CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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Agenda Items 5, 6, 7, 8, and 9
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Fiftieth Session Panama, 12 – 16 November 2018

Comments of Panama

Agenda Item 5

Apendix I

GENERAL PRINCIPLES ON FOOD HYGIENE: GOOD HYGIENE PRACTICES (GHPs) and HAZARDOUS ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)

(For comments at Step 3 through CL 2018/69-FH)

(i) General Comments

Panama backgrounds, values and appreciates this important piece of work drafted by the EWG (reference document: **CX/FH18/50/5**). Panama agrees with the revision of the three-part document (Introduction, GHP, HACCP), taking into account the discussions at the CCFH49 and the written comments submitted; clarify the relationship between the three types of control measures: **GHP**, **essential control measures** for food safety applied and unapplied to the **critical control points (CCPs)**; clarify how **Food Business Operators (FBO)** come to understand the hazards associated with their business and determine the types of control measures needed to control the hazards.

Principal Concepts and Guidelines

In general terms, Panama agree with:

- 1. The Food Business Operators (FBO) [should be] [need to] be able to control hazards relevant to their business and be able to produce and provide safe food.
- 2. ALL FBO should be aware of and understand the hazards associated with the food they produce and the measures required to manage those hazards so that food produced is safe and suitable for use.
- **3.** The FBO should understand and fllow the general principles of GHPs at all stages of the food chain and that provide a basis for the competent authorities to oversee food safety and suitability.
- 4. The FBO should undertake a review of potential hazards associated to their business, properly managed and taking into account that the complexity of the review can be adapted to the nature of the business. At a simple level this might require and awareness level that preventing illness should be addressed using basic control measures such as cooking and cooling but in more complex businesses, this could require more comprehensive analyses and a detailed understanding of specific hazards involved and the appropriate interventions (e.g. the application of Good Hygiene Practices (Chapter 1) or HACCP principles, as described in Chapter 2)
- 5. Good Hygiene Practices (GHPs) lay the foundation for the production of safe and suitable food. GHPs maintain the hygiene of a process and apply broadly to all food businesses. It should be noted that for some GHPs a higher level of control (e.g. with increased monitoring and verification) may be needed to provide safe and suitable food, and thus the level of control and the frequency of monitoring and verification will need to be applied appropriately. For example, the cleaning of equipment and surfaces which come in contact with ready-to-eat food would normally warrant a greater level of control and frequency of monitoring than, say, the cleaning of walls and ceilings, because if food contact surfaces are not properly cleaned, this could lead to direct contamination of food. For some other activities, Prerequisite Programmes (PRPs), which include GHPs, Good Manufacturing Practices (GMPs) and Good Agricultural Practices (GAPs), as appropriate, should be applied.
- 6. It is recognised that implementation of HACCP principles may be challenging for some businesses, e.g. primary production, where it can be difficult to establish Critical Control Points (CCPs). In reviewing operations and potential hazards, including a hazard analysis conducted within the HACCP framework, FBOs should consider the GHPs that are being, or that have been, established and how effective they are or will be at controlling the hazard. This will indicate whether GHPs are sufficient to address the safety and suitability of food associated with the operation or whether HACCP-based controls are

required. FBOs without the resources to carry out a site-specific review of hazards may use external resources such as existing HACCP models provided by the competent authority or food industry1, references, standards, regulations, or Codes of Practice and adapt these to the specific site circumstances.

(ii) Specific Comments:

II. INTRODUCTION

III. Title: 'Comparison of GHPs and HACCP Controls'

Subtitles: "GHPs applied for food safety and suitability" vs "HACCP control measures applied to enhance food safety".

IV.

Ι.

V. **Position:** Panama would be in agreement with the comparison as a reference; although GHPs and CCPs are both "control measures" (the first for general conditions and the second for specific cases, with a higher level and/or more thorough for essential control of significant hazards related with food safety).

VI.

VII. In this sense, we consider that the title and subtitle should be modified as following:

VIII.

IX. Title: "Comparison of GHPs and CCPs"

X. Subtitle: "GHPs applied to food safety and suitability" vs "CCPs control measures applied to food safety improvement"

XI.

XII. Justification: Based on the definitions form the CAC/RCP 1-1969.

XIII. Food Hygiene Systems – The combination of hygiene practices, including those that require additional attention and that, when taken as a whole, ensures that food is safe and suitable for its intended use.

XIV.

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

XVI.

XVII. HACCP System: A system which identifies, evaluates, and controls hazards which are significant for food safety through implementation of control measures at identified critical control points. XVIII.

XIX. Critical Control Point (CCP): A step at which a control measure essential for a significant hazard can be applied to prevent or eliminate a food safety hazard or reduce it to an acceptable level in a HACCP plan.

XX.

GENERAL PRINCIPLES

Food safety hazards should be controlled using a science based preventive approach to ensure food safety and suitability.

Position: Panama considers this statement is incorrect: "Acceptable level of food safety".
 We consider correct the following statement: "Acceptable hazard level (for food safety)"
 XXII.

XXIII. Justification: Based on the following standard of reference:

XXIV.

XXV. Guidelines for the validation of control measures for food safety (CXG-69-2008) – III. Definitions

XXVI.

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

XXVIII.

The acceptable and inacceptable levels need to be defined taking into account the global objectives once identified the CCPs in the HACCP.

Acceptable level: low hazard level for food safety, which considers and acceptable hazard level for the consumer. The acceptable level of the final product, sometimes denominated previewed level, should be declared in the description of the product and normally established on an equal or inferior level as in the regulated limit, if there is one. In an intermediate stage of the product flow chart it can be established for a hazard with an acceptable level superior to the one on the final product, in condition that this could reach an acceptable level. (Annexed to the document: Manual for the application of HACCP in the prevention and control of mycotoxines –Capacitation and Reference Center FAO/OIEA for the control of

food with pesticides – Rome, 2003 – Appendix I: Definitions of terms). Acceptable level: refers to "Level that doesn't harm or doesn't represent a significant hazard"

DEFINITIONS

XXIX. Critical Control Point (CCP): A step at which a control measure essential for a significant hazard can be applied to prevent or eliminate a food safety hazard or reduce it to an acceptable level in a HACCP plan.

XXX. Position: Panama considers necessary highlight it as an "essential step"

XXXI.

XXXII. Justification: Based on the definitions from the CAC/RCP 1-1969.

XXXIII. Critical Control Point (CCP): A step at which a control measure essential for a significant hazard can be applied to prevent or eliminate a food safety hazard or reduce it to an acceptable level in a HACCP plan.

XXXIV.

XXXV.

XXXVI.

XXXVII. [FIRST CHAPTER]

XXXVIII. GOOD HYGIENE PRACTICES

XXXIX. Hygienic production of food sources

Q2: Are there any FAO/WHO programmes which can be referenced here?

XL.

XLI. **Position:** Panama proposes to solicit support to FAO/OMS foe the search of references regarding GHPs and traceability

- XLII. Justification: For example, REFERENCES FOR GHPs AND TRACEABILITY
- CAC/RCP 53-2003 HPs MANUAL FOR FRUITS AND LEAF GREENS (CXC 53-2003) Established in 2003. Revised in 2010 (new Annex III for leaf greens), 2012 (new Annex IV for melons), 2013 (new Annex for berries), 2017.
- Principles for traceability/tracking of products as a tool in the context of inspection and certification for foods CAC/GL 60-2006.

XLIII. XLIV. Facilities XLV. Water Supply XLVI.

Q3: Original text from CXC 1–1969 has been moved to the section on water. Is there agreement that this text fits here?

XLVII.

XLVIII. Position: Panama agrees.

XLIX.

L. Justification: The text from the section 5.5 Water CAC/RCP 1-1969, is in accordance with this new section.

LI.

LII. Temperature Control

LIII.

Q4: Do we need a paragraph to discuss monitoring of temperature of premises, equipment and food?

LIV.

Position: Panama considers is sufficient, without requiring any further paragraph.

LV.

LVI. Justification: The text from paragraph 43, pinpoint the need for facilities and adequate equipment for the different activities and for the temperature control of food. WATER

Note: The EWG has amended the original text from paragraphs 51 and 58 from the document CXC 1-1969. Although, it should be continued including the information from the considerations from FAO and WHO regarding water, in other words, allowing the possibility for referencing the guidelines from FAO and WHO, as long as possible provide with the specific codes of the product.

LVII. The current definition of water it's been revised by the WHO. The majority of people understand better the term potable, because it's the used term in the regulatory guidelines in various countries, but does it exist a more adequate term?

LIX. Position: Panama considers the term potable as the most utilized in the regulatory guidelines in many countries; although, it's important to know the results regarding the WHO revising on this topic.

LX.

LXI. Justification: Based on the need of information coming from FAO and WHO regarding water, and the CCFH discussion, it has been considered to take into account to the definition of water the expression "suitable to be used"

 LXII.
 SECTION 3: [Cleanliness], [Sanitation], Maintenance and plague control in the facility.

 LXIV.

Q5: Further discussion is required to determine whether the word 'Sanitation' should be used or whether it should be defined as there may be an issue when this term is translated. As a suggestion, the word 'Cleanliness' has been used in the title – is this acceptable? If it is, it can be used within the text.

LXV.

Position: Panama considers as mandatory to use the term "Cleansing and Disinfection" in place of sanitation.

LXVI.

LXVII. Justification: As mentioned in paragraphs 94 and 95 in the present document.

LXVIII.

LXIX. Methods and Procedures for Sanitization

LXX. Paragraph 95. When written the programs for cleansing and disinfection should indicate the following:

The areas, equipment elements and utensils that need to be cleaned, and when needed, disinfected;

The responsibility of particular duties;

The method and the cleaning frequency, and when needed disinfected,

The activities for vigilance and verification

Position: Panama considers that it should be included "corrective measures" and "documentation systems and registrations"

LXXI.

LXXII. Justification: Based on "Guidelines Section V – Operation Control" included in CAC/RCP 1-1969

LXXIII. 5.6 Direction and Supervision "The directors and supervisors should have knowledge enough regarding the principles and food hygiene practices for the evaluation of potential hazards, establish the propitious preventive and corrective measures, assuring efficacious vigilance and supervision.

LXXIV.

5.7 Documentation and Registrations

Personal Cleanse

Paragraph 113. For the hands, the staff should wash with water and soap, wetting the hands with water and then applying enough soap covering the whole surface; later on rinse with water (preferably potable water), dry the hands with a disposable towel paper or another method that doesn't contaminates the hands again. When using fabric towels, these should be washed with the adequate frequency. Hands disinfectants shouldn't replace the process of hand washing and it should only be used after the aforementioned.

Position: Panama considers the use of the term "ANTISEPTIC" instead of "DISINFECTANT".

Justification: The term disinfectant is used for inert surfaces

LXXV. Second Chapter LXXVI. HACCP and Application Guidelines LXXVII. LXXVIII.

Paragraph 134. For the satisfactory application of HACCP, it's necessary the participation of both auditors and working staff. It is also recommended a multidisciplinary approach, which should adequate for the food business activity, for example, expert knowledge in Agronomy, Veterinarian, Production, Microbiology, Public Health, Food Technology, Environmental Health, Chemistry and Engineering. The HACCP application is the preferred system for food safety in the framework of broader quality control systems.

LXXIX.

LXXX. Position: Panama recommends to use the term animal health instead of veterinarian health, and include other disciplines such as: Public health, human medicine, epidemiology, or other terms for example: Medicine Specialists and/or Human Health (including epidemiology).

Justification: The World Organization for Animal Health is the intergovernmental institution on charge of improving animal health in the world. Advise CAC/RCP 1-1969 – Established in 1969. Amend 1999. Revisions in 1997 and 2003. Editorial corrections, 2011. Also it is required a multidisciplinary approach which will have to include, when applies, experts in agronomy, veterinarians, production staff, microbiologists, medicine and public health specialists, food technologists, experts in environmental health, chemists and engineers, depending on the type of study.

HACCP System and Guidelines for its application

Q6 Validation has been added to Principle 6 on verification because the application text for Principle 6 included a statement on validation. However, it may be more appropriate to include 'Validation' under Principle 3. What do members think?

LXXXI. The Definitions which were here have been moved to an earlier section.

LXXXII.

LXXXIII.

LXXXIV.

LXXXV. Position: Panama would be in agreement with incorporation the validation of the principle 3, but considers it should also be maintain in principle 6.

LXXXVI.

LXXXVII. Justification: Based on the HACCP System and Guidelines for its application, in the CAC/RCP 1-1969. Both principles 3 (Establish critical limits) and 6 (establish confirmation procedures for the implementation of HACCP systems and its efficacious performance), require a validation procedure in order to determine its efectivity.

LXXXVIII.

LXXXIX. Guidelines for the application of HACCP System XC. Introduction XCI.

DIRECTRICES PARA LA APLICACIÓN DEL SISTEMA DE APPCC

Introduction

138. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration should be given to the impact of raw materials and other ingredients, food production practices, food manufacturing practices (including whether processes control hazards adequately under GHP or whether significant hazards remain and require control under HACCP), likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

Position: Panama recommends using the term Critical Control Points (CCP) instead of HACCP, in the context of what it's been expressed in parenthesis "...(including the process that properly controls the associated hazard through GHPs or if important hazard persist then is necessary a control through CCP)" this is due to the persistence of important or significant hazard for food safety, which makes the establishment of CCP necessary as a part of the HACCP system.

XCII.

XCIII. Justification: Based on the definitions in CAC/RCP 1-1969.

XCIV. Food hygiene system: The combination of hygiene practices, including those that require additional attention and that, when taken as a whole, ensures that food is safe and suitable for its intended use.

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

XCVI. HACCP: A system which identifies, evaluates, and controls hazards which are significant for food safety through implementation of control measures at identified critical control points.

XCVII. Critical Control Point (CCP): A step at which a control measure essential for a significant hazard can be applied to prevent or eliminate a food safety hazard or reduce it to an acceptable level in a HACCP plan.

XCVIII. XCIX. Application C. CI.

Paragraph 147.

The HACCP team should identify the scope of the HACCP system and applicable prerequisite programmes and is responsible for writing the HACCP plan. The scope should describe which segment of the food chain is involved and the general classes of hazards (biological, chemical, physical) to be addressed (e.g. does it cover all classes of hazards or only selected classes).

CII.

CIII.

CIV. **Position:** Panama agrees in "The application should describe the affected segment of the food chain" CV.

CVI. Justification: Based on "Guidelines for the application of HACCP system" in CAC/RCP 1-1969.

CVII. CVIII.

Application

Assemble HACCP Team and Identify Scope (Step 1)

It should be determined where to apply the HACCP plan, which will describe the affected segment of the food chain.

List all potential hazards associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards (Step 6 and Principle 1)

"The HACCP team should compile a list with all the hazard that can be reasonably foreseen in every step according to the application, from the primary production, elaboration, fabrication and distribution until the moment of consumption.

Determine Critical Control Points (Step 7 and Principle 3)

Q7 decision tree at Diagram 2 provided by Brazil and amended by UK. Are Members content with this inclusion?

CIX.

CX.

CXI. Position: Panama does not agree with including this new decision flow chart, for now, until it is clarified or improved the proposal, which is rather confusing. Panama considers the current flow chart (CAC/RCP 1-1969) as functional, as long as it is applied logically and with the required level of comprehension.

CXII.

CXIII. Justification: Based on "Guidelines for the application of the HACCP system" from CAC/RCP 1-1969.

CXIV.

Application

7. Determination of the CCPs (Principle 2)

^{CXV.} Since CODEX published the flowchart, this has been used many times for capacitation. In many cases, it has been useful to explain the logic and the level of comprehension needed to determine the CCPs, this is not specific for all the operations in the food chain, for example, the slaughter, in consequence, should be used having in considerations the opinion from professionals and, in some cases, will be modified.

CXVII.

CXVIII. FlowChart 2 – Example for a Decision Sequence in order to identify the CCPs (answer the different questions in order)

CXIX. CXX.

Establish validation and verification procedures (Step 11 and Principle 6)

Q8: This section has been retitled and includes additional text - are members content with the amendments?

Position: Panama agrees with the new title

Justification: As explained previously. (Principles for HACCP System)

172. After validation, verification activities should be performed on an ongoing basis to ensure the HACCP system functions as intended and continues to operate effectively. Verification, which includes observations,

auditing, calibration, sampling and testing, and records review, can be used to determine if the HACCP system is working correctly and as planned. Examples of verification activities include:

• Calibration or verification of the instruments precision, utilized for vigilance and verification.

Position: Panama suggests eliminate the word "precision" and change (or) for (and/or). In consequence, recommends a modification as followed: "Calibrate and/or verify the utilized instruments for vigilance and control, with the objective of accomplishing the accuracy of the measurements".

Justification: Taking into account the objective of the text, which is to obtain reliable results in the measurements, the international measurement vocabulary (IMV) defines it as measurement accuracy. The textual definition for measurement accuracy is the proximity in the concordance between a measured value of magnitude (precision) and a real measured value (veracity). Based on the aforementioned, expressing in the document "calibration or precision verification" does not considers a complete control of the measurement, for this reason it is suggested that the text should be modify taking into account the established in the **ISO 17025:2017**

Agenda Item 6

(i) General Comments

Panama appreciates this important work prepared by the EWG (reference document: CX/FH18/50/6)- EWG Report- Project (Appendixes I and II) issue 3.

Panama considers this revision will proportionate the necessary harmonization of the sampling planes and the orientation about sampling among them; the latest orientation for histamine (REP18/FH Appendixes II) should be included to the code (CXC 53-2003) as a separate section, situated after section 9 (Elaboration of fresh, frozen and chopped fish).

Panama agrees with the advance in the amendments project to the present code (CAC/RCP 52-2003), which harmonizes the code with "orientation regarding histamine recently included in the CAC during the 41st session, appendix I (issue 3), and also agrees with the majority of the amendments to the sampling orientations to the products norms" included in the sampling sections, exam and analysis, from the Appendix II (issue 3); and also supports its advance.

Agenda Item 7

General Comments

Panama appreciates and backgrounds the advance of this important work prepared by the EWG (reference document CX/FH18/50/7) – Revised Proposal for Practices Code (Appendix I), issue 3.

Panama will be in agreement with the application including the management of allergens throughout the food chain as a complement of the GHPs, and it should include the allergies and food hyper-sensibilities, excluding the non-immunologic etiological hyper-sensibilities, such as lactose intolerance and sulfites sensibility.

Panama agrees with the Proposal document describing the 8 principal groups or types of food associated to immunologic reactions such as allergens of greater importance worldwide and maintain the best coherence as possible regarding the General Norm for pre-packed food labeling (CXS 1-1985). In the same way, the country agrees with the objectives, which provides with orientation regarding the FBO, in order to elaborate policies and procedures aimed to identify allergens in every area of production, preparation, and food service, applying these management practices and efficacious control.

(ii) Specific Comments

INTRODUCTION

Paragraph 11. Cross contact with allergens could be due to a series of factors in the elaboration of food, some of which have higher possibilities of contact with other allergens. The control measures applied to reduce to the minimum any cross contact, depending on the hazard. In some cases, it may not be possible to avoid cross contact even after the application of preventive measures and the FBO. Although, it may be possible to reduce cross contact to the extent the allergen concentration could be below the threshold that causes a reaction to the consumer.

Position: Panama proposes to consider to ask for scientific and technical support to WHO to evaluate, To what extent the concentration of the allergen, that could be present as a consequence of cross contact, could be below the threshold of the batch causing a reaction to the allergic consumer? And, the need to establish limits for allergens concentration that could be tolerated (toleration threshold).

Justification: There are medical treatments, which consists in the oral administration of the food allergen related to the symptom cause, starting with minimal amounts and progressively increased until reaching the

normal ration according to age or the maximum tolerated dose. It should be a establishment of immunologic tolerance, prepping the cellular and serologic mechanism, in order to correct an inadequate reaction throughout a process of progressive increase of the tolerated threshold concentration. Reference: BOL PEDIATR 2010; 50: 80-86 - REUNIÓN DE PRIMAVERA DE LA SCCALP Mesa Redonda: Inmunoalergia Inducción de tolerancia en alergia a alimentos E. ALONSO-LEBRERO, V. FUENTES APARICIO, L. ZAPATERO REMÓN Sección de Alergia. Hospital Materno-Infantil Gregorio Marañón. Madrid.

5.2 Fundamental Aspects regarding hygiene control

5.2.2 Small sells and restoration services

5.2.2.1 Reduction to the minimum of cross contact during preparation

Paragraph 79. The food preparing operators should only use the ingredients included in the recipe and do not substitute an ingredient by other, unless when the replacement ingredient doesn't have any allergen. The operators should not use food with unknown allergen profiles and never guess or assume there isn't presence of any allergen. The staff should consider viable and if necessary dedicate cooking means such as water or oil, exclusively to food with specific allergen profiles in order to avoid cross contact with allergens, for example avoid to use the same frying oil for fish or potatoes, especially because when leaving in the oil particles that may have allergens.

Position: Panama solicits modify the last sentence as following "It may be necessary [validate the effectiveness of the filtering procedure] for frying oil, in order to eliminate any particle containing allergens, when it's probable that such particles end in another food with a different allergen profile.

Justification: Panama considers that 'filtering the frying oil could be insufficient to eliminate the allergen traces' because the effectiveness of the filtering process depends entirely of the method and type of filtration.

SECTION VI – Establishment: Maintenance and Sanitization

6.2 Cleaning Programs

6.2.1 Fabrication

Paragraph 115. The assurance of an effective cleaning process is denominated cleanliness validation. The validation is the evaluation of the cleaning method for ensuring these are adequate to reduce to the minimum cross contact with allergens. The cleaning process should be validated through a visual evaluation (making sure the equipment is visually clean) and, when suitable, through an analytical testing program. The efficacy of the cleaning process should be verified after every cleaning operation in order to assure the continuity of the validated procedures.

Position: Panama supports the proposed ALTERNATIVE TEXT.

Justification: With the alternative text there should be a methodology for the verification of the effectiveness of the cleaning process or having the tools or equipment to perform this process.

SECTION IX – INFORMATION REGARDING PRODUCTS AND CONSUMERS SENSIBILIZATION

9.2 Product Information

9.2.1 Fabrication

ALTERNATIVE TEXT

Paragraph 145. All food products and ingredients should have the adequate information so other fabricants or food elaborators and consumers know if the food contains any allergen. This includes any preventive labeling regarding allergens, for example: "it may contain....". Although, it is preferable avoid the systematic use of these warnings, which may reduce the available foods in the market for allergic consumers.

Position: Panama supports the proposer ALTERNATIVE TEXT.

Justification: Considered as clearer and complete.

Agenda Item 8

(i) General Comments

Panama appreciates and supports the advance of this important document prepared by the EWR

(Reference document: CX/FH18/50/8) – proposal for guidelines presented in the Appendix I, issue 3.

Panama agrees with "The purpose of this new work is to offer orientations to the competent authorities discussing the management of food borne crisis and outbreaks, including the communication between

national and regionals programs, and INFOSAN. We expect this document to contribute to the definition of the role of the different competent authorities and the collaboration with FBO and other parts, during the food borne crisis of the outbreaks". (REP18/FH).

Panama considers that the application should be focused to situations defined as "**emergencies related to food safety**" other than "incidents regarding isolated cases" or "contamination punctual events with no human disease related to food safety"

Panama considers important the harmonized application of the **principles for risk analysis**, among them the evaluation of risks, risk management and risk communication, as described in Codex Alimentarius, the foundation for the establishment of a system for the preparation and management of the 'emergency situations' related to food safety. For this reason it is preferred to use the expression 'outbreak evaluation' instead of the expression 'rapid risk evaluation' in order to maintain the coherence with the definition and Codex focus, as indicated among other members.

(ii) Specific Comments:

INTRIDUCTION

Paragraph 8. The decision to classify an outbreak as an emergency or a crisis should be done by the competent authorities and it will depend on their capacity and competence to handle [emergency situations/incidents/events] related with food safety and the category of the food borne disease outbreak. What it can be a "normal situation" in a country, could be as an emergency or crisis in other.

Position: Panama considers this decision to classify an outbreak as an emergency or crisis should be based upon the detailed guidelines from the International Sanitary Regulations and INSOFAN (especially when it comes to situations that could have international implications).

Justification: Considers that if the decision is left to discretion of the competent authorities from each country, it would not be coherent with the purpose and the application of these guidelines.

APPLICATION

Paragraph 10. These guidelines proportionate orientation to the competent authorities for the management of [emergency situations/incidents/events] related with food safety, including the communication between the national and regional programs with international networks such as International Network of Authorities in Food Safety (INFOSAN). The orientations convey the preparation, detection, response, and recuperation, with the intention of limiting the scope of these events. The application is limited to biological hazards.

Position: Panama supports the proposed content. Although, considers the application should be focusing in "situations" defines as "emergencies related to food safety", limited to biological hazards.

Justification: Based on the definitions from CAC/GL 19-1995 and the International Sanitary Regulation (2005).

Emergency related to food safety: A situation, whether is accidental or intentional, where the competent authority identifies the risk that is still no controlled from grave prejudicial effects for public health related to the consumption of foods, and requires urgent measures. (CAC/GL 19-1995).

Response to the emergency related to food safety: A process through which the risks are evaluated, then decisions are taken for risk management and these risks are communicated against time limitations, and possibly, data and incomplete knowledge. (CAC/GL 19-1995)

International Sanitary Regulation (2005) – Public Health emergency of international importance. Means an extraordinary event, according to the present Regulation, it has been determined that: i) constitutes a risk for public health from other states due to the international propagation of a disease, and ii) it must require a coordinated international response;

Event means the manifestation of a disease or a potentially pathogenic happening.

Risk for public health means the probability of a disease or a potentially pathogenic happening; adversely affecting human population's health, considering in particular the possibility of being spread internationally or supposing a grave and direct hazard.

Suspicious makes reference to every person, luggage, container, transport mean, merchandise or postal package that a member state may consider to have been exposed to a risk to public health and could be a possible source of additional illness propagation.

Paragraph 11. These guidelines describe the role of the competent authorities and the collaboration in structure of formal networks between them and at different levels. Also, includes the collaboration and communication con other FBO and other interested parts, before and during [emergency

situations/incidents/events] related with food safety. At last, it also emphasizes about the maintenance of the structures and the capacitation methods for the improvement of the response from part of the networks.

Position: Panama supports these guidelines describing the role of the competent authorities and the collaboration in structures of formal networks between them and at different levels; and the collaboration and communication with the FBO and other interested parts.

Justification: Based on the need to establish guidelines to elaborate a database (unique) at a local level bound to INFOSAN in order to improve the time of response upon an outbreak.

DEFINITIONS

Paragraph 17. [Food borne outbreak]

- a) The number of observed cases exceeds the expected number.
- b) The incidence of two or more cases of a food borne disease caused by the ingest of a common food. CXXI.

Alternative

A food borne outbreak is an incident in which two or more people experiment the same disease upon the ingest of a common food and an epidemiological analysis implies the food as the source of disease.

Emergency situation related to food safety, the definition is included in CXG 19-1995.

Related events with food safety, if necessary.

Related incidents with food safety, if necessary.

Vigilance is the systematic and permanent recompilation of the test results in humans, animals and food with the purpose of applying the adequate control measures. One of the principal objectives of vigilance is to follow up the unsatisfactory results throughout research and possible execution of measures.

Follow up is the performance of frequent analysis in order to detect microbiological contamination in food that can provide useful information about prevalence.

A grouping is, in epidemiological terms, an accumulation of patients with the same disease (cases) in a determined timeframe and reduced space. In microbiological terms, strains (for example, bacteria or virus) with the same determined molecular profile or with highly related profiles identified by the sample analysis from the cases.

Fast evaluation of risks, if necessary.

Outbreak evaluation, if necessary.

Position: Panama supports the proposed alternative definitions.

Justification: Based on the definitions included in CAC/GL 19-1995

Agenda Item 9

(i) General comments

Panama appreciates this important work prepared by Chile, United States of America and Uruguay (reference document: CX/FH18/50/9) – 'Discussion document" and "Project document" which presents the need of a guideline from Codex for *Escherichia coli* responsible of producing Shiga toxin in bovine meat, unpasteurized milk and cheese made off unpasteurized milk, leafy greens and germinated seeds.

Panama agrees with the scope of this new work, especially for considering it will contribute to the prevention and reduction of problems in public health, based in "JEMRA report", FAO/WHO, 2018.

Panama considers of critical importance the application of specific programs for food safety, especially in slaughters and meat processing places, keeping the vigilance on the performance of processes in hygiene control, throughout adequate procedures, including the counting of hygiene indicator bacteria, present in food and the processing surroundings (for example *E. coli* O157 in chopped bovine meat and precursors), and measurement of critical parameters of elaboration in critical control points. Moreover, considers necessary the application of strict controls and the adoption of a scope based in the risk for fruits and vegetables, with the objective of prioritizing the high risk products and establish controls based in the associated risk.