

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
the United Nations



World Health
Organization

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Agenda Item 4

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CODEX COMMITTEE ON FOOD HYGIENE

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

Comments submitted by:

El Salvador, European Union, India, Japan, Kenya, Panama, Senegal, Thailand, African Union

El Salvador

El Salvador agradece el documento remitido por la Secretaría del Codex preparado por el Reino Unido y copresidido por estados Unidos de América, Francia, Ghana, India y México.

Se ha revisado el anteproyecto de revisión del apéndice 1, El Salvador presenta los comentarios del debate sobre los diferentes puntos:

Sobre el párrafo 8 (recomendaciones del GTE) :

i) **Si todas las empresas deberían realizar un análisis de peligros y, en ese caso, de qué modo se puede adaptar para que resulte adecuado a la naturaleza y el tamaño de la empresa y si se están aplicando sistemas de control de la inocuidad de los alimentos basados en BPH o en APPCC.**

Comentarios:

El concepto de BPH en el ámbito de aplicación nacional se cubre con el RTCA 67.06.55:09 Buenas Practicas de Higiene para Alimentos no Procesados y Semiprocesados. Dicha normativa establece una serie de lineamientos que aseguran la inocuidad del producto y no solamente aspectos de limpieza.

Consideramos que no todas las empresas deben realizar un análisis de peligro, y de aplicarse este podría realizarse de acuerdo el rubro de la empresa, basado en el APPCC.

Se propone que en el documento se establezca la separación de BPH con APPCC de una forma clara y sin ambigüedad en el texto.

Sobre el párrafo 8 (recomendaciones del GTE) :

ii. **Si el enfoque actual de los *Principios Generales de Higiene de los Alimentos* (BPH y APPCC cuando es necesario) continúa siendo adecuado o si debería introducirse el concepto de medidas de control en otros lugares además de los PCC (denominados provisionalmente BPH mejoradas). Entre las posibles alternativas se plantea adaptar el texto vigente para indicar que existen algunos controles de BPH a los que debe prestarse más atención, elaborar una terminología nueva y un texto específico centrado en las medidas de control en otros lugares además de los PCC y explicar la relación entre los diferentes tipos de medidas de control con las BPH y el APPCC.**

Comentarios :

Consideramos que el enfoque actual de las BPH y APPCC continua siendo adecuado y que no es necesario incorporar un nuevo concepto de BPH mejoradas. Se considera que medidas de control en otros lugares además de los PCC (denominado provisionalmente BPH mejoradas), se cubren con los PRP que incluyen las BPH, BPF, BPA.

Sobre el párrafo 4 A El Salvador apoya un apartado del párrafo en mención:

4. [A. Los programas de requisitos previos (PRP), que incluyen las buenas prácticas de higiene (BPH), las buenas prácticas de fabricación (BPF) y las buenas prácticas agrícolas (BPA), según proceda,

constituyen la base para producir alimentos inocuos e idóneos.] [Las BPH se aplican en líneas generales a todas las empresas alimentarias sin necesidad de llevar a cabo un análisis de peligros. En relación con los recursos externos (modelos existentes, referencias, normas, reglamentación o códigos de prácticas proporcionados por la autoridad competente, el Codex o la industria alimentaria), puede establecerse que, para que algunos operadores de empresas de alimentos, las BPH son suficientes para que controlen todos los peligros para la inocuidad alimentaria.

Sobre la sección del párrafo 4 A que no es clara para la interpretación es :

“Sin embargo, como no todos los peligros plantean el mismo riesgo, puede que sea necesario prestar especial atención a determinados peligros que un análisis de peligros específico para el lugar haya determinado que son significativos y aplicar [medidas de control en los puntos críticos de control (PCC) o en otros lugares distintos] O [medidas de control de APPCC] en el marco de un sistema de análisis de peligros y puntos críticos de control (APPCC) (véase el cuadro comparativo más adelante).”

Comentario :

Consideramos que se habla de dos términos, A) las medidas de control en los puntos críticos de control y B) del término de medidas de control en otros lugares distintos a los PCC. El término B) no aplicaría si está contemplándose en un marco de un sistema APPCC. por lo tanto debe redactarse la propuesta de una forma clara que sea congruente con el término de la definición APPCC.

Sobre la sección del párrafo 4 A siguiente :

“de Los operadores de empresas de alimentos que carezcan de los recursos necesarios para llevar a cabo un análisis de peligros pueden utilizar los recursos externos indicados anteriormente o planes genéricos de APPCC proporcionados por la autoridad competente o la industria alimentaria, que deben adaptarse al lugar concreto].”

Comentario:

Consideramos que al adaptar un APPCC genérico a un APPCC específico para la empresa que lo pretenda implementar, deberá invertir siempre recursos y estaría sujeto a la disponibilidad de Planes APPCC de la autoridad competente, por lo tanto no se apoya el texto de esta sección mencionada.

El Salvador apoya la medida de crear un grupo de trabajo electrónico para continuar la revisión del CAC/RCP 1-1969 de modo que se apruebe el texto en el trámite 5 en fecha prevista del 2019 y en el trámite 8 en 2021.

Antecedentes.

El Organismo Salvadoreño de Reglamentación Técnica-OSARTEC, es por facultad de Ley el Punto de Contacto de Codex, a partir del mes de septiembre de 2011.

Tema 4: Anteproyecto de revisión de los Principios Generales de Higiene de los Alimentos (CAC/RCP 1-1969) y su anexo sobre el análisis de peligros y de puntos críticos de control (APPCC) en el trámite 4. [CX/FH 17/49/5]

El Salvador agradece el documento remitido por la Secretaría del Codex preparado por el Reino Unido y copresidido por Estados Unidos de América, Francia, Ghana, India y México.

Se ha revisado el anteproyecto de revisión del apéndice 1, El Salvador presenta los comentarios del debate sobre los diferentes puntos :

Sobre el párrafo 8 (recomendaciones del GTE) :

iii. **Si deberían abordarse los controles de la producción primaria en una sección específica del documento o si el documento debería elaborarse de manera que se refuercen las referencias a lo largo de todo el texto para demostrar el modo en el que se aplican las orientaciones en todas las fases de la cadena alimentaria.**

Comentarios:

El Salvador apoya que el documento en revisión. [CX/FH 17/49/5] se suprima la sección sobre producción primaria y reemplazarla por un breve párrafo general que dejase claro que el documento se aplica a la producción primaria cuando proceda y que el texto, a lo largo de todo el documento, se redacte de tal modo que se incluyese claramente la producción primaria.

Sobre el párrafo 9 (recomendaciones del GTE) :

Párrafo 9. Es necesario así mismo examinar el formato y la estructura del documento para alcanzar

un acuerdo sobre hasta que punto se deberían revisar estos aspectos y ajustarlos a los de otros documentos como ISO 22000. Se debería continuar examinando la terminología y las definiciones a medida que se elabora el texto, para garantizar que sean coherentes y estén bien definidas. Por ejemplo, el término “sistema de higiene de los alimentos” (que se acordó en la 48.ª reunión del CCFH) provoca confusión y podría definirse o reemplazarse por “sistema de control de la inocuidad alimentaria”, un término que se ha definido en el documento de validación del Codex.

Comentario:

El Salvador ha examinado el formato y la estructura del documento y considera que debe establecerse claramente en la Introducción, que es referente a las BPH y Puntos Críticos de Control (APPCC), asegurando definir de manera clara la **delimitación** entre los términos BPH y APPCC, para evitar la confusión de los mismo y poder lograr su total comprensión.

Apoyamos que en el Capítulo 1 se aborde las Buenas Prácticas de Higiene y en el Capítulo 2 Sistemas de Análisis de Peligros y de Puntos Críticos de Control (APPCC) y Directrices para su Aplicación.

Consideramos que no es necesario ajustar la estructura del documento en mención a documentos como ISO 22000, esto justificado en que la estructuración actual del documento es adecuada.

Observaciones Generales sobre otros párrafos del documento :

PRINCIPIOS GENERALES DE HIGIENE DE LOS ALIMENTOS: BUENAS PRÁCTICAS DE HIGIENE (BPH) Y EL SISTEMA DE ANALISIS DE PELIGROS Y PUNTOS CRITICOS DE CONTROL (APPCC)

En el párrafo 13:

13. Los operadores de empresas de alimentos deberían aplicarlas prácticas de higiene y los principios de inocuidad de los alimentos que se establecen en el presente documento a fin de:

- **Garantizar que los consumidores cuenten con información clara y fácilmente comprensible que les permita determinar la presencia de alérgenos alimentarios, proteger sus alimentos de la contaminación y evitar la proliferación o la supervivencia de patógenos de transmisión alimentaria al almacenar, manipular y preparar correctamente los alimentos;**

COMENTARIO:

SE RECOMIENDA SEPARAR EL SIGUIENTE PÁRRAFO Y AGREGAR EL TEXTO SUBRAYADO DE LA SIGUIENTE MANERA:

- 1) Garantizar que los consumidores cuenten con información clara, veraz, completa y oportuna y fácilmente comprensible según las directrices del CCFL que les permita además determinar la presencia de alérgenos alimentarios.
- 2) Proteger sus alimentos de la contaminación y evitar la proliferación o la supervivencia de patógenos de transmisión alimentaria al almacenar, manipular y preparar correctamente los alimentos.

En el párrafo 14 del documento en revisión, “PRINCIPIOS GENERALES”

Comentario:

El Salvador considera que debe separarse los principios generales de BPH y principios generales de APPCC (ya establecidos en el segundo capítulo del documento.) para su comprensión y poder relacionar con claridad ambos conceptos por separado.

Sobre las definiciones citadas en la Introducción del Documento a continuación mencionadas:

“Definiciones”

[A elaborar en función de los términos utilizados en la segunda y tercera parte]; incluir aquí las definiciones que ya figuran en la sección 2.3 de RCP-1, para facilitar el debate al respecto.

Sistema de higiene de los alimentos - La combinación de prácticas de higiene y de medidas de control que, en conjunto, garantiza que los alimentos son inocuos y aptos para su uso previsto.

Sistema de control de la inocuidad alimentaria4 - La combinación de medidas de control que, en su conjunto, asegura que el alimento sea inocuo para su uso previsto.

Medida de control

Medidas de control de los peligros

Peligro significativo

[Análisis de peligros básico]

Comentarios:

El Salvador recomienda definir la terminología relacionada a los diferentes temas a revisar en el anteproyecto (**CAC/RCP 1-1969**) para garantizar la coherencia entre la definición y las opiniones a emitir por los países sobre los textos de los diferentes temas que se modifican o cuando se adicionan nuevos textos.

Sobre las definiciones de Sistema de Higiene de los Alimentos y Sistema de Control de la Inocuidad Alimentaria, se apoya la definición de Sistema de Higiene de los Alimentos termino acordado en la 48.^a reunión del CCFH, dicha definición es consecuente con la definición de higiene de los alimentos del CODEX citada en la normativa en revisión, modificada en el 2003.

Consideramos que el Sistema de Control de la inocuidad alimentaria forma parte del Sistema de Higiene de los alimentos, por lo que se recomienda dejar por separado los conceptos.

Respecto a las definiciones de medida de control y medidas de control de los peligros que no se menciona en este apartado de la introducción sobre su concepto, lo encontramos definido en el capítulo 2 , consideramos que el concepto medida de control ya define que es para prevenir o eliminar un peligro, consideramos que hay duplicidad de termino al establecer la definición “medida de control de los peligros.”

De manera general respecto a las definiciones del anteproyecto en revisión consideramos que debe realizarse un consolidado de las definiciones pertinentes a BPH y APPCC, para evitar duplicidad de términos que genere confusión en el mismo documento.

En el PRIMER CAPÍTULO; BUENAS PRÁCTICAS DE HIGIENE en la sección de la Introducción en el párrafo 2.

2. Un sistema basado en BPH puede ser suficiente para controlar todos los peligros inherentes a las actividades. Cuando se identifiquen peligros significativos para la inocuidad alimentaria en la actividad, deberían controlarse, bien a través de la aplicación de BPH mejoradas diseñadas para controlar un peligro específico para la inocuidad alimentaria o, cuando proceda, en forma combinada con la aplicación de APPCC. Revisando el sistema implementado de BPH y cuando proceda, aplicar el Sistema APPCC (texto agregado)

Comentarios:

El Salvador propone eliminar el texto tachado y adicionar el texto mencionado. Consideramos que las BPH son suficiente para controlar todos los peligros inherentes a las actividades (como menciona el texto.) no se apoya el término de BPH mejoradas.

European Union

Comments on the points raised in paragraphs 8 and 9 of the EWG report

As the EWG recommendation is to discuss and reach agreement on the fundamental concepts highlighted in these two paragraphs and as the comments on these paragraphs are general and relevant for the whole document, they are provided first.

Paragraph 8(i):

- The EUMS consider that all businesses should carry out a hazard analysis and suggest it should be an overarching principle that is given more prominent in the document. Derogation could only be considered for primary producers (only GHPs).
- Based on the hazard analysis a FBO can justify if GHPs are sufficient.
- The nature of a business is related to the type of activity and its associated risks (processing of food, only storage and distribution of (prepacked) food, need for temperature requirements, etc.). The extent of a food hygiene system (FHS, including GHPs, HACCP) depends on the nature of the business. It is also important that the guidance provides a clear definition of hazard analysis and what this involves and how it might be adapted to different businesses and production activities as the nature and extent of the hazard analysis can be different in different circumstances. All businesses must take responsibility for the safety of food they produce. This means they should understand the hazards associated with their business and control measures that should be applied to eliminate or reduce the risk to an acceptable level. At a simple level this might require an awareness that ingredients/raw material could be contaminated by food pathogens and potential risks should be controlled using basic hygiene measures such as cooking, chilling, preventing cross contamination and effective cleaning but in larger, more complex businesses, this could require more extensive analysis and a detailed understanding of specific hazards involved and the appropriate risk management interventions. It is our view that both these simple and complex examples are

considered hazard analysis. The depth of hazard analysis needs to take into account the nature of the raw materials/ingredients, the processing and the final product as well as the size of the business.

- Since risks are the same for the same kind of activity (same nature), the same FHS should be applied independently of the size of the business. Adaptation to the size of a business within the same activity/FHS is possible by adapting the frequency of monitoring and verification activities to ensure an approach, proportionate to the amounts of food placed on the market by the business. Small businesses can also be allowed to provide more general and simplified description of GHPs, refer to generic guidance for GHPs and validation, reduce recording, etc.

Paragraph 8(ii):

- The EUMS support the need to include "control measures at places other than CCP (enhanced GHPs)". The question is not whether they need to be included in the document, but how. To keep FHSs simple, easier to understand and consistent with (the new) ISO 22000, the same approach and terminology should be used.
- Our preference is not to introduce enhanced GHPs as new concept with new terminology into the guidance document. We agree that there are some GHPs where enhanced controls are required and this could be reflected in the text. We also note the preference from some industry stakeholders to introduce terminology and concepts based on ISO 22000 as there is already a level of understanding of these approaches within the food industry. However, this is not true of all businesses and the relationship between the different types of control within GHP and HACCP-based systems is not yet well understood by all. We would suggest introducing new concepts and terminology is unnecessary, adds complexity and may lead to more confusion which would be inconsistent with the CCFH objectives for simplification of the guidance document. We agree the text needs to be developed so that the relationship between GHPs and CCPs is explained clearly using examples where required. This can be done once agreement on fundamental principles has been reached.

Paragraph 8(iii):

- The EUMS believe that it is more appropriate to maintain a specific section on primary production since this allows to adapt; taking into account that these are almost exclusively very small businesses, a HACCP system might be considered disproportionate and risks need to be addressed differently (e.g. environmental contamination) than in post-harvest businesses. We would also support inclusion of appropriate references throughout the text with examples to help indicate how controls might apply to primary production.

Paragraph 9

- The EUMS support as much consistency with ISO 22000 as possible, including terminology. Past experience shows that differences between the Codex standards and the ISO have only contributed to add confusion in the application of FHSs.
- The GPFH should be a standalone document that lays down foundation principles. Other standards and guidance documents (produced by Codex or other organisations) should further interpret and expand on those principles where this is felt necessary.
- The format and structure of the guidance should lead the reader through the different controls so they can understand the requirements and how these might apply to their business. At this stage, we consider it is appropriate to have an overarching Introduction, with Chapters on GHP and HACCP. We would also suggest consideration of an additional chapter on hazard analysis as understanding hazard analysis and how this should be carried out is fundamental to implementing the appropriate food safety control system. Once agreement has been reached on fundamental concepts the document can be reviewed and text amended accordingly
- It is important that the Codex documents and ISO 22000 complement each other and that there are no conflicts but, these documents have different objectives and are designed for slightly different purposes so they need not be the same. Again agreement in fundamental concepts is needed before an appropriate balance can be achieved.

1. COMMENTS ON THE PROPOSED DRAFT REVISION OF THE GENERAL PRINCIPLES OF FOOD HYGIENE AND ITS HACCP ANNEX (CX/FH 17/49/5, APPENDIX I)

Additional general comments

As a general comment, the EUMS would like to indicate that we keep the terminology used in the draft revision for practical reasons. However, this does not indicate support for this terminology which the EUMS find confusing, inconsistent and should be further discussed (see comment on EWG report).

Specific comments to the main text (Introduction/Objectives/Scope/Use/General Principles)

Paragraph 3

It is proposed to delete the second sentence (or it should be reformulated).

Rationale: confusing (editorial and on content) and repetition: the concept is reflected in paragraph 7.

Paragraph 4

The EUMS support Option 4B (considered as essential), but some redrafting would be necessary. Because this is a key element in the revision (link between GHPs and HACCP, role of hazard analysis) and some confusion remains between PRPs, GHP, GMP, wording used in specific Codex guidelines, etc., further elaboration of the proposed text would be appreciated, capturing the notions described below. Alternatively, it can be considered to move this paragraph to the section on "USE" since it is quite strange to find this information before the objectives (paragraph 7, third bullet) are mentioned.

"4. B. All businesses must understand the risks associated with their business and be able to carry out a hazard analysis to identify appropriate hygiene and safety controls that should be applied. The complexity of the hazard analysis will vary according to the activities including, but not solely determined by, size of the business. The hazard analysis will determine the level of control required and the type of food safety management system that should be applied. Prerequisite Programmes (PRPs), which include Good Hygiene Practices (GHPs), Good Manufacturing Practices (GMPs), and Good Agricultural Practices (GAPs), as appropriate, lay the foundation for producing safe and suitable food.] [GHPs apply broadly to all food businesses (including primary producers). [Chapter Two] describes the Hazard Analysis and Critical Control Point (HACCP) principles. HACCP principles can basically be applied throughout the food chain from primary production to the delivery to the final consumer and their implementation should be guided by scientific evidence of risks to human health. The application of any HACCP principle might however be considered disproportionate to the risk for primary producers. ~~Following a basic~~ **Following the hazard analysis and an assessment of food hygiene measures,** it may be decided that GHPs are sufficient for some FBOs to control all food safety hazards (**no need to elaborate the other HACCP principles**). In other cases there may be a need to pay particular attention to certain hazards determined as significant by a site-specific hazard analysis and to apply [control measures at critical control points (CCPs) and/or at places other than CCPs] ~~OR [HACCP control measures]~~ within a Hazard Analysis and Critical Control Point (HACCP) system (see Comparison Table below). **FBOs may use existing models, references, standards, regulations, or Code of Practices or generic HACCP plans provided by the competent authority or food industry subject to adaptation to the site provided such measures deliver the necessary safety controls** ~~FBOs without the resources to carry out a site-specific hazard analysis may use existing models, references, standards, regulations, or Code of Practices or generic HACCP plans provided by the competent authority or food industry subject to adaptation to the site.~~

Rationale:

- See comment on EWG report (see Section 2) as regards the selection of 4B, in particular:
 - all FBOs must carry out a hazard analysis in principle;
 - Based on the hazard analysis a FBO can justify if GHPs are sufficient.
- This paragraph can be easily merged with paragraph 5.
- Some issues need to be clarified, e.g. when HACCP is not required at all, when only a hazard analysis is sufficient.
- HACCP do not apply to the final consumption.
- Not sure if the proposed footnotes are appropriate here since these are not guidelines provided by the food industry.
- Additional paragraph inserted at the end to introduce the requirement that all businesses must carry out a hazard analysis and that the complexity of this will vary according to the nature, not just the size, of the business

Paragraph 5

Propose to delete/merge with paragraph 4 (see above).

Rationale: partly repetition and it would be clearer if the recommendations contained in both paragraphs are closely linked.

Paragraph 6

The EUMS would like to propose to put the Table in an Annex/Appendix. It can be maintained for the time being but its added value should be re-evaluated during the course of the revision since many aspects might be covered by definitions or clear from the revised text itself. However, the EUMS consider that in the current draft the concept of "enhanced GHPs", and what is expected from the FBO for these "enhanced GHPs", is not sufficiently clear and should be further elaborated.

Rationale: editorial + need to be considered at a later stage.

Paragraph 8

The EUMS would like to understand what does "hygiene and food safety conditions" mean.

Rationale: "hygiene and food safety conditions" are not defined, nor further used in the text. Are they different from other wording used? If not, consistency of wording might be appropriate.

Paragraph 9

It is proposed to merge the 2 sentences as follows:

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

Rationale: Clearer and avoids repetition

Paragraph 12

It is propose to amend the first sentence as follows: "12. Competent authorities should decide how best they should ~~apply~~**incorporate** these general principles ~~into through~~ legislation, regulation or guidance, **and ensure their application by food businesses to:**"

Rationale: Competent authorities do not apply themselves the general principles. An attempt was made to better describe the role of competent authorities.

Paragraph 13 first sentence

It should be clarified what "hygienic practices and food safety principles" are or wording consistent with the rest of the text should be used.

Rationale: wording not used elsewhere in the text.

Paragraph 13 third bullet

It is proposed to replace "by demonstrating" by "including the demonstration of" or "e.g.". In addition, it should be clarified what "food safety practices" are or wording consistent with the rest of the text should be used.

Rationale: cultivating food safety culture is more than the examples provided. The wording "food safety practices" is not defined nor used elsewhere in the text.

Paragraph 14 General Principles

- Point (ii): the term "contaminants" should be changed to "hazards"

Rationale: the term hazards is in line with the remaining text and the concept of biological, chemical and physical hazards;

- Point (iii): it is proposed to amend it as follows: "GHPs should provide the foundation for an **effective** HACCP system, where **required applied, to be effective.**"

Rationale: it should be clearer that a HACCP is required if such outcome of the hazard analysis + editorial

Paragraphs on "Management Commitment" (15-16)

It is proposed to redraft these paragraphs as follows:

~~"Management Commitment~~**Food Safety Culture**

15. Fundamental to the successful functioning of any food hygiene system is the **establishment and maintenance of an appropriate food safety culture acknowledging the importance of human behaviour of all individuals in a business in providing safe and wholesome foods. Following elements are important in cultivating a positive food safety culture:**

- **Commitment of the management and all employees to the safe production of food**

- **Leadership to set the right direction and to engage all employees in food safety practices**
- **Risk awareness of the importance of food safety and hygiene by all employees in the business**
- **Open and clear communication between all employees in the business, including communication of deviations and expectations**
- **The availability of sufficient resources to ensure the safe and hygienic handling of food**

~~commitment from management to incorporate food safety into the business objectives of the food business and to communicate the importance of producing safe food, both for the consumer and the business.~~

16. Management commitment should result in the continual improvement of ~~Managers should continually improve the effectiveness of the food hygiene systems in place by:~~

- ensuring that roles and responsibilities are clearly communicated in the food business;
- ~~• ensuring the availability of resources;~~
- maintaining the integrity of the food hygiene system when changes are planned and implemented;
- verifying that controls are working and documentation is up to date;
- ensuring the appropriate training and supervision are in place for personnel;
- ensuring compliance with relevant regulatory requirements; and
- ~~• enabling a strong food safety culture by demonstrating commitment to providing safe and suitable food and encouraging appropriate food safety behaviours."~~

Rationale: Management commitment is only part of a food safety culture, which is a broader concept that is relatively new and therefore needs to be better described.

Annex I Proposed Decision Tree

The EUMS support the inclusion of a decision tree but, this needs to be developed once agreement has been reached on the different control measures that might apply and how these might be reflected in the document. Further reflection is also needed on the following points:

- It does not seem appropriate to have 2 different decision trees in different parts of the text (as it is understood that the current decision tree (Diagram 2 in the Annex to CAC/RCP 1-1969) for a very similar purpose. The trees should therefore be merged. Alternatively, a second simplified tree could be considered.
- Q1: GHPs should exist at each step of the process and therefore the question may not be very relevant.
- Q3: A generic GHP might be a starting point but the need to customize to each business/process must always be considered. Whether such customising is needed or not, does not seem relevant as long as the GHP is evaluated for its efficiency.

Rationale: The proposed decision tree is not the clearest and most effective one. Alternative decision trees have been published merging the new and the existing one and should be considered.

Specific comments to [Chapter One] Good Hygiene Practices

Paragraph 4: Propose to delete.

Rationale: Seems redundant by the introduction of the main document. In addition it is proposed to maintain the section on primary production.

Primary production

It is proposed to maintain this part as this as a separate section

Rationale: see comments on EWG report

Paragraphs 28-29

These paragraphs, if maintained, should just make a cross-reference to paragraphs 19-21 of [Chapter 2].

Rationale: Since a hazard analysis is always considered necessary and product description and flow diagrams are essential for such hazard analysis, these recommendations are more appropriate in [Chapter 2] where the hazard analysis is described.

Paragraphs 34-35

Propose to delete or merge with paragraphs 4-5 of the main document. In addition, we have a problem with the concept of "**basic** hazard analysis".

Rationale: Largely repetition of paragraphs 4-5 of the main document. No confusion should be created by creating different types of hazard analysis, although some could be simplified (e.g. considering all microbiological hazards together in such hazard analysis).

Paragraphs 36-37

Propose to delete. Recommendations (on validation etc) of enhanced GHPs may be merged with other parts of the texts on GHPs.

Rationale: Repetition of other parts of the document (on preliminary steps and hazard analysis in [chapter 2], paragraphs 31-33 on monitoring, validation and verification on GHP, paragraphs 4-5 of the main document).

Specific process steps

It should be considered to maintain the original text from CAC/RPC1-1969.

Rationale: This is a general document. It is worth mentioning process steps which influence the safety of the food.

[Paragraph 42

It is proposed to delete this paragraph or to replace it by a cross-reference to CAC/GL 21-1997.

Rationale: Repetition of recommendations made elsewhere].

Paragraph 53

It has been the norm for the GHP/HACCP text to be the base code for all other hygiene codes. Any additional information is then added into the commodity specific codes. Therefore it is not appropriate for the base code to refer to the Fruit and Vegetable code (CAC/RCP 53-2003) for further information on water use in primary production. The base code should have all the basic information and commodity codes should only have the extra specific information.

India

A. INTRODUCTION

a) Paragraph 4

Comment: We support the option 4 A with some changes as under:

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

Rationale:

India reiterates its comment. GHP is a standalone food hygiene measure and can be referred to as a PRP only in reference to HACCP, that is, when a decision to implement HACCP has been taken. Thus, this sentence is confusing as it tends to refer to GHPs as a PRP in absolute terms. This document talks about only GHP and HACCP and hence reference to PRPs is not required. Therefore, this sentence can be deleted to address the above ambiguity without any loss of contextual information.

b) Comparison Table:

Comment: We propose the following amendments in the table:

	Good Hygiene Practices (GHPs)	[Control Measures at Places Other than CCPs] ¹ [Enhanced GHPs]	Control Measures at Critical Control Points (CCPs)

¹ **Comment:** These measures do not amount to control measures as per existing definition. Hence the term Enhanced GHP is appropriate for such measures.

Scope	General basic conditions and activities to create the environment (external and internal) for safe food. Not specific to any hazard but results in some prevention of contaminants.	Food Hygiene measures specific to a product or group of products. These significantly <u>control the likelihood of introducing food safety hazards to, and/or the contamination or proliferation of food safety hazards in, the products or in the processing environment.</u> <u>The Enhanced GHPs are</u> quantifiable.	Specific to a product or group of products. Controls at production steps that are critical to reduce significant hazards in foods to an acceptable level
Criteria	Some aspects of GHPs may be measurable or observable e.g. hand washing	Criterion measurable or observable which separates acceptable <u>food hygiene measures / conditions and activities from unacceptable and that require an evaluation of the impact on the product. For e.g. cleaning, filter size etc.</u>	Critical limit which separates acceptable products from unacceptable ☑ measurable (e.g. temperature, pH, aw), or ☑ observable (e.g. visual checks, appearance, texture)

c) GENERAL PRINCIPLES

Comment: We would like to delete points (iv till vii) as these appear to be more of procedural steps than General principles.

d) Definitions

Comment: We propose to move all the definitions to the introduction section and also propose the definitions for 'Enhanced GHP' and 'Basic Hazard Analysis' as under:

- **“Enhanced GHP: GHP identified by basic hazard analysis as significant to control the likelihood of introducing food safety hazards to, and/or the contamination or proliferation of food safety hazards in, the products or in the processing environment for a given step”.**

- **“Basic Hazard Analysis: The process of collecting and evaluating information on Food hygiene measures that control the likelihood of introducing food safety hazards to, and/or the contamination or proliferation of food safety hazards/ contamination in, the products or in the processing environment, to decide which of these significantly control food safety hazards / contamination and thus need to be addressed through enhanced GHPs.**

B. [CHAPTER ONE], GOOD HYGIENIC PRACTICES

a) PRIMARY PRODUCTION

Comment: We would like to retain this section on primary production either by reproducing the text or by cross-referring to RCP-1. Further, we also propose to include the following under this section:

- **Documentation and Record Keeping: Records should be kept as appropriate to enhance the ability to verify the effectiveness of the control systems.**

- **Training: The process should be in place to ensure that the**

• **Personnel responsible for handling storage and transportation of primary produce are aware of their role and responsibility.**

• **Any deterioration and contamination to the food by pest, potentially hazardous chemical or waste is avoided**

• **Records of such training wherever possible should be maintained**

- **Traceability: the ability to track any food, feed, food-producing animal or substance that will be used for consumption, through all stages of production, processing and distribution and individual shall maintain records for step forward and a step backward traceability.**

b) SECTION I: ESTABLISHMENT DESIGN AND FACILITIES

i) Para 6

Comment: We propose the following amendments to the text:

~~“[Site boundaries should be clearly defined. Landscaping near a food.....pest harbourage. Where necessary, experts should be consulted for advice on appropriate plants for use in landscaping].”~~

Rationale: This particular requirement appears to go beyond the scope of this document therefore deleted.

ii) FACILITIES, Water supply

Comment: We propose to delete the term ‘supply’ from the heading ‘water supply’. Please see our comments on paragraphs 51-58 also.

Rationale: The term “supply” restricts the scope of the quality aspects of water to be taken into consideration.

iii) Temperature Control, Para 18

Comment: We propose the following amendments to the text:

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

Rationale: To be consistent with the process flow as mentioned under para 26.

c) SECTION II: CONTROL OF OPERATION

i) Paragraphs 28 to 33

Comment: We propose to delete paragraphs 28 to 33 and reproduce the information under relevant elements in the paragraph 36 under “Control of Food Hazards”.

ii) Control of Food Hazards, Para 34

- Para 34

Comment: We propose the following amendments to the text:

~~“GHPs control most food hazards which may [contaminate] **render food unsafe by way of contamination of** food products, **e.g.** though food handlers, incoming raw materials or other ingredients or the work environment. A basic hazard analysis should determine whether the application of GHPs is sufficient [adequate] for some FBOs to control all of the relevant food hazards. **FBO should determine whether the application of GHPs is sufficient to control all of the relevant food hazards by applying the Decision Tree given at Annex... resulting in the identification of Enhanced GHPs that ensure food safety.**”~~

Rationale: to bring more clarity to the text.

- Para 35

Comment: We propose to delete the paragraph 35

Rationale: The concept in para 35 is already captured in paragraphs 36 and 37.

- Para 36

Comment: In line with our comment at ‘a)’ above, we propose to merge the text from paragraphs 28 to 33 under the points i-iv and point ix in para 36 as under:

i. Describing the products: **It may be described individually or in groups in a manner that will not compromise the identification and analysis of food safety hazards or other factors such as suitability. Grouping should be based on having similar inputs and ingredients, process steps and intended purpose.**

ii. Applicable regulatory requirements: **The Competent Authority should establish acceptable hazard levels for the food.**

iii. Identifying the intended usage: **The FBO should document the intended use of the food and, if appropriate: specify if it is intended for any specific consumer groups e.g. infants, elderly, immuno-compromised individuals; whether it is Ready to eat or as a material [product] that would undergo further processing further processing is intended; list any relevant specifications or important characteristics associated with the food.**

iv. Constructing a flow chart: **The FBO should develop a flow diagram to cover all steps in the operation for a specific product. The same flow diagram may be used for a number of similar products (see product description above) that are produced using similar processing steps. The process steps should be confirmed as accurate by checking against the actual process.**

ix. Establishing a GHP.....Enhanced GHPs: **The FBO should document procedures for monitoring control measures as relevant to the business. Procedures could include responsible personnel, method of monitoring including frequency and sampling regime if applicable and monitoring records to be kept. The frequency of monitoring should be appropriate to ensure consistent process control.**

iii) Key Aspects of Hygiene Control Systems, Title

Comment: We propose to amend the title as under:

“Key Aspects of **Food** Hygiene Control Systems”

Rationale: To be consistent with the Codex text.

iv) WATER

Comment: We are of the opinion that all aspects relating to water should be described at one place only. Therefore, we propose to shift paragraphs 51 to 58 under the heading, i.e. “Water” under FACILITIES section.

iv) RECALL PROCEDURES, Para 60

Comment: We propose to modify the text as under:

“Food Business Operators (FBOs) Manager should ensure..... should be considered.”

Rationale: To be consistent with the term- FBO.

d) SECTION IV: PERSONAL HYGIENE

i) Personal cleanliness, Para 85

Comment: The text may be modified as under and square brackets deleted:

“When required..... Rinse hands with clean, running water and dry thoroughly with **preferably** a single-use towel or other method that do not re-contaminate hands. ~~Multiple use cloth drying towels should not be used.~~ Hand sanitizers should not replace hand washing and should be used only after hands have been washed.]

Rationale: The first part is itself focussed on single used towels and hence the subsequent statement “Multiple use cloth drying towels” doesn’t seem to be necessary.

e) SECTION VI: PRODUCT INFORMATION AND CONSUMER AWARENESS

i) Objectives:

Comments: India proposes modification in the text under first bullet as under:

- adequate and accessible information is available to the next person in the food chain to enable them to handle, store, process, prepare and display the product safely and correctly **including information related to allergens**

Rationale: Allergens are effectively addressed in modes of consumer information like labelling and consumers can take effective steps in avoiding consumption of food containing allergens.

C. [CHAPTER TWO], HAZARD ANALYSIS AND CRITICAL CONTROL POINTS

a) Para 20, Identify intended use (Step 3)

Comment: We propose to replace the existing text in the paragraph with the following new text:

“The FBO should document the intended use of the food and if appropriate identify: any specific consumer groups e.g.: infants, elderly, immuno-compromised individuals; whether it is ready-to-eat or further processing is intended; any relevant specifications or important characteristics associated with the food.”

Rationale: To be consistent with the GHP document under para 36.

b) Para 25

Comment: India proposes to delete the entire paragraph.

Rationale: The same is mentioned under Paragraph 1 of the GOOD HYGIENIC PRACTICES [CHAPTER ONE]

c) Para 26

Comment: It is proposed that basic Hazard Analysis under GHP be kept generic and not hazard specific. Therefore, the paragraph may be modified as under:

~~[Significant hazards] which are of such a nature that their elimination or reduction to acceptable levels is essential to the production of safe food should be identified and controlled by hazard control measures designed to remove or reduce significant hazards to an acceptable level. This may be achieved with the application of good hygiene practices, some of which may need to be enhanced to target a specific hazard, [for example, cleaning equipment to control contamination of ready-to-eat foods with *Listeria monocytogenes*) include example and cross refer to guidance (under development by the EWG) on hazard analysis). In other instances, hazard control measures will need to be applied at critical control points.]~~

Enhanced GHP can ensure food safety by control of some hazards, while their may be others that essentially need to be targeted with more stringent controls that would eliminate or reduce them to acceptable levels. Such hazards will be identified through the GHP decision tree and the Hazard control measures which need to be applied at critical control points would be addressed through the HACCP approach.

Rationale: This existing text calls for hazard specific Hazard Analysis - which will be challenging for small / developing nations.

d) Establish Critical Limits for Each CCP (Step 8), Para 30

Comment: The text may be revised as under:

“Critical limits should be specified for each Critical Control Point which separates the acceptable ~~processes~~ **process** and ~~products~~ from unacceptable. In some appearance and texture.”

Rationale: For more clarity.

e) Establish a monitoring system for each CCP (Step 9), Para 33

Comment: The text is proposed to be modified as under:

“Monitoring limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. ~~The adjustments should be taken before a deviation occurs.~~ Data derived actions when indicated.”

Rationale: Adjustments in the process before the deviations occur can only happen when Action Limits (limits more stringent than Critical Limits are set and are being monitored). In their absence, monitoring will identify deviations with respect to Critical Limits after they have occurred.

f) Establish corrective actions (Step 10), Para 37

Comment: The text may be modified as under:

“The actions should ensure that the CCP has been brought under control. Actions taken should include proper disposition of the affected product and identify the root cause of the loss of control to prevent a recurrence. Deviation and product disposition procedures should be documented. ~~in the HACCP record keeping.~~

Rationale: There deleted text is redundant. Also the term ‘HACCP record keeping’ is not explained anywhere.

g) Establish Verification procedures (Step 11), Para 38

Comment: We propose to establish the system for validation. We may refer to Guidelines for Validation of food safety control measures (CAC/GL 69-2008) which can be included after para 40.

Rationale: Validation of control measure is important to ensure that the controls measure will be effective as per their intended use.

h) Training, Para 46

Comment: We propose the following modification in the text:

“Training of personnel effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel to be ~~stationed~~ **responsible** at each Critical Control Point.

Rationale: With the use of new improved technology, personnel are not required to be stationed at every CCP.

Japan

Japan would like to reiterate its appreciation to the Co-chairs of EWG, the United Kingdom, France, Ghana, India, Mexico and the United States of America, who led this challenging task and succeeded in providing a sound basis for further discussion.

Observing the comments on the proposed draft already expressed by the Committee members (CX/FH 17/49/5 Add.1), we have an impression that there are too many points of argument in the draft and it is getting extremely difficult to see a big picture. At the 47th Session, the Committee agreed that one of the main objectives of this new work is to help implementation of GHP and HACCP by small and/or less developed food businesses (SLDBs) (refer to the Project Document in REP16/FH), and we believe it is essential to keep this in mind in the course of discussion. Also, to move the discussion forward efficiently, we would like to suggest that, in accordance with the recommendations from the EWG, CCFH49 should first focus and reach agreement on the fundamental concepts of the work, especially on the following points:

- whether all FBOs should complete a hazard analysis or not (regarding para 4A/4B, Introduction);
- whether to introduce the concept of control measures at places other than CCPs (so-called “enhanced GHPs”); and
- the format and structure of the draft document.

We consider that:

- there are cases where it can be determined that GHPs are sufficient for certain types of business to control all food safety hazards without conducting hazard analysis (even a “basic” hazard analysis) by referring to external resources (which could be based on the process of hazard analysis).
- there are some doubts about the usefulness to fully elaborate the concept of control measures at places other than CCPs (so-called “enhanced GHPs”) in the Codex text as it might create more confusions especially among SLDBs while large and/or advanced FBOs implementing ISO 22000 or some GFSI-recognized schemes must already be familiar with OPRP concept. We believe briefly introducing the concept of “enhanced GHP” in the HACCP part would be sufficient as a Codex text.
- by minor amendments of the structure proposed by the EWG, the draft document will be user-friendly and in line with the structure of the original document to avoid the confusions among FBOs, especially SLDBs. Our proposal on the structure of the draft document is as follows:

Proposal on the structure of the draft document	Rationale
INTRODUCTION part	
INTRODUCTION [Comparison Table] OBJECTIVES SCOPE USE GENERAL PRINCIPLES Management Commitment Definitions ANNEX I Proposed Decision Tree to Identify [Enhanced GHPs]	We propose to put this comparison table in square brackets during the work and to decide its fate (keep it or delete it) upon the completion of the text. The decision tree is not needed as it is rather confusing.
GHPs part	
INTRODUCTION SECTION I: PRIMARY PRODUCTION Box (OBJECTIVES, RATIONALE) Environmental hygiene Hygienic production and food sources Handling, storage and transport Cleaning, maintenance and personal hygiene at primary production	We propose to restore the entire section on primary production since that section included recommendations specific to primary production stage and is heavily referred to by various Codex texts related to food hygiene, including the Code of Hygienic Practices for Fresh Fruits and Vegetables (CAC/RCP 53-

<p>SECTION II: ESTABLISHMENT DESIGN AND FACILITIES Box (OBJECTIVES, RATIONALE) Equipment ESTABLISHMENT Design and layout of food establishment [and equipment] Internal structures and fittings Temporary/mobile food establishments and vending machines FACILITIES Water supply Drainage[and waste disposal] Cleaning facilities Personnel hygiene facilities and toilets Temperature control Air quality and ventilation Lighting Storage EQUIPMENT General Food control and monitoring equipment</p> <p>SECTION III: CONTROL OF OPERATION Box(OBJECTIVES, RATIONALE) [Product description] [Process description] [Monitoring procedures] [Validation of GHP] [Preventative and corrective actions] [Verification of GHP]</p> <p>CONTROL OF FOOD HAZARDS KEY ASPECTS OF HYGIENE CONTROL SYSTEMS Time and temperature control Specific process steps Formulation Microbiological and other specifications Microbiological cross-contamination Physical contamination Chemical contamination Allergenic Contamination INCOMING MATERIALS PACKAGING WATER Water supply Water in contact with food As an ingredient Ice and steam in direct contact with food MANAGEMENT AND SUPERVISION DOCUMENTATION AND RECORDS RECALL PROCEDURES</p> <p>SECTION IV: ESTABLISHMENT MAINTENANCE, SANITATION AND</p>	<p>2003).</p> <p>Editorial.</p> <p>We propose to move the paragraphs 28-33 to the HACCP part in order to maintain the original format and structure as much as possible. (Perhaps, short texts regarding <i>monitoring, corrective actions for procedures and verification</i> applicable to GHPs could be kept here, though.)</p> <p>The contents of <i>CONTROL OF FOOD HAZARDS</i> should be re-considered depending on the agreement on the fundamental concepts of the work.</p>
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<p>PEST CONTROL</p> <p>Box(OBJECTIVES, RATIONALE)</p> <p>General</p> <p>Cleaning procedures and methods</p> <p>Sanitation [Cleaning and disinfection] Programmes</p> <p>Monitoring Effectiveness</p> <p>PEST CONTROL SYSTEMS</p> <p>General</p> <p>Preventing access</p> <p>Harbourage and infestation</p> <p>Monitoring and detection</p> <p>Eradication</p> <p>Waste Management</p> <p>MONITORING EFFECTIVENESS</p> <p>SECTION IV V: PERSONAL HYGIENE</p> <p>Box(OBJECTIVES, RATIONALE)</p> <p>Health Status</p> <p>Illness and Injuries</p> <p>Personal Cleanliness</p> <p>Personal Behaviour</p> <p>Visitors</p> <p>SECTION V VI: TRANSPORTATION</p> <p>Box(OBJECTIVES, RATIONALE)</p> <p>General</p> <p>Requirements</p> <p>Use and Maintenance</p> <p>SECTION VI VII: PRODUCT INFORMATION AND CONSUMER AWARENESS</p> <p>Box(OBJECTIVES, RATIONALE)</p> <p>Lot identification</p> <p>Product Information</p> <p>Product Labelling</p> <p>Consumer Education</p> <p>SECTION VII VIII: TRAINING</p> <p>Box(OBJECTIVES, RATIONALE)</p> <p>Awareness and Responsibilities</p> <p>Training Programmes</p> <p>Instruction and Supervision</p> <p>Refresher Training</p> <p>Management Commitment</p>	
HACCP part	
<p>PREAMBLE</p> <p>DEFINITIONS</p> <p>PRINCIPLES OF THE HACCP SYSTEM</p> <p>GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM</p> <p>INTRODUCTION</p> <p>Flexibility for small and/or less developed food businesses</p> <p>Scope</p> <p>APPLICATION</p>	

<p>Assemble HACCP Team (Step 1) Describe product (Step 2) Identify intended use (Step 3) Construct flow diagram (Step 4) On-site confirmation of flow diagram (Step 5) List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (Step 6) Determine Critical Control Points (Step 7) Establish critical limits for each CCP (Step 8) Establish a monitoring system for each CCP (Step 9) Establish corrective actions (Step 10)</p> <p>Establish verification procedures (Step 11) Establish documentation and record keeping (Step 12) TRAINING</p>	<p>If we were to introduce the concept of control measures at places other than CCPs (so-called “enhanced GHPs”), presenting a short text on the concept in <i>Step 6</i> might be sufficient.</p> <p>Additional guidance on hazard analysis could be beneficial for SLDBs.</p> <p>Additional guidance on verification and validation should be provided in <i>Step 11</i>.</p>
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Kenya

General Comment:

Kenya appreciates the efforts of the electronic working group (EWG) in revising the *General Principles of Food Hygiene* (GPFH) and coming up with this draft standard for members to comment on and for discussion at CCFH49.

Based on our observations, we recommend that this draft document be in line with the codex format and structure, we propose that “Chapter” be changed to “Part” so the document consists of an Introduction, Part 1 on Good Hygiene Practices and Part 2 on HACCP.

Issue: Par. 8(i): All food businesses to undertake hazard analysis

Comment: Kenya proposes that all food businesses should undertake food hazard analysis and therefore support option B for the introduction.

Rationale: Food businesses have a responsibility to inform themselves and be aware of the hazards associated with their processes. Food businesses can seek information from Competent Authorities or other recognized bodies. All food businesses are capable of undertaking hazard analysis and implementation of HACCP principles. Small businesses should be encouraged to perform hazard analysis before implementing good hygienic practices, GAP and/ or GMP.

Issue: Para. 8(ii): Introduction of “enhanced GHPs”

Comment: Kenya does not support the introduction of the term “enhanced GHP” as applied throughout the table of comparison of GHPs and HACCP control measures. We also recommend that we delete “[~~Enhanced GHPs~~]” in the third row

Rationale: There should be no introduction of the new terminologies even though some control measures may require more attention, validation and monitoring e.g. Listeria in the environment, contamination of allergens and training should take all this into account. Further, the objective of the introduction of the concept of “enhanced GHP” can be addressed by effective implementation of GMP.

	Good Hygiene Practices (GHPs)	[Control Measures at Places Other than CCPs][Enhanced GHPs]	Control Measures at Critical Control Points (CCPs)
Scope	General basic conditions and activities to create the environment (external and internal) for safe food. Not specific to any hazard but results in some prevention of contaminants.	Control measures for significant hazard(s) in food and/or the processing environment that are not specifically quantifiable or where a specific limit does not relate directly to a quantifiable level of hazard control.	Specific to a product or group of products. Controls at production steps that are critical to reduce significant hazards in foods to an acceptable level.
When identified?	Before hazard analysis, or Adaptation after hazard analysis.	[After basic hazard analysis [at places other than CCPs][enhanced GHPs]] After Hazard analysis [for control measures at CCPs]	
Validation of the effectiveness of the control measure	Where needed, generally not carried out by FBOs themselves, e.g. cleaning products validated for effective use by manufacturer.	Yes, validation should be carried out (<i>Guidelines for the Validation of Food Safety Control Measures CAC/GL 69-2008</i>)	
Criteria	Some aspects of GHPs may be measurable or observable e.g. hand washing	Criterion measurable or observable which separates acceptable procedure from questionable and that requires an evaluation of the impact on product (e.g., cleaning).	Critical limit which separates acceptable products from unacceptable <ul style="list-style-type: none"> ▪ measurable (e.g. temperature, pH, aw), or ▪ observable (e.g. visual checks, appearance, texture).
Monitoring	Yes, where relevant [and feasible]	Yes, but usually non-continuous. Frequency dependent on the operation.	Yes, in real time; <ul style="list-style-type: none"> ▪ continuous, or ▪ at frequency sufficient to ensure CCP in control
Corrective actions when loss of control is indicated	<input type="checkbox"/> For procedures and practices: Yes, [where relevant]. <input type="checkbox"/> For products: Usually not necessary.	<ul style="list-style-type: none"> ▪ For procedures and practices: Yes. ▪ For products: When necessary, based on the situation evaluation. Product should not be introduced into commerce until the evaluation is completed. 	<input type="checkbox"/> For products: Yes. Pre-determined actions for products. <input type="checkbox"/> For procedures and practices: Yes, corrective actions as appropriate to restore control and prevent recurrence
Verification	Yes, where relevant, usually scheduled	Yes. Scheduled verification of implementation of control measures	
Record keeping (e.g. monitoring records)	Yes, where relevant	Yes	
Documentation (e.g. documented procedures)	Yes, where relevant	Yes	

Section I: Establishment design and Facilities

Issue: Defining Site boundaries and Landscaping of a food facility

Comment: Kenya does not support the defining of site boundaries and landscaping of food facilities and therefore suggests to delete the statement **“Site boundaries should be clearly defined. Landscaping near a food facility should be properly designed to minimise attractants and pest harbourage. Where necessary, experts should be consulted for advice on appropriate plants for use in landscaping”**. Kenya proposes that food processing facilities should be designed to prevent harborage of pests.

Rationale: The provisions in the statement are too prescriptive yet this can be achieved by several pest management measures.

Para 7: Equipment

Design and layout of food establishment [and equipment]

Comment: we propose the deletion of 'and equipment'

Rationale: 'equipment' is part of the food establishment.

Para 12-13: Drainage and Waste disposal management

Issue: There is the need to clarify waste collection/disposal site location.

Comment: The current statement of section 13 on “Drainage and Waste Disposal” needs to be modified. The statement “The waste collection/disposal site should be located away from the food establishment to prevent pests infestation” should be replaced with the statement **“The waste disposal site should be located away from the food establishment to prevent pest infestation and contamination”**.

Rationale: The proposed sentences provide clarity as to the responsibility of the food business in ensuring that the collection and disposal of waste are done in a manner that prevents pest infestation and cross contamination of food.

Cleaning facilities

para15. Adequate, suitably designated facilities should be provided for cleaning [~~food~~], utensils and equipment coming into contact with food. Such facilities should have an adequate supply of hot and cold potable water where appropriate.

Comment: We propose deletion of 'food' as bracketed

Para16: Personnel hygiene facilities and toilets

bullet 1: adequate means of cleaning, washing and drying hands, including soap, wash basins and [~~where appropriate~~], a supply of hot and cold (or suitably temperature controlled) water;

Comment: we agree with the statement and therefore propose to open the brackets of "**where appropriate**".

Para. 28-33 Section II: Control of Operations-Additional Sections on product, process description, monitoring procedure

Issue: Whether additional sections on product description, process description and monitoring procedures should be included in the text.

Comment: Kenya does not support the additional sections on product description, process description and monitoring procedures. We propose that the section be part of the annex.

Rationale: The proposed additional sections are adequately addressed in the section that covers HACCP. Therefore there is no need to include them in Section II. This is to avoid duplication and complication in the implementation.

Para 34. GHPs control most food hazards which may [~~contaminate~~] food products, e.g. though food handlers, incoming raw materials or other ingredients or the work environment. A basic hazard analysis should determine whether the application of GHPs is sufficient [~~adequate~~] for some FBOs to control all of the relevant food hazards.

Comment: Remove the square brackets

Para 35. Where significant food safety hazards are identified, and a more targeted approach is necessary, hazard-specific control measures should be implemented. Such hazard [~~specific~~] control measures may be based on GHPs designed to control a specific food safety hazard e.g. cleaning of a meat slicer to control *Listeria monocytogenes*. These 'enhanced' GHPs should be subject to monitoring, corrective actions and verification and where appropriate, be documented.

Comment: delete 'specific'

Para 36 and 48: whole

Comment: remove square brackets

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

Comment: delete 'critical' and open square brackets

Panama

English

(i) General Comments

Panama endorses, values and be grateful for this important work prepared by the GTE (reference document: CX/FH 17/49/5).

Background

The 48th session of CCFH (CCFH48) agreed to establish an EWG, to continue the work on the revision of the General Principles of Food Hygiene, continue the revision of the Introduction and the second (Good Hygiene Practices (GHPs)) and third (HACCP) parts in parallel for circulation for comments at Step 3; consider if aspects on staff commitment and responsibility for food safety, including food safety culture, should be incorporated; and consider the use of examples of control measures at all steps in the food chain (including those that cannot be addressed as CCPs), as well as a comparison table between GHP, CCP and any other types of control measures, to better understand the issues and support the work.

Among the GTE recommendations to the committee, we highlight the following: "Discuss and reach agreement on the **fundamental concepts highlighted at Paragraph 8**¹ to allow the work to continue and support further development of the text; and determine next steps, for so text is adopted at Step 5 in 2019 and Step 8 in 2021".

Concepts and main guidelines:

1. Panama agrees that **GHPs**² the fundamental basis for **Food Business Operators (FBO)** to apply, with **responsibility** and **commitment**, **adequate control measures** in **all phases of the food chain, from primary production to final consumption**, establishing the **necessary hygienic conditions** for the production of **safe food suitable for consumption**, thus contributing to the promotion of a **culture of food safety**.
2. Panama considers that the **FBOs** should define which are the basic [and necessary] hygiene control measures that must be carried out at each stage³ according to the nature of the operation and the pertinent contaminants.
3. Panama agrees with the recommendation given by the CCFH regarding the adoption, whenever possible, of an approach based on the **HACCP System**⁴ to "**raise the level of food safety foods**".
 - The **HACCP System** allows the **identification, evaluation and control of significant [specific] hazards [and control measures]** in order **to guarantee** the safety of the food.
 - The **HACCP System** can be **applied along the entire food chain**, from the primary producer to the final consumer.
 - The purpose of the **HACCP system** is to get **the control to focus on the CCPs**.
 - The **HACCP System** must be **applied separately to each specific operation**. This **scope will determine which segment of the food chain is involved** and which **general categories of hazards** are to be addressed (for example, it will indicate whether all kinds of hazards are covered or only certain classes).
 - The **HACCP team** should list **all the hazards** that can reasonably be expected to occur in **each phase, from primary production, processing, manufacturing and distribution to the point of consumption**.

² **Food hygiene:** all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain. (CAC/RCP 1-1969. Amendment 1999. Revisions 1997 and 2003. Editorial corrections 2011).

³ **Step:** A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption. Ref: HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION - ANNEX TO CAC/RCP 1-1969 (REV. 4 - 2003).

⁴ Ref: CAC/RCP 1-1969 (REV. 4 - 2003).

- The **HACCP team** should conduct a **hazard analysis** to identify, in relation to the **HACCP plan**, which hazards whose **removal or reduction to acceptable levels** is indispensable**, by its nature, **to produce a safe food**.
- The HACCP team should build a **flow diagram**. This has **to cover all the phases of the operations related to a determined product**.
- When applying the **HACCP system** to a **specific operation**, the **phases before and after** said operation must be taken into account.
- Although the application of the **HACCP system** to **food safety** has been considered here, the concept could be applied to **other aspects of food quality**.

4. Panama considers that the "**decision tree**"⁵ that is currently applied to **identify CCPs** is functional and adequate. However, although it agrees with the EWG that it should be reviewed, it considers that the key to the "*apparent difficulty in its application*" would be in the correct **interpretation of the definition** of what is understood as "**an acceptable level**"⁶ of the "possible presence of a hazard".

5. Panama considers that "depending on the **specific security requirements in the control procedures required** to comply with an "**adequate level of control**", based on a **hazard analysis**⁷ (within the framework of a risk analysis), to decide if the **application of GHPs alone** is considered sufficient or if the **rigorous application of a documented plan** based on the 7 principles of the HACCP system (**HACCP Plan**) is necessary".

Ref.: **HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION - ANNEX TO CAC/RCP 1-1969 (REV. 4 - 2003)**

(ii) Specific Comments

1. Panama agrees with "the need to continue analyzing some fundamental principles"; however, it considers that **all food companies** or **Food Business Operators (FBO)** should carry out a **hazard analysis** (at least basic).
2. With respect to the proposal to introduce the concept "**Enhanced GHPs**", Panama is of the opinion that it could be technically considered as equivalent to the concept of "**OPRP (operational prerequisite programme)**"^{8*}
3. Note: Different versions of **paragraph 4** (4A and 4B) have been proposed covering the possible outcomes of the forthcoming discussions on whether **all food companies should be required to carry out hazard analysis**. **Observations:**
4. [A. **Prerequisite Programmes (PRPs)**, which include **Good Hygiene Practices (GHPs)**, **Good Manufacturing Practices (GMPs)**, and **Good Agricultural Practices (GAPs)**, as appropriate, **lay the foundation** for producing **safe and suitable food**.] [**GHPs** apply broadly to **all food businesses** without the need for conducting a hazard analysis. Referring to **external resources** (existing models, references, standards, regulations, or Codes of Practice provided by the competent authority, Codex or food industry), it may [could] be determined that **GHPs** are sufficient for **some FBOs** to control all [certain] food safety hazards. Yet, since **not all hazards pose the same risk**, there may be a need to pay particular attention to

⁵ **DIAGRAM 2 - EXAMPLE OF DECISION TREE TO IDENTIFY CCPs (ANSWER QUESTIONS IN SEQUENCE): Q1** Do control preventative measure(s) exist?; **Q2** Is the step **specifically designed** to **eliminate** or **reduce** the likely occurrence of a hazard **to an acceptable level?** (**); **Q3** Could contamination with identified hazard(s) occur in excess of **acceptable level(s)** or could these increase to **unacceptable levels?** (**); **Q4** Will a **subsequent step** eliminate identified hazard(s) **or reduce** likely occurrence to an **acceptable level?** (**).

(**) **Acceptable** and **unacceptable levels need to be defined** within the overall objectives in identifying the CCPs of HACCP plan.

⁶ **Acceptable level:** The **level of a safety hazard** which is considered to present an **acceptable, low risk to the consumer**. The acceptable level of the final product, sometimes referred to as a **target level**, should be stated in the **product description** and would normally be set **at, or below, any regulatory limits**. **An acceptable level for a hazard at an intermediate step** in the commodity flow diagram **can be set higher than that of the final product, provided that the acceptable level in the final product will be achieved**. (*Annex to the document: Manual on the Application of the HACCP System in Mycotoxin Prevention and Control - FAO/IAEA Training and Reference Centre for Food and Pesticide Control - Rome, 2001 - Appendix I: Definition of terms*). It refers to the "Level that does not cause damage or nor there is a significant risk of it".

⁷ **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**. Ref: **CAC/RCP 1-1969 - Adopted 1969. Amendment 1999. Revisions 1997 and 2003**.

⁸ ***Observation:** "... consider that they are **essential control measures for the control of the hazards, but they do not have "absolute" control over the hazards**. In addition, the **operational prerequisite** may work in combination with other control measures to prevent, eliminate, reduce or maintain a hazard to an **acceptable level**; they can even be found in different stages of the process. And finally, **its failure does not automatically imply that a product is dangerous**".

certain hazards determined as **significant** by a site-specific hazard analysis and to apply **[control measures [specific] at critical control points (CCPs) [within a Hazard Analysis and Critical Control Point (HACCP) plan]** and/or at places other than CCPs] OR ~~[HACCP control measures] within a Hazard Analysis and Critical Control Point (HACCP) system~~ (see Comparison Table below). **FBOs** without the resources to carry out a **hazard analysis** may use **external resources** as listed above or **generic HACCP plans** provided by the competent authority or food industry¹, subject to adaptation to the site].

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

4. [B. **Prerequisite Programmes (PRPs)**, which include **Good Hygiene Practices (GHPs)**, **Good Manufacturing Practices (GMPs)**, and **Good Agricultural Practices (GAPs)**, as appropriate, lay the foundation for producing **safe and suitable food**.] **[GHPs apply broadly to all food businesses**. Following a **basic hazard analysis** and an **assessment of food hygiene measures [applicable]**, it may [could] be decided that **GHPs** are sufficient for **some FBOs** to control all [certain] food safety hazards. In other cases there may be a need to pay particular attention to **certain hazards** determined as **significant** by a site-specific hazard analysis (more specialized and strict) and to apply **[control measures [specific] at critical control points (CCPs) [within a Hazard Analysis and Critical Control Point (HACCP) plan]** and/or at places other than CCPs] OR ~~[HACCP control measures] within a Hazard Analysis and Critical Control Point (HACCP) system~~ (see Comparison Table below). **FBOs** without the resources to carry out a **site-specific hazard analysis** (more specialized and strict ⁹) may use existing models, references, standards, regulations, or Code of Practices or generic HACCP plans provided by the competent authority or food industry² subject to adaptation to the site.]

4. After a detailed review and respective analysis, **Panama proposes to the EWG and CCFH** to consider a **third version of paragraph 4** (4C) that attempts to cover possible outcomes of the forthcoming debates, including the possibility of requiring **all food companies to carry out a Hazard analysis, at least basic:**

4. [C. **Prerequisite programs (PRP)**, which include **Good Hygiene Practices (GHPs)**, **Good Manufacturing Practices (GMPs)**, and **Good Agricultural Practices (GAPs)**, as appropriate, are the **basis** for producing **safe** and **suitable** food.] [The **GHPs** are applied in general terms to **all food companies**. After a **basic hazard analysis** and an **assessment of [applicable] hygiene measures** of food, it could be decided that **GHPs** are sufficient for **some food business operators** to control **certain food safety hazards**. However, since not all hazards pose the same risk, it may be necessary to pay special attention to **certain hazards** that a **site-specific hazard analysis (more specialized and strict)** has determined are **significant** and to apply **[control measures [specific] at critical control points (CCPs) [within a Hazard Analysis and Critical Control Point (HACCP) plan]** and/or at places other than CCPs] (see comparative table below). **FBOs** without the resources to carry out a **site-specific hazard analysis** (more specialized and strict ¹⁰) may use existing models, references, standards, regulations, or Code of Practices or **generic HACCP plans** provided by the competent authority or food industry² subject to adaptation to the site.]

5. Comparison of GHPs, [Control Measures at Places Other than CCPs][Enhanced GHPs] [OPRP (operational prerequisite programme)] and HACCP [PCC] Control Measures

Panama agrees, in general terms, with the contents of the table of references to the **control measures in places other than the improved PCC** or ~~Enhanced GHPs~~ **[OPRP (operational prerequisite programme)]**. However, Panama has proposed that in substitution of the term "Enhanced GHPs", which refers to "certain control measures in places other than the CCPs", the use of the term "**OPRP (operational prerequisite programme)**".

6. With respect to ANNEX I - Proposed Decision Tree to Identify [Enhanced GHPs] [OPRP (operational prerequisite programme)]. Panama agrees, in general terms, with the content thereof; however, it is advisable to apply the concept "**OPRP (operational prerequisite programme)**"; and the concept of "**acceptable level**" as "*the low level of safety hazard that is considered to be an acceptable risk to the consumer. The acceptable level of the final product, sometimes called the expected level, must be declared in the product description and will normally be set at a level equal to or lower than the regulatory limit, if any. In an intermediate phase of the product flow diagram, an acceptable level higher than that of the final product can be set for a hazard, on condition that the acceptable level is reached*". Ref: **Annex to the document: Manual on the Application of the HACCP System in Mycotoxin Prevention and Control - FAO/IAEA Training and Reference Centre for Food and Pesticide Control - Rome, 2001 - Appendix I: Definition of terms**). It refers to the "*Level that does not cause damage or nor there is a significant risk of it*".

⁹ Idem.

⁽¹⁾² FAO/WHO Guidance to governments on the application of HACCP in SLDBs - ISSN 0254-4725

¹⁰ Idem.

⁽¹⁾² FAO/WHO Guidance to governments on the application of HACCP in SLDBs - ISSN 0254-4725

7. With respect to the first and second chapters, Panama presents some observations:

[FIRST CHAPTER] - GOOD HYGIENE PRACTICES - SECTION II: CONTROL OF OPERATIONS - CONTROL OF FOOD HAZARDS

Observations on the following paragraphs:

34. **GHPs** control the **most food hazards which may** [contaminate] **[and / or be present in]** food products, e.g. through **food handlers, incoming raw materials** or **other ingredients** or the **work environment**. A **basic hazard analysis** should determine whether the application of **GHPs is sufficient** [adequate] for **some FBOs** to control all [certain] of the relevant [significant] food **hazards**.

35. Where **significant** food **safety hazards** are identified [and / or if a higher level of control, protection, security and / or trust is required], and a more targeted approach [and / or strict] is necessary, **hazard-specific** [more effective and / or strict] **control measures** should be implemented. Such **hazard** [specific] [and significant] **control measures** may be based on **GHPs designed** to control a specific [and significant] food safety hazard e.g. cleaning of a meat slicer to control *Listeria monocytogenes*. These 'enhanced' **GHPs [OPRP (operational prerequisite programme)]** should be subject to monitoring, corrective actions and verification and where appropriate, be documented.

36. **FBO** should **control food hazards** through a **hazard analysis system** that involves: i. Describing the Product; ii. Applicable regulatory requirements; iii. Identifying the intended usage – Ready to eat or as a material [product] that would undergo **further processing**; iv. Constructing a flow chart; v. Conducting a **hazard analysis** for identifying the food safety hazards as microbiological, chemical or physical at each step of the flow chart; vi. Identifying and defining the **Good Hygienic Practices** for controlling these hazards; vii. Categorizing the **GHP controls** as generic [of the hazards] or **hazard-based controls** [specific and significant] to be managed as either **Enhanced GHPs [OPRP (operational prerequisite programme)]** or by application of [specific **control measures** at the **critical control points (CCP)** within a **Hazard Analysis and Critical Control Point (HACCP) plan**] principles of HACCP using a **Decision Tree Model** as given in [Annex I to the introduction]; viii. **Validating / effectiveness** of the **Enhanced GHPs [OPRP (operational prerequisite programme)]**: **Enhanced GHPs [OPRP (operational prerequisite programme)]** should be validated to obtain evidence that **GHP control measures** are **capable of controlling hazards**. **FBOs** may not always need to commission studies themselves to validate GHP control. They **could be based on existing literature, guidance** from competent authority or carried out by a third party e.g. cleaning products validated for effective use by the manufacturer etc. (Aligned with new text created in the Section II for HACCP); ix. Establishing a **GHP Plan** for monitoring, initiating corrective actions, verification of GHPs and **Enhanced GHPs [OPRP (operational prerequisite programme)]**

37. Where **hazard control measures** [GHPs or **enhanced GHPs [OPRP (operational prerequisite programme)]**] are identified **as being unable to reduce the food** [significant] **hazard** to an **acceptable level**¹¹, a **food hygiene system [food safety control system]** based on HACCP [system] should be implemented and this is discussed further in [Chapter 2].

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

Observations on the following paragraphs:

2. The **HACCP system**¹², which is science based and systematic, **identifies specific hazards** [and significant] and **measures for their control to ensure** the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention of hazards rather than relying mainly on end-product testing.

DEFINITIONS

¹¹ **Acceptable level:** The **level of a safety hazard** which is considered to present an **acceptable, low risk to the consumer**. The acceptable level of the final product, sometimes referred to as a **target level**, should be stated in the product description and would normally be set **at, or below, any regulatory limits**. An acceptable level for a hazard at an intermediate step in the commodity flow diagram can be set higher than that of the final product, provided that the **acceptable level in the final product will be achieved**. (*Annex to the document: Manual on the Application of the HACCP System in Mycotoxin Prevention and Control - FAO/IAEA Training and Reference Centre for Food and Pesticide Control - Rome, 2001 - Appendix I: Definition of terms*). It refers to the "Level that does not cause damage or nor there is a significant risk of it".

¹² **HACCP:** A system which identifies, evaluates, and controls hazards which are significant for food safety. *Ref: CAC/RCP 1-1969 - Adopted 1969. Amendment 1999. Revisions 1997 and 2003.*

[Hazard Control Plan] [HACCP plan]¹³: A document prepared in accordance with the principles of **HACCP system**, which identifies appropriate control measures to ensure control of hazards which are **significant** for food safety in the operation [in the segment of the food chain considered]. This could support a system of control measures based [principally] on GHPs alone or a combination of GHPs and [certain] CCP controls.

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

GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

Observations on the following paragraphs:

Panama agrees with the approach reflected in:

25. In some cases, it may be acceptable for a **hazard analysis** to be carried out by **FBOs** which identifies groups of hazards (microbiological, physical, chemical) in order to control the sources of these hazards. Generic HACCP-based tools provided externally, for example, by industry or regulators, are designed to assist with this step.

26. **[Significant hazards]** which are of such a nature that their elimination or reduction to **acceptable levels** is **essential** to the production of **safe food** should be identified and controlled by **hazard control measures designed** to remove or reduce **significant hazards** to an **acceptable level**¹⁴. This may be achieved with the application of **good hygiene practices**, some of which may need to be enhanced [and / or **raise the security level of control** through a **OPRP (operational prerequisite programme)**] to target a specific [and significant] hazard, [for example, cleaning equipment to control contamination of ready-to-eat foods with *Listeria monocytogenes*] include example and cross refer to guidance (under development by the EWG) on hazard analysis). In other instances, hazard control measures will need to be applied at critical control points.]

Spanish

Apéndice I

PRINCIPIOS GENERALES DE HIGIENE DE LOS ALIMENTOS: BUENAS PRÁCTICAS DE HIGIENE (BPH) Y EL SISTEMA DE ANÁLISIS DE PELIGROS Y PUNTOS CRÍTICOS DE CONTROL (APPCC)

Preparado por el Grupo de Trabajo Electrónico (GTE) presidido por el Reino Unido y copresidido por Estados Unidos de América, Francia, Ghana, India y México

(i) Observaciones generales

Panamá respalda, valora y agradece este importante trabajo preparado por el GTE (documento de referencia: CX/FH 17/49/5).

Antecedentes

En su 48.^a reunión (CCFH48), el CCFH acordó crear un GTE, para continuar el trabajo sobre la revisión de los *Principios Generales de Higiene de los Alimentos*, continuar la revisión de la introducción y la segunda (**buenas prácticas de higiene (BPH)**) y tercera parte (**APPCC o HACCP por sus siglas en inglés**) en forma simultánea, para su difusión con objeto de recabar observaciones en el trámite 3; analizar si se deberían incorporar los aspectos relativos al **compromiso** y la **responsabilidad** del personal en materia de inocuidad de los alimentos, entre otros, una **cultura de inocuidad** de los alimentos; y considerar la posibilidad de incorporar **ejemplos de medidas de control en todas las fases de la cadena alimentaria** (incluso de aquellas que no pueden abordarse como PCC), así como un **cuadro comparativo entre BPH, PCC y cualquier otro tipo de medida de control**, para comprender mejor las cuestiones y respaldar el trabajo.

Entre las recomendaciones del GTE al comité destacamos lo siguiente: "Debatir y alcanzar un acuerdo sobre los **conceptos fundamentales** destacados en el **párrafo 8**"ⁱⁱ, para poder continuar el trabajo y

¹³ **HACCP plan:** A document prepared in accordance with the principles of HACCP **to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.** Ref: CAC/RCP 1-1969 - Adopted 1969. Amendment 1999. Revisions 1997 and 2003.

¹⁴ **Acceptable level:** The **level of a safety hazard** which is considered to present an **acceptable, low risk to the consumer**. The acceptable level of the final product, sometimes referred to as a **target level**, should be stated in the **product description** and would normally be set **at, or below, any regulatory limits**. **An acceptable level for a hazard at an intermediate step** in the commodity flow diagram **can be set higher than that of the final product, provided that the acceptable level in the final product will be achieved.** (*Annex to the document: Manual on the Application of the HACCP System in Mycotoxin Prevention and Control - FAO/IAEA Training and Reference Centre for Food and Pesticide Control - Rome, 2001 - Appendix I: Definition of terms*). It refers to the "Level that does not cause damage or nor there is a significant risk of it".

respaldar que se siga elaborando el texto; y determinar las próximas medidas, para que se apruebe el texto en el trámite 5 en 2019 y en el trámite 8 en 2021”.

Conceptos y lineamientos principales:

6. Panamá está de acuerdo en que las **BPH**¹⁵ constituyen la **base fundamental** para que los **Operadores de Empresas de Alimentos (OEA)** apliquen, con **responsabilidad y compromiso**, **medidas adecuadas de control** en **todas las fases de la cadena alimentaria**, desde la **producción primaria hasta el consumo final**, estableciendo las **condiciones de higiene necesarias** para la producción de **alimentos inocuos y aptos para el consumo**, contribuyendo con ello al fomento de una **cultura de inocuidad** de los alimentos.

7. Panamá considera que los **OEA** deberían definir cuáles son las **medidas de control de higiene básicas [y necesarias]** que se deben efectuar en **cada etapa**¹⁶ según la **naturaleza de la operación** y los **contaminantes pertinentes**.

8. Panamá esta de acuerdo con la recomendación dada por el CCFH relativa a la adopción, siempre que sea posible, de un **enfoque basado** en el **Sistema de APPCC**¹⁷ [**HACCP por sus siglas en ingles**] para **“elevar el nivel de inocuidad de los alimentos”**.

➤ El **Sistema de HACCP**, permite **identificar, evaluar y controlar peligros [específicos] significativos [y medidas para su control]** con el fin de **garantizar** la inocuidad de los alimentos.

➤ El **Sistema de HACCP** puede **aplicarse a lo largo de toda la cadena alimentaria**, desde el productor primario hasta el consumidor final.

➤ La **finalidad** del **sistema de HACCP** es lograr que **el control se centre en los PCC**.

➤ El **Sistema de HACCP** deberá **aplicarse por separado a cada operación concreta**. Dicho **ámbito de aplicación** determinará qué **segmento de la cadena alimentaria está involucrado** y qué **categorías generales de peligros** han de abordarse (por ejemplo, indicará si se abarca toda clase de peligros o solamente ciertas clases).

➤ El **equipo de HACCP** deberá enumerar **todos los peligros** que puede razonablemente preverse que se producirán en **cada fase, desde la producción primaria, la elaboración, la fabricación y la distribución hasta el punto de consumo**.

➤ El **equipo de HACCP** deberá llevar a cabo un **análisis de peligros** para identificar, en relación con el **plan de HACCP**, cuáles son los peligros cuya **eliminación o reducción a niveles aceptables** resulta indispensable**, por su naturaleza, **para producir un alimento inocuo**.

➤ El **equipo de HACCP** deberá construir un **diagrama de flujo**. Éste ha de **abarcar todas las fases de las operaciones relativas a un producto determinado**.

➤ Al aplicar el **sistema de HACCP** a una **operación determinada**, deberán tenerse en cuenta las **fases anteriores y posteriores** a dicha operación.

➤ Si bien aquí se ha considerado la **aplicación del sistema de HACCP** a la **inocuidad de los alimentos**, el concepto **podría** aplicarse a **otros aspectos de la calidad de los alimentos**.

9. Panamá considera que el **“árbol de decisión”**¹⁸ que se aplica actualmente para **identificar los PCC**, es funcional y adecuado. No obstante, aunque está de acuerdo con el GTE en que se debería revisar el mismo, considera que la clave de la **“aparente dificultad en su aplicación”** estaría en la correcta

¹⁵ **Higiene de los alimentos:** Todas las **condiciones y medidas necesarias** para **asegurar** la inocuidad y la aptitud de los alimentos **en todas las fases de la cadena alimentaria**. (CAC/RCP-1 (1969), Rev. 3 (1997), enmendado en 1999).

¹⁶ **Fase:** Cualquier punto, procedimiento, operación o etapa de la cadena alimentaria, incluidas las materias primas, desde la producción primaria hasta el consumo final. Ref: **SISTEMA DE ANÁLISIS DE PELIGROS Y DE PUNTOS CRÍTICOS DE CONTROL (HACCP) - DIRECTRICES PARA SU APLICACIÓN - Anexo al CAC/RCP 1-1969, Rev. 4 (2003)**.

¹⁷ Ref: **CAC/RCP-1 (1969), Rev. 3 (1997), enmendado en 1999**.

¹⁸ **DIAGRAMA 2 - EJEMPLO DE UNA SECUENCIA DE DECISIONES PARA IDENTIFICAR LOS PCC (responder a las preguntas por orden sucesivo): P1 ¿Existen medidas preventivas de control?; P2 ¿Ha sido la fase específicamente concebida para eliminar o reducir a un nivel aceptable la posible presencia de un peligro?; P3 ¿Podría producirse una contaminación con peligros identificados superior a los niveles aceptables, o podrían estos aumentar a niveles inaceptables?; P4 ¿Se eliminarán los peligros identificados o se reducirá su posible presencia a un nivel aceptable en una fase posterior?.**

** Los **niveles aceptables** u inaceptables **necesitan ser definidos** teniendo en cuenta los objetivos globales cuando se identifican los PCC del plan de HACCP.

interpretación de la definición de lo que se entiende como “un nivel aceptable”¹⁹ de la “posible presencia de un peligro”.

10. Panamá considera que “dependiendo de los **requerimientos específicos de seguridad en los procedimientos de control exigidos** para cumplir con un “**adecuado nivel de control**”, con fundamento en un **análisis de peligros**²⁰ (en el marco de un análisis de riesgo), habría que decidir si se considera suficiente la aplicación solo de BPH o si es necesario la **aplicación rigurosa de un plan documentado** basado en los 7 principios del sistema HACCP (**Plan de HACCP**)”.

Ref.: SISTEMA DE ANÁLISIS DE PELIGROS Y DE PUNTOS CRÍTICOS DE CONTROL (HACCP) - DIRECTRICES PARA SU APLICACIÓN - Anexo al CAC/RCP 1-1969, Rev. 4 (2003).

(ii) Observaciones específicas

8. Panamá está de acuerdo con “la necesidad de continuar analizando algunos principios fundamentales”; sin embargo, considera que **todas las empresas alimentarias** u **Operadores de Empresas de Alimentos (OEA)** deberían llevar a cabo un **análisis de peligros (al menos básico)**.

9. Con respecto a la propuesta de introducir el concepto: “**BPH mejoradas**”, Panamá es de la opinión que el mismo podría ser considerado técnicamente como equivalente al concepto de “**PRO (prerrequisito operativo)**”^{21*}

10. Nota: Se han propuesto distintas versiones del **párrafo 4** (4A y 4B) que abarcan los posibles resultados de los próximos debates sobre si se debería exigir a **todas las empresas alimentarias la realización de análisis de peligros**. Observaciones:

4. [A. Los **programas de requisitos previos (PRP)**, que incluyen las **buenas prácticas de higiene (BPH)**, las **buenas prácticas de fabricación (BPF)** y las **buenas prácticas agrícolas (BPA)**, según proceda, **constituyen la base** para producir alimentos **inocuos e idóneos**.] [Las **BPH** se aplican en líneas generales a **todas las empresas alimentarias** sin necesidad de llevar a cabo un análisis de peligros. En relación con los **recursos externos** (modelos existentes, referencias, normas, reglamentación o códigos de prácticas proporcionados por la autoridad competente, el Codex o la industria alimentaria), ~~puede~~ [podría] establecerse que, para que algunos **operadores de empresas de alimentos**, las **BPH** son suficientes para que **controlen todos [determinados] los** peligros para la inocuidad alimentaria. Sin embargo, como **no todos los peligros plantean el mismo riesgo**, puede que sea necesario prestar especial atención a **determinados peligros** que un **análisis de peligros** específico para el lugar [más especializado y estricto] haya determinado que son **significativos** y aplicar **[medidas de control [específicas]** en los **puntos críticos de control (PCC)** [en el marco de un **plan de análisis de peligros y puntos críticos de control (APPCC)**] o en otros lugares distintos] ~~o [medidas de control de APPCC] en el marco de un sistema (plan) de análisis de peligros y puntos críticos de control (APPCC)~~ (véase el cuadro comparativo más adelante). Los **operadores de empresas de alimentos** que carezcan de los **recursos necesarios** para llevar a cabo un **análisis de peligros** [específico para el lugar (más especializado y estricto²²)] pueden utilizar los **recursos externos** indicados anteriormente o **planes genéricos de APPCC** proporcionados por la autoridad competente o la industria alimentaria¹, que deben adaptarse al lugar concreto].

O [4B es otra **versión alternativa** de este párrafo si las delegaciones apoyan el **enfoque de que todos los operadores de empresas de alimentos realicen un análisis de peligros**]

¹⁹ **Nivel aceptable:** **Nivel bajo de peligro** para la **inocuidad** que se considera que **supone un riesgo aceptable para el consumidor**. El nivel aceptable del producto final, denominado a veces **nivel previsto**, deberá declararse en la **descripción del producto** y normalmente se fijará en un **nivel igual o inferior al límite reglamentario**, si lo hay. En una **fase intermedia** del diagrama de flujo del producto **se puede fijar para un peligro un nivel aceptable superior al del producto final**, a condición de que en éste se alcance el nivel aceptable. (Anexo al documento: **Manual Sobre la Aplicación del Sistema de Análisis de Peligros y de Puntos Críticos de Control (APPCC) en la Prevención y Control de las Micotoxinas - Centro de Capacitación y Referencia FAO/OIEA para el Control de los Alimentos y los Plaguicidas - Roma, 2003 - Apéndice I: Definiciones de los términos**). Se refiere al “*Nivel que no produzca daño ni exista un riesgo significativo de ello*”.

²⁰ **Análisis de peligros:** Proceso de recopilación y evaluación de información sobre los peligros y las condiciones que los originan **para decidir cuáles son importantes con la inocuidad de los alimentos** y, por tanto, **planteados en el plan** del Sistema de HACCP. Ref: CAC/RCP-1 (1969), Rev. 3 (1997), enmendado en 1999.

²¹ ***Observación:** “...considerar que son **medidas de control esenciales** para el control del peligro, pero no tienen el control “**absoluto**” sobre el peligro. Además, el **prerrequisito operativo** puede trabajar en combinación con otras medidas de control para prevenir, eliminar, reducir o mantener un peligro a un **nivel aceptable**; incluso pueden encontrarse en distintas etapas del proceso. Y por último, **su falla no implica automáticamente que un producto sea peligroso**”.

²² ***Observación:** **análisis de peligros específico para el lugar:** análisis de peligros más **especializado y estricto** (diferente de básico) que permita un “**alto nivel de control y/o de garantía o aseguramiento de la inocuidad**”.)

4. [B. Los **programas de requisitos previos (PRP)**, que incluyen las **buenas prácticas de higiene (BPH)**, las **buenas prácticas de fabricación (BPF)** y las **buenas prácticas agrícolas (BPA)**, según proceda, establecen las bases para producir alimentos **inocuos e idóneos.**] [Las **BPH** se aplican en líneas generales a **todas las empresas alimentarias.** Tras un **análisis básico de peligros** y una **evaluación** de las **medidas de higiene** [aplicables] de los alimentos, ~~puede~~ [podría] **decidirse** que las **BPH** **son suficientes** para que **algunos operadores de empresas de alimentos** **controlen todos [determinados] los peligros** para la inocuidad alimentaria. En **otros casos**, **puede** que sea necesario prestar especial atención a **determinados peligros** que se haya establecido son **significativos** a través de un **análisis de peligros** específico para el lugar (más especializado y estricto) y aplicar **medidas de control** (específicas) **en los puntos críticos de control (PCC)** [en el marco de un **plan de análisis de peligros y puntos críticos de control (APPCC)**] o en **otros lugares distintos**] ~~o [medidas de control de APPCC] en el marco de un sistema (plan) de análisis de peligros y puntos críticos de control (APPCC)~~ (véase el cuadro comparativo más adelante). Los **operadores de empresas de alimentos** que carezcan de los recursos necesarios para llevar a cabo **análisis de peligros** específicos para el lugar (más especializados y estrictos ²³) pueden utilizar modelos, referencias, normas, reglamentaciones o códigos de prácticas existentes o planes genéricos de APPCC proporcionados por la autoridad competente o la industria alimentaria², que deben adaptarse al lugar concreto.]

11. Luego de una revisión detallada y análisis respectivo, **Panamá propone al GTE y CCFH** considere una **tercera versión del párrafo 4** (4C) que intenta abarcar posibles resultados de los próximos debates incluyendo la posibilidad de exigirle a **todas las empresas alimentarias la realización de un análisis de peligros, al menos básico:**

4. [C. Los **programas de requisitos previos (PRP)**, que incluyen las **buenas prácticas de higiene (BPH)**, las **buenas prácticas de fabricación (BPF)** y las **buenas prácticas agrícolas (BPA)**, según proceda, constituyen la **base** para producir alimentos **inocuos e idóneos.**] [Las **BPH** se aplican en líneas generales a **todas las empresas alimentarias.** Tras un **análisis básico de peligros** y una **evaluación** de las **medidas de higiene** (aplicables) de los alimentos, ~~podría~~ **decidirse** que las **BPH** **son suficientes** para que **algunos operadores de empresas de alimentos** **controlen determinados peligros** para la inocuidad alimentaria. Sin embargo, como **no todos los peligros plantean el mismo riesgo**, **puede** que sea necesario prestar especial atención a **determinados peligros** que un **análisis de peligros específico para el lugar (más especializado y estricto)** haya determinado que son **significativos** y aplicar **medidas de control** (específicas) en los **puntos críticos de control (PCC)** en el marco de un **plan de análisis de peligros y puntos críticos de control (APPCC) o en otros lugares distintos**] (véase el cuadro comparativo más adelante). Los **operadores de empresas de alimentos** que carezcan de los recursos necesarios para llevar a cabo **análisis de peligros específicos** para el lugar (**más especializados y estrictos**) pueden utilizar modelos, referencias, normas, reglamentaciones o códigos de prácticas existentes o **planes genéricos de APPCC** ~~proporcionados~~ (validados) por la autoridad competente o la industria alimentaria², que **deben adaptarse al lugar concreto.**]

12. **Comparación entre las BPH [medidas de control en lugares distintos de los PCC] [BPH mejoradas] [PPRO (prerrequisito operativo)] y las medidas de control de APPCC [PCC]**

Panamá está de acuerdo, en términos generales, con el contenido del cuadro de referencias a las **medidas de control en lugares distintos de los PCC** o **BPH mejoradas [PPRO (prerrequisito operativo)]**. Sin embargo, Panamá ha propuesto que en substitución del uso término "**BPH mejoradas**", el cual hace referencia a "ciertas medidas de control en lugares distintos de los PCC", la utilización del término "**PPRO (prerrequisito operativo)**".

13. Con respecto al **ANEXO I - Árbol de decisión propuesto para identificar [BPH mejoradas] [PPRO (prerrequisito operativo)]**, Panamá está de acuerdo, en términos generales con el contenido del mismo; sin embargo, considera conveniente aplicar el concepto "**PPRO (prerrequisito operativo)**"; y el concepto de "**nivel aceptable**" como "*el nivel bajo de peligro para la inocuidad que se considera que supone un riesgo aceptable para el consumidor. El nivel aceptable del producto final, denominado a veces nivel previsto, deberá declararse en la descripción del producto y normalmente se fijará en un nivel igual o inferior al límite reglamentario, si lo hay. En una fase intermedia del diagrama de flujo del producto se puede fijar para un peligro un nivel aceptable superior al del producto final, a condición de que en éste se alcance el nivel aceptable*". Ref.: Anexo al documento: Manual Sobre la Aplicación del Sistema de Análisis de Peligros y de Puntos Críticos de Control (APPCC) en la Prevención y Control de las Micotoxinas - Centro de Capacitación y Referencia FAO/OIEA para el Control de los Alimentos y los

²³ Ídem.

^(1y2) Directrices FAO/OMS para los gobiernos sobre la aplicación del sistema de APPCC en **empresas alimentarias pequeñas y/o menos desarrolladas** ISSN 0254-4725.)

Plaguicidas - Roma, 2003 - Apéndice I: Definiciones de los términos). Se refiere al “Nivel que no produzca daño ni exista un riesgo significativo de ello”.

14. Con respecto al primer y segundo capítulo, Panamá presenta algunas observaciones:

[PRIMER CAPÍTULO] - BUENAS PRÁCTICAS DE HIGIENE - SECCIÓN II: CONTROL DE LAS OPERACIONES - CONTROL DE LOS PELIGROS ALIMENTARIOS

Observaciones a los siguientes párrafos:

34. Las **BPH** controlan la **mayoría de los peligros alimentarios que pueden** [contaminar] **[y/o estar presentes en]** los productos alimenticios, es decir, a través de los **manipuladores de alimentos**, **los insumos de materias primas u otros ingredientes** o el **entorno de trabajo**. Un **análisis básico de peligros** debería establecer si la aplicación de **BPH es suficiente** [adecuada] para que **algunos operadores de empresas de alimentos** controlen todos [determinados] los **peligros** alimentarios pertinentes **[significativos]**.

35. Si se **identifican peligros significativos** para la inocuidad alimentaria [y/o si se requiere un **mayor nivel de control, protección, seguridad y/o confianza**] y es necesario un enfoque más específico [y/o estricto], deberían aplicarse **medidas de control** [más efectivas y/o estrictas] para **peligros** específicos [y significativos]. Dichas **medidas de control** para **peligros** [específicos] [y significativos] pueden basarse en **BPH diseñadas** para controlar un **peligro** específico [y significativo] para la inocuidad alimentaria, como limpiar una cortadora de carne para controlar la presencia de *Listeria monocytogenes*. Estas BPH ‘mejoradas’ **[PPRO (prerrequisito operativo)]** debería estar sometidas a vigilancia, a medidas correctivas y a verificación y, cuando proceda, deberían documentarse.

36. [Los **operadores de empresas de alimentos** deberían **controlar los peligros** alimentarios a través de un **sistema de análisis de peligros** que incluya: i. Describir el producto; ii. Los requisitos reglamentarios aplicables; iii. Determinar el uso previsto – Listo para el consumo o material [producto] que será sometido a una **elaboración ulterior**; iv. Elaborar un diagrama de flujo; v. Llevar a cabo un **análisis de peligros** para establecer los peligros para la inocuidad alimentaria de tipo microbiológico, químico o físico en cada fase del diagrama de flujo; vi. Identificar y definir las **buenas prácticas de higiene** para controlar estos peligros; vii. **Clasificar** los **controles de BPH** como **controles genéricos** [de los peligros] o **controles basados en los peligros [específicos y significativos]** para manejarlos como BPH mejoradas **[PPRO (prerrequisito operativo)]** o bien a través de la aplicación de [medidas de control específicas en los **puntos críticos de control (PCC)** en el marco de un **plan de análisis de peligros y puntos críticos de control (APPCC)**,] **los principios de APPCC** utilizando un **modelo de árbol de decisión** como el que figura en el [Anexo I de la introducción]. viii. **Validación / eficacia** de las BPH mejoradas **[PPRO (prerrequisito operativo)]**: Se deberían validar las BPH mejoradas **[PPRO (prerrequisito operativo)]** para obtener pruebas de que las **medidas de control basadas en BPH** son **capaces de controlar los peligros**. Puede que los **operadores de empresas de alimentos** no siempre necesiten encargar ellos mismos estudios para validar el control mediante BPH. Las **validaciones podrían basarse** en las **publicaciones existentes**, en **orientaciones** de la autoridad competente o ser realizadas por terceros, como en el caso de los productos de limpieza de eficacia validada por el fabricante. (En consonancia con el nuevo texto de la sección II para APPCC). ix. Creación de un **plan de BPH** para llevar a cabo la vigilancia, iniciar medidas correctivas, verificar las BPH y las BPH mejoradas **[PPRO (prerrequisito operativo)]**.]

37. Si se determina que las **medidas de control** de los **peligros** [BPH o BPH mejoradas **[PPRO (prerrequisito operativo)]**] **no son capaces de reducir el peligro alimentario [significativos] hasta un nivel aceptable²⁴**, se debería aplicar un **sistema de higiene de los alimentos [sistema de control de la inocuidad de los alimentos]** basado en [el sistema] APPCC y se profundiza sobre esta cuestión en el [segundo capítulo].

[SEGUNDO CAPÍTULO] - SISTEMA DE ANÁLISIS DE PELIGROS Y DE PUNTOS CRÍTICOS DE CONTROL (APPCC) Y DIRECTRICES PARA SU APLICACIÓN

Observaciones a los siguientes párrafos:

²⁴ **Nivel aceptable: Nivel bajo de peligro** para la inocuidad que se considera que supone un **riesgo aceptable para el consumidor**. El nivel aceptable del producto final, denominado a veces **nivel previsto**, deberá declararse en la descripción del producto y normalmente se fijará en un **nivel igual o inferior al límite reglamentario**, si lo hay. En una **fase intermedia** del diagrama de flujo del producto **se puede fijar para un peligro un nivel aceptable superior al del producto final, a condición de que en éste se alcance el nivel aceptable**. (Anexo al documento: Manual Sobre la Aplicación del Sistema de Análisis de Peligros y de Puntos Críticos de Control (APPCC) en la Prevención y Control de las Micotoxinas - Centro de Capacitación y Referencia FAO/OIEA para el Control de los Alimentos y los Plaguicidas - Roma, 2003 - Apéndice I: Definiciones de los términos). Se refiere al “Nivel que no produzca daño ni exista un riesgo significativo de ello”.

2. El **sistema de APPCC**²⁵, que tiene fundamentos científicos y un carácter sistemático, permite **identificar peligros específicos [y significativos] y medidas para su control** con el fin de **garantizar** la **inocuidad** de los alimentos. El APPCC es un instrumento para evaluar los peligros y establecer sistemas de control que se centran en la prevención, en lugar de basarse principalmente en realizar pruebas sobre el producto final.

DEFINICIONES

~~[Plan de control de los peligros]~~ **[Plan de APPCC o HACCP, por sus siglas en inglés]²⁶: Documento** preparado de conformidad con los principios del **sistema de HACCP**, que identifica **medidas de control adecuadas** para **garantizar el control** de los **peligros significativos** para la inocuidad de los alimentos ~~en la actividad~~ **[en el segmento de la cadena alimentaria considerado]**. Podría respaldar un sistema de medidas de control basadas **únicamente [principalmente] en BPH**, o en una combinación de **BPH** y de ~~controles de~~ **[determinados] PCC**.

~~[Plan de APPCC: Un plan de control de peligros que ha determinado puntos críticos de control].~~

DIRECTRICES PARA LA APLICACIÓN DEL SISTEMA DE APPCC

Observaciones a los siguientes párrafos:

Panamá está de acuerdo con el enfoque reflejado en:

25. En algunos casos, puede ser aceptable que los **operadores de empresas de alimentos** lleven a cabo un **análisis de peligros**, que identifique grupos de peligros (microbiológico, físico, químico) para controlar las fuentes de estos peligros. Los instrumentos genéricos basados en APPCC obtenidos externamente, por ejemplo, procedentes de la industria o de los organismos reguladores, están concebidos para prestar ayuda en esta fase.

26. Se deberían determinar y controlar [los **peligros significativos**] que sean de tal naturaleza que su eliminación o reducción a **niveles aceptables** resulte **fundamental** para la producción de alimentos **inocuos**, mediante **medidas de control de los peligros diseñadas** para eliminar o reducir **peligros significativos** a un **nivel aceptable**²⁷. Esto puede lograrse mediante la aplicación de **buenas prácticas de higiene**, algunas de las cuales puede ser necesario mejorar [y/o **eleva el nivel de seguridad del control** mediante un **PRO (prerrequisito operativo)**] para hacer frente a un **peligro específico [y significativo]** [por ejemplo la limpieza del equipo para control de la contaminación de alimentos listos para el consumo con *Listeria monocytogenes*] incluir un ejemplo y hacer referencia a las orientaciones (que está elaborando el GTE) sobre análisis de peligros). En otros casos, se deberán aplicar las medidas de control de los peligros a los puntos críticos de control.]

Senegal

Observation générale : veiller à la traduction partout du terme « Hazard » en « danger » dans la version française

Contexte : Para. 8(i): toutes les entreprises devraient mener à bien une analyse des **risques dangers**

Position: Le Sénégal recommande que l'analyse de **risques dangers** ne soit pas une obligation pour toutes les entreprises alimentaires.

Justification : Toutes les entreprises du secteur alimentaire ne sont pas en mesure d'effectuer une analyse des risques et de mettre en œuvre les principes HACCP. Cependant, les entreprises alimentaires ont la responsabilité de s'informer et d'être conscientes des dangers associés à leurs processus. Les entreprises alimentaires peuvent demander des informations auprès des autorités compétentes ou d'autres organismes reconnus. Les petites entreprises devraient être encouragées à mettre en œuvre de bonnes pratiques d'hygiène plus réalisables à leur niveau qu'au système HACCP.

²⁵ **Sistema de HACCP:** Sistema que permite identificar, evaluar y controlar peligros significativos para la inocuidad de los alimentos. *Ref: CAC/RCP-1 (1969), Rev. 3 (1997), enmendado en 1999.*

²⁶ **Plan de HACCP:** Documento preparado de conformidad con los principios del sistema de HACCP, de tal forma que su cumplimiento **asegura el control de los peligros que resultan significativos para la inocuidad de los alimentos en el segmento de la cadena alimentaria considerado**. *Ref: CAC/RCP-1 (1969), Rev. 3 (1997), enmendado en 1999.*

²⁷ **Nivel aceptable:** **Nivel bajo de peligro** para la inocuidad que se considera que supone un riesgo aceptable para el consumidor. El nivel aceptable del producto final, denominado a veces **nivel previsto**, deberá declararse en la descripción del producto y normalmente se fijará en un **nivel igual o inferior al límite reglamentario**, si lo hay. En una fase intermedia del diagrama de flujo del producto se puede fijar para un peligro un nivel aceptable superior al del producto final, a condición de que en éste se alcance el nivel aceptable. (**Anexo al documento CAC/RCP-1 (1969), Rev. 3 (1997)**). Se refiere al "Nivel que no produzca daño ni exista un riesgo significativo de ello".

Contexte : Para. 8(ii): L'introduction du terme "BPH renforcées".

Position : Le Sénégal ne soutient pas l'introduction du terme "BPH renforcées".

Les nouvelles terminologies ne devraient pas être introduites même si certaines mesures de contrôle peuvent nécessiter plus d'attention, de validation et de surveillance, par ex. *Listeria* dans l'environnement, la contamination des allergènes et tout cela devrait être prise en compte par la formation. De plus, l'objectif de l'introduction du concept de « GHP amélioré » peut être résolu par la mise en œuvre efficace des BPF.

Para 8 (iii): Bonnes Pratiques d'Hygiène - Production Primaire

Contexte : La section sur la production primaire (CAC / RCP 1-1969) devrait-elle être conservée dans le document actuel ?

Position : Le Sénégal soutient la nécessité de garder une section distincte sur la production primaire dans le document actuel.

Justification : Certaines dispositions s'appliquent uniquement à la production primaire qui a des exigences spécifiques. Dans ce cas, le Sénégal recommande l'inclusion de la section sur la production primaire. Cependant, la section devrait être développée à part pour renforcer les références dans tout le document pour montrer comment les directives s'appliquent à toutes les étapes de la chaîne alimentaire.

Contexte: Par. 9: Alignement des terminologies du Codex sur ISO 22000

Position : Le Sénégal n'appuie pas l'alignement de la terminologie du Codex sur l'ISO 22000 pour l'instant. La question devrait être revue lorsque la révision initiée par l'ISO 22 000 sera terminée.

Justification : L'ISO 22000 est actuellement en cours de révision. Par conséquent, il faut attendre la finalisation de la révision. Le travail du Codex doit rester la base et la source d'autres normes.

Contexte: Annexe I, par. 4: Autres paragraphes suggérés 4A et 4B:

Position du Sénégal: Les deux paragraphes introductifs sont acceptables. Cependant, le Sénégal soutient l'adoption du paragraphe 4A. De plus, le paragraphe devrait être révisé selon les besoins des petites entreprises.

Justification: Le paragraphe 4A offre plus de flexibilité pour les petites entreprises et est dépourvu du concept « **BPH renforcées** » qui sera difficile à comprendre et à mettre en œuvre par de petites entreprises. Il souligne également que les BPH sont suffisants pour que certaines entreprises alimentaires contrôlent tous les dangers liés à la salubrité des aliments.

Annexe i: Champ d'application

Contexte : l'utilisation du mot « conditions » dans l'expression « conditions de sécurité alimentaire » et la restriction des pratiques d'hygiène nécessaires à mettre en œuvre uniquement lors de la fabrication de produits alimentaires

Position : Le Sénégal recommande le remplacement du mot « conditions » par le mot « mesures » et le remplacement du mot « dans la fabrication » par « le long de la chaîne alimentaire » dans la deuxième ligne du champ d'application. Le nouveau champ d'application se lira comme suit: « Ce document constitue un cadre de principes généraux pour la production d'aliments sûrs et appropriés pour la consommation humaine en définissant les mesures d'hygiène et de salubrité alimentaire nécessaires à certaines étapes de la chaîne alimentaire.>>

Justification : L'énoncé fournit la clarté et l'application des mesures de contrôle de la salubrité des aliments non seulement dans la fabrication, mais dans toute la chaîne alimentaire.

Annexe I: Définitions

Contexte : La définition de "BPH renforcées"

Position : Il n'est pas nécessaire de définir «**BPH renforcées**»

Justification : Le terme "**BPH renforcées**" peut être pris en charge par les **BPH**. En outre, il s'agit d'éviter les confusions et les difficultés dans la mise en œuvre des BPH parmi les opérateurs économiques, en particulier les petites entreprises. L'application des BPH dans les entreprises devrait être encouragée car plus simple et plus facile à mettre en œuvre.

Contexte: Annexe I: Définition de "Système d'hygiène alimentaire"

Position: Le Sénégal est favorable à la définition actuelle de "Systèmes d'hygiène alimentaire".

Justification : Le concept du principe actuel qui sous-tend la définition englobe l'idée que l'hygiène alimentaire comprend la sécurité et la convenance. Cette définition est également conforme à la définition donnée dans le Manuel de procédure du Codex.

Contexte : **Annexe I: Arbre de décision proposé pour identifier "GHP amélioré"**

Position : Le Sénégal considère l'arbre de décision proposé comme utile. Cependant, par souci de clarté, il est nécessaire de changer l'énoncé «passer à l'étape suivante, commencer par Q1» par «étape suivante du processus, commencez par Q1».

Justification : Fournit une clarté dans les étapes de l'arbre de décision.

Section I: Conception de l'établissement et installations

Contexte : **Définir les limites du site et l'aménagement paysager d'une installation alimentaire**

Position : Le Sénégal ne soutient pas la définition des limites du site et l'aménagement paysager des installations alimentaires et suggère donc de supprimer l'énoncé **«Les limites du site devraient être clairement définies. L'aménagement paysager à proximité d'une installation alimentaire devrait être conçu de manière à minimiser les attractifs et les ravageurs. Le cas échéant, les experts devraient être consultés pour des conseils sur les plantes appropriées à l'aménagement paysager »**

Justification : Les dispositions de la déclaration sont trop prescriptives. Plusieurs mesures de lutte antiparasitaire peuvent permettre de réduire au minimum l'attrait des ravageurs et le portage.

Para 13: Drainage et élimination des déchets

Contexte : **Il est nécessaire de clarifier l'emplacement du site de collecte / d'élimination des déchets.**

Position : L'énoncé actuel de la section 13 «**Drainage et élimination des déchets**» doit être modifié. L'énoncé **«Le site de collecte / élimination des déchets doit être situé loin de l'établissement alimentaire pour prévenir l'infestation des organismes nuisibles»** devrait être remplacé par l'énoncé **«La collecte des déchets sur place doit être effectuée de manière à prévenir l'infestation des parasites et la contamination croisée des aliments . Le site d'élimination des déchets devrait être situé loin de l'établissement alimentaire pour prévenir l'infestation et la contamination par les ravageurs »**.

Justification : Les phrases proposées clarifient la responsabilité du secteur alimentaire en veillant à ce que la collecte et l'élimination des déchets soient effectuées de manière à prévenir l'infestation par les ravageurs et la contamination croisée des aliments.

Para. 28-33 Section II : Contrôle des opérations - Sections supplémentaires sur le produit, la description du procédé, la procédure de suivi

Problème/Contexte: Des sections supplémentaires sur la description du produit, la description du processus et les procédures de suivi devraient-elles être incluses dans le texte?

Position: Le Sénégal n'est pas favorable avec les sections supplémentaires sur la description du produit, la description du processus et les procédures de surveillance. En plus, pour la question de la praticabilité des documents et autres pour toutes les entreprises, le Sénégal propose de l'examiner plus attentivement pour voir s'il y a lieu d'accorder plus de souplesse en utilisant les mots «le cas échéant»

Justification: Les sections supplémentaires proposées sont abordées de manière adéquate dans la section qui couvre le système HACCP. Par conséquent, il n'est pas nécessaire de les inclure dans la section II. Ceci afin d'éviter la duplication et la complication dans la mise en œuvre.

Para. 48-Contamination allergénique

Position: Le Sénégal soutient le texte tel que rédigé par le GTe sur la contamination allergénique et la nécessité d'informer les consommateurs lorsqu'il est possible qu'une contamination croisée par des aliments contenant des allergènes ne puisse être évitée.

Raisonnement : La technologie actuelle pourrait ne pas être en mesure d'éliminer toutes les traces d'allergènes. De même, les BPH peuvent ne pas être en mesure de prévenir de manière adéquate la contamination involontaire par des substances allergènes.

Paragraphe 66 : Section III : Note entre crochets

Question / Contexte : **Note au paragraphe.66 entre crochets**

Position : Le Sénégal propose de supprimer les crochets sur cette partie.

Justification : L'énoncé implique la nécessité de dédier les outils de nettoyage en fonction de l'état d'hygiène des zones Cela est conforme aux BPH.

► Paragraphe 68

Pas besoin de définir le mot nettoyage (**Sanitation**)

- Des inquiétudes ont été exprimées quant au fait que le document appelle la formation des membres d'équipage de poissons dans les principes HACCP dans la mesure du possible et que ce ne soit peut-être pas pratique pour les petits opérateurs d'autres pays. Le comité devra examiner si la réponse du GTE à cette préoccupation est acceptable.
- Le Sénégal soutient l'avancement du document à l'étape 5, avec le tableau des espèces de poissons entre crochets, à condition que le CCFH soit en mesure de résoudre les problèmes soulevés dans les commentaires à la session concernant le statut des salmonidés impliqués dans la production d'histamine. Dans le cas contraire, le document ne devrait pas avancer.
- Poulie X22 4 - Une préoccupation a été exprimée quant à savoir s'il convient d'envisager de rejeter un lot entier de livraison de navire «à risque» en fonction d'une température interne dans un échantillon de poisson dépassant 4° C. comme indiqué dans le document.

Para. 69 : Section III : Programmes d'assainissement [Nettoyage et désinfection]

Question / Contexte : Déclaration au para. 69 cherche à définir l'assainissement.

Position : Le Sénégal soutient la définition de «assainissement» et recommande donc de maintenir la définition entre crochets.

Justification : Fournit une clarté et une mise en œuvre facile.

CHAPITRE 2: Définitions : Système d'analyse des risques et de points critiques (HACCP) et lignes directrices pour son application / ses définitions de GHP et HACCP.

Question / Contexte : Définition de «mesure de maîtrise des risques» à élaborer et «plan de maîtrise des risques» entre crochets

Position : Le Sénégal n'appuie pas l'élaboration des définitions de «mesure de maîtrise des risques» et du «plan de maîtrise des risques».

Justification : La définition de «mesure de maîtrise» est définie dans la terminologie HACCP comme «toute action ou activité pouvant être utilisée pour prévenir ou éliminer un danger pour la salubrité des aliments ou pour le ramener à un niveau acceptable». Cette définition présuppose que les mesures de contrôle sont applicables aux dangers. De plus, le «Plan HACCP» est défini comme «un document préparé conformément aux principes HACCP pour assurer la maîtrise des dangers significatifs pour la sécurité alimentaire dans le segment de la chaîne alimentaire considéré». Cette définition est suffisante pour prendre en compte les risques significatifs que la définition proposée du «plan de contrôle HACCP» vise à contrôler. Par conséquent, le besoin de définir une «mesure de maîtrise des risques» n'est pas nécessaire. Le «Plan de maîtrise des dangers» avec sa définition proposée peut créer une confusion dans le choix d'un système de mesures de contrôle basé sur le seul GHP ou une combinaison.

Para. 26: Application des principes HACCP

Enjeux / Contexte : Le terme «dangers significatif» entre crochets a été défini.

Position: Le Sénégal recommande de reconsidérer le concept de «dangers significatifs» et son application dans le cadre du système HACCP et demande que le GTE donne des orientations à cet effet.

Raisonnement : l'idée selon laquelle «Les dangers significatifs » sont proposés est de nature à rendre leur élimination ou leur réduction à un niveau acceptable pour des aliments sains et qui doivent être contrôlés par des «mesures de maîtrise des dangers» conçues pour éliminer ou ramener les dangers significatifs à un niveau acceptable. Cela peut se faire par l'application des bonnes pratiques d'hygiène. Cela peut rendre plus difficile la compréhension et la mise en œuvre du principe du danger significatif et des «Bonnes Pratiques d'Hygiène», en particulier pour différencier les BPH des «BPH renforcées».

Thailand

We would like to thank the Electronic Working Group for preparing the draft. We would like to provide general and specific comments as follows:

1. Should all businesses complete a hazard analysis?

Thailand does not think that all business should complete hazard analysis. For example, farmer and business producing low risk food may not need to conduct any hazard analysis. Farmer, specifically small holders, may not have enough knowledge and resource to conduct even basic hazard analysis. Farmer should be able to follow related Good Agricultural Practices without completing the hazard analysis.

The competent authority should be able to determine which type of food or business should or should not complete the basic hazard analysis.

Furthermore, specific food of which Codex's specific standard (Code of Hygienic Practice for Eggs and Egg Products, Code of Hygienic Practice for Meat, Code of Practice for Fish and Fishery Products) has already covered such as eggs, meat, milk and fish should be able to skip the basic hazard analysis since the related practices covered by different Codes are already based on science.

The basic hazard analysis as appeared in Annex I Proposed Decision Tree to Identify [Enhanced GHPs] is still difficult to use. The business still need knowledge and resource to consider every question together with the document appeared in detail in Chapter 1 paragraphs 28-33.

If needed, the basic hazard analysis should be done through the use of existed model and published resource. It should be easy for the business and use less resource compared to the full hazard analysis under HACCP.

Also, the business that has already adopted the HACCP system should not have to complete basic hazard analysis again.

2. The current approach remains appropriate or the concept of control measures at other places than CCPs should be introduced.

Currently, other places than CCPs are already controlled but they may be called differently such as SOP, SSOP, OPRP, control point or enhanced GHP. The explanation should be clearly given in the revised text.

3. Primary production should be addressed by a specific section or not?

We do not agree with the deletion of the Section on Primary Production. The existed text in Section 3 Primary Production of the current version of CAC/RCP1 should be restored and revised as necessary.

The detail in Section 3 Primary Production is well known and generally accepted as the concept of GAP. Farmers at primary production level hardly implement GHP or GMP. Also, the structure of CAC/RCP1 with the Section on Primary Production has already been adopted by a large number of the specific Code of Hygienic Practices.

In adapting current Sections 4-10 to be used for primary production, the detail should be a lot more flexible. The current detail is more appropriate to corporate farm but it is difficult to apply for small and medium holder farmers.

4. Format and structure of the document to be aligned with ISO 22000

Format and structure of the revised text is not necessary to be aligned with ISO22000 since they are two different texts. However, some definitions may be revised if needed to avoid confusion.

SPECIFIC COMMENT

INTRODUCTION

Paragraph 4

We prefer 4A.

Rationale: We do not support the approach that all business complete the basic hazard analysis.

Roles of Competent Authorities, Food Business Operators, and Consumers (Paragraph 13 bullet point 3)

~~cultivate a strong food safety culture by demonstrating their~~ commitment to providing safe and suitable food and encouraging appropriate food safety practices;

Rationale: The concept of 'food safety culture' is new and may be too specific for small FBOs.

Management commitment (Paragraph 16 bullet 7)

~~enable a strong food safety culture by demonstrating~~ commitment to providing safe and suitable food and encouraging appropriate food safety **practices** behaviours;

Rationale: The commitment from the management is necessary for successful implementation of the food hygiene system. However, the concept of 'food safety culture' is new and may be too specific for small FBOs.

Page 9 Annex I Proposed Decision Tree to Identify [Enhanced GHPs]

It is not clear that this Decision Tree is the only tool to conduct the basic hazard analysis or not. We think this Decision Tree is only one of the tools to conduct basic hazard analysis. The existing model, information, and experience may be used to conduct basic hazard analysis instead of using the Decision Tree.

In order to use the decision tree, FBOs need to have certain knowledge on food safety hazards and how to eliminate.

Also, we propose to remove the word 'validate' at the bottom of Page 9.

Rationale: The detail of validation of enhanced GHP should be specified in Chapter 1. It is not relevant to the Decision Tree.

[CHAPTER ONE] GHP

Page 12 Personnel hygiene facilities and toilets paragraph 16 bullet point 1

We would like to propose removing the square bracket as follows:

- adequate means of hygienically washing and drying hands, including soap, wash basins and [where appropriate], a supply of hot and cold (or suitably temperature controlled) water;

Rationale: Hot, cold or temperature controlled water is not necessary in certain area such as tropical climate since the water temperature does not affect the willingness to wash hands of the workers.

Section II Control of operation (paragraphs 28-33)

We do not agree with the addition of paragraphs 28-33. We think it is adequately addressed in the other part of the text such as Control of Food Hazards, and Key Aspects of Hygiene Control Systems

Rationale: The detail is part of HACCP application. It does not give any differentiation between FBOs who apply only GHP and the FBOs who apply both GHP and HACCP.

Also, in applying the added detail, the large amount of documentation will be required. We think that only necessary detail should be specified such as monitoring.

Water in contact with food (paragraph 53)

The quality of water used in primary production should be suitable for its intended purpose. ~~For additional information on water for primary production, see relevant codex texts e.g. Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) and Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).~~

Rationale: CAC/RCP1 is the main text for general principles of food hygiene for all types of food. We are not sure whether it should refer to the specific Code such as the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003).

Waste Management (paragraph 78)

Waste stores should be kept appropriately clean ~~and free of pests~~ and be resistant to pest infestation.

Rationale: We would like to give some flexibility in managing waste stores. To keep the waste stores free of pests is not likely to be practical.

[CHAPTER TWO] HACCP

Flexibility for less developed food businesses (paragraph 11)

...This flexibility should take into account the nature and **size** of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints.

Rationale: In considering flexibility, nature and size should be both taken into account. When small business carries high risk, that flexibility might not be given to the business.

List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (paragraph 25)

In some cases, it may be acceptable for a **simpler** ~~more basic~~ hazard analysis to be carried out by FBOs which identifies groups of hazards (microbiological, physical, chemical) in order to control the sources of these hazards without the need for a full hazard analysis...

Rationale: the words 'basic hazard analysis' should not be used here. It might cause confusion due to the use of the same words at the beginning of the text.

Establish a monitoring system for each CCP (paragraph 33)

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in real-time to make adjustments to ensure control of the process to prevent violating the critical limits...

Rationale: In some situations, the monitoring might not be able to do in real-time. The monitoring should be done in time so that the process can be adjusted to ensure of the control. Also, real-time monitoring is already mentioned as one of CCP characteristics in the Comparison Table in page 5-6.

Establish documentation and record keeping (paragraph 43)

Record examples are:

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

Rationale: Training is an important part of the application of HACCP system.

African Union

Issue: Par. 8(i): All food businesses to undertake hazard analysis

Position: AU recommends that not all food businesses should undertake food hazard analysis

Rationale: Not all food businesses are capable of undertaking hazard analysis and implementation of HACCP principles. However, food businesses have a responsibility to inform themselves and be aware of the hazards associated with their processes. Food businesses can seek information from Competent Authorities or other recognized bodies. Small businesses should be encouraged to implement good hygienic practices which are more feasible at their level than the HACCP system.

Issue: Para. 8(ii): Introduction of “enhanced GHPs”

Position: AU does not support the introduction of the term “enhanced GHP”.

Rationale: There should be no introduction of new terminologies even though some control measures may require more attention, validation and monitoring e.g. control measures for *Listeria* in the environment, contamination of allergens and training should take all this into account. Further, the objective of the introduction of the concept of “enhanced GHP” can be addressed by effective implementation of GMP.

Para 8(iii): Good Hygiene Practices-Primary Production

Issue: Discussions on whether the section on Primary production (CAC/RCP 1-1969) should be maintained in the current document.

Position: AU supports the need to keep a separate section on primary production in the current document.

Rational: Some provisions only apply to primary production activities which have specific requirements, in this case, AU recommends the inclusion of the section on primary production. However, the section should be developed to strengthen references throughout the document to demonstrate how the guidance applies to all stages of the food chain.

Issue: Para. 9: Alignment of Codex terminologies to ISO 22000

Position: AU does not support the alignment of Codex terminology with ISO for now.

Rationale: The ISO 22000 is currently under revision and therefore there is a need to wait until the revision is completed. The Codex Alimentarius Commission is the preeminent food standards programme with the mandate to develop international food standards and to promote coordination of all food standards work undertaken by international governmental and non-governmental organizations. CAC standards must remain the basis and source for other standards.

Issue: Appendix I, para. 4: Suggested alternative paragraphs 4A and 4B:

Position: Both introductory paragraphs are acceptable. However, AU supports the adoption of paragraph 4A. Further, the paragraph should be revised to provide a statement to reflect the need for flexibility to meet the needs of small businesses.

Rationale: Paragraph 4A provides more flexibility for the small businesses and is devoid of the “enhanced GHP” concept which will be difficult to understand and implemented by small businesses. It also stresses that GHP are sufficient for some food businesses to control all food safety hazards.

Appendix I: Scope

Issue: The use of the word ‘conditions’ in the phrase “food safety conditions” and restriction of necessary hygiene practices to be implemented only when manufacturing of food products.

Position: AU recommends the replacement of the word ‘conditions’ with the word ‘measures’ and replacement of the phrase “in the manufacture” with “along the food chain” in line two of the scope. The new scope will read “this document provides a framework of general principles for producing safe and suitable food for human consumption by outlining necessary hygiene and food safety ~~conditions~~ **measures** to be implemented ~~in the manufacture~~ **along the food chain** and recommending where appropriate, specific food safety control measures at certain steps throughout the food chain”

Rationale: The statement provides clarity and emphasizes the importance of applying food safety control measures throughout the food chain and not only during manufacturing.

Appendix I: Definitions

Issue/background: The Definition for “Enhanced GHP”

Position: There is no need to define “enhanced GHP”.

Rationale: The proposed definition i.e. “enhanced GHP” can be taken care of by GHPs. Further, this is to avoid misunderstanding and difficulty in the implementation of GHPs among business operators especially the small businesses. The application of GHPs in food business operations should be encouraged since it is more feasible and easy to implement.

Issue: Appendix I: Definition of “Food Hygiene System”

Position: AU agrees with the current definition of “Food Hygiene Systems”.

Rational: The concept of the current principle underpinning the definition encompasses the idea that food hygiene includes food safety and food suitability. This definition is also in line with the definition in the Codex Procedural Manual.

Section I: Establishment design and Facilities

Issue: Defining Site boundaries and Landscaping of a food facility

Position: AU does not support the defining of site boundaries and landscaping of food facilities and therefore suggests to delete the statement “**Site boundaries should be clearly defined. Landscaping near a food facility should be properly designed to minimize attractants and pest harborage. Where necessary, experts should be consulted for advice on appropriate plants for use in landscaping**”

Rationale: The provisions in the statement are too prescriptive. The objective of minimizing pest attractant and harbourage can be achieved by several pest management measures.

Para 13: Drainage and Waste disposal

Issue: There is the need to clarify waste collection/disposal site location.

Position: AU recommends that the current statement in section 13 on “Drainage and Waste Disposal” should be modified. The statement “The waste collection/disposal site should be located away from the food establishment to prevent pests infestation” should be replaced with the statement “**The waste collection on-site should be undertaken in a manner that prevents pests infestation and cross contamination of food.** The waste **disposal** site should be located away from the food establishment to prevent pest infestation **and contamination**”.

Rationale: The proposed sentences provide clarity as to the responsibility of the food business in ensuring that the collection and disposal of waste are done in a manner that prevents pest infestation and cross contamination of food.

Para. 28-33 Section II: Control of Operations-Additional Sections on product, process description, monitoring procedure

Issue: Discussions on whether additional sections on product description, process description and monitoring procedures should be included in the text.

Position: AU does not support the additional sections on product description, process description and monitoring procedures.

Rationale: The proposed additional sections are adequately addressed in the section on HACCP. Therefore there is no need to include them in Section II. This is to avoid duplication and complication in the implementation.

Para. 48-Allergenic Contamination

Issue: Inclusion of the concept that, where cross contamination from foods containing allergens cannot be prevented, consumers should be informed.

Position: AU supports the addition of the section on allergenic contamination and the need to inform consumers where there is possibility that cross contamination from food containing allergens cannot be prevented.

Rationale: Current technology may not be able to eliminate all traces of allergens. Similarly, GHP may not be able to adequately prevent unintentional contamination from allergenic substances.

Para 66: Section III: Statement in Square brackets

Issue: Statement in Par.66 in square brackets

Position: AU supports the statement in para.66 and therefore recommends the removal of the square brackets on the statement.

Rationale: The statement suggests the need to separate cleaning tools for cleaning different areas depending on hygienic status of the different areas in the food operating facilities. This is in line with GHP.

Para. 69: Section III: Sanitation [Cleaning and disinfection] programmes

Issue: Statement in par. 69 seeks to define Sanitation.

Position: AU supports the definition for 'sanitation' and therefore recommends removing the square bracket and endorsing the definition.

Rationale: Provides additional information that promotes clarity and ease of implementation

CHAPTER 2: Definitions: Hazard Analysis and Critical Point (HACCP) System and Guidelines for its application/definitions

Issue: Definition of "hazard control measure" to be developed and "Hazard Control Plan" in square brackets

Position: AU does not support the development of the definitions for "hazard control measure" and "Hazard Control Plan".

Rationale: "Control measure" is defined in HACCP terminology as "any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level". This definition pre-supposes that control measures are applicable to hazards. Furthermore, "HACCP Plan" is defined as "A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration". This definition is sufficient to account for the significant hazards that the proposed definition of "HACCP control Plan" aims to control, hence there is need to define "hazard control measure". The introduction of the terminology "Hazard Control Plan" with its proposed definition has the potential to cause confusion in the choice of the system of control measures based on GHP alone or a combination of GHP and HACCP.

ⁱ 8. **EWG members** agree that further consideration of fundamental principles is required to support development of the text, in particular whether:

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

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

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

ⁱⁱ 8. Los **miembros del GTE** están de acuerdo en que es necesario continuar examinando los principios fundamentales para respaldar la elaboración del texto y, en particular:

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- i. Si **todas las empresas** deberían realizar un **análisis de peligros** y, en ese caso, de qué modo se puede adaptar para que resulte adecuado a la naturaleza y el tamaño de la empresa y si se están aplicando **sistemas de control de la inocuidad de los alimentos basados en BPH o en APPCC**.
- ii. Si el **enfoque actual** de los *Principios Generales de Higiene de los Alimentos* (BPH y APPCC cuando es necesario) **continúa siendo adecuado** o si debería introducirse el **concepto de medidas de control en otros lugares además de los PCC (denominados provisionalmente BPH mejoradas)**. Entre las posibles alternativas se plantea adaptar el texto vigente para indicar que **existen algunos controles de BPH a los que debe prestarse más atención**, elaborar una **terminología nueva** y un texto específico **centrado en las medidas de control en otros lugares además de los PCC** y explicar la **relación entre los diferentes tipos de medidas de control con las BPH y el APPCC**.
- iii. Si deberían abordarse los **controles de la producción primaria** en una sección específica del documento o si el documento debería elaborarse de manera que se refuercen las referencias a lo largo de todo el texto para demostrar el modo en el que **se aplican las orientaciones en todas las fases de la cadena alimentaria**.