CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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MATTERS ARISING FROM THE WORK OF FAO AND WHO AND OTHER INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS

Progress Report on the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) and Related Matters

Prepared by FAO and WHO

INTRODUCTION

1. As Codex endeavours to provide risk management guidance on a wide range of issues pertinent to the safety and quality of food in international trade in order to protect consumer health, FAO and WHO aim to provide the relevant scientific advice in a timely manner. This paper describes the scientific advice and related outputs that FAO and WHO have developed relevant to the specific agenda items of the 44th Session of the Codex Committee on Food Hygiene (CCFH) and provides an update on follow-up activities in relation to the items on the agenda of the Committee.

A) RECENT FAO/WHO ACTIVITIES RELEVANT TO THE ONGOING WORK OF CCFH

Histamine in fish and fishery products *(relevant to Agenda Item 2)*

2. During the 31st Session of CCFFP, the Committee accepted FAO/WHO's offer to provide scientific support in addressing the issue of histamine criteria in various fish and fishery products, examining their public health and trade impacts. To facilitate this, FAO/WHO implemented a joint Expert Meeting on the Public Health Risks of Histamine and other Biogenic Amines from Fish and Fishery Products in Rome on 23-27 July, 2012.

3. Currently, Codex standards include histamine criteria under two sections (a) decomposition and (b) hygiene and handling. The meeting concluded that while sensory evaluation remains a highly useful tool for quality control programs, acceptable sensory quality cannot be taken as final assurance of low histamine, nor can low histamine be taken as final assurance that fish is not decomposed. In view of this, the expert meeting decided to focus their advice on histamine limits and related sampling plans to those focused on consumer protection.

4. The meeting concluded that a dose of 50 mg histamine is the no-observed-adverse-effect level (NOAEL) that could be used as the appropriate hazard level and based on a serving size of 250g, calculated the maximum concentration of histamine in a serving that would not cause adverse effect to be 200 mg/kg. Based on data made available by industry, the meeting noted that when food business operators apply good hygienic practices (GHP) and HACCP, an achievable level of histamine in fish products was lower than 15 mg/kg. Since the problem is related to only fish with high histidine levels and the information on the fish species likely to be involved would be important for risk management, the meeting developed the most comprehensive list to date of fish associated with SFP based on data from different parts of the world.

5. The expert meeting concluded that the risk from SFP is best mitigated by applying basic GHPs and where feasible, a HACCP system. Appropriate sampling plans and testing for histamine should be used to validate the HACCP systems, verify the effectiveness of control measures, and detect failures in the system. In order to provide more explicit guidance on sampling approaches, the meeting analysed a range of sampling plans implemented under different scenarios of histamine levels as defined by mean and standard

deviation and presented examples of attributes sampling plans appropriate to different levels of tolerance for samples above 200 mg/kg, and for different assumptions about the standard deviation of histamine concentration within lots. The spread of contamination levels in the batch (i.e., standard deviation of contamination levels) has a strong effect on the tolerable average contamination level and, thus, on the number of samples that must be tested to 'accept' the batch. Appropriate selection of the criterion against which test units comprising the sample will be assessed for compliance (m value), can considerably improve the time- and cost-effectiveness of sampling – requiring the least number of samples to be tested to achieve the same level of confidence about the disposition of the lot being assessed.

6. The Executive Summary of the report has been included in Annex I and the final report that will be subjected to editing and formatting is available at http://www.fao.org/fileadmin/user_upload/agns/news_events/1_FAO-WHO_Expert_Meeting_Histamine.pdf. In addition, following the recommendation of the expert meeting, FAO and WHO are working to make the mathematical tools that were used in this expert meeting to develop different sampling plans available in an easy to use format.

Pilot Initiative to enhance participation in Codex texts and other activities related to the revision of the Principles for the Establishment and Application of Microbiological Criteria in Foods (*relevant to Agenda Item 4*)

a) Pilot Initiative to enhance participation in Codex texts and development of examples

7. Following the decision of the 43rd Session of the Codex Committee on Food Hygiene (CCFH) to establish a physical Working Group (pWG) to continue the revision of the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) and to elaborate practical examples on the establishment and application of microbiological criteria for different purposes to aid the revision of the Principles, the need to facilitate the active participation of less experienced countries in the elaboration of these practical examples was identified. It was therefore agreed to pilot an initiative using a "mentoring" approach through the coupling of more experienced lead countries and/or observer organizations (*mentors*) with less experienced countries (*mentees*). FAO and WHO, including the Codex Secretariat and the Codex Trust Fund Secretariat, supported this pilot mentoring initiative since the beginning to effectively plan, facilitate, and finally evaluate the usefulness of this initiative. An overview of this initiative is provided in Annex 2 of this report. The support of the Codex Trust Fund for this initiative continues through to the 44th Session by supporting those involved in the development of the examples to also participate in this session of the Committee. FAO/WHO would like to recognize the time and effort contributed by all the working group members which resulted in a very positive initial feedback on this pilot. The short term evaluation of this initiative will be completed after the 44th CCFH.

8. As indicated in CX/FH 12/44/6-Add.1 FAO and WHO are willing post the examples which have been developed on their websites if the Committee decides that is the best location for them.

b) Request from the 43rd CCFH on statistical and mathematical aspects of microbiological criteria

9. FAO and WHO have taken note of the request of the last session of the Committee FAO/WHO to provide technical support on the development of the Annex on the statistical and mathematical aspects, while also noting that this was not a priority of the Committee. FAO and WHO have tentatively planned to address this request in 2013 pending confirmation from the Committee that they still need this work to proceed.

c) Development of a web-based tool to assess the performance of microbiological sampling plans

10. A user friendly web-based tool (WBT) to assess presence/absence sampling plans and concentration-based sampling plans has been developed by FAO/WHO. Following additional testing and finalisation the tool will be available from 1st November 2012 at www.mramodels.org/sampling. This tool aims to provide those responsible for the elaboration and implementation of sampling plans for microbiological testing as part of their food safety control and verification activities with the means of designing sampling plans that meet their needs and assessing their performance under a range of different contamination levels.

Follow-up action by CCFH

11. FAO and WHO welcome feedback from all Delegations of CCFH on the pilot initiative to enhance participation in Codex and all feedback will be considered in the final evaluation of this initiative. FAO and WHO also welcome confirmation from the Committee if the technical support on the development of the

Annex on the statistical and mathematical aspects should proceed. Feedback on the web-based tool and any additional information/guidance individuals/countries might need to apply the tool should be directed to the FAO/WHO JEMRA Secretariat. FAO/WHO will continue to develop support materials to facilitate application of the tool in 2013.

Parasites in food and their impact on public health and trade *(Relevant to Agenda Item 5)*

a) Ranking of foodborne parasites

12. The 42nd Session of the CCFH (December 2010) requested FAO and WHO to review the current status of knowledge of parasites in food to better assess the global problem associated with these, the commodities involved and the related public health and socio-economic/trade issues to identify parasite/commodity groups of greatest concern. In order to address this request FAO and WHO initiated a series of activities this culminated in an expert meeting on 3-7 September 2012. Preceding the meeting, relevant data were identified and collated through a formal "call-for-data", a literature review and written reports prepared by experts representing different regions. A list of 95 potential foodborne parasites was initially identified for consideration. Through a stepwise documented process this was reduced to a list of 24 parasites for ranking. Experts further identified specific vehicles of transmission for each of the 24 parasites. The parasites were ranked using a multicriteria-based approach. The criteria used in the ranking process can be summarized as: 1) global number of illnesses, 2) global distribution, 3) morbidity-acute, 4) morbidity-chronic, 5) percentage chronic, 6) mortality, 7) potential for increase in human illness burden, 8) trade relevance, 9) socio-economic impact. Each criterion was then weighted by the experts in terms of their importance. Three criteria for disease severity (3, 4, and 5) were combined into one criterion, giving a total of 7 criteria weights, reflecting the relative importance of each criterion to the overall score. The overall score for each parasite was calculated by normalized parasite criteria scores multiplied by fractional weights and summed.

13. The primary outputs of the expert meeting were the development of the ranking tool and the actual global ranking, based primarily on public health concerns, i.e., 85% of weights. The global ranking of foodborne parasites by "importance" and their primary food vehicle in descending order was as follows:

Taenia solium – Pork

Echinococcus granulosus – Fresh produce

Echinococcus multilocularis – Fresh produce

Toxoplasma gondii – Meat from small ruminants, pork, beef, game meat (red meat and organs)

Cryptosporidium spp. – Fresh produce, fruit juice, milk

Entamoeba histolytica – Fresh produce

Trichinella spiralis – Pork

Opisthorchiidae – Fresh water fish

Ascaris spp. – Fresh produce

Trypanosoma cruzi – Fruit juices

Giardia duodenalis – Fresh produce

Fasciola spp. – Fresh produce (aquatic plants)

Cyclospora cayetanensis – Berries, fresh produce

Paragonimus spp. – Fresh water crustacean

Trichuris trichiura – Fresh produce

Trichinella spp. – Game meat (wild boar, crocodile, bear, walrus, etc.)

Anisakidae – Salt water fish, crustaceans and cephalopods

Balantidium coli – Fresh produce

Taenia saginata – Beef

Toxocara spp. – Fresh produce

Sarcocystis spp. – Beef and pork

Heterophyidae – Fresh and brackish water fish

Diphyllobothriidae – Fresh water / salt water fish

Spirometra spp. – Fish/reptiles/amphibians

14. This ranking should be considered a "picture" in time and representative of the information available at the time, the criteria used for ranking and the weighting which was given to those criteria. Also, some of these parasites had very similar rankings so it may be more relevant to consider the parasites in groups of concern e.g. top 5 or top 10 rather than the individual ranking position. With more information or with changing human and/or animal behaviours, and/or with climate changes, parasite scoring and subsequent ranking could also change. As with many phases of risk analysis, it may be important to repeat and update the process on a regular basis. In fact, with heavily weighted public health criteria, the ranking results in part reflect risk defined as a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard in food. If the parasites are ranked only on trade criterion scores, the order of importance changes: *Trichinella spiralis*, *Taenia solium*, *Taenia saginata*, Anisakidae and *Cyclospora cayetanensis* are the top five. In this way, individual criteria can be considered, for example by CCFH, outside of the total scoring and the weighting processes to assure specific concerns can be addressed transparently and separately if needed.

15. Since criteria weights were calculated separately from the individual parasite scoring, alternative weighting schemes reflecting the judgments of risk managers could be used to generate alternate ranking, using the scoring of the parasites undertaken by the expert meeting. Thus, the ranking process which was developed was considered to be as important an output of the meeting as the ranking result, since it allows the global ranking to be updated through changes in scoring and/or to reflect the priorities of different groups of risk managers or stakeholders through different weighting. The process can be completely rerun at national or regional levels using data more specific to that particular country or region.

16. Finally, the meeting also highlighted some considerations for risk management including knowledge on foodborne attribution and possible approaches for the control of some of these foodborne parasites. Reference is also made to existing risk management texts as appropriate. The preliminary report is available at http://www.fao.org/food/food-safety-quality/a-z-index/foodborne-parasites/en/ and http://www.who.int/foodsafety/micro/jemra/meetings/sep12/en/index.html.

Follow-up action by CCFH

17. This information together with the global ranking of the parasites and the identification of the primary food vehicle aims to support the decision- making process within CCFH in terms of its future work on foodborne parasites. However, it should be noted that management of specific parasites may then require further scientific input which it was not feasible to provide as part of the above mentioned process.

b) Peer review of risk profiles of *Trichinella* spp and *Cysticercus bovis*

18. At the 43rd Session of the CCFH, the Committee agreed to send the risk profiles, attached to CX/FH 11/43/6, to FAO/WHO for peer review and inclusion in the repository of risk profiles on the FAO and WHO websites. The risk profiles for *Trichinella* spp. and *Cysticercus bovis* have been peer-reviewed by selected experts in the area of parasitology. Their suggestions and comments are currently being addressed and the updated risk profiles will be made available on the FAO and WHO websites by the end of 2012.

c) Risk based examples for *Trichinella* spp. and *Cysticercus bovis*

19. The 43rd session of the Committee also requested FAO/WHO to develop risk-based examples for *Trichinella* spp. and *Cysticercus bovis* to illustrate the level of consumer protection likely to be achieved with different post-harvest risk management options, depending on the availability of data and information. Some preliminary discussions have been held, and FAO and WHO will work with collaborators to develop these examples for the 45th session of the Committee.

B) FOLLOW-UP ACTIVITIES TO PREVIOUS WORK OF THE COMMITTEE

Expert meeting on methodology for detection and enumeration of *Vibrio parahaemolyticus* and *Vibrio vulnificus* in seafood

20. The 42nd Session of the CCFH requested FAO/WHO to continue the work on *Vibrio* in four steps: recommend test methods for quantification of *Vibrio parahaemolyticus* and *Vibrio vulnificus* in seawater and bivalves; develop data collection strategies, encourage data collection in different regions, and modify/develop risk assessment models. It will take several years to fully address this request, and progress will also be dependent on available resources.

21. An expert meeting was organised in Ottawa, Canada on October 17-19, 2011 to (a) identify possible end uses of *Vibrio* methodologies (b) look at the performance characteristics of available methods and provide recommendations on the requirements for different end uses (c) provide recommendations for collection of data to support national/regional risk assessments. The output of this Expert Meeting and subsequent discussions are being used to develop a "Guidance document" addressing performance characteristics of *Vibrio* methodology and approaches for data collection. 5. As a follow up to this and in starting to address step 3 above, a Regional training Workshop for Asia on *Vibrio* methodologies is scheduled to be held in Singapore during November 19-23, 2012. This is being implemented with support of the International Life Sciences Institute (ILSI). About 14 countries are expected to participate in the training with the expectation that some of the participating countries will use this training to support data collection pertaining to bivalve species produced there. FAO and WHO would also like to express their appreciation to those countries that are supporting this initiative through the provision of trainers.

22. FAO and WHO recognise the need to organize such training in other regions and are actively seeking resources to facilitate this and welcome any support that Members can provide.

C) OTHER RELATED ISSUES

WHO Expert Consultation in collaboration with FAO and OIE: The Global View of Campylobacteriosis

23. A WHO Expert Consultation on the Global View of Campylobacteriosis was organized in collaboration with FAO and OIE and hosted by the WHO Collaborating Centre for Reference and Research on Campylobacter, Utrecht University, Netherlands on 9-11 July 2012. The objectives were1) To review the progress made since the previous two consultations in 2000 and 2002, note successful approaches and lessons learned and identify challenges in controlling Campylobacter from farm to table and reducing the human health burden and attributable health consequences; 2) To consider cross-cutting areas, such food and waterborne campylobacteriosis and antimicrobial resistance, and take into account the context of both developed and developing countries: 3) To provide options for the WHO, FAO and OIE for developing ways forward to reduce Campylobacter in the food chain and the burden of foodborne campylobacteriosis. The meeting was organized under the following thematic areas 1) Burden of disease and health impact; 2) Surveillance, antimicrobial resistance; 3) Source attribution; 4) Impact of control measures.

24. The consultation report will be published shortly and will present discussions, future steps and options for lowering the burden of foodborne and waterborne campylobacteriosis and associated antimicrobial resistance.

FAO Food Safety Expert Roster

25. FAO has established a roster of food safety experts to support its food safety work through the delivery of timely scientific advice and technical assistance to support member countries. Food safety professionals with relevant expertise are invited to apply. The roster can be found at: http://www.fao.org/food/expert-roster/en/

D) PUBLICATIONS

26. All the publications in Microbiological Risk Assessment (MRA) Series are available on the FAO (http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/) and WHO (www.who.int/foodsafety/publications/micro/en/index.html) websites. Forthcoming publications in this series include:

- Risk Assessment tools for *Vibrio parahaemolyticus* and *Vibrio vulnificus* associated with seafood: Meeting report. Microbiological Risk Assessment Series 20 - FAO/WHO
- *Salmonella* spp. in bivalve molluscs: Meeting report. Microbiological Risk Assessment Series 21 - FAO/WHO
- Guidance on the selection and application of methods for the detection and enumeration of human pathogenic *Vibrio* spp. in seafood. Microbiological risk assessment Series 22 - FAO/WHO
- Histamine in fish and fishery products: Meeting report. Microbiological risk assessment Series 23 - FAO/WHO

Prevention and control of *Salmonella* and enterohaemorrhagic *Escherichia coli* in tree nuts

27. FAO published this short document under the "EMPRES Food Safety lessons learned series". In the series, FAO aims to develop and disseminate technical information highlighting relatively new food safety risks and address potential mitigation options throughout the food chain. The document provides an overview of the problem addressing aspects such as the recent outbreaks linked to tree nuts, introduction and survival of these pathogens in tree nuts as well as some recommendations for control both pre- and post-harvest. These short documents aim to raise awareness of issues such as those related to *Salmonella* and *E. coli* in tree nuts and support member countries in their efforts to control foodborne illness and possibly prevent similar outbreaks from occurring in their countries. The document is available in English and can be found at: http://www.fao.org/fileadmin/templates/agns/pdf/EMPRES_FS_SeriesNo2.pdf.

Annex 1

EXECUTIVE SUMMARY OF THE JOINT FAO/WHO EXPERT MEETING ON THE PUBLIC HEALTH RISKS OF HISTAMINE AND OTHER BIOGENIC AMINES FROM FISH AND FISHERY PRODUCTS, JULY 23-27, 2012

Scombrotoxin fish poisoning (SFP) (often called "histamine poisoning") is caused by ingestion of certain species of marine fish that contain high levels of histamine and possibly other biogenic amines. Codex Alimentarius through its standards and guidelines aims to provide countries with the basis for which to manage issues such as histamine formation. Several of the existing standards include maximum levels for histamine in different fish and fishery products. The need to harmonize such limits and ensure the associated guidance on the relevant sampling plans and other aspects of sampling resulted in the 31st Session of the Codex Committee on Fish and Fishery Products (CCFFP) agreeing to look into the issue of histamine limits in more detail. The Committee established an electronic Working Group in order to facilitate this work and identified the need for scientific advice from FAO and WHO to support this work.

FAO and WHO convened an expert meeting at the FAO headquarters in Rome from 23 – 27 July 2012 to address the public health risks of histamine and other biogenic amines from fish and fishery products. This report summarizes the outcome of that meeting.

Histamine is produced by bacterial actions, e.g. spoilage and fermentation, in fish species which have a naturally high level of the amino acid histidine. Generally, this takes place at a temperature of more than 25° C over a period of more than 6 hours or for longer at lower abuse temperatures.

A hazard identification, where all biogenic amines were considered, concluded that there is compelling evidence that histamine is the most significant causative agent for SFP and that histamine can be used as an indicator of SFP. There are no difficulties in analyzing histamine and a number of suitable methods are available. The different species of fish that are reportedly responsible for SFP were identified including those with a high histidine level which have the potential to cause SFP. Noting, that this information should be easily accessible to support risk-based approaches to SFP management, the expert meeting developed the most comprehensive list of fish associated with SFP to date.

The hazard characterization concluded that a dose of 50 mg of histamine, which is the no-observed-adverse-effect level (NOAEL), is the appropriate hazard level. At this level healthy individuals would not be expected to suffer any of the symptoms associated with SFP. Also no cumulative effect for consecutive meals with fish was expected, since histamine usually leaves the body within a few hours.

Using the available fish and fishery products consumption data combined with expert opinion the meeting agreed that a serving size of 250 g captured the maximum amount eaten in most countries at a single eating event. Based on the hazard level of 50 mg of histamine and the serving size of 250 g, the maximum concentration of histamine in that serving was consequently calculated to be 200 mg/kg. When food business operators apply good hygienic practices (GHP) and hazard analysis critical control point (HACCP), an achievable level of histamine in fish products was reported to be lower than 15 mg/kg, based on data made available by industry (using a test method with a lower detection limit of 15 mg/kg).

Recognizing that the purpose of testing is not to control the problem of SFP, but rather to verify that all the necessary control measures have been effectively implemented, identify failures in the system and remove implicated products from the market, different sampling approaches and associated plans were presented. In order to provide more explicit guidance on sampling approaches the meeting analysed a range of sampling plans implemented under different scenarios of histamine levels as defined by the log-transformed mean and standard deviation. Example of attributes sampling plans appropriate to different levels of tolerance for samples above 200 mg/kg, and for different assumptions about the standard deviation of histamine concentration within lots were presented. The sampling plans shown were two class plans and indicate the number of analytical units required to be tested in order to have 95% confidence that the batch as a whole satisfies the desired specified low proportion of samples (such as 1 in 10000) to exceed 200 mg/kg. The spread of contamination levels in the batch (i.e., the log-transformed standard deviation of contamination levels) has a strong effect on the tolerable average contamination level and, thus, on the number of samples

that must be tested to 'accept' the batch. Appropriate selection of the criterion against which test units comprising the sample will be assessed for compliance (m value), can considerably improve the time- and cost-effectiveness of sampling – requiring the least number of samples to be tested to achieve the same level of confidence about the disposition of the lot being assessed.

The expert meeting concluded that histamine formation and SFP can be easily controlled. The risk from SFP is best mitigated by applying basic GHPs and where feasible, a HACCP system. Appropriate sampling plans and testing for histamine should be used to validate the HACCP systems, verify the effectiveness of control measures, and detect failures in the system. Sensory evaluation remains a highly useful tool for quality control programs, but acceptable sensory quality cannot be taken as final assurance of low histamine, nor can low histamine be taken as final assurance that fish is not decomposed. As a result the conclusion of the expert meeting was to focus their advice on histamine limits and related sampling plans to those focused on consumer protection.

Several areas for which further research will be needed have been identified, including the need to clarify the critical role played by histamine and other biogenic amines in the pathogenesis of SFP.

Annex II

PILOT PROJECT TO ENHANCE PARTICIPATION IN THE EARLY DEVELOPMENT OF CODEX TEXTS AND PROMOTE EXCHANGE AMONG MORE EXPERIENCED AND LESS EXPERIENCED COUNTRIES

This paper depicts a novel approach regarding the elaboration of Codex documents in technical areas that are challenging for countries with less experience, by engaging them in the work in a collaborative and participatory manner. The pilot project was funded by the Codex Trust Fund (CTF) under Objective 2: Strengthening participation in Codex.

Background

The 43rd Session of the Codex Committee on Food Hygiene (CCFH) agreed to establish a physical Working Group (pWG) to continue the revision of the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) and to elaborate practical examples on the establishment and application of microbiological criteria for different purposes to aid the revision of the Principles. This work had been identified within the CCFH as a relatively complex issue and one where new approaches needed to be considered to facilitate the development of the Codex texts in a manner that enabled broad participation and facilitated greater understanding of the issues under discussion.

In order to facilitate the active participation of less experienced countries in the elaboration of these practical examples, it was further agreed to pilot an initiative using a "mentoring" approach through the coupling of more experienced lead countries and/or observer organizations (*mentors*) with less experienced countries (*mentees*). Practical examples were developed by seven identified drafting teams comprising member countries and/or observers as either lead/mentor or contributor/mentee to allow for knowledge transfer and ownership of the process and the examples. The practical examples developed were discussed at the pWG held in Parma, Italy from 29 May to 1 June 2012. The Codex Trust Fund (CTF) provided support for mentees from CTF eligible countries to attend the pWG in Parma.

Selected FAO and WHO staff, including the Codex Secretariat and the CTF Secretariat, have supported this pilot mentoring initiative since the beginning to effectively plan, implement, and finally evaluate the usefulness of this initiative. This work included an assessment of delegates to be supported by the CTF to attend the physical meeting in Parma, and continuous assessment of the progress and results of this pilot initiative in order to gain insight into the strengths and weaknesses of approaches such as this and distil out the lessons to be learnt for consideration in designing future initiatives.

The drafting groups communicated mainly electronically. Two of the seven groups set up periodic group teleconferences to advance and explain certain key points as they progressed on their examples. Most of the groups had a work plan with clear deadlines to meet. An FAO staff member participated in an observer capacity and also provided support to the groups on communication, procedural and technical issues as required.

At the end of the period for the elaboration of examples, the mentors and mentees were sent an online questionnaire for evaluation of the pilot initiative. This was followed up by focus group discussions at the pWG in Parma, Italy. An overview of these initial evaluation activities are provided below.

Preliminary results

Feedback from less-experienced countries (*mentees*).

Overall, the mentees were very satisfied with the pilot initiative and in particular the quality of the mentors' work and their participation in the discussion. They noted that this activity had also enabled them to engage with colleagues/experts in their country at a much earlier stage in the development of a Codex document and facilitate a broader discussion of the issues at country level. The mentoring process was also reported as a valuable learning experience that had heightened their understanding of and ability to work with a complex subject area.

The mentees highlighted the sharing of knowledge, data and learning experiences with other countries on specific topics, and the identification of key national experts in the field for improved country discussion as the main advantages of the approach.

With regards to disadvantages, the participants requested additional support through the creation of a virtual library, enabling access to current references unavailable in their countries. They also stated that they would have liked more time for discussion on the subject matter.

The mentees called attention to how the mentor/mentee initiative and participation in the physical working group allowed for a very different kind of participation in Codex. In the traditional approach countries read the documents, discuss within their countries, define national positions and go to the Codex committee session with this national position. Participating in the mentoring initiative and the physical working group had allowed mentees to work on the documents from a bottom-up approach, improving the preparation for CCFH and leading the national process around the document in their own country.

The mentees stated that this approach might be most usefully applied in Codex for general subjects that affect almost all kinds of foods in all countries and for specific tasks of high complexity.

Feedback from the lead countries / observer organizations (*mentors*)

The mentors highlighted their overall satisfaction with the pilot. In addition to achieving the objectives, mentors had gained a greater understanding of the needs of specific countries and experience in using a mentoring approach to respond to these.

Feedback from the mentors also highlighted the commitment of mentees to contribute, but noted the range of experience and knowledge influenced the manner in which the work was undertaken and the rate of progress. However, overall it was considered that less experienced countries and more experienced countries, working together as a team, brought broader perspectives to the discussion and increased the knowledge of all involved.

Among the disadvantages expressed by the mentors were the formalities (e.g. NCC procedures) in some countries that can slow the momentum of the work, and the different languages and time zones which complicate “live” discussions.

Both mentors and mentees stated that they would take part in a mentoring process again and would recommend other countries to take part in this type of initiative.

Of particular importance is that both mentors and mentees noted that the initiative started out with the labels of "mentors" and "mentees" but that the collaboration had resulted in the disappearance of the hierarchical relationship possibly associated with these terms and created a feeling that all had been a "winner" in the process.

Conclusions

The assessment of this pilot initiative at the time of writing has been very positive. Both mentors and mentees found that it had: achieved the desired outcome (drafting of seven examples of use of microbiological criteria); been an enriching experience; provided insights into how the Codex standard setting process works; had a number of positive side effects; could be considered as an approach to be used and/or adapted for future application in specific areas to advance Codex work.

The key learning points that FAO/WHO have drawn from the process are summarized below.

The mentoring approach as piloted:

- was successful in increasing knowledge and understanding of a complex, technical but important issue area in Codex (use of microbiological criteria) for standard development;
- was successful in achieving a specific outcome (drafting of seven examples of use of microbiological criteria);
- could be considered for use in other specific areas of Codex (particularly for enhancing knowledge and understanding of complex or technical issues) or adapted for use within already existing mechanisms for working on Codex documents (e.g. designating "mentor" countries within electronic working groups to play a role in enhancing knowledge, understanding and effective participation of countries in such groups);
- allowed for the development of relationships between mentors and mentees that continue beyond the exercise and can be used for exchange on any number of queries or issues related to participation in Codex.

Codex might wish to consider the potential to replicate this approach in CCFH and other Committees to promote understanding, applicability and ownership of Codex texts.

A full assessment of the project will be undertaken in two steps: (i) a short term evaluation focusing on the results and impact on the CCFH work on microbiological criteria; and (ii) a medium-long term evaluation on the potential to replicate the approach and its impact on effective participation.