



JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD HYGIENE
Forty-eighth Session

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**PROPOSED DRAFT GUIDANCE ON HISTAMINE CONTROL AND SAMPLING PLANS FOR
HISTAMINE**

HISTAMINE WORKPLAN

Prepared by the Electronic Working Group led by Japan and the United States of America

Governments and interested international organizations are invited to submit comments on the **recommendations in the histamine workplan** 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 with a copy to: The Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Rome, Italy, email: codex@fao.org **by 20 October 2016**.

Background

The 71st Session of the Executive Committee (CCEXEC71) (June 2016) of the Codex Alimentarius Commission (CAC) recommended that the work on histamine control guidance and sampling plans (formerly proposed in the Codex Committee on Fish and Fishery Products) should be carried out by the Codex Committee on Food Hygiene (CCFH). CCEXEC recommended that once approved by CAC the work be included on the agenda of the CCFH48 with consideration of a timeline for completion of work in light of its forward workplan.¹ The 39th session of the CAC (2016) approved the new histamine work and assigned it to CCFH.²

Previous work on histamine was carried out in CCFFP during the 32nd (2012), 33rd (2014), and 34th (2015) sessions with support from an FAO/WHO expert consultation. The [Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products](#), July 2012, Rome, provides recommendations for the control of histamine and the development of sampling plans for histamine.

In 2013, the FAO and WHO developed the [FAO/WHO Histamine Sampling Tool](#) for designing histamine sampling plans, which was updated in 2015 (ref FFP/34 CRD/12) to better support CCFFP work on sampling plans. CCFFP acknowledged that the sampling tool provided a sound basis for further development of sampling plans for the agreed work (REP 16/FFP Para 72).

The [Report of the 34th Session of the CCFFP](#) (REP16/FFP) Para 67-74 and Para 80, discussed the scope and content of the intended histamine work. Para 80 indicated agreement to base the work on the [Discussion Paper on Histamine](#) (CX/FFP 15/34/10) and the discussion in plenary, and that Japan and the U.S. would (1) prepare a project document for new work for submission to the CCEXEC and CAC and (2) lead an EWG and develop the documents for comment at Step 3. The [Discussion Paper on Histamine](#) and

¹ REP16/EXEC, para. 15

² REP16/CAC, paras 98-99, Appendix V

the discussion at CCFFP34 are the basis for the [Histamine Project Document](#) (Annex II of CX/CAC 16/39/7), and for the Terms of Reference listed below.

The draft documents that were anticipated to be prepared a CCFFP eWG for comments at Step 3 were not prepared by the current CCFH eWG as the work was only recently approved by CAC39 and, due to insufficient time before CCFH48. The CCFFP terms of reference and the Histamine Project Document provide the direction for Japan and the U.S. to draft the documents, and the 2016 CCFH EWG discussed further questions to facilitate progress of the work.

Terms of Reference for Development of Documents

Part A. Revision of the Code of Practice for Fish and Fishery Products (Code) (CAC/RCP 52-2003)

- a) Revise control guidance for the hazard of scombrototoxin fish poisoning, using histamine as the marker biogenic amine for control, and using a HACCP-based approach.
- b) Ensure that the guidance covers the entire food chain (harvesting, storage, handling, processing, and distribution.)
- c) Include where appropriate scientific information about histamine formation with the purpose of informing on the importance of time/temperature controls.
- d) Determine if any products with greater risk for histamine formation because of unique processing methods need specialized or revised control guidance.
- e) Incorporate into the Code, Table 2.3 (*Scientific names, free histidine levels and mean annual production levels for fish associated with scombrototoxin fish poisoning or high free histidine levels*) from the FAO/WHO Expert Report, revising the list where necessary to include relevant information (e.g., the proposed removal of salmon from the list).

Part B. Revision of sampling plans/guidance in commodity standards

- a) Align histamine sampling guidance across the relevant commodity standards for fish and fishery products
- b) Design risk-based histamine sampling plans for the sampling section of applicable fish and fishery product commodity standards. Develop different sampling plans for different purposes that are practical, feasible, and not adding a burden to producers while still ensuring food safety.
- c) Include appropriate supplemental sampling guidance needed for consistency of analytical results, including (but not limited to):
 - Which part of the fish to sample
 - The size of the sample unit
 - Proper handling of sample to prevent further histamine formation
 - What constitutes a “lot”
 - The procedure for “pooling” samples.

Results of the EWG

The electronic working group consisted of 20 countries, the EU, and FAO (see Annex 1 for the list of participants). Fourteen countries (Australia, Brazil, Canada, France, Germany, Ghana, Japan, Kenya (two members), Morocco, New Zealand, Norway, Senegal, Thailand, and the United States), one member organization (European Union), and one international organization (FAO) replied to the questionnaire.

Following are the six questions asked of the EWG and a summary of EWG member responses.

1. Approach to the revision of the Code of Practice for Fish and Fishery Products

Appendix I [that was attached to the EWG circular] lists the guidance found in different sections of the Code where scombrototoxin (indicated by histamine) is identified as a potential hazard. Histamine control guidance is similar among operations; therefore it is possible to consolidate histamine control guidance into a single

annex in the Code and reference the annex in the appropriate sections of the Code. This approach would be consistent with the request that CCFH ensure that the guidance is HACCP-based and covers the entire food chain (harvesting, storage, handling, processing, and distribution.) (Histamine Project Document section 3a (CX/CAC 16/39/7). It would also minimize repetition of guidance, and facilitate the addition of new products to the Code in the future.

Alternatively, it may be possible to elaborate histamine guidance separately in each applicable section of the Code. Or, a hybrid approach may be used to provide guidance as needed.

The best location(s) for the guidance may be determined after the scope and extent of the guidance developed by CCFH is realized, as well as a determination as to whether guidance would differ for specific fish standards; therefore, a flexible approach may be to first draft global control guidance in a single document, and then determine how to best fit the guidance into the existing Code.

Question 1: Based on the discussion above, what approach is preferred for drafting the histamine control guidance?

EWG Comments:

The majority of EWG members support the first option, which is to consolidate histamine control guidance into a single annex in the Code and reference the annex in the appropriate sections of the Code.

However, a few members support a more flexible approach. One member supports drafting a Codex document and determining the best fit for the guidance after drafting. One member commented that the format of the Code of Practice for Fish and Fishery Products should be taken into consideration, and existing histamine guidance may need revision regardless of the approach used.

2. Incorporation of Table 2.3 (*Scientific names, free histidine levels and mean annual production levels for fish associated with scombrototoxin fish poisoning or high free histidine levels*) from the FAO/WHO Expert Meeting into the Code and standards

Table 2.3 contains columns for 'market name'; 'scientific name' (family, genus, and species); 'histidine level'; and 'mean annual production' (tonne 2006-10).

- 1) In CCFFP there was general agreement that "mean annual production" data were irrelevant for the purpose of considering application of histamine controls during production, and should be removed from the incorporated table.
- 2) It was noted in CCFFP that the "market name" varies widely among and within countries, and that the market names may cause confusion and should be removed.
- 3) Removing the histidine (histamine precursor) level data was suggested in CCFFP because of concern that some users may interpret the data to mean that certain species are low risk and do not need temperature controls. This would be inappropriate because the experts determined that they are associated with scombrototoxin fish poisoning (SFP).

The information discussed in 1), 2), and 3), if removed, will remain available in the referenced FAO/WHO Expert Report.

Question 2: Should the incorporated table exclude the data about 1) annual production, 2) market name and 3) histidine levels?

EWG Comments:

The EWG consensus was to remove the data on annual production.

The majority of members support removing the data on the histidine level, and a few support including.

The majority of members support removing the data on the market name, and a few support including.

FAO suggested to determine the purpose of the table first. By this approach, FAO suggested CCFH can determine which data should be retained in the table.

3. Inclusion of Salmonidae in the list of susceptible species

Several CCFFP members recommended excluding Salmonidae from the table because, while salmon have caused illnesses with SFP-like symptoms, the histamine levels in suspect salmon were low, and it has been postulated that unknown toxin(s) may be responsible for the illnesses.

Question 3: Should Salmonidae be included or excluded when incorporating Table 2.3 into the Code, or possibly included with a footnote?

EWG Comments:

There was more or less equal support for excluding or including Salmonidae when incorporating Table 2.3 into the Code. Among members that support including Salmonidae, a few suggested including salmon with a footnote.

It was suggested that further research on salmon and SFP-like syndrome is needed to determine whether Salmonidae should be included or excluded from the table.

4. Replace Family lists in commodity standards with reference to the FAO/WHO susceptible species list

CCFFP recommended considering how to integrate the planned new table in the Code with the existing susceptible species lists in the commodity standards. This can be done by replacing the existing lists in the standards with a reference to the new table in the Code.

Question 4: Should the existing susceptible species lists in the commodity standards be replaced with a reference to the new table of susceptible species that will be incorporated into the Code?

EWG Comments:

The consensus was to replace the existing lists in standards with a reference to the new table of susceptible species that will be incorporated into the Code.

One member recommended including the list of species, or Families, in the standards, and another member supports listing the list of relevant fish species in the standards and in the Code.

5. Start histamine control guidance work first, followed later by work on sampling plans.

It is anticipated that an EWG will be established following CCFH48 that will work on Draft Histamine Control Guidance to be prepared by Japan and the U.S. for EWG comment and revision. In the following year the EWG could comment on Histamine Sampling Plan Guidance that the U.S. and Japan can prepare in the interim. This approach allows progress on control guidance, and allows more time to prepare draft sampling plan guidance, which is more complicated.

Question 5: Should work start on Histamine Control Guidance first, followed later by Histamine Sampling Plan Guidance?

EWG Comments:

All members support starting work on Draft Histamine Control Guidance first, to be prepared by Japan and the U.S. for EWG comment and revision, and postpone working on developing Histamine Sampling Plan Guidance to the following year after Japan and the U.S. will have produced a document for comments by the EWG.

6. Sampling plans for different purposes.

Usually a commodity standard has a single sampling plan, or criteria with a reference, for the purpose of determining if an inspected lot complies with a health-based limit in the standard. It was discussed in CCFFP that some countries use more complex strategies for the control of food safety, where sampling is used differently from the traditional lot inspection accept/reject model. CCFH may wish to consider alternative sampling plans for different purposes as noted in the project document (CX/CAC 16/39/7, section 3b.) Alternative purposes should be clearly defined in order to develop appropriate sampling plans and/or guidelines.

Different types of plans will have different procedures (e.g. sampling frequency, number of samples, and decision limits) and different required information for use (e.g. data from past results, detail of sample source (processor, vessel, date), process control records, etc.) that will require more time to develop.

By default, a sampling plan (or risk-based criteria) is needed for the purpose of inspecting imported lots (that have undergone unknown temperature controls in the food chain) for determining compliance with the histamine safety provision in commodity standards, because this is a principal scenario considered during development of Codex commodity standards.

Question 6: Should CCFH consider alternative sampling plans for different purposes, and subsequently clearly define the different purpose(s) that require development of sampling plans/guidance?

EWG comments:

Most members agree that if sampling plans for different purposes are needed, then the purposes should be clearly defined.

Several members support sampling plans for different purposes. One member identified two different purposes, one to verify exporting country's food control systems where these are known to be effective, and one to ensure specific consignments are safe where the catching and processing conditions are unknown or not under a trusted system of industry control and regulatory oversight.

However, the majority of members had various reservations, or needed more information in order to make a decision. Some members think it is too early at this point to decide on whether or not a number of alternative sampling plans may be needed, and the decision should be made after working on the Code or after development of a sampling plan draft document by Japan and the U.S. for comment. One member finds it difficult to comment at this point on whether or not multiple sampling plans would be necessary because the question is unclear and it is difficult to understand why there would be a number of sampling plans included under different purposes. Another country says that any alternative sampling plans and associated guidance are not necessary at the moment.

In general, if alternative sampling plans and associated guidance are prepared, they should be scientifically sound and feasible to implement.

Discussion and Recommendations to CCFH

1. Approach to revision of Code of Practice for Fish and Fishery Products.

Members favour drafting a single section, at least initially. It should be noted that the Code of Practice for Fish and Fishery Products is a HACCP-based document with integrated complementary sections that already contain histamine controls; therefore, revision of language within existing sections will be required to meet the mandate. CCFH should attempt to adhere to the intended format of the Code (See Code Introduction, "How to use this Code") where possible, and place guidance in a new annex or section, where appropriate, for clarity or to reduce repetition.

Recommendation to CCFH:

Japan and the United States should draft revised histamine guidance taking into consideration the existing format of the Code and minimization of cross-references. Elaboration of a new annex or section for histamine control guidance should be considered; however, the Code needs to be carefully studied, and the final format may need to be reconsidered when the draft document is available for comment.

2. Data in FAO/WHO Table of fish associated with scombrototoxin fish poisoning or high free histidine levels.

Most of the EWG members suggest excluding information on 1) annual production, 2) histidine level and 3) market name of susceptible fish species.

There are mixed viewpoints to remove or include Salmonidae. The retention of Salmonidae depends on the purpose of the Table, A) To list fish associated with SFP, or B) To list fish that develop high histamine. Salmonidae are associated with SFP-like illnesses, but do not appear accumulate high histamine. More research on salmon and SFP-like syndrome is needed.

Recommendations to CCFH:

Integrate the Table without data on annual production, histidine level, and market names (Family and scientific names only).

CCFH should discuss the purpose of inclusion of the table, and, depending on the purpose, the inclusion of Salmonidae should be decided.

3. Replace current Family lists in the commodity standards with reference to the FAO/WHO susceptible species list.

Members agree that the existing lists in applicable commodity standards should be replaced with reference to the updated list of susceptible species. It was also suggested that it is important to include the list of susceptible species in the applicable commodity standards. This proposal has merit, considering the substantial benefit to food safety to include the species list directly in the standards, and the relative ease of adding an annex to the applicable standards (unlikely to need update in the foreseeable future).

Recommendations to CCFH:

Replace the existing susceptible Family lists in commodity standards with a reference to the updated susceptible species list (reformatted table).

Locate the list in the Code (as appropriate during revision).

Consider locating the list (or applicable species in the list) as an annex in the applicable commodity standards, in addition to the Code.

4. Start histamine control guidance work first, followed later by work on sampling plans.

There was unanimous agreement to postpone work on sampling plan guidance for commodity standards in order to allow time for Japan and the U.S. to draft the revision to the Code of Practice for Fish and Fishery Products, and subsequently draft the commodity standard sampling guidance revision document for comment.

Recommendation to CCFH:

Japan and the U.S. should draft the revision of the Code of Practice for Fish and Fishery Products for EWG comment following CCFH48 (November 2016). Subsequently, Japan and the U.S. should prepare the histamine sampling plan guidance document for EWG comment following CCFH49 (November 2017).

5. Alternative sampling plans for different purposes

Members had mixed viewpoints on the need for alternative sampling plans for different purposes with most appearing to need further information to understand the reason for multiple plans.

The concept of alternative purposes arose in CCFFP in order to overcome difficulty agreeing on the risk-based sampling plans designed to provide a degree of statistical assurance that a lot in isolation complies with the histamine safety limit in the commodity standard. For risk-based sampling plans addressing isolated lots, the FAO/WHO experts recommended that the histamine decision limit should be lowered (below the safety limit) in order to attain a feasible sample size that provides at least a minimum level of public health protection. However, some countries said that they do not sample to insure individual lot safety or compliance with the commodity standard, but use sampling to screen lots already expected to be safe through monitoring and evaluation of processor HACCP systems. These countries use sampling plans with decision limits near the safety limit and small sample sizes that do not provide information about the safety of an individual lot, but with continued good results, add confidence that a control system is working properly.

Recommendation to CCFH:

CCFH should discuss and determine if alternative sampling plans are needed (in commodity standards or the Code), and if so, clearly define the purpose. If an alternative sampling plan purpose is agreed to, then Japan and the U.S. should research and draft sampling guidance for this purpose, in addition to drafting guidance for the risk-based plan used to determine individual lot compliance with the commodity standard. It is recommended that only the purpose, and not a specific plan, is discussed before the EWG document is produced. CCFH work in this subject area should be scientifically sound and feasible to implement.

Relevant Codex and FAO/WHO Documents

[Discussion Paper on Histamine](#) (CX/FFP 15/34/10), CCFFP 34th Session, October 2015

[Report of the 34th Session of the CCFFP](#) (REP16/FFP), Para 67-74 and Para 80

[Histamine Project Document](#) (CX/CAC 16/39/7, Annex II)

[Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products](#), July, 2012, Rome

[FAO/WHO Histamine Sampling Tool](#)

[General Guidelines on Sampling](#) (CAC/GL 50-2004)

[Principles for the Use of Sampling and Testing in International Food Trade](#) (CAC/GL 83-2013)

[Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods](#) (CAC/GL 21-1997)

[Code of Practice for Fish and Fishery Products](#) (CAC/RCP 52-2003)

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