para (viii) and (ix) would read as follows:

"(viii) HACCP should determine validated **significant** hazards control measures that are essential to increase the level of food safety.

(ix) The application of **significant** hazards control measures should be subject to monitoring, verification and documentation."

DEFINITIONS

Para 15:

Corrective action

Malaysia prefers Option B (US) for the definition of corrective action and correction. However, Malaysia would like to propose to include the word "at CCPs" after the word "deviation occurs" in the definition of corrective action, to strengthen the definition. Therefore, the definition for corrective action would read as follows:

"**Corrective action** Any action taken when a deviation occurs **at CCPs** to correct the problem, to segregate and evaluate any food impacted by the deviation and determine appropriate disposition of the food, and to identify the cause of the problem and reduce the likelihood it will reoccur."

Critical Control Point (CCP)

Malaysia is of the view that the word "eliminate" should be retained in the definition of critical control point (CCP) in view that all hazards can be controlled. The effectiveness of the control measures depend on the type of hazards and the control measure implemented. A microbiological hazard may not be eliminated but it is possible for physical hazards. Metal fragments or foreign matter can be eliminated by introducing effective control measure e.g. magnet catcher or X-ray machine specifically designed to detect foreign matter in the food. Therefore, the definition for critical control point (CCP) would read as follows:

"A step at which hazard control measure(s) is (are) can be applied and is (are) essential to prevent or **eliminate** or reduce a **significant** hazard or reduce it to an acceptable level."

Flow diagram

Malaysia is of the view that the flow diagram should be a complete sequence of operations. Therefore, the definition for flow diagram would read as follows:

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

Hazard control measure

Malaysia is of the view that the definition for hazard control measure should include the word "eliminate" to be consistent with the definition of CCP proposed by Malaysia. Therefore, the definition for hazard control measure would read as follows:

"**Hazard control measure** Any action that can be used to **eliminate or prevent or reduce** to address a food safety significant hazard or reduce it to an acceptable level present in a food or the environment or occurring during the production process, to ensure its level in food does not exceed an acceptable level."

Significant hazard

Malaysia is of the view that the significant hazard is the result of an unacceptable food safety risk and it

needs a control measure in place. Therefore, the definition for significant hazard would read as follows:

"Significant hazard A hazard identified by the hazard analysis as having that could result in an unacceptable food safety risk to consumers and need to be controlled."

MEXICO

Comments	Rationale
The version in Spanish uses the acronyms APPCC and HACCP interchangeably to refer to the Hazard Analysis and Critical Control Point System. We propose only using the acronym in English.	The use of the English acronym, "HACCP," is common in Spanish-speaking countries, with an annotation in parentheses stating "by its acronym in English."

Regarding the recommendations in Point 18, we submit the following:

Paragraph	Comments
a) Consider the proposed draft as presented in Appendix I. In particular, specific attention should be paid to the approach proposed for the differential management of CCPs, depending on the type of monitoring which is available in a given context.	We do not believe that CCP categories should be established. The HACCP methodology indicates that hazard control measures should be established at the appropriate steps of the process; if the hazards are significant, the steps at which the measures are applied are identified as CCP. Hazard control measures should be verifiable at the time and step at which they are applied , underscoring that these measures are applied within certain parameters (critical limits) that must be observed and, thus, should be measured in real time. [Even when the abovementioned cannot be observed in possible circumstances, the nomenclature of CCP should not be made more complicated.]
b) Pursue the revision of CAC/RCP 1-1969 with an approach consistent with the one that has been implemented to date, and to establish an eWG to that effect. In order to allow an effective and inclusive work to achieve this goal in a timely manner, the prospective eWG should use modern technologies, i.e. work through the Codex Alimentarius bulletin board www.forum.codex-alimentarius.net . A complementary system using mass mailing should also be considered. Specific attention should be paid to the question of an effective translation system and its costs for the host member country(ies) or organization(s).	It would be appropriate to use a complementary mailing system to distribute documents. Furthermore, it would be advisable to create a glossary of terms in Spanish to have an effective system for translating electronic documents and interpreting international meetings.
c) Regarding the amendments and revisions in Appendix I, attention should be paid to:	
The appropriateness of an introductory paragraph to the General Introduction section, with the scope to explain the importance of the standard CAC/RCP 1-1969 and to provide general information regarding the international context it is part of.	See "specific comments," paragraphs 1 and 2.
Determining if the concepts of "GHP-based control measures" and "HACCP-based control measures," which have been recently used in Codex documents, could be appropriate for the revision of CAC/RCP 1-1969.	The differentiation between "GHP-based control measures" and "HACCP-based control measures" is useful, as it allows for drawing a clear difference when these measures are to be applied throughout the production process.
The need for additional definitions, including: Potential hazard; Food business operator (FBO); Operational Prerequisite Program.	The definition of potential hazard is included in the "specific comments."
The improvement of proposed or existing definitions, including: Environment, Food safety and Food suitability, Primary production.	Comments were made on the definitions for: Environment, Food safety and Food suitability in the definitions section "specific comments."
The deletion of 'condition of' in the definition of Hazard.	We propose deleting 'condition of' in the definition of Hazard, given that it is a function of risk, not hazard.
The deletion of 'eliminate' from the definition of CCP.	We feel the word 'eliminate' should remain in the definition of CCP.

<p>To consider the exact meaning of the terms 'Corrective action' and 'Correction' and to agree on related definitions.</p>	<p>Definitions for the terms 'corrective action' and 'correction' were proposed.</p>
-----------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------

Specific Comments

Paragraph	Changes	Rationale
<p>1.</p>	<p>Option B: People have the right to expect the food they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury are at best unpleasant; at worst, they can be fatal. But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation lawsuits. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence. International food trade, and foreign travel, are increasing, bringing important social and economic benefits. But this also makes the spread of illness around the world easier. Eating habits too, have undergone major change in many countries over the last two decades and new food production, preparation and distribution techniques have developed to reflect this. Effective hygiene control, <u>through the implementation of Good Hygienic Practices (GHP) and the Hazard Analysis and Critical Control Point (HACCP) system</u>, therefore, is vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage. Everyone, including farmers and growers, manufacturers and processors, food handlers and consumers, has a responsibility to assure that food is safe and suitable for consumption. Everyone, including farmers and growers, manufacturers and processors, food handlers and consumers, has a responsibility to assure that food is safe and suitable for consumption. These General Principles lay a firm foundation for ensuring food hygiene and should be used in conjunction with each specific code of hygienic practice, where appropriate, and the guidelines on microbiological criteria. The controls described in this General Principles document are internationally recognized as essential to ensure the safety and suitability of food for consumption. The General Principles are commended to <u>Governments competent authorities</u>, Governments, food business operators (including individual primary producers, manufacturers, processors, food service operators and retailers) and consumers alike.</p>	<p>We believe that Option B is the best option as the introductory paragraph. We propose replacing "litigation" with "lawsuits" when referring to legal conflicts. We propose adding "through the implementation of Good Hygienic Practices (GHP) and the Hazard Analysis and Critical Control Point (HACCP) system," to clarify the method this document will use to effectively control hygiene.</p>
<p>2.</p>	<p>Option A: This document shows how food safety and food suitability can be enhanced throughout the food chain from primary production to the final consumer, including manufacturing and distribution. To achieve this goal, each business establishes its own control system taking into account its <u>characteristics and</u> specific requirements. <u>This document should also help competent authorities establish appropriate oversight mechanisms.</u></p>	<p>We choose Option A as the most appropriate. The control system businesses establish are also based on their own characteristics. The document could also help authorities establish oversight mechanisms in food businesses.</p>
<p>3.</p>	<p>- GHPs are part of prerequisite programs which should always be implemented in any operating food business. [Translator's note: the change does not impact the English version.] - GHPs, in general, only need basic knowledge and skills. [Translator's note: the change does not impact the English version.]</p>	<p>Translation comments</p>
<p>5.</p>	<p>- HACCP application will not be effective without prior implementation of GHPs. [Translator's note: the change does not impact the English version.]</p>	<p>Translation comments An HACCP system can be applied even to primary production, which could result in the absence of CCP. However, the good</p>

	<p>- HACCP may not be applicable to all type of food businesses, in particular at the stages of primary production. However, the principles of HACCP can be applied to certain activities related to primary production [e.g. administration of veterinary drugs].</p> <p><u>The HACCP system is applicable to all types of food businesses throughout the production chain, including primary production; however, it would be possible for only some of the principles to be applicable at some stages.</u></p> <p>- HACCP requires specific knowledge and skills. [Translator's note: the change does not impact the English version.]</p>	<p>hygienic practices implemented stem from hazard analysis and the application of control measures.</p> <p>Translation comments</p>
7.	<p>This document provides a framework for producing foods that are safe and suitable for human consumption by setting out necessary hygiene conditions and applying, where appropriate, enhanced control measures at certain production steps. The document is intended for use by food business operators and countries competent authorities, as appropriate.</p>	<p>We propose using 'competent authorities' and striking footnote 3, in order to streamline the terminology used in other Codex texts.</p>
8.	<p>The document provides a foundational structure for other, more specific, codes applicable to particular food sectors. Such specific codes and guidelines should be read in conjunction with this document. [Translator's note: the change does not impact the English version.]</p>	<p>Translation comments</p>
10.	<p>The text indicates where such questions are likely to arise by using the phrases "where necessary" and "where appropriate." In practice, this means that, although the requirement is generally appropriate and reasonable, there will nevertheless be some situations where it is neither necessary nor appropriate on the grounds of food safety and suitability, given production/processing condition/practices, among other factors. In deciding whether a requirement is necessary or appropriate, an assessment of the risk should be made. This approach allows the requirements in this document to be flexibly and sensibly applied with a proper regard for the overall objectives of producing food which is safe and suitable for consumption. In so doing it takes into account the wide diversity of food processing practices and varying degrees of risk involved in producing food.</p>	<p>This would specify what is taken into consideration when using the term "where necessary."</p>
	<p>Roles of Governments competent authorities, food business operators, and consumers</p>	<p>We propose using 'competent authorities', in order to streamline the terminology used in other Codex texts.</p>
11.	<p>Governments Competent authorities should decide how best they should apply these general principles through legislation, regulation and guidance appropriate guidelines, to:</p>	<p>Replace "governments" with "competent authorities"</p> <p>We do not believe there is a better way to apply the general principles. However, implementation thereof should be the most appropriate for each country's situation.</p>
13.	<p>i) The recommended way to maximize food safety and suitability is a two [phase/component] preventive approach.</p> <p>iii) GHPs should ensure that food is produced in a sanitary environment and reduce the burden of contaminants, whether hazardous or not.</p> <p>vii) HACCP should identify all hazards associated with the production process and its environment, and specify the significant ones that should be controlled because they can occur at an unacceptable level. [Translator's note: the changes do not impact the English version.]</p>	<p>We maintain that the words "phase/component" can be used together, as we talk about phases when stating that the GHPs should be applied prior to applying the HACCP system. However, we could also talk about components, since they can be established simultaneously.</p> <p>We do not feel that "whether hazardous or not" really clarifies the text.</p> <p>Comment on wording to clarify the idea.</p>
Footnote No. 2	<p>For instance, food preferences are not the same for different categories groups of consumers, making food which is safe possibly not suitable to certain categories</p>	<p>We propose replacing the word 'categories' with 'groups', since the word</p>

	groups. Thus, food must not only be safe but must also be suitable to meet the dietary needs of target consumers.	category can be interpreted as a level or hierarchy.
Footnote No. 3	For the purpose of this document, each time the terms "country", "government", "national" are used, the provision applies both to Codex Members (Rule I) and Codex Member Organisations (Rule II), i.e. regional economic integration organisation (REIO) — see Codex Alimentarius Commission, Procedural Manual.	We propose using the term 'competent authorities' to streamline this text with the terminology used by Codex.
Definitions		
	Contaminant: Any biological, chemical, or physical agent, or other objectionable matter or physical object (i.e. foreign matter or other substances) not intentionally added to present in food that may compromise food safety or suitability.	We propose leaving 'objectionable matter' in to include any other type of material. We feel that the term 'present' gives a broader definition that does not call for determining intent, which may not be identified.
	Environment: The surroundings of the food and processing equipment within the establishment, including air but excluding humans.	We do not believe you can exclude people from the environment, given that humans also impact the environmental condition of plants and are part of the surrounding of the food within establishments.
	Food safety: Assurance The condition that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.	When we talk about assurances, we refer to the certainty or surety that a food will not cause harm to the consumer. However, it is not possible to guarantee that a food will not affect a person's health, such as the case of allergens. Therefore, we propose changing the word to condition.
	Food safety: Assurance Quality or characteristic of that the food that is acceptable for human consumption according to its intended use.	Suitability is no guarantee, but a quality or characteristic of a food is.
	Good Hygienic Practices: Programs that are part of the prerequisites aiming specifically at food hygiene, applied in the establishment. [Translator's note: the last change only applies to the Spanish version.]	This clarifies that GHPs are not the only prerequisites. GHPs are applicable to the entire establishment [Translator's note: this comment addresses a word change only affecting the Spanish.]
	Prerequisite programs: Procedures and actions measures taken to maintain hygienic conditions throughout the food chain that include operational and hygienic conditions and provide the foundation for the HACCP system.	We feel that this definition broadens the term for prerequisite programs, as not all programs target hygienic conditions.
	Corrective action: [Translator's note: the change does not affect the English.] Any action or procedure to be taken that should be applied when the results of monitoring at the CCP indicate a loss of control present a deviation from the established critical limits.	Corrective actions derive from deviations from critical limits. We feel that the word "apply" is more appropriate, given that the corrective actions that were already adopted by the business should be applied.
	Correction: Action to eliminate a detected nonconformity.	This definition should be included because corrective actions focus on deviations from the critical control limits and corrections may be applied to other aspects of the productive process.
	Critical Control Point (CCP): A step at which hazard control measure(s) is(are) can be applied and is(are) essential to prevent or eliminate reduce a hazard or reduce it to an acceptable level.	We propose keeping the word "eliminate," given that there are steps that focus specifically on elimination, e.g. the destruction of pollen during fermentation, in relation to the cider and vinegar making process, or the elimination of physical objects of a certain size using filters or magnets.
	Critical criterion: A criterion that separates acceptability from unacceptability with respect to the safety of the food.	A critical limit may or may not be measurable, as such it is not necessary to introduce the concept of 'critical

		criteraion'. Including new terms could cause confusion surrounding what already exists.
	Critical limit: A numeric value or established criterion- characterizing the critical criterion of a measurable parameter that can be monitored in a timely manner that separates acceptability from unacceptability at a certain step.	A critical limit should be a numeric value or criterion established by a business.
	Deviation: Failure to meet a critical limit criteraion .	Comment based on the previous proposal.
	Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan. [Translator's note: the change does not affect the English version.]	This comment aims to clarify that significant hazards are identified using hazard analysis.
	Hazard control measure: Any action that can be used to prevent or eliminate to address a food safety significant hazard or reduce it to an acceptable level present in a food or the environment or occurring during the production process, to ensure its level in food that it does not exceed an acceptable level.	Comment on translation and wording.
	Significant hazard: A hazard identified by the hazard analysis as having to be controlled that, upon evaluation of its severity and probability of occurring, is deemed important for safety and should be included as a hazard control measure to ensure safety.	We propose this definition to clarify when a hazard is considered significant.
	Validation: Element of verification focused on obtaining and evaluating evidence Element of verification focused on obtaining and evaluating evidence Obtaining evidence that the elements of the HACCP plan are effective a hazard control measure or combination of hazard control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.	It should be clearer that validation is an element of verification. The definition should also specify that the effectiveness of the hazard control measure can be determined by obtaining and evaluating evidence. The document in English talks about obtaining evidence.
	Potential hazard: A known hazard or one reasonably associated with the raw materials, ingredients, packaging materials, or processing steps that the hazard analysis should consider.	We feel the concept of potential hazard should be included to clarify the first principle.

NICARAGUA

Rationale

Nicaragua proposes:

- Including the term **contaminated** to prevent any misinterpretation.
- Eliminating the last item since it includes already-mentioned ideas.

International food trade, and foreign travel, are increasing, bringing important social and economic benefits. But this also makes the spread of illness around the world easier. Eating habits too, have undergone major change in many countries over the last two decades and new food **primary** production, **transformation, storage, preparation** and distribution techniques have developed to reflect this. Effective hygiene control, therefore, is vital to avoid the adverse human health and economic consequences of ~~foodborne~~ **caused by contaminated foods**, foodborne injury, and food spoilage.

Rationale

We propose adding the terms **primary, transformation, and storage** to clearly define the stages along the food chain.

The controls described in this General Principles document are internationally recognized as essential to ensure the safety and suitability of food for consumption. The General Principles are commended to Governments, food business operators (including individual primary producers, manufacturers, processors, food service operators and retailers) and consumers alike. [Translator's note: change does not affect the English.]

Rationale

We recommend changing the terms to improve understandability of the paragraph.

2. Nicaragua feels Option B is more appropriate (with some changes to the wording), as it clearly and concisely explains the idea.

[This Introduction will outline the general **hygienic** principles that should be **implemented and enforced** ~~understood and followed~~ by food businesses and **which** would help governments to establish appropriate oversight. It will then define specific terms and expressions applicable to the document.]

3. The first section will describe Good Hygienic Practices for Food Safety and Suitability (GHPs), **which** GHPs are the basis of any food safety control system:

- GHPs are aimed at preventing or reducing the level of contaminants so that the ~~suitability of the end product as well its safety~~ **of the end product** will not be compromised.

Rationale

Proposed change for wording and comprehension purposes.

The appropriate application of appropriate GHPs in food businesses **favors the production of food that is safe and suitable for consumption**. ~~provides a sanitary environment that supports the production of safe and suitable food~~

Rationale

Proposed change for wording and comprehension purposes.

GHPs, in general, only need basic **specific** knowledge and **basic** skills.

Rationale

We feel it is necessary to have specific knowledge of GHPs.

5. The second section will describe the Hazard Analysis and Critical Control Point System for Food Safety (HACCP).

- HACCP application ~~will not be~~ **is** effective ~~without~~ prior implementation of GHPs.

Rationale

Proposed change for wording and comprehension purposes.

OBJECTIVES

6. Recommend an HACCP-based approach as a means to ~~enhance~~ **guarantee** food safety;

Rationale

The goal is to aim for guaranteeing food safety, not enhance levels.

SCOPE

7. This document provides a **reference** framework for producing foods that are safe and suitable for human consumption by setting out necessary hygiene conditions and applying, where appropriate, enhanced control measures at certain production steps. The document is intended for use by **the food industry business operators and countries and government authorities**, as appropriate.

Rationale

Proposed change for wording and comprehension purposes.

Roles of Governments, food business operators, and consumers

11. Governments should decide how best they should apply these general principles through legislation, regulation and guidance to:

- Protect consumers adequately from illness or injury caused by **contaminated** food; policies need to consider the vulnerability of the population, or of different groups within the population;

Rationale

Nicaragua proposed including the term **contaminated** to prevent any misinterpretation.

BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM

i. The recommended way to maximize food safety and suitability is a two [phase/component] preventive approach.

Rationale

Nicaragua agrees with uses the term "phase," as it specifies the order of application.

(v) The application of GHPs should be subject, ~~where appropriate,~~ to **monitoring, verification and documentation**

Rationale

Compliance with GHPs is mandatory. Thus, there should be discretion in the monitoring, verification, and documentation.

Definitions applying within the whole document

Good Hygienic Practices: Good Hygienic Practices Prerequisite programs aiming specifically at food hygiene and **suitability**, applied in the establishment.

Rationale

We recommend including the term "suitability" to complement the aim of the GHPs.

Corrective action: Option B (US)

[Any action taken when a deviation occurs to correct the problem, to segregate and evaluate any food impacted by the deviation and determine appropriate disposition of the food, and to identify the cause of the problem and reduce the likelihood it will reoccur.]

Rationale

Nicaragua feels that the best option is that proposed by the United States, which clearly and expressly defined the term "corrective action."

HACCP plan: [Translator's note: change does not affect the English] A document prepared in accordance with the principles of HACCP that describes the actions to be taken to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration.

Rationale

The correct acronym in Spanish is APPCC.

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan. [Translator's note: the change does not affect the English version.]

Rationale

Proposed change for wording and comprehension purposes.

NEW ZEALAND

New Zealand would like to thank France and Co-Chairs Chile, Ghana, India and the United States of America along with the electronic Working Group for the extensive work done to-date to initiate this very important document of revision of the General Principles of Food Hygiene and its HACCP Annex. New Zealand would like to submit the following comments:

General comments:

New Zealand suggests that in most cases, food safety and suitability are achieved by application of GHP, where no CCPs are determined. Food safety is enhanced by application of HACCP.

New Zealand would like to suggest that 'control measure' is elaborated in the revision process, with its own section covering GHP-based, hazard-based and risk-based control measures with a brief description of each. We believe this reflects the modern direction CCFH is already promoting in its recent practical guidelines on controlling specific hazard-food combinations such as *Campylobacter* and *Salmonella* in chicken meat (CAC/GL

– 78-2011) and *Salmonella* in beef and pork meat (CAC/GL 87-2016). This would not only encourage the reader to consider the potential control measures at three levels and the differences between them, but also gives the opportunity within this revised document to link to recent Codex texts on risk analysis, risk management metrics and the like.

Specific comments on the draft text:

Paragraph	Comment	Rationale
NZ supports Para 1 Option B		Comprehensive and easily understood
Para 2: NZ supports Option A	This document shows how food safety and food suitability can be achieved enhanced throughout the food chain from primary production to the final consumer, including manufacturing and distribution . To achieve this goal, each business establishes its own food safety control system taking into account these principles , its own specific requirements and any requirements set by the government .	Remove superfluous wording as already covered in whole of food chain approach. Adds clarity to how each business establishes its food safety control system within its country
Para 2. Option B	This Introduction will outline the general principles that should be understood and followed by food businesses and help governments to establish appropriate oversight. It will then define specific terms and expressions applicable to the document	Not necessary as the document as a whole will do this, not just the Introduction
3.	The first section will describe <i>Good Hygienic Practices for Food Safety and Suitability (GHPs)</i> . GHPs are the basis of any food safety control system: - GHPs are aimed at preventing or reducing the level of contaminants so that the safety and suitability of the end product as well its safety will is not be compromised. - GHP provides a sanitary environment and foundation that supports the production of safe and suitable food.	'Safety and suitability' This is consistent with other parts of document Add Para 4 in here as another indent with the word 'foundation' as GHP is the foundation for HACCP.
	- GHPs, in general, only need basic knowledge and skills.	Delete this last indent as it is better covered in indent 3 of the draft document. Employees need knowledge and skills relevant to the task; some GHP is more complex than others.
4.	The application of appropriate GHPs in food businesses provides a sanitary environment that supports the production of safe and suitable food.	See above inclusion in Para 3.
5.	The second section will describe the <i>Hazard Analysis and Critical Control Point System for Food Safety (HACCP)</i> . - HACCP application will not be effective without prior implementation of GHPs. - HACCP is a systematic preventive approach that aims to enhance food safety where this is appropriate and feasible, by improving the control of significant hazards over that achieved by the GHPs. - HACCP enhances food safety by the use of hazard-based accomplishes this with the help of hazard control measures applied at critical control points (CCPs), where appropriate . - HACCP is may not be applicable to all types of food businesses, across the food chain , in particular at the stages of primary production. However, the principles of HACCP can be applied to certain activities related to primary production [e.g. administration of veterinary drugs].	Food safety already in the definition of HACCP Delete 'application to be consistent with other indents HACCP, where possible, improves the control of significant hazards Uses terms already used by Codex (hazard-based) and notes that this is using CCPs as appropriate HACCP is applicable across the food chain but may or may not have one or more CCPs.
Objectives 6.	The <i>General Principles of Food Hygiene for Food Suitability and Safety and Suitability: Good Hygienic Practices (GHPs) and Hazard Analysis and Critical Control Point System (HACCP)</i> aims to: - identify the good hygienic practices applicable throughout the food chain (including primary production through to the final consumer) to provide food that is safe and suitable for human consumption; - recommend a hazard- an HACCP- based approach as a means to enhance food safety;	Throughout the food chain means from primary production to consumption Use terminology recently used by CCFH

	- provide a base for guidance that may be needed for specific hygiene codes applicable to specific food for sectors across of the food chain, processes, or commodities to amplify the hygiene requirements specific to those areas.	Provides the base upon which many codes are built with further specific information
Scope7.	This document is intended for governments, food business operators and consumers. It provides a framework for producing foods that are safe and suitable for human consumption by setting out necessary hygiene conditions and applying, where appropriate, enhanced control measures at certain production steps across the food chain . The document is intended for use by food business operators, and countries1, as appropriate.	Put last sentence first and add consumers. Delete 'production' as is associated with primary production, and 'steps' will suffice. Need to cover whole of food chain approach within scope. Put the last sentence at the beginning and add consumer. Remove the word 'use'.
Use 10. Third sentence	In deciding whether a requirement is necessary or appropriate, any relevant risk assessment should be considered .	Risk assessment information should be considered where available and relevant to the hazard. The risk assessment may inform the acceptable level of a particular hazard and could provide a link to risk-based control measures.
ROLES OF GOVERNMENTS, FOOD BUSINESS OPERATORS, AND CONSUMERS 11.	Governments should decide how best they should apply these general principles through legislation , regulation and guidance to: - protect intended consumers adequately from illness or injury caused by food; policies need to consider the vulnerability of the population, or of different groups within the population; - provide assurance that food is safe and suitable for human consumption;	'Intended' covers specific of the population, remove superfluous wording
12. Second indent	- ensure that consumers have clear and easily-understood information including ingredient content, by way of labelling and other appropriate means, to enable them to protect their food from contamination and prevent the growth/survival of foodborne pathogens by storing, handling and preparing it correctly; and	Remove specific inclusions at this stage that would be covered in detail later in the document.
13.	Consumers should recognize their role by following relevant guidance and instructions and applying appropriate food hygiene measures to ensure that their food is safe and suitable	Align with wording used for governments and food businesses and relate to guidance rather than instructions. Focuses on food safety and suitability
BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM	(i) The recommended way to maximize food safety and suitability is a two [phase/component] preventive approach. (ii) The implementation of GHPs is the first [phase/component], of the design of a food safety control system. (iii) GHPs should ensure that food is produced in a sanitary environment and reduce the burden of contaminants, whether hazardous or not. (iv) GHPs are a prerequisite to the implementation of a HACCP system, because they provide the foundation for a HACCP system to be effective. (v) The application of GHPs should be subject, where appropriate, to validation , monitoring, corrective action , verification and documentation. and recordkeeping (vi) The implementation of HACCP, where needed and feasible, is the second [phase/component] of the design of an effective food safety control system.	Make this Para 14. Remove 'basic' (i) 'Phase' preferred (and consequential change). (ii) Just use GHP to start each principle for consistency. Implementation and design clashes here as well, design coming first. (v) Delete unnecessary words and align with previous indents (v) Other key activities applied to GHP added (vi) Delete unnecessary words and align with other indents. (vi) HACCP should be applied across the food chain.

	<p>(vii) HACCP should identify all hazards associated with the production process and its environment, and specify the significant ones that should be controlled because they can occur at an unacceptable level.</p> <p>(viii) HACCP should determine validated hazard-based control measures that are essential to manage the level of hazard to an acceptable level and validate the measures increase the level of food safety.</p> <p>(ix) The application of hazard-based control measures for each CCP should be subject to validation, monitoring, corrective action, verification, and documentation and recordkeeping.</p> <p>(x) Changes in the food business, e.g. new process, new ingredient, new product, new equipment, should lead to a review of both GHPs and the HACCP plan to determine if modifications are needed.</p>	<p>(vii) GHP can look after hazards associated with the environment by controlling sources of hazards.</p> <p>(viii) uses terminology already in use by CCFH and quantifies food safety in relation to acceptable level of hazards. Validation follows.</p> <p>(ix) added in other relevant components for hazard-based control measures</p> <p>(x) for consistency, just use HACCP as above.</p>
Definitions for the whole document	<p>Cleaning The removal of contaminants soil, food residue, dirt, grease or other objectionable matter.</p> <p>Control (verb) <u>To take all necessary actions to ensure and maintain compliance with requirements</u> criteria established in the HACCP plan.</p>	<p>Cleaning - Deleted unnecessary words and simplified.</p> <p>Control - Generic definition not specific for HACCP</p>
	<p>Control (noun) <u>The state wherein correct procedures are being followed and criteria are being met.</u></p> <p>Environment <u>The internal and external surroundings of the food production and processing equipment within the establishment, including air but excluding humans.</u></p> <p>Establishment Any building or area in which food is present handled and the surroundings under the control of the same management.</p> <p>Flow diagram <u>A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.</u></p> <p>Good Hygienic Practices <u>Prerequisite programs aiming specifically at food hygiene, applied in the establishment.</u></p> <p>GHP-based: control measures that are generally qualitative in nature and are based on empirical scientific knowledge and experience. They are usually prescriptive and may differ considerably between countries</p>	<p>Control - Generic definition not specific for HACCP</p> <p>Environment - Environment is important both internally and externally. Food production equally important as processing. Examples too restrictive</p> <p>Establishment - Food may be grown, harvested processed, stored, distributed. May be more than handled.</p> <p>Flow diagram - Generic definition, not specific for HACCP</p> <p>GHP - See general comment for use of Practice rather than Practices by Codex</p> <p>GHP-based - As used in recent Codex Guidelines to distinguish the difference between GHP and hazard-based control measures</p>
Definitions cont;	<p>Hazard A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.</p> <p>Primary production These <u>The first steps in the food chain up to and including, for example, raising of animals, growing of crops and harvesting and fish slaughter, milking, fishing.</u></p> <p>Validation <u>Obtaining evidence that the elements of the HACCP plan are effective a hazard control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.</u></p>	<p>Hazard - Support the deletion of 'or condition of'</p> <p>Primary production - Examples reflecting growing and raising rather than harvesting which is considered primary processing.</p> <p>Validation - Use Codex definition as it covers wider than hazard-based control measures</p>
Definitions specific to HACCP system	<p>Control (verb) To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.</p> <p>Control (noun) The state wherein correct procedures are being followed and criteria are being met.</p> <p>Option B (US)</p> <p>[CCP] Corrective action [Any action taken when a deviation occurs to</p>	<p>Control - Moved to generic section</p> <p>Control - Moved to generic section</p> <p>[CCP] Corrective action -Support Option B but do not think that 'Correction' is also</p>
	<p>correct the problem, to segregate and evaluate any food impacted by the deviation and determine appropriate disposition of the food, and to identify the cause of the problem and reduce the likelihood it will reoccur.]</p>	<p>needed as activities all covered under 'Corrective action'.</p> <p>Note: Consider definition for corrective action for GHP as well</p>

	<p>Correction: [An action taken in lieu of corrective actions to identify and correct a problem when a deviation does not impact the safety of the food (e.g. recleaning insanitary equipment before production begins).]</p> <p>Critical Control Point (CCP) A step at which hazard – based control measure(s) is(are) can be applied and is(are) essential to prevent or eliminate-reduce a hazard or reduce it to an acceptable level.</p> <p>Criterion: separates acceptability from unacceptability in relation to food safety</p> <p>Critical limit: A criterion which is required to be met at a CCP and can be monitored in a timely manner.</p> <p>Deviation Failure to meet a critical <u>limit</u> limit criterion.</p> <p>Flow diagram A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.</p> <p>HACCP application: can include a hazard identification and analysis with no Critical Control Points being determined, or, a hazard identification and analysis with the CCP determination resulting in one or more CCPs</p> <p>HACCP plan A document prepared in accordance with the principles of HACCP that describes the actions to be taken to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration.</p> <p>Hazard analysis <u>The collection and evaluation of information on hazards and how the food process impacts on those hazards</u> leading to their presence to decide <u>whether any hazards</u> which are significant for food safety and therefore should be <u>controlled at one or more CCPs</u> addressed in the HACCP plan.</p> <p>Hazard-based control measure: control measure developed from scientific knowledge of the likely level of control at a step or specific steps in a food chain, have a quantitative basis and can be validated as to their efficacy in hazard control at the step. There may be more than one hazard-based control</p>	<p>CCP – Remove ‘prevent’ as that is covered by GHP and keep ‘eliminate’ to cover parasite hazards. Criterion – simplified definition</p> <p>CL - New definition proposed that uses key features such as measurability in relation to the criterion selected Deviation - Aligned ‘Deviation’ with CL definition Flow diagram - Moved to generic section HACCP application - New definition proposed to cover HACCP with or without one or more CCPs.</p> <p>HACCP plan - Current definition is limited to actions, prefer to use HACCP application that can allow flexibility in content. Hazard analysis - Reflected impact of the food process on the hazard analysis and revised wording to relate to possibility of one or more CCPs rather than a HACCP plan. This supports flexibility in the way HACCP is applied. Hazard-based control measure - New definition proposed from recent Codex text.</p>
	<p><u>measure contributing to achievement of an acceptable level of hazard</u></p> <p>Hazard control measure Any action that can be used to prevent or eliminate to address a food safety significant hazard or reduce it to an acceptable level present in a food or the environment or occurring during the production process, to ensure its level in food does not exceed an acceptable level.</p> <p>[CCP] Monitoring: The act of conducting a planned sequence of observations or measurements of hazard control measure parameters criteria to assess whether a CCP the measure is under in control</p> <p>Significant hazard A hazard identified by the hazard analysis as <u>being at an unacceptable level</u> having to be controlled.</p> <p>Validation Obtaining evidence that the elements of the HACCP plan are effective a hazard control measure or combination of hazard control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.</p> <p>[HACCP] Verification The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan <u>whether the HACCP application a hazard control measure is or has been operating as intended.</u></p>	<p>Hazard control measure - Delete in favour of hazard-based control measure already used by Codex</p> <p>[CCP] monitoring - Delete unnecessary wording to simplify. Note - Consider monitoring for GHP as well Significant hazard - Provide definitive link to unacceptable level of hazard. Validation - Moved to generic section [HACCP] verification - Allows specific focus on HACCP application. Note - Consider definition of verification for GHP</p>

Paraguay appreciates the opportunity to comment and agrees with the document. However, Paraguay wishes to make the following comments.

i) General Comments

Paraguay suggests the following changes in the *Spanish version*:

a. [Translator's note: these changes only apply to the Spanish version. The English text uses "suitability" and "suitable"]. Replace the term "*idoneidad*" and/or "*alimento idóneo*" with "*aptitud*" and/or "*alimento apto*," where appropriate, so that a single term is used throughout the document. The proposed draft currently uses both, making it inconsistent.

Justification:

We suggest using the term "*aptitud*" as we consider that it is widely used both nationally and regionally and is rooted in the context of food safety.

b. Use the acronym APPCC in the Spanish version, instead of the English acronym HACCP, throughout the document.

c. Include the definition of "*Food Business Operator*" in Section 14, Definitions, to clarify its scope as the term is used throughout the document but is not defined.

d. Consider the possibility of organizing Section 14, Definitions, in alphabetical order, to establish an order.

ii) Specific Comments

INTRODUCTION

Paraguay agrees with the language used in Option B.

Justification:

We are of the opinion that the wording of Option B is simpler and may be understood not only by those with technical knowledge of the subject but also by the general public/consumer. It is also broader than Option A, as it includes social responsibility issues.

This notwithstanding, we suggest including footnote ², as shown below:

Paragraph 1

OPTION B:

Current wording

People have the right to expect the food they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury are at best unpleasant; at worst, they can be fatal. But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.

Proposed draft:

People have the right to expect the food they eat to be safe and suitable for consumption. **Even if food safety remains the most important concern of modern societies, new demands to improve people's health and welfare with the food they consume are becoming increasingly important.**² Foodborne illness and foodborne injury are at best unpleasant; at worst, they can be fatal. But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.

Justification:

We propose including the sentence in footnote ² of Option A because we believe it is important to note that food preferences among different categories of consumers may not be the same, and that safe foods may not be suitable for certain categories of consumers. For example, while food containing gluten and food allergens is safe for most consumers, it is not suitable for persons with gluten intolerance or allergy to some of their ingredients.

Paragraph 2

Paraguay agrees with Option B

Paragraph 3

Current wording:

- GHPs, in general, only need basic knowledge and skills.

Proposed draft:

- GHPs, in general, ~~only~~ need basic knowledge and skills.

Justification:

The use of the adverb "only" does not emphasize the obligation of having the knowledge and competencies to implement GHPs.

Paragraph 5**Current wording:**

- HACCP systems are not effective without prior implementation of GHPs.

Proposed wording:

[Translator's note: the change only affects the Spanish version, elimination of a "no" is proposed.]

Justification:

Striking the word "no" will improve the syntax.

Current wording:

- HACCP may not be applicable to all type of food businesses, in particular at the stages of primary production. However, the principles of HACCP can be applied to certain activities related to primary production [e.g. administration of veterinary drugs].

Proposed wording:

- HACCP may not be applicable to all type of food businesses, in particular at the stages of primary production. However, the principles of HACCP can be applied ~~to certain activities related to primary production [e.g. administration of veterinary drugs]~~ **to all activities in the food production chain, including primary production, even if there is no CCP.**

Justification:

We propose changing the paragraph, pursuant to Section 13, paragraph 1 of the *Work of the EWG*, which notes that the "*appropriate scope of the HACCP system*" is one of the points that requires further discussion. We support the comments made by several EWG representatives indicating that this system is applicable to all type of food businesses in the entire food production chain, including primary production, even if there is no CCP.

We have discussed this point and concluded that clearly it is difficult to apply HACCP to all type of businesses since not all the CCPs necessary for the full implementation of the system may be present. However, the product description, flow diagram, hazard analysis, and verification of the system are applicable even when no critical control points are identified.

BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM**Principle i)****Current wording:**

- (i) The recommended way to maximize food safety and suitability is a two [phase/component] preventive approach.

Proposed wording:

- (i) The recommended way to maximize food safety **and suitability** [*aptitud* in Spanish] is a two [phase/~~component~~] preventive approach. [Translator's note: the changes only apply to the Spanish version.]

Justification:

We suggest using the word "*aptitud*" instead of "*idoneidad*" for the same reasons expressed under General Comments.

We also suggest eliminating "components" given that GHPs are a prerequisite for implementing a HACCP system and provide the foundation for its effectiveness. A progressive implementation addresses the technical issues that may arise, in an orderly and progressive manner, in addition to providing more time to adapt to the changes required by the implementation, thereby making it sustainable over time.

Principle ii)**Current wording:**

(ii) The implementation of GHPs is the first [phase/component] of the design of a food safety control system.

Proposed wording:

(ii) The implementation of GHPs is the first [phase/~~component~~] of the design of a food safety control system.

Justification:

We suggest eliminating the word "component" as the implementation of GHPs is a prerequisite for implementing a HACCP system and provides the foundation for its effectiveness. A progressive implementation addresses the technical issues that may arise, in an orderly and progressive manner, in addition to providing more time to adapt to the changes required by the implementation, thereby making it sustainable over time.

Principle v)

Current wording:

(v) The application of GHPs should be subject, where appropriate, to monitoring, verification and documentation.

Proposed wording:

(v) **The application of GHPs** should be subject, ~~where appropriate~~, to monitoring, verification and documentation.

Justification:

The use of the phrase "where appropriate" does not emphasize the obligatory nature of GHP monitoring, verification, and documentation, which are the backbone and support of the system.

Principle x)

Current wording:

(x) Changes in the food business, e.g. new process, new ingredient, new product, new equipment, should lead to a review of both GHPs and the HACCP plan to determine if modifications are needed. Modifications should be documented and when necessary validated.

Proposed wording:

(x) Changes in the food business, e.g. new process, new ingredient, new product, new equipment, should lead to a review of both GHPs and the HACCP plan to determine if modifications are needed. Modifications should be documented and ~~when necessary~~ validated.

Justification:

The use of the phrase "when necessary" detracts from the need to validate the effectiveness of a hazard control measure or combination of hazard control measures applied to achieve a specific outcome in the system.

Definitions applicable to the entire document

Paragraph 15

Current wording:

Contaminant: Any biological or chemical agent, or other objectionable matter *or physical object (i.e. foreign matter or other substances)* not intentionally added to food that may compromise food safety or suitability.

Proposed wording:

Contaminant: Any biological or chemical agent, or other objectionable matter *or physical object (i.e. foreign matter or other substances)* not intentionally added to food that may compromise food safety or suitability. [Translator's note: the change does not affect the English version.]

Justification:

To improve readability.

Prerequisite programs: Procedures and actions taken to maintain hygienic conditions throughout the food chain that provide the foundation for the HACCP system.

NOTE: Prerequisite programs include good hygienic practices (GHPs) and actions aiming at or resulting in

providing hygienic conditions within good agricultural practices (GAPs), good veterinarian practices (GVPs), good manufacturing practices (GMPs), good production practices (GPPs), good distribution practices (GDPs).

Comment:

We request clarification on whether Good Production Practices (GPPs) mentioned in the note to the definition of "Prerequisite Programs" refer to "Good Husbandry Practices".

Definitions specific to the HACCP system

Paragraph 15

Paraguay agrees with Option B of the proposed definitions for "Corrective action" and "Correction":

Option B (United States of America)

Corrective action Any action taken when a deviation occurs to correct the problem, to segregate and evaluate any food impacted by the deviation and determine appropriate disposition of the food, and to identify the cause of the problem and reduce the likelihood it will reoccur.

Correction: An action taken in lieu of corrective actions to identify and correct a problem when a deviation does not impact the safety of the food (e.g. recleaning insanitary equipment before production begins).

SWITZERLAND

General Comments:

We would like to thank the EWG led by France and co-chaired by Chile, Ghana, India and the United States of America for preparing this document.

The 47th session of CCFH agreed to consider convening a PWG prior to the 48th session. According to the provisional agenda, there is no meeting foreseen prior to this session (e.g. on Sunday, November 6). However, we are of the opinion, that the advancement of the document could benefit from a PWG and ask you to reconsider this point.

Generally, we support increased alignment with ISO terminology as this helps drive further effective implementation of GHP/HACCP and consistency across the food sector.

Specific comments to Appendix I of CX/FH 16/48/5:

Paragraph 1: We support Option B of this paragraph

Paragraph 2: We support Option A of this paragraph with the below modification

This document ~~shows~~ **provides guidance on** how food safety and food suitability can be enhanced throughout the food chain from primary production to the final consumer, ~~including manufacturing and distribution~~. To achieve this goal, each business establishes its own control system taking into account its specific requirements.

Rationale: The proposed additions is to make the text clearer. Text regarding - "including manufacturing and distribution" is deleted as this is already covered when it is mentioned primary production to the final consumer and so there is no need to highlight this text separately.

Paragraph 3 part 1: Amend the text as below:

GHPs are aimed at preventing or reducing the level of contaminants, **as far as practicable**, so that the suitability of the end product as well its safety will not be compromised.

Paragraph 3 part 3: Amend the text as below:

All employees should be trained in GHPs as appropriate to their job activities; ~~it is important that food handlers have basic knowledge of the impact GHPs can have on the safety and suitability of food.~~

Paragraph 3 part 4: propose to delete the text, as it is not clear who needs the skills and knowledge.

~~GHPs, in general, only need basic knowledge and skills~~

Paragraph 4: Propose to delete text in this paragraph, as this is the repetition of text in Paragraph 3. Instead, we propose adding the following text as new Paragraph 3:

~~The application of appropriate GHPs in food businesses provides a sanitary environment that supports the production of safe and suitable food.~~

GHPs and HACCP are phases of any food safety control system, where GHPs form the foundation for the implementation of effective HACCP-based procedures.

Rationale: it is important to stress the link GHP – HACCP, as there is common difficulty in food businesses to distinguish between the two phases.

Paragraph 5 part 4: Amend the text as below:

~~HACCP may not be is applicable to all type of food businesses across the food chain, in particular at the stages of primary production. However, the principles of HACCP can be applied to certain activities related to primary production [e.g. administration of veterinary drugs].~~

Rationale: No part of the food chain should be exempted from application of HACCP. Most likely, there will be no CCP's at primary production level, nevertheless, primary production sites should carry out hazard analysis and implement hazard control measures, as appropriate.

Paragraph 5 part 5: propose to delete the text, as it is not clear who needs the skills and knowledge.

~~HACCP requires specific knowledge and skills~~

Paragraph 6 part 1: Amend the text as below:

~~identify~~ **provide guidance on the application of** the good hygienic practices applicable throughout the food chain (including primary production through to the final consumer) to provide food that is safe and suitable for human consumption

Rationale: This document will not identify good hygienic practices but will provide guidance on the application of GHP.

Paragraph 6 part 3: Amend the text as below to make the text clearer.

~~provide a guidance that may be needed for specific codes for sectors of the food chain, processes, or commodities~~ **sector specific codes of practice** to ~~amplify~~ **establish** the hygiene requirements specific to those ~~areas~~ **sectors**.

Paragraph 7: Amend the text as below:

This document provides a framework for producing foods that are safe and suitable for human consumption by setting out necessary hygiene conditions and applying, where appropriate, ~~enhanced~~ **specific** control measures at certain production steps. The document is intended for use by food business operators and countries³, as appropriate.

Paragraph 11 Part 2: amend the text as below to make it more clear and appropriate

provide assurance that food is **safe and** suitable for human consumption;

Paragraph 12 Part 2: Amend the text as below:

~~ensure that consumers have clear and easily-understood information including ingredient content, by way of labelling and other appropriate means, to enable them to protect their food from contamination and prevent the growth/survival of foodborne pathogens by storing, handling and preparing it correctly; and~~

Rationale: Mentioning the ingredient content and the way to provide information to consumers is not necessary at this point. It should be covered in the relevant labelling or food information to consumer guidelines or standards.

Numbering before heading “Basic principles ...” is needed.

(i): Amend the text as below:

The recommended way to ~~maximize~~ **assure** food safety and suitability is a two [phase/component] preventive approach.

(ii): Amend the text as below

The implementation of GHPs is the first [phase/component], of the design of a food safety control system.

(iii): Amend the text as below

GHPs should ensure that food is produced in a sanitary environment and reduce the ~~burden~~ **level** of contaminants, ~~whether hazardous or not~~.

(v): Amend the text as below

The application of GHPs should be subject, where appropriate, to monitoring, verification, **corrective action** and documentation.

(vi): Amend the text as below

The implementation of HACCP, where needed and feasible, is the second [~~phase/component~~] of the design of an effective food safety control system.

(ix): Amend the text as below

The application of hazard control measures should be subject to monitoring, verification, **corrective action (in case of deviation), validation** and documentation.

(x): Amend the text as below

Changes in the food business, e.g. new process, new ingredient, new product, new equipment, should lead to a review of both GHPs and the HACCP plan to determine if modifications are needed. **Decisions made during the evaluation and review, whether modifications are implemented or not**, should be documented and when necessary validated.

Paragraph 14, Definition for “Food Hygiene”: consider alignment with definition in procedural manual:

Food Hygiene comprises conditions and measures necessary for the production, processing, storage and distribution of food designed to ensure a safe, sound, wholesome product fit for human consumption.

Paragraph 14, Definitions for “Corrective action” and “Correction”: we support option A.

URUGUAY

Uruguay appreciates the opportunity to comment on the Proposed Draft Revision of the General Principles of Food Hygiene (CAC/RCP 1-1969) and commends the coordinators of the electronic working group for their work.

General comments on the document:

1. Uruguay believes the review process for the document is appropriate. In general, we see that the document aims to be clear and accessible to encourage stakeholder use and understanding.
2. To this end, we believe it is beneficial to have hyperlinks that enable access to the official documents cited throughout the document, by accessing the Codex website www.fao.org/fao-who-codexalimentarius, to encourage access to information in other Codex documents, as well as FAO and WHO guidelines.
3. We feel that the Scope of this document is confusing regarding **whether it includes primary production**, since it is included in the introduction and the objectives, but not in the Scope.

Regarding point 13 **“Background,”** Uruguay does not agree with applying the HACCP to primary production. However, regarding the GHPs, it should be involved all along the chain, including primary production. The Scope encompasses the entire document, not just the Annex to the HACCP system. As such, we feel it's necessary to clarify this concept.

4. Uruguay is also of the opinion that the GHPs should be established before setting an HACCP plan and that **the implementation of the HACCP system is a two-phase process**, not two-components. It is important to implement and consolidate the GHPs to be able to implement the HACCP.
5. Uruguay prefers the term “idóneo” over “apto” [*does not affect the English, both mean suitable*], as it is more common and better understood.
6. Uruguay believes that many of the NOTES should remain in the document because they clarify concepts and definitions, and should, thus, be added to the text.

Specific comments on the document (Appendix 1):

INTRODUCTION

1. Uruguay prefers Option B

Option B:

People have the right to expect the food they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury are at best unpleasant; at worst, they can be fatal. But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.

International food trade, and foreign travel, are increasing, bringing important social and economic benefits. But this also makes the spread of illness around the world easier. Eating habits too, have undergone major change in many countries over the last two decades and new food production, preparation and distribution

techniques have developed to reflect this. Effective hygiene control, therefore, is vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage.

Everyone, including farmers and growers, manufacturers and processors, food handlers and consumers, has a responsibility to assure that food is safe and suitable for consumption.

These General Principles lay a firm foundation for ensuring food hygiene and should be used in conjunction with each specific code of hygienic practice, where appropriate, and the guidelines on microbiological criteria.

The controls described in this General Principles document are internationally recognized as essential to ensure the safety and suitability of food for consumption. The General Principles are commended to Governments, food business operators (including individual primary producers, manufacturers, processors, food service operators and retailers) and consumers alike.

2. Uruguay feels that Option B would be better with the question about the scope, which is broader in Option A, which is the concept of the original document and is referenced in other paragraphs as well, like in the point 5, bullet 4. On this point, Uruguay proposed the following:

Option B with an addition:

This document shows the general principles **to be applied throughout the food chain from primary production to the final consumer, including manufacturing and distribution**, that food businesses should understand and follow, and that they should help the government to establish appropriate monitoring mechanisms. It will then define specific terms and expressions applicable to the document.

5. The second section will describe the *Hazard Analysis and Critical Control Point System for Food Safety (HACCP)*.

HACCP application will not be effective without prior implementation of GHPs.

- HACCP is a preventive approach that aims to enhance food safety where this is appropriate and feasible, by improving the control of hazards over that achieved by the GHPs. [*Translator's note: change does not affect the English*]

- HACCP accomplishes this with the help of hazard control measures applied at critical control points (CCPs).

- HACCP may not be applicable to all type of food businesses, in particular at the stages of primary production. ~~However, the principles of HACCP can be applied to certain activities related to primary production [e.g. administration of veterinary drugs].~~

- HACCP requires specific knowledge and skills.

SCOPE

7. This document provides a framework for producing foods that are safe and suitable for human consumption by setting out necessary hygiene conditions and applying, where appropriate, enhanced control measures at certain **steps in the production food chain**. The document is intended for use by food business operators and countries, as appropriate.

USE

General Aspects

8. The document provides a foundational structure for other, more specific, codes applicable to particular food sectors. [*Translator's note: change does not affect the English*] Such specific codes and guidelines should be read in conjunction with this document.

9. Each section in this document states both the objectives to be achieved and the rationale behind those objectives in terms of the safety and suitability of food. [*Translator's note: change does not affect the English*] ~~There will inevitably~~ **It is probable that there will** be situations where some of the specific requirements contained in this document are not applicable. The fundamental question in every case is "what is necessary and appropriate on the grounds of the safety and suitability of food for consumption?"

10. The text indicates where such questions are likely to arise by using the phrases "where necessary" and "where appropriate." In practice, this means that, although the requirement is generally appropriate and reasonable, there will nevertheless be some situations where it is neither necessary nor appropriate on the grounds of food safety and suitability. In deciding whether a requirement is necessary or appropriate, an assessment of the risk should be made. [*Translator's note: change does not affect the English*] This approach allows the requirements in this document to be flexibly and sensibly applied with a proper regard for the overall objectives of producing food which is safe and suitable for consumption. In so doing it takes into account the wide diversity of food processing practices and varying degrees of risk involved in producing **and handling** food.

BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM

- i) The recommended way to maximize food safety and suitability is **the implementation of** a two [~~phase/component~~] preventive approach.
- ii) The implementation of GHPs is the first [~~phase/component~~], of the design of a food safety control system.
- iii) GHPs should ensure that food is produced in a sanitary environment and reduce the burden of contaminants, whether hazardous or not.
- iv) GHPs are a prerequisite to the implementation of a HACCP system, because they provide the foundation **thereof** for a HACCP ~~system to be effective~~.
- v) The application of GHPs should be subject, where appropriate, to monitoring, verification and documentation.
- vi) The implementation of HACCP, where needed and feasible, is the second [~~phase/component~~] of the design **and implementation** of an effective food safety control system.
- vii) HACCP should identify all hazards associated with the **food, its** production process and its environment, and specify the significant ones that should be controlled, **to prevent them from reaching** ~~because they can occur at an unacceptable level~~.
- viii) HACCP should determine validated hazard control measures that are essential to **obtain** ~~increase the level of~~ food safety.

DEFINITIONS

Definitions applying within the whole document

15. Notes are for explanatory purpose and are not part of the definitions.

Uruguay feels that many of the notes are a significant contribution and clarify important concepts.

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

NOTE: Many, but not all, biological agents (microorganisms) are removed by cleaning. Cleaning is prerequisite to disinfection, which is needed where cleaning is not effective enough against biological contaminants.

Contaminant Any biological or chemical agent, or other objectionable matter or physical object (i.e. foreign matter or other substances) not intentionally added to food that may compromise **their** ~~food~~ safety or suitability.

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

Environment The surroundings of the food and processing equipment within the establishment, including air but excluding humans.

Establishment Any building or area in which food is handled and the surroundings under the control of the same management. [*Translator's note: change does not affect the English*]

Food suitability Assurance that food is ~~acceptable~~ **appropriate** for human consumption according to its intended use.

Hazard A biological, chemical or physical agent in, ~~or condition of,~~ food with the potential to cause an adverse health effect **for the person consuming it**.

NOTE: Examples of hazards include bacteria and their toxins, viruses, parasites, prions, allergens, heavy metals, mycotoxins, foreign bodies, pieces of solid food that can cause choking.

Prerequisite programs Procedures and actions taken to maintain hygienic conditions throughout the food chain, that provide the foundation for the HACCP system.

NOTE: Prerequisite programs include good hygienic practices (GHPs) and actions aiming at or resulting in providing hygienic conditions within good agricultural practices (GAPs), good veterinarian practices (GVPs), good manufacturing practices (GMPs), good production practices (GPPs), good distribution practices (GDPs).

Definitions specific to the HACCP system

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

Option A (based on ISO 9000)

Corrective action [Action on the process or the environment to eliminate the cause of a

detected nonconformity and to prevent its recurrence.]

Correction [Action to eliminate a detected nonconformity.]

Critical criterion A criterion that separates acceptability from unacceptability with respect to the safety of the food.

NOTE: A critical criterion can be a critical limit, or an observable action criterion or an action limit demonstrating that the hazard control measure at a CCP is in control.

~~**Critical limit** A criterion that separates acceptability from unacceptability.~~ A numeric value characterizing the critical criterion of a measurable parameter that can be monitored in a timely manner.

NOTE 1: A critical limit relates to a measurement, of e.g. time, temperature, pH, water activity, pressure. [Translator's note: change does not affect the English]

NOTE 2: When a hazard control measure is the combination of more than one action, there may be several critical limits that must be complied together, e.g. for temperature and time, pH and water activity. [Translator's note: change does not affect the English]

NOTE 3: A critical limit is a characteristic of a hazard control measure that can be monitored in real time ~~timely~~. Yet, for hazard control measures that cannot be ~~timely~~ monitored in real time, various types of criteria have to be used; hence, a wide definition is given for "Critical criterion" and a narrow one for "Critical limit."

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

HACCP plan [change does not affect the English] A document prepared in accordance with the principles of HACCP that describes the actions to be taken to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration. [Translator's note: change does not affect the English]

Hazard control measure Any **measure or** action that can be used to ~~prevent or eliminate~~ to address a food safety significant hazard ~~or reduce it to an acceptable level~~ present in a food or the environment or occurring during the production process, to ~~ensure its level in food does not exceed~~ **reduce it to** an acceptable level.

Monitoring The act of conducting a planned sequence of observations or measurements of **defined** hazard control measure **parameters** ~~criteria~~ to assess whether a ~~CCP~~ the measure is ~~under in control~~ **working effectively.**

Significant hazard A hazard identified by the hazard analysis as having to be controlled, **through a specific control measure.**

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

UNITED STATES OF AMERICA

GENERAL COMMENTS

The United States appreciates the efforts of the electronic working group (EWG) to begin the draft revision of the *General Principles of Food Hygiene* (GPFH). The U.S. was a member of that EWG and one of the 5 co-chairs. Based on our review of comments from the EWG members and discussions we have had with others on this document, we recognize that there is much work still to be done and look forward to the discussions at the 48th Session of the Codex Committee on Food Hygiene (CCFH48).

One of the key issues this document was attempting to address relates to the recognition that control of hazards at critical control points (CCPs) established in a HACCP plan does not address all the essential controls needed to ensure a safe food. For example, there have been many food safety outbreaks that have been related to contamination of ready-to-eat products with pathogens such as *Listeria monocytogenes* that have found a harborage site on equipment or in the food processing environment. In general, there is not a particular step in the processing of ready-to-eat products at which a CCP (as currently defined and applied in HACCP) can be established to address the hazard of environmental pathogens, nor can the procedures needed to manage the risk of contamination from the environment be monitored in a timely fashion (i.e., during the processing of the product). In addition, for the control measures applied for environmental pathogens, a deviation may not pose the same risk to safety with respect to the product as a deviation from a traditional CCP.

The document takes an approach that attempts to incorporate such controls as a different type of CCP in a HACCP plan. To do so, it proposes to introduce new terminology (e.g., hazard control measure, critical criterion) and two types of CCPs (CCP Type A, for hazards with critical limits monitored "in real time," and CCP Type B, where this is not the case). As described in the Background, a deviation from CCP Type A results in

product being considered potentially unsafe, so it is not marketed, and a deviation from CCP Type B results in the need for a decision to be made about the lot. The U.S. believes that the approach as presented has been confusing and has resulted in too many changes that are probably unnecessary. We are not clear about the “request not to modify the concept of CCP,” but we think that the approach of CCP type A and CCP Type B does just that. Moreover, those familiar with the history of HACCP will remember the concepts of CCP 1 and CCP 2, in which CCP 1 fully controlled a hazard (e.g., a heat treatment that kills a pathogen), whereas CCP 2 was one that reduced but did not eliminate a hazard (e.g., a carcass wash for *Salmonella*). This concept never caught on, and we think the approach of CCP Type A and CCP Type B would meet the same fate. Moreover, we disagree with the approach to deviations for CCP Type A and CCP Type B; even for deviations at CCPs that are monitored through real time measurement (“CCP Type A”) there may be procedures for evaluating and releasing product. (We recognize that these boxes only contain brief descriptors that would be explained more fully in the HACCP section of the document when it is developed, but we think the diagram is likely to cause concern as presented.)

We think there should be a simpler approach that achieves the desired outcome of implementing “hazard control measures” that do not fit within the current application of HACCP CCPs.

One EWG member has suggested using the concept of GHP-based control measures and Hazard-based control measures, as these terms have been used in two Codex documents on control of pathogens in certain raw meats. These terms have been defined in the Guidelines for the Control of Nontyphoidal *Salmonella* spp. in Beef and Pork Meat (CAC/GL 87-2016) as follows:

- *Good hygienic practice (GHP)-based:* They are generally qualitative in nature and are based on empirical scientific knowledge and experience. They are usually prescriptive and may differ among countries.
- *Hazard-based:* They are developed from scientific knowledge of the likely level of control of a hazard at a step (or series of steps) in a food chain. They are based on a quantitative base estimate in the prevalence and/or concentration of *Salmonella*, and can be validated as to their efficacy in hazard control at a specific step. The benefit of a hazard-based measure cannot be exactly determined without a specific risk assessment; however, any significant reduction in pathogen prevalence and / or concentration is expected to provide a certain level of human health benefit.

There may be merit in considering whether these terms could work in this document (or would only add to the confusion), but we think the current definitions of these terms may be too targeted to the documents in which the terms have been used. Others have suggested using the ISO concept of operational prerequisite programs (OPRP: a prerequisite program identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the product or in the processing environment). In the U.S. we combine HACCP CCPs with Sanitation Standard Operating Procedures (SSOPs) or other prerequisite programs in a food safety system, and, most recently, we have introduced the concept of “preventive controls” that include process controls (e.g., those in HACCP plans), food allergen controls, sanitation controls (specific for hazards), and supply-chain controls. Thus, the concept of “hazard control measures” beyond HACCP CCPs is not new, but approaches have been varied and there is not an internationally-accepted approach that incorporates terminology and guidelines for those procedures and programs that are essential for food safety other than HACCP CCPs. We think that one intended goal in revising the GPFH and its HACCP annex is to achieve consensus on strengthening control of hazards by describing a program that encompasses all the essential controls for food safety, which would include both controls at CCPs and other controls. We think that the introduction of the terms “critical criterion,” and “hazard control measure,” combined with a simplified definition of “corrective action,” could work together with more extensive guidelines on their application and could result in a more acceptable approach.

SPECIFIC COMMENTS

INTRODUCTION

Paragraph 1

Comment: Two options were provided for the first part of the introduction. Option B is derived from the introduction to the existing GPFH, with a deletion of sentences related to the structure of the document (which will change). Option A brings in health and welfare, food preferences and dietary needs. It also brings in wording about psychological trauma as a “hidden foodborne injury.” We recommend using Option B with deletion of one sentence:

~~These General Principles lay a firm foundation for ensuring food hygiene and should be used in conjunction with each specific code of hygienic practice, where appropriate, and the guidelines on microbiological criteria.~~

Rationale: We prefer Option B because Option A brings in issues not relevant to food safety and suitability and that are outside the scope of CCFH. We think the points made in the sentence recommended for deletion belong in the “Use” section of the document.

Paragraph 1

Comment: Delete the commas after “trade” and “travel” in the first sentence of the second paragraph in Option B:

International food trade, and foreign travel, are increasing, bringing important social and economic benefits.

Rationale: Editorial.

Paragraph 2

Comment: Two options were provided for the second paragraph of the introduction. We prefer a hybrid of the two options:

This document will outline the general principles that should be understood and followed by food businesses and will help governments establish appropriate oversight in order to achieve and maintain food safety and suitability. The principles outlined in the document are intended for use throughout the food chain, from primary production to the final consumer, [including manufacturing and distribution,] with each business developing its own control plan, taking into account the nature of the operation, the relevant hazards, and appropriate control measures that can be applied.

Rationale: Edited to merge the key concepts in each paragraph and to clarify “its specific requirements”. We have put “including manufacturing and distribution” in square brackets, as we believe it can be deleted to shorten a long sentence, since manufacturing and distribution are in the food chain between primary production and the final consumers; however, we recognize that others may want to retain this, as these are the primary sectors in which HACCP is applied.

Paragraphs 3 and 4

Comment: Revise the chapeau of paragraph 3 to incorporate paragraph 4 as follows:

The first section will describe Good Hygienic Practices for Food Safety and Suitability (GHPs). GHPs are the basis of any food safety control system. **The application of appropriate GHPs in food businesses provides a sanitary environment that supports the production of safe and suitable food.**

Rationale: The sentence from paragraph 4 explains the sentence about GHPs being the basis of any food safety control system, and, thus, these should appear together.

Paragraph 3, bullet 4

Comment: Revise as follows:

Implementation of GHPs, in general, only needs basic knowledge and skills.

Rationale: Some GHPs do require more than basic knowledge and skills, e.g., the appropriate types of cleaners and sanitizers and how to use them, yet in many instances the implementation of the GHP is fairly basic.

Paragraph 4, bullet 4

Comment: Add an “s” to “type”

HACCP may not be applicable to all types of food businesses...

Rationale: Editorial

Paragraph 4, bullet 5

Comment: Revise as follows:

Implementation of HACCP requires specific knowledge and skills.

Rationale: For consistency with the revised bullet on GHPs. It is the implementation of HACCP, in particular the hazard analysis, that requires specific knowledge and skills.

OBJECTIVES**Paragraph 6, chapeau**

Comment: Edit the title:

General Principles of Food Hygiene for Food **Safety** **Suitability** and **Suitability** **Safety**: Good Hygienic Practices (GHPs) and **[the]** Hazard Analysis and Critical Control Point System (HACCP)

Rationale: Editorial, to match the title of the document. We recommend that “the” be added to the title of the document as well, but have put it in square brackets here as it is not currently in the title.

Paragraph 6, bullet 2

Comment: This bullet uses the term “HACCP-based approach” (“recommend an HACCP-based approach as a means to enhance food safety”). We are not suggesting a change at this time, but want to point out that we will need to clarify what this means if we intend something other than a HACCP system, with its 7 principles, and, if not, we should change this to “HACCP-system” to avoid introducing a new term whose meaning is not clear.

SCOPE**Paragraph 7**

Comment: Revise as follows:

This document provides a framework for producing foods that are safe and suitable for human consumption by setting out necessary hygiene conditions and applying, where appropriate **and necessary, enhanced additional food safety** control measures ~~at certain production steps~~ **for certain activities**. The document is intended for use by food business operators and ~~countries~~³ **governments**, as appropriate.

³ ~~For the purpose of this document, each time the terms “country”, “government”, “national” are used, the provision applies both to Codex Members (Rule I) and Codex Member Organisations (Rule II), i.e. regional economic integration organisation (REIO)—see Codex Alimentarius Commission, Procedural Manual.~~

Rationale: We believe that this better conveys that HACCP control measures are food safety control measures in addition to GHPs. We have changed “production steps” to “certain activities” to better capture that the essential hazard control measures may not be at processing step, e.g., they could be cleaning of a slicer to prevent contamination of meat with *Listeria monocytogenes* or transfer of milk allergen from cheese to meat when the same slicer is used for both foods.

The term “governments” is used later in the document; we think it would be preferable to use a single term. The footnote was based on the Principles for Microbial Risk Analysis; we no longer think it is needed (we recommended it when the sentence had the terms “industry” and “countries” and had footnotes for both), and we think it could be confusing here.

USE**Paragraph 9**

Comment: Delete (or put in square brackets) the first sentence:

~~Each section in this document states both the objectives to be achieved and the rationale behind those objectives in terms of the safety and suitability of food.~~

Rationale: It is unclear whether this will be the format we follow, especially with moving HACCP guidelines out of an annex and into the main document.

Paragraph 12

Comment: Revise the second bullet as follows:

ensure that consumers have clear and easily-understood information, including ingredient content, by way of labelling and other appropriate means, to enable them to protect their food from contamination and prevent the growth/survival of foodborne pathogens by storing, handling and preparing it correctly **and for allergic consumers to identify allergenic ingredients**; and

Rationale: To provide a food safety reason for including ingredient content.

BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM**Paragraph (i)**

Comment: We prefer to use “component” rather than “phase.”

Rationale: “Phase” can be defined as “a distinct period or stage in a process of change or forming part of something’s development” or “a distinguishable part in a course, development, or cycle.” As such, it can suggest something that ends. “Component” can be defined as “one of the parts of something (such as a system or mixture); an important piece of something.” Thus, “phase” can suggest something that ends and something else (another phase) begins, whereas a component is a part of something else. We think that both GHPs and HACCP are components, or parts, of a food safety system and GHPs continue to be used even when HACCP is subsequently applied in the operation.

Paragraph (vii)

Comment: Edit as follows:

HACCP should identify all hazards associated with the ingredients, the production process and ~~its~~ the environment, and specify the significant ones that should be controlled because they can ~~occur at an unacceptable level~~ cause illness or injury in the absence of control.

Rationale: Many of the hazards that need to be addressed are associated with the raw materials and other ingredients. While some may consider this aspect to be encompassed by the “production process,” we think it important to be explicit that the hazard analysis should cover ingredients. We revised the end to more clearly tie the text to food safety.

Paragraph (viii)

Comment: Edit as follows:

HACCP should determine ~~validated~~ science-based hazard control measures that are essential to increase the level of food safety.

Rationale: The key point in this bullet needs to be the determination of hazard control measures that are essential for food safety. Not all these control measures will need to be validated, but there should be a scientific basis for the measure. As an example, if cleaning a slicer is determined to be an essential control measure for *Listeria monocytogenes*, we would not expect a business to validate that the cleaning procedure removes the specific organism, but we would expect that the cleaning compounds used would be those designed to remove the types of soil (fats and proteins) on the slicer and to reduce associated microorganisms. Similarly, we would not expect a business to validate the efficacy of their disinfection of the slicer but, rather, to use disinfectants that have been demonstrated by the manufacturers as appropriate (which may not be done with the pathogen of concern) and, where required, approved by a competent authority for the specific use. Moreover, we think “validation” belongs in the point that follows.

Paragraph (ix)

Comment: Edit as follows:

The application of hazard control measures should be subject to monitoring, verification (including, where appropriate, validation) and documentation.

Rationale: The need for validation is more appropriate here. Depending on our approach to verification and validation, this point may need revision; however, we have made the insertion here as if validation will continue to be part of the verification principle.

Paragraph (x)

Comment: Edit as follows:

Changes in the food business, e.g. new process, new ingredient, new product, new equipment, should lead to a review of both GHPs and the HACCP plan to determine if modifications are needed. Modifications to the food safety system should be documented and, when necessary, validated.

Rationale: Clarification as to which modifications should be documented.

DEFINITIONS

General Comment

We would prefer not to separate definitions specific for the HACCP system from other definitions. This will likely result in unproductive discussions as to where to place certain definitions. For example, it would seem that a definition for HACCP is specific to the HACCP system (currently it is in the definitions applying within the whole document), and a definition for monitoring (currently in the definitions specific to the HACCP system) should be applicable to GHPs as well. We think that definitions such as “control” could be broadened to include GHPs.

With respect to the need for additional definitions, we do not see a need to define “potential hazard” (this can be explained in the HACCP section to be developed), “food business operator” (this has been used in multiple documents and there has been no confusion about what it means), and “operational prerequisite program” (unless we decide to use the concept in the document). As we develop this document, it is likely we will find terms that need to be added to the definitions and we will identify these as we move forward.

Contaminant

Comment: Revise as follows:

Any biological, ~~or chemical~~ or physical agent, ~~or physical object (i.e. foreign matter or other substances)~~ not intentionally added to intended to be present in food that may compromise food safety or suitability.

Rationale: We have revised the first part to address concerns about the inconsistency with respect to physical contaminants and physical hazards in the hazard definition. We think that the key difference in the “agents” here compared to those in the definition of “hazard” is that not all contaminants cause illness or injury. The term “agent” can be a physical object (one definition of the term is “something that produces or is capable of producing an effect”).

The second change reflects our concerns about how to address intentional adulteration in this definition in light of economically-motivated adulteration of proteinaceous foods/ ingredients with melamine and of spices with dyes containing lead oxides. Such compounds were intentionally added for purposes of economic gain. Our suggested revision does not fully address our concern, but we think it is better this way. We are open to other solutions.

Good Hygienic Practices

Comment: Revise to change “in the establishment” to “by food business operators”:

Prerequisite programs aiming specifically at food hygiene, applied ~~in the establishment~~ **by food business operators**.

Rationale: For consistency throughout the document; avoids the perception that these do not apply at primary production.

Hazard

Comment: We do not object to the removal of “or condition of” from the definition.

Rationale: We think the main reason this term was included was to address choking hazards for young children. However, we believe that many foods can present choking hazards and this aspect would be considered by businesses outside their HACCP plans.

Corrective action and Correction

Comment: We recommend defining a single term, “corrective action,” as follows:

Corrective action: any action taken when a deviation occurs in order to correct the problem and minimize the potential for it to reoccur.

Rationale: We find the wording of Option A to be unclear (and it brings in new terminology such as “nonconformity”) and the wording of Option B to be more specific than needed for a Codex document. We see no need to specify whether an action is a “corrective action” or a “correction” and feel that for this document a more general definition that captures any action that is taken when there is a problem is appropriate.

Critical Control Point

Comment: Revise as follows:

A step **or activity** at which **a** hazard control measure(s) is(are) applied and **which** is(are) essential to prevent **a hazard** or reduce ~~a hazard~~ **it** to an acceptable level.

Rationale: Mostly editorial. Including both the singular and plural is unnecessary and awkward. “Activity” is added to capture hazard control measures (such as the cleaning of a slicer) that are applied at places other than a processing step. (Note: this would not be needed if we retain the definition of “step,” which includes “procedure, operation or stage.”) The end of the definition is revised for grammar, because one does not “prevent a hazard to an acceptable level.”

Critical criterion and Critical limit

Comment: We suggest the following revisions.

Critical criterion: A criterion that separates acceptability from unacceptability with respect to the safety of the food.

NOTE A critical criterion can be a critical limit (**see definition**), or an observable ~~action~~ **activity or feature** ~~criterion or an action limit~~ demonstrating that the hazard control measure [at a CCP] is in control.

NOTE Examples of an observable activity or feature are ensuring that the label placed on a food lists all the allergens, that a screen to remove hazardous foreign material is in place, that a critical preservative has been added during batch preparation.

Critical limit: A numeric value characterizing the critical criterion of a measurable parameter that can be monitored in a timely manner.

NOTE 1 A critical limit relates to a measurement, of e.g. time, temperature, pH, water activity, pressure.

NOTE 2 When a hazard control measure is the combination of more than one action, there may be several critical limits that must be complied **with** together, e.g. for temperature and time, pH and water activity.

Rationale: The intent of having two separate definitions is to recognize that there are criteria that have measurable numerical limits (e.g., a temperature) and those that do not (e.g., cleaning takes place between foods with different allergen profiles). We think that, despite the notes, this was not clear and has caused confusion, especially since some food businesses include observable features as “critical limits” in existing HACCP plans. We also think that “observable action criterion or an action limit” is not clear. The revisions and the addition of an example of a critical criterion that is not measurable are intended to help clarify the concept. We also have placed “at a CCP” in square brackets until we resolve the issue of whether all hazard control measures are applied at CCPs. The addition of “with” is editorial.

Significant hazard

Comment: Revise as follows:

A hazard identified by the hazard analysis as ~~having to be controlled~~ **requiring control in order to ensure the safety of the food.**

Rationale: The revision better ties the need for control to ensuring safe food.

FAO

i) General Comments

- FAO suggests to reduce the extensive use of the future tense and use the present tense instead to better reflect the style of the final text.
- Please ensure that the order of the terms “safety and suitability”, when used together, is maintained as in the title of the document (safety first and suitability second) throughout the text.
- In paragraph 12 a title “BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM” is introduced, however there is no follow-up text or any definitions on food control systems. This is a new term which is being introduced is potentially confusing. In addition there is already a Codex Text developed by CCFICS which includes principles for national food control systems, there is no reference to this (CAC/GL 82-2013 Principles and Guidelines for National Food Control Systems). While we consider it useful to see hygiene management presented in the context of an overall food control system, we believe this should be done in the introduction and not by the inclusion of such a heading. FAO would welcome a section in the introduction where linkages to food control systems are made.
- Definitions: It is unclear whether the notes will be part of the final text.

ii) Specific Comments

Paragraph 1

FAO proposes to retain Option B

Rationale: *It includes the following important aspects*

- *States that people have the right to expect food to be safe and suitable*
- *Refers to economic including trade aspects and food waste better integrated.*
- *Refers to changes in behavior and corresponding adaptations of technology*
- *States that the General Principles lay a firm foundation for ensuring food hygiene*
- *Mentions the internationally recognized character of text as well as government application (and option B in paragraph 2 suggests what governments should do with text)*

However as noted in the General Comments some additional text to introduce the hygiene management in the context of Food Control Systems would be welcome.

Paragraph 2

FAO proposes to retain Option B, modified as follows for clarity:

[This **document** Introduction will outline the general principles that should be understood and followed by food businesses and help **should be used by** governments to establish appropriate oversight. ~~It will then define specific terms and expressions applicable to the document.~~]

Paragraph 3

FAO proposes the following editorial and substantive changes to the text:

The first section will describe *Good Hygienic Practices for Food Safety and Suitability (GHPs)*. GHPs are the basis of any food safety control system:

- GHPs are aimed at preventing or reducing the level of contaminants so that the **safety and** suitability of the end product ~~as well as its safety~~ will not be compromised.
 - GHPs are part of prerequisite programs which should always be implemented in any operating food business.
 - All employees should be trained in GHPs as appropriate to their job activities; it is important that **all** food handlers have basic knowledge of the impact **that** GHPs can have on the safety and suitability of food.
- ~~———— GHPs, in general, only need basic knowledge and skills.~~

Rationale: *this is a weak statement, not a principle and beyond scope of this text*

Paragraph 4

FAO proposes to remove the word appropriate as it is subjective and unnecessary:

The application of ~~appropriate~~ GHPs in food businesses provides a sanitary environment that supports the production of safe and suitable food. No comment

Paragraph 5, Bullet 2

FAO proposes the following change:

- HACCP is a ~~preventive~~ **systematic** approach that aims to enhance food safety where this is appropriate and feasible, by improving the control of hazards over that achieved by the GHPs.

Rationale: *GHPs are also preventive and HACCP is a logical approach for control of operations that takes the hazard control to a next level and enables food businesses to focus controls of key hazards at critical points (key steps).*

Paragraph 5, Bullet 5

Propose to delete

- ~~HACCP requires specific knowledge and skills.~~

Rationale: *this is a statement on general needs, not a principle*

Paragraph 6 - chapeau

In line with the general comments, the sequence of terms for “safety and suitability” should be used consistently throughout.

The General Principles of Food Hygiene for Food **Safety** and Suitability ~~and Safety~~: Good Hygienic Practices (GHPs) and Hazard Analysis and Critical Control Point System (HACCP) aims to:

Paragraph 11 – bullet 2

Include ‘ safe ‘ for clarity and consistency

- provide assurance that food is **safe and** suitable for human consumption;

Paragraph 13 - title

Please refer to our comments under i) General Comments. FAO does not understand the inclusion of this title “BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM”. The text following the title bears no relation to food safety control systems and it cannot be the objective of the GPFH to define “national food safety control systems”. If the intention was to include a chapter on how this text fits into a food safety control system, then this would need to be done in the introduction section. In the current text no linkages are made to food control systems. If the intention is to make reference to national food safety control systems, then FAO would suggest to cross-reference the relevant CCFIX texts and include an explanation that the GHP/HACCP principles will only succeed if supported by the food control system.

Paragraph 13 – bullets

The following edits are proposed for clarity.

- (i) The recommended way to maximize food safety and suitability is a two [phase/~~component~~] preventive approach.
- (ii) The implementation of GHPs is the first [phase/~~component~~] of the design of a food safety control system.
- (iii) GHPs should ensure that food is produced in a sanitary environment and reduce the burden of contaminants, whether hazardous or not.

- (iv) GHPs are a prerequisite to the implementation of a HACCP system, because they provide the foundation for a HACCP system to be effective.
- (v) The application of GHPs should be subject, where appropriate, to monitoring, verification and documentation.
- (vi) The implementation of HACCP, where needed and feasible, is the second [phase/component] of the design of an effective food safety control system.
- (vii) HACCP should identify all hazards associated with the production process and its environment, and specify the significant ones **hazards** that should be controlled because they can occur at an unacceptable level.

Paragraph 15 - Definitions

Please clarify whether the Notes are to be remain in the final text e.g. as footnotes.

Paragraph 15 – Definition of cleaning

Text edited for clarity.

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

CODEX NOTE Many, but not all, biological agents (microorganisms) are removed by cleaning. Cleaning is prerequisite to disinfection, which ~~is needed where cleaning is not effective enough against biological contaminants~~ **should be undertaken if there is a need to further reduce the microbial count to acceptable levels.**

Paragraph 15 – definition of prerequisite programs

We note that this is also defined in the code of practice for fish and fishery produce and it is important to maintain consistency. The existing Codex definition is: Prerequisite programme: A programme that is required prior to the application of the HACCP system to ensure that a fish and shellfish processing facility is operating according to the Codex Principles of Food Hygiene, the appropriate Code of Practice and appropriate food safety legislation.

In addition this definition does not allow consideration of prerequisite programs which may not be strictly related to maintaining hygiene e.g. traceability. The following edits are suggested:

[NEW] Prerequisite programs Procedures and actions taken to maintain hygienic conditions throughout the food chain, **prior to the application of the HACCP system and that** provide the foundation for **the implementation** of HACCP system.

Paragraph 15 - Definitions for Corrective action and Correction

FAO proposes to retain Option B as it is more comprehensive. However, at his stage FAO suggests to not finalize the definition, but to agree on what is trying to be captured, and include the final definitions when the text has been further developed

Paragraph 15 - Definition for Critical control Point

Propose the following edit for clarity.

[MODIFIED] Critical Control Point (CCP) A step at which hazard control measure(s) is(are) applied and is(are) essential to prevent **a hazard** or reduce a hazard to an acceptable level.

Paragraph 15 - Definition for Critical limit

Propose the following edit for clarity.

[MODIFIED] Critical limit A numeric value characterizing the critical criterion of a measurable parameter that can be monitored in a timely manner **using parameters that can be measured during the operation.**

CODEX NOTE 1 A critical limit relates to a measurement, of e.g. time, temperature, pH, water activity, pressure.

CODEX NOTE 2 When a hazard control measure is the combination of more than one action, there may be several critical limits that must be complied together, e.g. for temperature and time, pH and water activity.

CODEX Rationale for the two above definitions: The original definition was “Critical limit”. A criterion that separates acceptability from unacceptability”. A critical limit is a characteristic of a hazard control measure that can be monitored **in a timely manner**. Yet, for hazard control measures that cannot be timely monitored, various types of criteria have to be used; hence, a wide definition is given for “Critical criterion” and a narrow one for “Critical limit”.

IDF

The International Dairy Federation (IDF) would like to thank the Electronic Working Group led by France and co-chaired by Chile, Ghana, India and the United States of America for preparing this document. IDF support increased engagement with ISO as this helps drive further alignment and consistency across the food sector.

Please, below find the comments of IDF to the recommendations in para. 18 of CX/FH 16/48/5.

Re. para, 18 a) – Consideration of the proposed draft

General comment on the approach proposed for the differential management of CCPs

IDF fully concurs with an approach based on prerequisite programmes (including GHPs) and two types of control measures classified according to their nature and role within a food safety control system.

However, we have concerns that the introduction of type A / type B CCPs will confuse rather than facilitate the application. Such an approach will be perceived as a look-a-like “CCP₁/CCP₂-approach” which has never been generally accepted. This approach will also pose problems to the food industry, including confusion for current users of the ISO 22000 OPRP concept (steps where OPRPs are applied would have to be considered as CCPs, in addition to the “true” CCP-related control measures)

Instead, we suggest applying a three-tier approach consisting of:

- Hazard control measures having defined critical limit(s), and where non-compliance with a critical limit results in the affected end products being considered as potentially unsafe (=CCPs)
- Hazard control measures having defined action criteria, and where non-compliance is indicative of malfunction of the control measure resulting in the end products with increased probability of being unsafe (=new class similar to OPRPs as used by ISO 22000)
- Basic conditions and good hygienic practices (=PRPs)

The above should be clearly distinguished

- (i) between PRPs and hazard control measures and
- (ii) between the two classes of hazard control measures.

With regard to the latter, it is too simple to use timeliness of monitoring as the distinguishing parameter.

Classically, one does expect a control measures at a CCP to be continuously monitored, or at least being monitored on a regular basis (Principle 4) and in a timely manner to ensure control of affected lots of end product, particularly because the values being monitored are critical (critical limits). The key concepts are critical limits and timely monitoring to ensure control of affected lots.

The new class of hazard control measures can be distinguished from the above by not having critical limits, but other criteria defining acceptability, and/or be based on monitoring (measurement or observation) that may or may not be timely to ensure control of affected lots.

Specific comments to Appendix 1

Paragraph 1: Introduction

We support Option B of this paragraph

Paragraph 2: Introduction

We prefer option A, however slightly amended to clarify the message, as follows:

“This document ~~shows~~ provides guidance on how food safety and food suitability can be enhanced throughout the food chain from primary production to the final consumer, ~~including manufacturing and distribution~~. To achieve this goal, each business establishes its own control system taking into account its specific requirement and will help governments to establish appropriate oversight”.

Para. 3 – GHPs

- The first section of the revised Codex document should address prerequisite programmes (PRPs), including GHPs. The current draft correctly states in the second indent that GHPs are part of PRPs.
- In the first indent, the phrase “as far as reasonably practicable” should be added after “level of contaminants”, so that the indent reads:

“GHPs are aimed at preventing or reducing the level of contaminants, as far as reasonably practicable, so that the suitability of the end product as well its safety will not be compromised”

- The last indent should be deleted, as this is not a correct statement. Alternatively, it could read as follows:

“The basis of GHP is a general foundation of knowledge and skills”

Para.4 – GHP

This paragraph is the repetition of text in Para. 3 and could be deleted.

Para. 5 - HACCP

This paragraph should reflect the approach described in our general comments. Having different classes of CCPs is confusing.

In the first indent, refer to PRPs rather than to GHPs, as other basic procedures not complying with the understanding of GHP are essential, for instance, traceability, emergency procedures, good laboratory practices, etc.

The fourth indent implies that HACCP is not suitable or applicable at primary production – would not we have ‘hazard control measures (not necessarily measurable at a timely manner) for produce production e.g. water for irrigation, use of compost/manure in berry/produce production? In our view, HACCP can be applied throughout the food chain. Technical feasibility of HACCP should not be confused with legal obligation to apply it, i.e. the use of HACCP is the choice of the farm but mandating HACCP through legislation is the choice of competent authorities (a risk management option).

Para. 6 - Objectives

This document will not identify good hygienic practices but will provide guidance on the application of GHP. In the first indent, replace *“Identify the good hygienic practices...”* with *“Provide guidance on the application of the good hygienic practices...”*

Para. 7 – Scope

Control measures are not enhanced but are selected to control specific hazards. Therefore, replace *“enhanced”* with *“specific”*.

Para. 11 – Role of governments

The 2nd indent should also cover food safety. Amend into:

- *“provide assurance that food is safe and suitable for human consumption;”*

Basic principles for a food safety control system – Principle (ii)

GHPs are established during the design – not implemented

Basic principles for a food safety control system – Principle (iii)

Replace *“burden of contaminants”* with *“level of contaminants”*

Basic principles for a food safety control system – Principle (viii)

The wording of the indent should be improved. We suggest it to read *“HACCP should identify hazard control measures that are essential to control the hazards identified as significant. Their capability to control the significant hazards should be validated”*.

Basic principles for a food safety control system – Principle (x)

The last sentence should be amended as follows:

“~~Modifications~~Decisions made during the evaluation and review, whether modifications are implemented or not, should be documented and when necessary validated”

Para. 15 - Definitions of correction/corrective action

We support Option A for the definitions of Corrective action and Correction.

Para. 15 – Definitions of critical limit/criterion

It is confusing to apply the same term “critical” for both true CCP-related control measures (type A) and the new class of hazard control measures.

We suggest keeping the term *critical limit* for true CCP-related control measures (type A) and possibly introduce other metrics for the other type of hazard control measures. The term used by ISO – *action criterion* - is an obvious choice.

Re. para, 18 b) – Management of the revision

Since the GPFH is among the most referenced Codex documents it is appropriate to address some of the activities in physical working groups.

Re. para, 18 c) – Specific issues of attention

Re: Definitions:

- No need for a definition of “**potential hazard**” as such terminology is confusing implying that it may sometimes be hazardous and sometimes not. A hazard is a hazard but a hazard may potentially occur.
- We find it appropriate to use the term **OPRP** (Operational Prerequisite Program) for the new class of hazard control measures. However, to avoid confusion it will be necessary to align Codex and ISO definitions.
- We agree with the deletion of “**condition of**” in the definition of hazard.

Re: The terms corrective action and correction

We agree with the ISO approach to apply two terms:

- **correction** covering actions related to the handling of affected product (location, recall, dispositioning, etc)
- **corrective action** covering actions related to the control system (bringing the control measure back into control, preventing reoccurrence).

Using two distinct terms facilitates focused intervention in case of deviation.

We assume that appropriate parts of the document will be dedicated to principles of correction/corrective action.

IFU

International Fruit and Vegetable Juice Association (IFU) comments on the proposed draft revision of the general principles of food hygiene (CAC/RCP 1-1969).

General Comment.

Page 2 Paragraph 8.

When there is a CCP deviation then corrective measures must be applied in order to control the CCP.

Rational. Improvement step to reduce the risk of re-occurrence.

Specific Comments.

Introduction 1.

We prefer option B as it includes factors concerning current lifestyles and the potential impact on food safety.

Introduction 2.

We prefer option A as it clarifies the principles are applicable all along the supply chain and specifies the consumer.

13. Consumers should recognize their role by following relevant instructions and applying appropriate food hygiene measures.

(vii) HACCP should identify all food safety hazards associated with the production process and its environment, and specify the significant ones that should be controlled because they can occur at an unacceptable level.

Rational. Provides clarity of the hazards that need to be identified.

Point 13 – vii & ix.

We recommend that the sentences are reworded to include the reference to CCP's versus having to validate all hazards.

Definitions applying within the whole document

Option A (based on ISO 9000)

Corrective action [Action on the process or the environment to eliminate the cause of a detected nonconformity and to prevent its recurrence.] Correction [Action to eliminate a detected nonconformity.]

Option B (US)

Corrective action [Any action taken when a deviation occurs to correct the problem, to segregate and evaluate any food impacted by the deviation and determine appropriate disposition of the food, and to identify the cause of the problem and reduce the likelihood it will reoccur.] Correction: [An action taken in lieu of corrective actions to identify and correct a problem when a deviation does not impact the safety of the food (e.g. recleaning insanitary equipment before production begins).]

We prefer Option A as this follows the international ISO standard.

SSAFE

PAGE #, SLIDE, PARAGRAPH	QUESTION or COMMENT	RECOMMENDATION (if any...)
Item 8, page 2	<p>We do not support introducing type A / type B CCPs.</p> <p>The eWG was tasked with “considering the need for a new class of hazard control measures for which management as CCPs presents challenge”. Though not said in the assignment, this refers to the concept of OPRP of ISO 22000.</p> <p>The option proposed by co-chairs states that all steps where hazard control measures are applied would be CCPs, either type A if the control measure has the features of a "true" CCP (timely monitoring and correction in case of deviation) or type B if the control measure belongs to the new class (no timely monitoring and/or poor predictive value of deviation).</p> <p>This option will pose problems to the food industry:</p> <ul style="list-style-type: none"> - confusion for current users of the OPRP concept: steps where OPRPs are applied would have to be considered as CCPs, in addition to steps already identified as CCPs where "true" CCP-related control measures are applied - this approach is equivalent to giving more flexibility on how to manage a CCP - proliferation of CCPs 	<p>We suggest adopting the 3-leg approach with clear distinction:</p> <ul style="list-style-type: none"> - Prerequisite programs - CCP = step in the process at which hazard control measure(s) is(are) applied, having defined critical limit(s), where measurement enables effective control of the product - [New class] = hazard control measure having defined action criteria, where measurement or observation enables effective control of the process and/or product
Page 4 Introduction #1		Recommend Option B
Page 4 Introduction #1 Option B Last sentence of first paragraph.	<p><i>Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.</i></p> <p>Delete this sentence since HACCP is only for food safety not quality - which is the cause of spoilage.</p> <p>Should add “weaken consumer confidence” to the sentence prior though.</p> <p>There have been difficulties keeping food safety and quality separate when doing HACCP as the quality dilutes the main focus on food safety and public health.</p> <p>Thus, I recommend to not mention food spoilage in this document as it does not belong in HACCP.</p>	<p><i>But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation and weaken consumer confidence. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.</i></p>
Page 4 Introduction #2	<p>Option A of this paragraph with modifications</p> <p>Rationale: The proposed additions is to make the text clearer. Text regarding - "including manufacturing and distribution" is deleted as this is already covered when it is mentioned primary production to the final consumer and so there is no need to highlight this text separately.</p>	<p>This document shows provides guidance on how food safety and food suitability can be enhanced throughout the food chain from primary production to the final consumer, including manufacturing and distribution. To achieve this goal, each business establishes its own control system taking into account its specific requirement and will help governments to establish appropriate oversight.</p>
Page 4 Introduction #2		Recommend Option B

Item 1, page 4	2 nd sentence of option + footnote not appropriate as it may refer to other issues than the hazards defined in the document, e.g. nutritional value	If option A, delete 2 nd sentence and footnote
Paragraph 3 part 1:		Amend the text as below: GHPs are aimed at preventing or reducing the level of contaminants, <u>as far as reasonably practicable</u> , so that the suitability of the end product as well its safety will not be compromised.
Paragraph 3 part 3:		Amend the text as below: All employees should be trained in GHPs as appropriate to their job activities; it is important that food handlers have basic knowledge of the impact GHPs can have on the safety and suitability of food.
Paragraph 3 part 4:		Amend the text as below to make it clearer: GHPs, in general, only need basic knowledge and skills <u>The basis of GHP is a general foundation of knowledge and skills</u>
Item 3, page 5	Last bullet point not relevant	Delete GHPs, in general, only need basic knowledge and skills
Page 5 #3 & #4	I understand how GHPs can play a role in suitability, but it does not fit into HACCP. So it will need to be very clear this distinction to remain in the document. (See earlier comment)	Remove any reference to suitability
Page 5 #4	Seems redundant to #3. Propose to delete text in this paragraph, as this is the repetition of text in Paragraph 3.	delete #3
Item 5, page 5	Prerequisites should be broaden to those not referred to as GHPs	HACCP application will not be effective without prior implementation of GHPs <u>and other prerequisite programs</u>
Item 5, page 5	We advocate for a category of hazard control measures different from CCP-related hazard control measures	HACCP accomplishes this with the help of hazard control measures applied at critical control points (CCPs).
Page 5 #6 first bullet	<u>(including primary production through to the final consumer)</u> Can we really control what the consumer will do with their food?	Should change to: (... through to the selling to the final consumer).
Paragraph 5 part 4:	No part of the food chain should be exempted from application of HACCP. Text is not clear as this seems to imply that HACCP is not suitable or applicable at primary production – would we not have 'hazard control measures (not necessarily measurable at a timely manner) for produce production e.g. water for irrigation etc.	Amend the text as below: HACCP may not be <u>is</u> applicable to all type of food businesses across the food chain. in particular at the stages of primary production. However, the principles of HACCP can be applied to certain activities related to primary production [e.g. administration of veterinary drugs].
Paragraph 6 part 1:	This document will not identify good hygienic practices but will provide guidance on the application of GHP.	Amend the text as below: identify <u>provide guidance on the application of</u> the good hygienic practices applicable throughout the food chain (including primary production through to the final consumer) to provide food that is safe and suitable for human consumption
Paragraph 6 part 3:		Amend the text as below to make the text clearer. provide a guidance that may be needed for specific codes for sectors of the food chain, processes, or commodities <u>sector specific codes of practice</u> to amplify <u>establish</u> the hygiene requirements specific to those areas <u>sectors</u> .
Paragraph 7:		Amend the text as below:

		This document provides a framework for producing foods that are safe and suitable for human consumption by setting out necessary hygiene conditions and applying, where appropriate, enhanced specific control measures at certain production steps. The document is intended for use by food business operators and countries ³ , as appropriate.
Page 5 Scope #7	<i>At certain production steps ... Are control measures only applied to the production steps? There may be distribution and/or displaying/storage and/or purchasing control measures needed which in my mind are not considered production steps.</i>	Delete the highlighted words from the sentence: <i>This document provides a framework for producing foods that are safe and suitable for human consumption by setting out necessary hygiene conditions and applying, where appropriate, enhanced control measures. at certain production steps.</i>
Paragraph 8:	Propose to delete this text as this is already covered under Paragraph 6 part 3	The document provides a foundational structure for other, more specific, codes applicable to particular food sectors. Such specific codes and guidelines should be read in conjunction with this document.
Paragraph 11 Part 2:	amend the text as below to make it more clear and appropriate	provide assurance that food is safe and suitable for human consumption;
Page 6 #12 second bullet	If we are going to keep suitability in this document, then Why isn't spoilage prevention mentioned here for suitability? See added words highlighted in yellow.	<i>ensure that consumers have clear and easily-understood information including ingredient content, by way of labelling and other appropriate means, to enable them to protect their food from contamination and prevent the growth/survival of foodborne pathogens and spoilage organisms and chemical spoilage by storing, handling and preparing it correctly; and</i>
Paragraph 12 Part 2:	Mentioning the ingredient content and how to provide information to consumers is not necessary here and should be covered in the relevant labelling or food information to consumer guidelines or standards.	Amend the text as below ensure that consumers have clear and easily-understood information including ingredient content, by way of labelling and other appropriate means, to enable them to protect their food from contamination and prevent the growth/survival of foodborne pathogens by storing, handling and preparing it correctly; and
Page 6 Title	BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM Why do the items listed under this title discuss suitability when the title only mentions food safety?	Either broaden the title to include Suitability or remove all items' following sections that discuss suitability.
Basic principles, page 6	<ul style="list-style-type: none"> - Broaden prerequisites to those not referred to as GHPs -> "GHPs and other prerequisite programs" - Monitoring, verification or documentation of prerequisite programs is not systematic Split identification of control measures and their validation into 2 items	(i) The recommended way to maximize food safety and suitability is a two [phase/component] preventive approach. (ii) The implementation of GHPs and other prerequisite programs is the first [phase/component], of the design of a food safety control system. (iii) GHPs and other prerequisite programs should ensure that food is produced in a sanitary environment and reduce the burden of contaminants, whether hazardous or not. (iv) GHPs and other prerequisite programs are a prerequisite to the implementation of a HACCP system, because they provide the foundation for a HACCP system to be effective. (v) The application of GHPs and other prerequisite programs should be subject, where appropriate, to monitoring, verification and/or documentation. (vi) The implementation of HACCP, where needed and feasible, is the second [phase/component] of the design of an effective food safety control system.

		<p>(vii) HACCP should identify all hazards associated with the production process and its environment, and specify the significant ones that should be controlled because they can occur at an unacceptable level.</p> <p>(viii) HACCP should select and categorize determine validated hazard control measures that are essential to increase the level of food safety control significant hazards.</p> <p><u>(new) The capability of the hazard control measures to control significant hazards should be validated</u></p> <p>(ix) The application of hazard control measures should be subject to monitoring, verification and documentation.</p> <p>(xi) Changes in the food business, e.g. new process, new ingredient, new product, new equipment, should lead to a review of both GHPs and other prerequisite programs, and the HACCP plan, to determine if modifications are needed.</p> <p>(xii) Modifications should be documented and when necessary validated</p>
Page 6 first principle and then following principles (i), (ii), (vi)	Recommend "component", not "phase"	<p>(i) <i>The recommended way to maximize food safety and suitability is a two component preventive approach.</i></p> <p>(ii) <i>The implementation of GHPs is the first component, of the design of a food safety control system.</i></p> <p>(vi) <i>The implementation of HACCP, where needed and feasible, is the second component of the design of an effective food safety control system.</i></p>
Paragraph 13 Part (i):		<p>Amend the text as below</p> <p>The recommended way to maximize food safety and suitability is a two [phase/component] preventive approach.</p>
Paragraph 13 Part (ii):		<p>Amend the text as below</p> <p>The implementation of GHPs is the first [phase/component], of the design of a food safety control system.</p>
Paragraph 13 Part (iii):		<p>Amend the text as below</p> <p>GHPs should ensure that food is produced in a sanitary environment and reduce the burden level of contaminants, whether hazardous or not.</p>
Page 6 principle IV	If we end up with the two component version this is not accurate any more.	<p><i>GHPs are ideally a prerequisite to the implementation of a HACCP system, because they provide the foundation for a HACCP system to be effective. GHPs must be working in order to be successful with HACCP.</i></p>
Paragraph 13 Part (v):		<p>Amend the text as below</p> <p>The application of GHPs should be subject, where appropriate, to monitoring, verification, corrective action and documentation.</p>
Paragraph 13 Part (vi):		<p>Amend the text as below</p> <p>The implementation of HACCP, where needed and feasible, is the second [phase/component] of the design of an effective food safety control system.</p>

Page 6 principle VII	Needs more details so the expectations are more complete and clear.	<i>HACCP should identify all practical hazards associated with the product from receiving until shipping, raw materials, packaging and its environments, specifying the significant ones that should be controlled because they can occur at an unacceptable level.</i>
Point 13 – vii	“HACCP should identify all hazards associated with the production process and its environment, and specify the significant ones that should be controlled because they can occur at an unacceptable level. “	Feel it should be “food safety hazards” vs all hazards
Point 13 – viii & ix	Sentences should be reworded to include the reference to CCP’s versus having to validate all hazards	
Paragraph 13 Part (ix):		Amend the text as below The application of hazard control measures should be subject to monitoring, verification, corrective action (in case of deviation), validation and documentation.
Paragraph 13 Part (x):		Amend the text as below Changes in the food business, e.g. new process, new ingredient, new product, new equipment, should lead to a review of both GHPs and the HACCP plan to determine if modifications are needed. Decisions made during the evaluation and review, whether modifications are implemented or not , should be documented and when necessary validated
definition of GHPs, page 7	Definition of Good Hygienic Practices not clear The note to definition of prerequisite programs is explicit	Delete the definition.
Page 7 Definitions: Note in Cleaning and the Disinfection definition	Disinfection is not commonly used in the food industry as we say Sanitation and they are different. Disinfection uses antimicrobial agents on non-living objects or surfaces to destroy or inactivate microorganisms. Disinfectants may not kill all bacteria, viruses, fungi and spores. Most disinfectants are weakened or inactivated by organic matter such as dirt and feces. Sanitation uses an antimicrobial agent on objects, surfaces or living tissue to reduce the number of disease-causing organisms to non-threatening levels. Sanitizing does not affect some spores and viruses. A practical method of sanitizing hands is to wash them with soap under running hot water for at least 20 seconds. Sterilization is using chemicals, temperature, gas and/or pressure to kill or inactivate all disease-causing bacteria, spores, fungi and viruses.	Exchange the word Disinfection anywhere it appears to Sanitation
Page 7 Definitions: Environment	<i>Environment The surroundings of the food and processing equipment within the establishment, including air but excluding humans.</i> Why are humans excluded here as we often swab the workers hands, gloves, uniforms, and even tools?	Change to include humans and tools.
Page 7 Definitions: Food Suitability	<i>Food suitability Assurance that food is acceptable for human consumption according to its intended use.</i>	A definition of Suitability - the quality of having the properties that are right for a specific purpose

	<p>Note 2 <i>For instance, food preferences are not the same for different categories consumers, making food which is safe possibly not suitable to certain categories. Thus, food must not only be safe but must also be suitable to meet the dietary needs of target consumers.</i></p> <p>This definition is confusing especially because the Note on the bottom of page 4 (directly above) speaks as it is the dietary needs and this is not part of HACCP.</p>	Please see the comments in the body of my email on this topic.
definition of Corrective action, page 8	Option A is more consensual, cf. ISO	Retain option A
Definitions of critical criterion, critical limit, page 8	Suggest keeping critical criterion/limit for true CCP-related control measures (type A) and possibly introduce other metrics for the other type of hazard control measure.	<p>Critical criterion A criterion that separates acceptability from unacceptability with respect to the safety of the food.</p> <p>NOTE A critical criterion can be a critical limit, or an observable action criterion or an action limit demonstrating that the hazard control measure at a CCP is in control.</p> <p>Critical limit A numeric value characterizing the critical criterion of a measurable parameter that can be monitored in a timely manner</p> <p>NOTE 1 A critical limit relates to a measurement, of e.g. time, temperature, pH, water activity, pressure.</p> <p>NOTE 2 When a hazard control measure is the combination of more than one action, there may be several critical limits that must be complied together, e.g. for temperature and time, pH and water activity or there may be critical limits applied in combination with critical criteria</p>
Definition of deviation, page 8	<p>The definition of deviation should be broadened to both types of hazard control measures. Critical limit/criterion should be specific to true CCPs. Action criterion has been proposed for the other type.</p> <p>In both cases, where criterion is not met, there is deviation. Difference lays in the action that follows evidence of deviation.</p> <p>In the case of true CCP-related control measure, predictive value of product unacceptability is high, correction is needed</p> <p>In the case of the new type of control measure, predictive value of product unacceptability is low, evaluation for release is needed</p>	
Page 9 Definitions: Significant Hazard	<p><i>Significant hazard A hazard identified by the hazard analysis as having to be controlled.</i></p> <p>All hazards identified on the hazard analysis have to be controlled somehow. The nonsignificant hazards are controlled by PRPs & GHPs while the significant hazards are controlled by control measures such as CCPs or OPRPs.</p>	<p><i>Significant hazard A high risk (combination of the probability of occurrence of harm and the severity of that harm) hazard identified by the hazard analysis as having to be controlled by a hazard control measure.</i></p>
definition of hazard, page 7	Put radionuclides in the list	NOTE Examples of hazards include bacteria and their toxins, viruses, parasites, prions, allergens, heavy metals, mycotoxins, radionuclides , foreign bodies, pieces of solid food that can cause choking

Page 3 #18 c) bullet 3		There is no need to add definitions for Potential Hazard, FBO, nor Operational PRP
---------------------------	--	------------------------------------------------------------------------------------