

**European Union comments**  
**CODEX COMMITTEE ON FOOD HYGIENE**  
**Forty-ninth Session**  
**Chicago, Illinois, United States of America,**  
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**Agenda Item 4: Proposed Draft Revision of the General Principles of Food Hygiene (CAC/RCP 1-1969) and its HACCP Annex (CX/FH 17/49/5)**

*Mixed Competence*  
*European Union Vote*

The European Union and its Member States (EUMS) would like to thank and congratulate the United Kingdom as chair and France, Ghana, India, Mexico and the United States of America as co-chairs of the EWG for the approach taken and the very useful preparatory work undertaken in view of a possible revision of CAC/RCP 1-1969.

**1. 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.

## **2. 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.