



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

#### Forty-eighth Session

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

### PROPOSED DRAFT REVISION OF THE GENERAL PRINCIPLES OF FOOD HYGIENE

Prepared by the Electronic Working Group led by France and co-chaired by Chile, Ghana, India and the United States of America

#### (At Step 3)

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Revision at Step 3 (see Appendix I) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*)  
**to:** Ms Barbara McNiff, US Department of Agriculture, Food Safety and Inspection Service, US Codex Office, email: [Barbara.McNiff@fsis.usda.gov](mailto:Barbara.McNiff@fsis.usda.gov) with a copy **to:** The Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Rome, Italy, email: [codex@fao.org](mailto:codex@fao.org) **by 30 September 2016.**

**Format for submitting comments:** In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in the Annex to this document.

#### **Background**

1. The 47<sup>th</sup> session of CCFH (CCFH47) agreed to:
  - a) Start new work on the revision of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and its HACCP annex;
  - b) Amend the project document to indicate that managerial aspects were not within the scope of the work;
  - c) Submit the project document to the Codex Alimentarius Commission for approval as new work;
  - d) Establish an EWG, chaired by France and co-chaired by Chile, Ghana, India and the United States of America, working in English, Spanish and French to prepare the proposed draft revision of the *General Principles* for circulation for comments at Step 3 and consideration at the next session of the Committee; and
  - e) Consider convening a PWG, working in English, French and Spanish, at the next session to prepare a revised proposal on the basis of the comments submitted.
2. CCFH47 agreed to the following time schedule: Approval of new work: 2016, adoption at Step 5: 2019, adoption at Step 8: 2021.
3. The new work was approved by CAC39 (July 2016).<sup>1</sup>
4. With the scope to facilitate exchange through the whole revision process, the EWG was conducted through the Codex bulletin board ([www.forum.codex-alimentarius.net](http://www.forum.codex-alimentarius.net)) with the support of the Codex Secretariat.

<sup>1</sup> REP16/CAC, paras 100 – 101, Appendix V

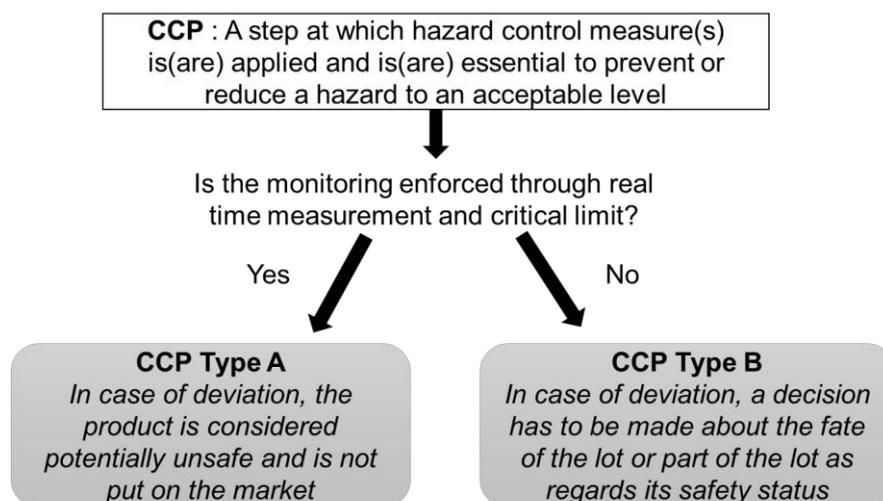
## **Work of the EWG**

5. An invitation was sent to all Codex members and observers to participate in the EWG. Then, a questionnaire was distributed to all of the EWG participants on 9 May 2016. Participants from 35 Codex members, one Member organization and eight Observer Organizations were registered as participants of the EWG. The list of Participants is attached as Appendix II.

6. The first draft prepared by the Chair and Co-Chairs only focuses on the first part of the document. The revision of the two sections, *i.e.* “General Principles of Food Hygiene” and “HACCP system” has not been undertaken because the work is being undertaken stepwise and general agreement is needed on the approach described in the general introduction.

7. The draft document proposed a new approach, in accordance with the request not to modify the concept of CCP (Critical Control Point) and to keep in line with the present HACCP Principles. Therefore, there is no change to the present consideration that CCPs are steps where it is necessary to apply any kind of control measure deemed essential against significant hazard(s) identified by the Hazard Analysis.

8. Given the wide diversity of CCPs that exists within the food chain, the new approach focuses on monitoring of hazard control measures. According to the present definition of the CCP, monitoring with respect to a critical limit pertaining to a real time measurement is the basis of control measures applied at CCPs. Yet, it is recognized that some control measures cannot be monitored against a critical limit and/or timely. The new approach includes them, as illustrated below.



9. The document introducing this approach and its application for the revision of CAC/RCP 1-1969 was circulated on 13 June 2016. There was a majority agreement on the proposed new approach. Deletion of ‘condition of’ in the definition of Hazard was accepted by the majority, as was the one of ‘eliminate’ in the definition of CCP. Based on the comments, the Chair prepared a revised draft (Appendix I) which took into account widely supported editorial comments but not those that were less consensual and that need further discussion.

10. There were objections relative to the first clauses in the Introduction. Hence, the proposal of one country is inserted as an option in the revised draft.

11. Most participants thought confusing that the terms ‘food business operators’ and ‘industry’ were used alternately with the same meaning. As they generally supported the expression ‘food business operators’, this latter expression was used in the revised draft.

12. The view that GHPs do not need ‘specific skills and knowledge’ was not shared by the members of the EWG. Thus, the Chair proposed to replace the related sentence by the proposal made by one respondent that: ‘GHPs, in general, only need basic knowledge and skills.’

13. Further discussion is needed on the following points:

- The appropriate scope of the HACCP system: several participants expressed the opinion that the HACCP system is applicable to any kind of food business all along the food chain, including the primary production, even if there is no CCP.

- New concepts: one respondent considered that GHPs are control measures and suggested to use the concepts of GHP-based control measures and Hazard-based control measures as in “*Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat (CAC/GL 78-2011)*”, and “*Guidelines for the Control of Non-typhoidal Salmonella spp. in Beef and Pork Meat (CAC/GL 87-2016)*”, and to modify other definitions accordingly.
- The general meaning of the terms ‘corrective action/correction’: two options were proposed but the participants of the EWG could not agree on the most appropriate one;
- If the most appropriate way to describe the HACCP system relates to a ‘two-phase process’ (underlining that GHPs are to be designed before the HACCP plan is established) vs. a ‘two-component’ process (meaning that GHPs and HACCP can be designed at the same time).

### **Additional comments**

14. A questionnaire was also distributed to the EWG participants, with the view to generate useful guidance regarding the way the revision work is performed.

15. Acknowledging that electronic tools are becoming more and more widely used, the referencing system should encompass hyperlinks that could give access to the referenced official documents through the Codex website [www.fao.org/fao-who-codexalimentarius/](http://www.fao.org/fao-who-codexalimentarius/). Those documents should encompass Codex guidelines and documents, and FAO and WHO guidelines.

16. Regarding the Bulletin Board, most of the respondents declared that they use it to make their own comments and to see comments made by other respondents. They also thought that it is useful to upload and download relevant documents and to share with other participants. Nevertheless, they would prefer a system that combine the use of the bulletin board and communication by direct mailing to all members registered in the EWG.

17. The most used language has been English. In the future, a courtesy translation system could be expected to improve participation.

### **Recommendations**

18. The WG recommends that the Committee:

- a) Consider the proposed draft as presented in Appendix I. In particular, specific attention should be paid to the approach proposed for the differential management of CCPs, depending on the type of monitoring which is available in a given context;
- b) Pursue the revision of CAC/RCP 1-1969 with an approach consistent with the one that has been implemented to date, and to establish an EWG to that effect. In order to allow an effective and inclusive work to achieve this goal in a timely manner, the prospective EWG should use modern technologies, *i.e.* work through the Codex alimentarius bulletin board [www.forum.codex-alimentarius.net](http://www.forum.codex-alimentarius.net). A complementary system using massive mailing should also be considered. A specific attention should be paid to the question of an effective translation system and its costs for the hosting(s) member country(ies) or organization(s);
- c) Regarding the amendments and revisions in Appendix I, should pay attention to:
  - The appropriateness of an introductory paragraph to the General Introduction section, with the scope to explain the importance of the standard CAC/RCP 1-1969 and to provide general information regarding the international context it is part of;
  - Determining if the concepts of ‘GHP-based control measures’ and ‘HACCP-based control measures’, which have been recently used in Codex documents, could be appropriate for the revision of CAC/RCP 1-1969.
  - The need for additional definitions, including: Potential hazard; Food business operator (FBO); Operational Prerequisite Program.
  - The improvement of proposed or existing definitions, including: Environment, Food safety and Food suitability, Primary production.
  - The deletion of ‘condition of’ in the definition of Hazard
  - The deletion of ‘eliminate’ from the definition of CCP.
  - To consider the exact meaning of the terms ‘Corrective action’ and ‘Correction’ and to agree on related definitions.

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

**(at Step 3)**

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

## INTRODUCTION

1.

Option A:

[Consumers worldwide have high expectations regarding food safety and food suitability. Even if food safety remains the most important concern of modern societies, new requests become more and more important to improve the health and the welfare of people regarding their food consumption<sup>2</sup>. The importance of food safety and food suitability cannot be over emphasized as they ensure the prevention of food borne illness and injuries and promote acceptability of food for human consumption. Food borne illnesses and injuries are not desirable and can be fatal. Some hidden foodborne injuries include psychological trauma. Food spoilage is wasteful, costly and adversely affects trade and consumer confidence. Effective safe food practices including Good Hygienic Practices (GHP) and application of Hazard Analysis and Critical Control Point (HACCP) System are therefore essential in avoiding the adverse human health of unsafe and unsuitable food. Such a two-phase/component approach will also provide assurance of the safety and suitability of food, adequately protect consumers from illness or injury caused by food and maintain consumer confidence.]

Option B:

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

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

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

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

2.

Option A:

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

Option B:

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

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<sup>2</sup> For instance, food preferences are not the same for different categories consumers, making food which is safe possibly not suitable to certain categories. Thus, food must not only be safe but must also be suitable to meet the dietary needs of target consumers.

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

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

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

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

- HACCP application will not be effective without prior implementation of GHPs.
- HACCP is a preventive approach that aims to enhance food safety where this is appropriate and feasible, by improving the control of hazards over that achieved by the GHPs.
- HACCP accomplishes this with the help of hazard control measures applied at critical control points (CCPs).
- HACCP may not be applicable to all type of food businesses, in particular at the stages of primary production. However, the principles of HACCP can be applied to certain activities related to primary production [e.g. administration of veterinary drugs].
- HACCP requires specific knowledge and skills.

## OBJECTIVES

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

- identify the good hygienic practices applicable throughout the food chain (including primary production through to the final consumer) to provide food that is safe and suitable for human consumption;
- recommend an HACCP-based approach as a means to enhance food safety;
- provide a guidance that may be needed for specific codes for sectors of the food chain, processes, or commodities to amplify the hygiene requirements specific to those areas.

## SCOPE

7. This document provides a framework for producing foods that are safe and suitable for human consumption by setting out necessary hygiene conditions and applying, where appropriate, enhanced control measures at certain production steps. The document is intended for use by food business operators and countries<sup>3</sup>, as appropriate.

## USE

### **General**

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

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

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

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

### **Roles of Governments, food business operators, and consumers**

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

- protect consumers adequately from illness or injury caused by food; policies need to consider the vulnerability of the population, or of different groups within the population;
- provide assurance that food is suitable for human consumption;
- maintain confidence in internationally traded food; and
- provide health education programs which effectively communicate the principles of food hygiene to food business operators and consumers.

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

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

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

### **BASIC PRINCIPLES FOR A FOOD SAFETY CONTROL SYSTEM**

- (i) The recommended way to maximize food safety and suitability is a two [phase/component] preventive approach.
- (ii) The implementation of GHPs is the first [phase/component], of the design of a food safety control system.
- (iii) GHPs should ensure that food is produced in a sanitary environment and reduce the burden of contaminants, whether hazardous or not.
- (iv) GHPs are a prerequisite to the implementation of a HACCP system, because they provide the foundation for a HACCP system to be effective.
- (v) The application of GHPs should be subject, where appropriate, to monitoring, verification and documentation.
- (vi) The implementation of HACCP, where needed and feasible, is the second [phase/component] of the design of an effective food safety control system.
- (vii) HACCP should identify all hazards associated with the production process and its environment, and specify the significant ones that should be controlled because they can occur at an unacceptable level.
- (viii) HACCP should determine validated hazard control measures that are essential to increase the level of food safety.
- (ix) The application of hazard control measures should be subject to monitoring, verification and documentation.
- (x) Changes in the food business, e.g. new process, new ingredient, new product, new equipment, should lead to a review of both GHPs and the HACCP plan to determine if modifications are needed. Modifications should be documented and when necessary validated

## DEFINITIONS

14. For the purpose of this Code, the following terms and expressions have the meaning stated. [Deletions from the previous GPFH version are shown by ~~strike-through font~~; additions are printed in *italic font*]

### Definitions applying within the whole document

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

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

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

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

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

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

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

**Establishment** Any building or area in which food is handled and the surroundings under the control of the same management.

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

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

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

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

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

**Hazard Analysis and Critical Control Point (HACCP)** A system that identifies, evaluates and controls hazards that are significant for food safety.

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

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

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

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

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

*Rationale: "Slaughter" does not belong to primary production, according to e.g. the Code of Hygienic Practice for Meat (CAC/RCP 58-2005).*

### Definitions specific to the HACCP system

**Control (verb)** To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

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

**Corrective action** ~~Any action to be taken when the results of monitoring at the CCP indicate a loss of control. (see options below)~~

Option A (based on ISO 9000)

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

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

Option B (US)

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

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

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

Rationale for the suppression of “to eliminate”: The HACCP approach takes for granted that for many control measures there is always a theoretical probability that a hazard remains (extremely low where there is a kill step with many log reductions). What food businesses have to ensure is that they reduce it to an acceptable level that will minimize the potential for illness or injury.

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

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

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

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

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

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

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

Rationale for the modification: Some essential hazard control measures do not allow defining critical limit(s). Nevertheless, deviation from the validated criterion can occur and needs to be detected.

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

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

**Hazard 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.

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

Rationale for the addition of “Hazard” in the expression and “significant” in the definition: It is suggested to use “control measure” in combination with “hazard” to clarify that “hazard control measures” are designed within the HACCP not against all hazards, but specifically against “significant” hazards identified through the “hazard analysis”. A suggested definition of “Significant hazard” is given below.]

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

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

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

Rationale for deletion: This word is self-defined; a definition does not seem useful.

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

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

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**Annex****GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS**

In order to facilitate the compilation and prepare a more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

- (i) General Comments
- (ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in **underlined/bold font** and deletion in ~~strikethrough font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.