DISCUSSION PAPER ON THE NEED FOR A REVISION OF THE GENERAL PRINCIPLES OF FOOD HYGIENE (CAC/RCP 1-1969) AND ITS HACCP ANNEX

(Prepared by Finland with input from New Zealand and the United States of America)

Background


2. Since its inception in the early 1970s, HACCP has become the universal food safety management system, on which most regulatory food control systems and international food safety standards (e.g., ISO 22000) are based. HACCP, or a similar approach of identifying hazards and establishing controls to prevent them, has also been used in guidance on the safety of feed and drinking water.

3. While the preventive food safety approach of the seven HACCP Principles is universally acknowledged as effective by most users, consistent understanding and practical implementation of some aspects of HACCP have proven to be difficult. This is especially true for small and less developed businesses (SLDBs), as well as for developing countries, which often lack access to appropriate technical assistance in the practical application of all the principles. Likewise, national governments/food control authorities may also encounter problems when required to assess compliance with requirements based on general HACCP principles compared to more prescriptive legal requirements.

4. At the 45th Session of the Codex Committee on Food Hygiene, the Delegation of Finland informed the Committee of its intention to review the General Principles for Food Hygiene (CAC/RCP 1-1969) and the annex on HACCP for possible revision by the Committee. It was noted that the General Principles for Food Hygiene was the basis for all codes of hygienic practice developed by CCFH, was widely used and referenced internationally and that there were several initiatives ongoing to update, in particular, the concept of HACCP. Therefore, it was important for the Committee to retain ownership of the General Principles and the Annex on HACCP. In order to assist with this review, Finland planned to have a colloquium of scientists, regulators and other relevant stakeholders in the second quarter of 2014 to address areas for update and revision, e.g. guidance on validation, the application of HACCP to small and medium enterprises, and HACCP plan figure and tables. The colloquium was held 4-6 June 2014 in Majvik, Finland; the report of that meeting is provided as an annex.

Discussion (Key concerns and how these could be addressed through a revision of the text):

5. The current HACCP Annex is well accepted internationally and has been adopted into legislation in many countries, as well as into industry standards and training. Because the seven principles of HACCP are widely recognized and well established, they should remain intact. However, there are many improvements to both the GPFH text and its HACCP Annex that would better clarify the relationship between the General Principles of Food Hygiene and HACCP and would provide additional HACCP guidance helpful to FBOs. Considerations for revisions are outlined below.

6. Because control measures can be implemented using GHPs or CCPs in a HACCP system, consideration should be given to better clarifying the relationship between the GPFH text and the HACCP Annex within the overall context of food safety management systems (FSMS). This is because of the interrelationship and the commonality of many activities, including, but not limited to: hazard analysis, controlling hazards with and without CCPs within a food safety system, and verification activities as appropriate to the control measure. The outcome of a revised GPFH document could ultimately be a more generic and all-embracing document, e.g., “General Principles for Food Safety Management Systems” that makes the relationship more explicit to aid regulatory control and to avoid businesses developing unnecessarily complex control arrangements. In revision of the GPFH text and the HACCP Annex to clarify the relationship of GHPs and HACCP, consideration should be given to including the HACCP principles in the “General Principles for Food Safety Management Systems,” leaving the guidance in an Annex (along with enhancing the existing guidance as discussed below).

7. Many HACCP principles, in particular Hazard Analysis (Principle 1), Verification (Principle 6) and Documentation (Principle 7), are horizontal in nature, and should be applied in any FSMS. Hazard Analysis is the fundamental principle when applying any kind of a preventive FSMS, and should not be artificially separated into applying only in HACCP systems. More clearly placing Hazard Analysis at the start of assessment of the safety for any kind of food process would help to objectively assess hazards and where they should be addressed, either within GHP or by the implementation of one or more CCPs within a HACCP system. Control measures that are part of GHPs often are subject to verification and documentation. In revising the GPFH text and the HACCP Annex, consideration should be given to how best to apply HACCP principles that can be more broadly applied.

8. Validation, management responsibility and commitment, identification of the scope, development of product and process descriptions, traceability, supplier management, storage procedures and processes, maintenance of the FSMS, training and review are further examples of horizontal activities that are integral parts of any functioning FSMS. In revising the GPFH text and the HACCP Annex, consideration should be given to how best to address such activities.

9. “Hazard” is defined as “A biological, chemical, or physical agent in, or condition of, food with the potential to cause and adverse health effect” (emphasis added). The meaning of this phrase is unclear; thus, the Codex definition of hazard warrants further discussion, especially in relation to the wording “or condition of” (with respect to the food) and what that might mean.

10. Further guidance for conducting a Hazard Analysis is needed, as currently there are many different approaches worldwide to carrying out this task. Current approaches are often poorly understood and are not consistently applied. Hazard Analysis is also commonly misunderstood as risk assessment, which, as defined by Codex, it is not, although both address likelihood and severity.

11. In the HACCP Annex, Hazard Analysis and the decision tree for determining CCPs focuses too much on microbiological hazards, while chemical and physical hazards are given less importance. This reflects the historic focus of HACCP when the initial guidelines were being developed, but chemical and physical hazards need to be addressed to cover issues such as, for example, the effective management of allergens with respect to food safety. In revising the GPFH text and the HACCP Annex, consideration should be given to how to incorporate additional guidance on chemical and physical hazards.

12. Further guidance for CCP determination is needed, as currently there are many different approaches to this worldwide. While a decision tree (HACCP Annex Figure 2 or a modified version) has been useful for some, others have found it confusing, and it would seem to incorrectly indicate that the outcome of its use should always be a CCP. Clarification is needed that it is acceptable to not have a CCP for a process (with an appropriate rationale provided, i.e. where effective arrangements are in place through prerequisite programs). In revising the GPFH text and the HACCP Annex, the decision tree should be reviewed and consideration should be given to clarifying its use and to the utility of providing alternatives to the decision tree.
13. Principles 3-5 (Critical limits, Monitoring and Corrective actions) are well understood, but could benefit from additional guidance. For example, corrective actions also need to cover the aspects of preventive actions, namely both immediate correction and long term actions to rectify the process so that non-compliances do not reoccur. Also, critical limits can be difficult to define for the controls of a physical hazard, while monitoring can in some instances be difficult to distinguish from verification. In revising the GPFH text and the HACCP Annex, consideration should be given to additional guidance to address these issues.

14. Validation is an important part of HACCP systems. There is a need to more clearly distinguish validation from verification within Principle 6. In revising the GPFH text and the HACCP Annex, consideration should be given to whether validation should become a new HACCP principle, whether it should be addressed as a horizontal issue in the FSMS context, or whether the verification principle should be modified as “Verification and Validation,” with both concepts being clearly defined in a single principle. The Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69 – 2008) were elaborated subsequent to the last revisions to the GPFH and its HACCP Annex. In revising the GPFH text and the HACCP Annex, consideration should be given to make specific reference to the validation document in the text of the HACCP Annex so it will gain more recognition and to foster its use.

15. In revising the GPFH text and the HACCP Annex, consideration should be given to revising Figures 1-3 of the HACCP annex in order to make them more user-friendly; consideration should be given to including real examples instead of empty tables. It would also be useful to make available examples of all documents expected to form a HACCP plan; this could lead to greater uniformity among plans and improved inter-cultural recognition of the same. This would be most useful to clarify for SLDBs exactly what is expected in a plan. This should be done in a way as to not restrict the flexibility in how food business operators format their HACCP plans.

16. In revising the GPFH text and the HACCP Annex, the Codex HACCP texts should be cross-checked for alignment of terminology with that in other food safety management guidance, where feasible. Consideration should be given to defining commonly applied concepts such as CPs/OPRPs, auditing, and even GHPs.

17. The HACCP annex is too focused on manufacturing, which makes it difficult to apply in a broader FSMS context to all FBOs in the food chain. Processes with no CCPs that rely on other control measures such as GHPs and other prerequisite programs for food safety do not fit easily in the current HACCP Annex text, and this has the potential to result in unnecessary or complex HACCP controls being required by competent authorities (or third-party auditors) or developed by businesses. In revising the GPFH text and the HACCP Annex, consideration should be given to whether control measures should be more broadly addressed so they can better be applied to non-manufacturing FBOs, and, if so, how.

18. The HACCP annex portrays FSMS development and implementation as following a linear logic, while in reality many “steps” can occur simultaneously, or in a different order. Any FSMS process is also iterative, with feedback loops to constantly improve the system, which is not stated in the current text. Maintenance of the system is an important aspect and needs to be included. Issues such as these could be addressed in revising the GPFH text and the HACCP Annex.

19. The structure of the GPFH text could be made more user friendly, e.g., reference to equipment found in different places in the GPFH text could be brought together; text could be added, such as traceability for handling recalls, supplier management, and storage procedures and processes (currently not covered). The concept of outsourced work could be addressed. Consideration could be given to including reference to CAC/GL 50 on sampling plans.

Recommendations:

20. In view of the international importance of the Codex HACCP texts to food safety management systems, it is recommended that CCFH review the General Principles of Food Hygiene (CAC/RCP 1-1969) and in particular its Annex: Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application with respect to the issues discussed above and give consideration to revising the GPFH text and its HACCP Annex (Project document attached as Appendix 2 in CX/FH 14/46/11)).

Aspects to Be Covered by Revision of the GPFH Text and its HACCP Annex

21. Any revision of the GPFH and its HACCP Annex should take into account the concerns raised in the Discussion above and focus on text to improve the Guidelines with respect to application of the HACCP principles, but retaining the seven principles to the extent possible. In revising the HACCP Annex to clarify the application of the principles, consideration should be given to consequential changes needed in the GPFH text.
to better integrate food safety management using HACCP CCPs and GHP controls. Following these changes, consideration should be given to whether other changes are appropriate in the GPFH.

**Need for Expert Scientific Advice**

FAO/WHO can facilitate this effort by reviewing their HACCP guidelines and determining if there is information useful to address the concerns raised.
Meeting Report of a Colloquium on the Need for a Revision of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and its HACCP Annex

Prepared by Finland with input from New Zealand and the United States

(FOR INFORMATION ONLY)

**Background**

1. With an aim to find solutions practical problems related to the implementation of HACCP, the Government of Finland arranged a scientific colloquium “HACCP – The Road Ahead” on 4-6 June 2014 in Majvik, Finland. The colloquium addressed the need to update the Codex Alimentarius’s General Principles of Food Hygiene (CAC/RCP 1-1969), and especially its Annex on HACCP by identifying areas of confusion and current practices that might be missing from the Codex texts. At the meeting, 87 experts representing 24 countries and three international organizations were present. Approximately half of the participants were regulators, while the rest represented the food industry and academia in equal parts. The meeting program consisted of one day of invited talks, one day of deliberations in breakout groups and one day of group reports and conclusions. The aim of the meeting was to discuss and, to the extent possible, reach a consensus on how to most effectively move forward with an improvement of the Codex HACCP text.

2. Following twelve presentations given by invited speakers on the subject, participants were asked to discuss the current Codex GPFH and HACCP Annex, and assess where change was most desirable, either within the current texts or as guidance. In particular, breakout groups were asked to consider three main topics:

   - The link between Good Hygienic Practices (GHP) and HACCP, with additional consideration of
     - Does the GPFH text need additions/deletions?
     - SLDBs: is HACCP the best approach and is suitable guidance available?
     - Can HACCP be effectively implemented throughout the food chain, e.g., primary production and retail operations?
   - Hazard Analysis, with additional consideration of
     - Is the Codex definition of a hazard confusing?
     - Is further guidance needed for critical limits, monitoring, corrective actions?
     - What are the critical criteria needed for determining a CCP?
   - Validation and Verification, with additional consideration of
     - Is the Codex validation document known and is it useful?
     - How to minimize duplication in in-house, government and third party verification activities
     - Diagrams, examples and other tools: how can they be improved on?

Conclusions of the Colloquium “HACCP – The Road Ahead”:

3. There is a well-established and clear relationship between the GPFH text and the HACCP Annex, to the extent that in their application by food business operators (FBOs), some parts merge from one to the other. Consideration should be given to better clarifying the relationship between the two texts within the overall context of food safety management systems (FSMS). This is because of the interrelationship and the commonality of many activities, including, but not limited to: hazard analysis, controlling hazards with and without CCPs within a food safety system, and verification activities as appropriate to the control measure. Subsequently, the outcome of a revised GPFH document could be a more generic and all-embracing document, e.g., “General Principles for Food Safety Management Systems” that makes the relationship more explicit to aid regulatory control and to avoid businesses developing unnecessarily complex control arrangements. Consideration could be given to the inclusion of animal feed in the scope; if not included, clarify that the document applies to food for human consumption. Consideration could also be given to including the HACCP principles in the “General Principles for Food Safety Management Systems,” leaving the guidance in an Annex (along with enhancing the existing guidance as discussed below).

4. Many HACCP principles, in particular Hazard Analysis (Principle 1), Verification (Principle 6) and Documentation (Principle 7), are horizontal in nature, and should be applied in any FSMS. Validation,

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3 Australia, Belgium, Canada, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Japan, Latvia, Malaysia, New Zealand, Norway, Peru, Poland, South Africa, Sudan, Sweden, Tanzania, United Arab Emirates, United Kingdom, United States of America, ALA – Latin American Poultry Association, FAO, and the European Commission.
management responsibility and commitment, identification of the scope, development of product and process descriptions, traceability, supplier management, storage procedures and processes, maintenance of the FSMS, training and review are also further examples of horizontal activities, and are integral parts of any functioning FSMS.

5. The FAO guidelines for the application of HACCP in SLDBs is a key document aimed at governments. It outlines means by which governments can develop strategies to facilitate HACCP uptake by FBOs. However, some components of the guidance have been disseminated to food businesses through other documents or guidelines. There is a clear need for better dissemination of relevant guidance, good practice and successful approaches taken by countries or applied in specific food sectors.

6. Hazard Analysis is the fundamental principle when applying any kind of a preventive FSMS, and should not be artificially separated into applying only in HACCP systems. More clearly placing Hazard Analysis at the start of assessment of the safety for any kind of food process would help to objectively assess hazards and where they should be addressed, either within GHP or by the implementation of one or more CCPs within a HACCP system. The Codex definition of hazard warrants further discussion, especially in relation to the wording "or condition of" (with respect to the food) and what that might mean.

7. Further authoritative guidance for conducting a Hazard Analysis is required, as currently there are many different approaches worldwide to carrying out this task. Current approaches are often poorly understood and are not consistently applied. Hazard Analysis is also commonly misunderstood as risk assessment, which it is not, although both address likelihood and severity. While Hazard Analysis is the responsibility of the food business, the thought process behind it could to a large extent be done by others, e.g. industry bodies or national governments, especially for SLDBs. This has been the approach taken successfully by many countries and there is a need to more actively disseminate this information.

8. In the Codex texts, Hazard Analysis and the decision tree for determining CCPs focuses too much on microbiological hazards, while chemical and physical hazards are given less importance. This reflects the historic focus of HACCP when the initial guidelines were being developed, but chemical and physical hazards need to be addressed to cover issues such as, for example, the effective management of allergens with respect to food safety.

9. Guidance for CCP determination is required, as currently there are many different approaches to this worldwide. While a decision tree (HACCP Annex Figure 2 or a modified version) has been useful for some, others have found it confusing, and it would seem to incorrectly indicate that the outcome of its use should always be a CCP. Clarification is needed that it is acceptable to not have a CCP for a process (with an appropriate rationale provided, i.e. where effective arrangements are in place through prerequisite programs). The decision tree may need review. Alternatives to the decision tree may also be useful.

10. Principles 3-5 (Critical limits, Monitoring and Corrective actions) are well understood, but could benefit from additional guidance. For example, corrective actions also need to cover the aspects of preventive actions, namely both immediate correction and long term actions to rectify the process so that non-compliances do not reoccur. Also, critical limits can be difficult to define for the controls of a physical hazard, while monitoring can in some instances be difficult to distinguish from verification.

11. There is a need to more clearly distinguish validation from verification within Principle 6. There was no consensus on whether validation should become a new HACCP principle, whether it should be addressed as a horizontal issue in the FSMS context, or whether verification should be modified as “Verification and validation” with both concepts being clearly defined. It was agreed that validation was an important part of HACCP systems, GHP and within FSMS and discussion did refer to the usefulness but perhaps the lack of visibility of the current Codex validation document (CAC/GL 69 2008). The Codex validation document is not very well-known, although it is used by various experts because of its many practical examples. To gain more recognition, there is a need to add the validation document to the Food Hygiene Basic Texts and specific reference made to it in the text of the HACCP Annex.

12. Figures 1-3 of the HACCP annex should be revised in order to make them more user-friendly; consideration should be given to including real examples instead of empty tables. It would also be useful to make available examples of all documents expected to form a HACCP plan; this could lead to greater uniformity.

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among plans and improved inter-cultural recognition of the same. This would be most useful to clarify for SLDBs exactly what is expected in a plan. It should not be viewed as restricting the flexibility in how food business operators format their HACCP plans.

13. The Codex HACCP texts should be cross-checked for alignment of terminology with that in other food safety management guidance, where feasible. It was suggested that commonly applied concepts such as CPs/OPRPs, auditing, and even GHP, could be defined.

14. The HACCP annex is too focused on manufacturing, which makes it difficult to apply in a broader FSMS context to all FBOs in the food chain. Processes with no CCPs that rely on other control measures such as GHPs and other prerequisite programs for food safety do not fit easily in the current HACCP texts and this has the potential to result in unnecessary or complex FSMS controls being required by national governments (or third-party auditors) or developed by businesses. (This issue could potentially be addressed if the Hazard Analysis came at an earlier stage – see Statement 10.) The concept of OPRPs (operational prerequisite programs) that is developed in ISO22000 was presented as a good means of highlighting key GHP activities that assist with the control of hazards.

15. The HACCP annex portrays FSMS development and implementation as following a linear logic, while in reality many “steps” can occur simultaneously, or in a different order. Any FSMS process is also iterative, with feedback loops to constantly improve the system, which is not stated in the current text. Maintenance of the system is an important aspect and needs to be included.

16. Although the focus was on reviewing the HACCP text, it was noted that some aspects in the GPFH text may also benefit from revision. For example, the structure of document may be made more user friendly, e.g., reference to equipment that is found in different places in the GPFH text could be brought together; some text could be added, such as traceability for handling recalls, supplier management, storage procedures and processes (currently not covered). The concept of outsourced work needs to be addressed. Reference to CAC/GL 50 on sampling plans may also be included.

17. The Colloquium agreed that the current HACCP text is essentially adequate and is well accepted internationally and has been adopted into legislation in many countries, as well as into industry standards and training. In particular, it was suggested that the seven principles of HACCP should remain intact as they are widely recognized and well established. However, there was full support to better clarify the relationship between the General Principles of Food Hygiene and HACCP by restructuring and supplementing the existing HACCP guidance text where necessary.

Recommendations of the Colloquium “HACCP – The Road Ahead” to CCFH

18. In view of the international importance of the Codex HACCP texts to food safety management systems, it is recommended that:

i. CCFH review the General Principles of Food Hygiene (CAC/RCP 1-1969) and in particular its Annex: Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application in terms of providing more guidance for many of the key parts of the current HACCP text

ii. CCFH consider an approach that clarifies the relationship between GHP and HACCP as part of a Food Safety Management System (FSMS). This would address many of the concerns about approaches to horizontal components that apply to more than one part of the FSMS

iii. CCFH consider the amount and nature of guidance proposed for many aspects of the current HACCP texts, mechanisms to better disseminate guidance, and successful approaches implementing the current HACCP texts to promote consistency of application across the food chain, user-friendliness and proportionality to size of business

iv. CCFH consider in any agreed revision process, the above listed conclusions of the June 2014 Majvick HACCP colloquium (detailed in points 7-21). However there might be other matters that should also be considered for revision during such a process.

v. CCFH consider requesting an update from FAO/WHO on their HACCP guidelines, including a list of current guidance and information relevant to the issues raised, as background to the revision process.