CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 10 **CX/FFP 14/33/12**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS

Thirty-third Session
Bergen, Norway
17 – 21 February 2014

Discussion Paper on Histamine

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

INTRODUCTION

At its 32nd session in Bali, the CCFFP agreed to establish an electronic working group, chaired by Japan and the United States of America, with the following terms of reference:

- *Assess how the CCFFP might use the expert advice and make recommendations with respect to approaches that the CCFFP could consider to integrate the advice into the relevant Standards and relevant sections of the Code of Practice on Fish and Fishery Products, taking into account the fact that histamine can be easily controlled by applying GHP and/or HACCP;*
- *Identify new questions that the CCFFP may need further clarification on;*
- *Identify areas in the report that may need further clarification;*
- *As appropriate, make recommendations on the histamine hygienic criteria and associated sampling plan;*
- *As appropriate, consider the views from CCFH on the report of the Joint FAO and WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products, if applicable.*

A total of thirty two countries, unions and observers registered to participate in the working group, and comments were received from 12 participants. Appendix 1 contains the list of the participants and their email addresses.

BACKGROUND

During the 31st Session in Tromso, CCFFP had an extended discussion on the histamine safety limit provision for the Fish Sauce Standard. This led to agreement to form an electronic working group to review histamine health risks, sampling plans, and trade issues. FAO/WHO offered 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. (CX/FFP 12/32/2-Add.1**)**. The Draft Expert Meeting Report was available one month before the 32nd CCFFP Session, and Japan and the United States drafted a discussion paper based on the Draft Expert Meeting Report[1]; however there was not enough time for the EWG to convene. Therefore at the 32nd Session in Bali, the CCFFP established the current EWG chaired by Japan and United States to assess the usefulness of the expert advice[2] and make any appropriate recommendations related to the histamine hygienic criteria and associated sampling plan.

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1 CX/FFP 12/32/14 Discussion Paper Histamine
Link: ftp://ftp.fao.org/codex/meetings/ccffp/ccffp32/fp32_14e.pdf

2 *Meeting Report* of the *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products; 23–27 July 2012.*
Link: http://www.fao.org/fileadmin/user_upload/agns/news_events/Histamine_Final_Report.pdf

COMMENT SUMMARY

The comments from EWG members addressed a variety of histamine topics that were covered or touched upon in the FAO/WHO Expert Meeting Report.

Listed below are the key topics discussed that relate to relevant Codex Standards or Codes of Practice of Fish and Fishery Products.

- Whether to retain the current histamine safety limit in standards, or to lower the limit based on dose response data, consideration of uncertainty, and other risk management factors.
- Whether to retain the current histamine sampling plan in standards, or to develop a new histamine sampling plan.
- Whether to consider higher histamine limits for products based on consumption levels , or other product characteristics.
- Whether the histamine limit for decomposition should be re-evaluated for inclusion in standards.
- Whether to retain current guidance on the sanitary control of histamine in the Codes of Practice of Fish and Fishery Products, or revise, or develop new guidance.
- Whether to retain the current format for listing histamine susceptible species in standards, or create a new central listing of susceptible species.

The key discussion points and viewpoints expressed in the comments are summarized below. EWG recommendations for consideration by the Committee are listed in the last section of this Report.

Histamine Safety Limit in Standards

Background

The "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius", *Codex Procedural Manual, 21st version,* page 107, should be read before reviewing safety-based limits in Codex standards. The paragraphs below from these principles address some points that were discussed by the working group:

> *3. Within the framework of the Codex Alimentarius Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment lies primarily with the joint FAO/WHO expert bodies and consultations (risk assessors).*
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> *11. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of un-certainty and the characteristics of the hazard.*
>
> *24. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.*
>
> *25. The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.*
>
> *27. While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in the food trade, Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers. Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.*

> *28. Risk management should follow a structured approach including preliminary risk management activities[25], evaluation of risk management options, monitoring and review of the decision taken. The ~~risk management~~ decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles[26].*
>
> *30. In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.*

The current histamine safety limit in Codex standards was not based on a formal risk assessment.

The FAO/WHO Expert Meeting Report identified an oral histamine no observed adverse effect level (NOAEL) of 50 mg and, based on an estimated 97.5% consumption level of 250g, calculated that the maximum concentration of histamine in fish that would not cause an adverse effect is 200 mg/kg.

During the course of the EWG there was discussion about the need for an appropriate uncertainty factor to apply to the NOAEL to account for human variability. The FAO/WHO Expert Meeting Report includes the following information about an uncertainty factor:

> *It is important to bear in mind that, while the NOAEL is an appropriate hazard threshold value to use for exposures in healthy subjects, this may not be the case for those members of certain segments of the population who may have an increased sensitivity (e.g. metabolic differences, physiological conditions, drug therapies). In these instances a lower hazard level may need to be considered (e.g. the use of an uncertainty factor [of 10]) or other specific risk management options such as fish consumption advisories should be considered.* (From page 33, except bracketed section from page 105)

The following paragraph on page 34 of the Expert Report is also helpful for the consideration of uncertainty:

> *Both the NOAEL and BMD assessments identified 50 mg of histamine per meal as the dose where either adverse effects were not noted or the estimate of additional risk (lower confidence level) is low. This dosage level will not apply to individuals with a specific sensitivity to histamine and would not apply to children, particularly because they consume more food per unit body weight than adults. It is also important to bear in mind that the 50 mg dosage was derived from data on a small number of subjects, and while the variation of response appears to be reflected in the study results further studies would be most helpful in refining this threshold value.*

EWG Discussion

Two members of the EWG commented that application of an uncertainty factor was not needed based on their assessment of the literature and illness data. The other EWG members supported continued consideration of an uncertainty factor to help protect a broader range of sensitive individuals including children. One member commented that the 'default' uncertainty factor (10) should be applied to the NOAEL, resulting in a 20 mg/kg histamine limit.

Two members suggested that CCFFP could ask the Codex Committee on Contaminants in Foods (CCCF) for advice on an appropriate uncertainty factor, and two members questioned if this would be appropriate. Three members doubted if any request should, or could, be made of the ad hoc FAO/WHO Expert Group. One member suggested that CCFFP in the plenary session should discuss who is the best placed to provide advice about applying an UF, and another member suggested that CCFFP consider in the plenary session if further consideration of the conclusions of the FAO/WHO expert group is needed.

One country suggested that further evaluation is needed on the contribution of other biogenic amines to scombrotoxin (i.e., cadaverine, putrescine, and tyramine.)

The Recommendations section of this discussion paper contains a suggested approach for consideration of the histamine limit by the Committee.

Sampling Plans

Several members commented that risk-based sampling plans designed to assure public safety were impractical because of the large number of samples required to achieve a measured degree of protection, as presented in the FAO/WHO Expert Meeting Report. EWG members agreed that good vessel and processor practices, and the use of HACCP systems, are the primary control for histamine, and that sampling is used to verify that these practices/systems are adequate.

It was discussed that sampling plans may be used at many points from harvest to distribution, and for different purposes (e.g., fish landing, plant reception, border, HACCP, screening, regulatory). It was suggested that the terminology used with sampling plans in Codex documents should be further defined. Of principal interest for further CCFFP discussion were sampling plans used to verify the histamine safety limit in Codex standards. Several viewpoints on this were expressed.

Two members supported the existing sampling plan in standards, and the use of existing Codex sampling guidance. Two members suggested using a 3-class sampling plan with large 'M' perhaps at the current 200 mg/kg limit and small 'm' at 100 mg/kg or lower, with the number of samples allowed between 'm' and 'M' ('c'), and the sample size ('n'), to be determined. Other members suggested listing various sampling plan options for consideration by the Committee.

When considering the risk-based sampling plan guidance in the Expert Report, two members pointed out that the standard deviation of histamine levels in lots varies considerably and is unknown beforehand. One member commented that because of different standard deviations the necessary sample size would vary, and recommended that competent authorities could refer to the FAO/WHO Histamine Sampling Tool[3] to establish and implement risk-based sampling plans.

One member was concerned with the cost related to compliance with proposed sampling due to the volume of samples. This may warrant further CCFFP discussion because different countries use different strategies to assure compliance with provisions in Codex standards.

Two members expressed the viewpoint that reduced sample sizes were appropriate when justified by historical data for the specific product (i.e., histamine levels, HACCP/cold chain records).

Sampling plan options for use in determining compliance with Codex histamine safety limits in standards are listed in the Recommendations section of this discussion paper.

Different Limits for Different Products Based on Consumption Levels and Product Characteristics

Most members agreed that higher limits could be considered for products with low consumption levels, and that the low consumption level needs to be defined.

One member suggested that proposed higher limits based on lower consumption levels should be based on reliable data and that the increased risk of illness should be estimated; in addition consumption of other foods (such as cheese) should be considered. One member suggested that limits should not be excessive for any product, and that the risk assessment should consider products consumed in small portions (such as fish sauce) with a fish meal that may be high in histamine.

One member suggested that the reference maximum serving size should be listed with the histamine limit so that competent authorities can make informed decisions based on their local consumption data.

Histamine Decomposition Limit

Several members commented that there should be one histamine limit because it is confusing to have both a histamine limit for safety and a different histamine limit as an indicator of decomposition in one standard. Some comments referred to the Joint FAO/WHO *Expert Meeting on the Public Health Risks of Histamine and other Biogenic Amines from Fish and Fishery Products* where sensory assessment was discussed in context of histamine risk management. Section 6.1.9 states:

[3] Link to FAO/WHO Histamine Sampling Tool: http://www.fstools.org/histamine/

However, the correlation between histamine content and odours of decomposition is often inconsistent (Fücker et al., 1974; Kimata, 1965; Veciana-Nogués et al., 1997). Histamine formation without significant odours of decomposition (Özogul et al., 2002), or odours of decomposition without rejectable histamine formation (Du et al., 2002), are both possible.

Two members (including the International Council of Grocery Manufacturers Associations) supported retaining a separate decomposition limit, unless a reduction of the safety limit made it irrelevant.

It should be noted that assessment of histamine as an indicator of decomposition (a quality provision) was not within the terms of reference of the Expert Meeting or this EWG, and further work should be initiated if CCFFP wishes to evaluate appropriate markers of decomposition for inclusion in standards.

Histamine Control Guidance

Several members were in favor of considering new or revised histamine control guidance. Japan volunteered to draft guidance, and the U.S. volunteered to assist if guidance were created. Other members provided examples of guidance and references to consider if new guidance was created. Some members did not express a firm opinion and appeared neutral. The International Council of Grocery Manufacturers Associations preferred to have the existing code enforced, and was concerned that new guidance could be unnecessarily restrictive.

Susceptible Species List

Table 2.3 of the FAO/WHO Expert Meeting Report, lists Scientific names, free histidine levels and mean annual production levels for fish associated with scombrotoxic fish poisoning or high free histidine levels. Members generally supported including this list, or a modified list, in the Code of Practice for Fish and Fishery Products or in a histamine guidance document. However, some members expressed the viewpoint that species harvested from colder waters are less susceptible to histamine formation even if they contain high histidine due to less chance to be exposed to elevated temperature and less chance to be exposed to histamine forming bacteria, and that histamine control strategies could be implemented because of a theoretical, rather than an actual, hazard.

RECOMMENDATIONS

The EWG has the following recommendations for consideration by the Committee:

Histamine Safety Limit

The appropriate histamine safety limit should be determined for Codex Fish Standards in two steps:

First Step - Uncertainty Factor (UF):

Although some members of the EWG indicated that the application of an UF was unnecessary, the EWG recommends that CCFFP:

1) Consider if the application of an UF is scientifically justified and if so, consider an appropriate UF and the reasons for its selection.

2) Consider the following and any other sources of uncertainty:

- Review of the primary and supporting dose/response studies used for the NOAEL (i.e., sample size, sample selection, data collected) in the light of application of an UF.
- The normal distribution of human histamine sensitivity.
- Common factors that may increase sensitivity.
- Knowledge of co-occurring biogenic amines.
- Sensitization by continued exposure to elevated histamine.

3) Recommend the appropriate uncertainty factor to apply to the NOAEL and 97.5% consumption level identified in the FAO/WHO Expert Report.

Table 1: The commonly used uncertainty factors discussed and their corresponding reference hazard levels based on the NOAEL and 97.5 percent consumption level identified in the Expert Report

Uncertainty Factor	Reference Histamine Hazard Level (mg histamine/kg fish flesh)
10 (default)	20
3.16	63.3 (63)
3	66.7 (67)

Second Step – Other risk management considerations (including other legitimate factors):

After agreeing on an appropriate uncertainty factor, the CCFFP should consider practical, social and economic factors that may affect the appropriate histamine limit. Examples of these factors to consider are:

- Frequency and severity of reported illnesses.
- Histamine levels desired by consumer and commercial buyers, and levels that can be practically attained by harvesters/processors?
- To what extent should the lower tail of the histamine sensitivity curve be protected by the limit, i.e., which highly sensitive individuals cannot practically be protected and should know, or be advised, to avoid certain fish.
- Levels of histamine in a lot that provide evidence of inadequate hazard prevention process controls used by the harvester/processor, and suggest a hazard may be present.
- Histamine limits used for lot sampling, taking into consideration high histamine variance observed in abused lots as a result of uneven time/temperature exposure and exponential bacterial growth and histamine formation.

A new electronic working group could be formed for more focused work (with terms of reference based on the above).

Sampling Plans to determine Compliance with the Histamine Safety Limit in Standards

The EWG recommends that CCFFP narrow sampling plan discussion to those plans used to determine compliance of lots with the histamine provisions in Codex Standards (i.e., border inspection). The EWG presents the following sampling plan options for consideration by the Committee:

Option 1: Retain the existing sampling plan (i.e., "No sample shall contain histamine that exceeds [the determined limit]").

Option 2: Combine the histamine 'decomposition limit' with the histamine 'safety limit' in the hygiene section of standards in order to eliminate confusion caused by two different histamine limits in one standard (i.e., "No sample shall contain histamine that exceeds [the safety limit], and the average of the samples units tested shall not exceed [the decomposition limit]"; or by applying a 3-class sampling plan with the 'safety limit' considered as 'M', and the 'decomposition limit' considered as 'm', and the acceptance number 'c' equal to the number of samples allowed between "m" and "M".)

Option 3: Consider 2 or 3 class risk-based sampling plans such as in the examples below.

Table 2: Examples of 2 and 3 class sampling plans designed by using the FAO/WHO Histamine Sampling Tool

Histamine Safety Limit 'M' (mg/kg)	Level of Protection	Confidence Limit	Standard Deviation (log_{10} scale)	'm' (mg/kg)	'c'	Sample Size 'n'
20	1 in 10,000	95%	1.35	5	0	> 50
20	1 in 10,000	95%	0.88	5	0	> 50
20	1 in 10,000	95%	0.5	5	0	> 50
20	1 in 10,000	95%	0.3	5	0	> 50
67	1 in 10,000	95%	1.35	5	0	> 50
67	1 in 10,000	95%	0.88	5	0	> 50
67	1 in 10,000	95%	0.5	5	0	41
67	1 in 10,000	95%	0.3	11	0	21
200	1 in 10,000	95%	1.35	5	0	> 50
200	1 in 10,000	95%	0.88	5	0	> 50
200	1 in 10,000	95%	0.5	10	0	22
200	1 in 10,000	95%	0.3	34	0	24
200	1 in 10,000	95%	0.3	17	1	24

'Level of Protection' is the maximum acceptable fraction of sample units from a lot allowed to exceed the 'Histamine Safety Limit' (in first column). 1 in 10,000 is used as an example because it is difficult to justify a further reduction in public safety.

'Confidence Limit' is the desired confidence limit that lots that do not meet the "level of protection" will be rejected by the sampling plan. The 95% confidence limit is used as an example because this limit is often used for statistical purposes.

'm' - Sample concentrations higher than 'm' are counted and compared to 'c'. If the count exceeds 'c' then the lot is rejected. In the examples 'm' is restricted to 5 mg/kg or above because levels below 5 mg/kg are near the method detection limit (~1 mg/kg) and were not considered advisable for a regulatory decision limit.

'c' is the acceptable number of sample above little 'm'. Note that only the last example in the Table is a true 3-class sampling plan with big 'M' and little 'm'.

'n' is the sample size. The example sample sizes were held below 24 where possible in order to represent a practical maximum number. Note that the FAO/WHO Sampling Tool gives no results for sample sizes above 50, therefore where the plan lists 'n' > 50 the number of sample needed is not determined and can be considered unacceptably high.

Standard Deviation (log_{10} scale): From page 38 of the Expert Report:

> *We observed that in surveys in which high contents of histamine were detected the standard deviations of the normal distribution describing log10 (C) were often high (above 1.3), yet the associated means were often low (below 0) (e.g. for mackerel in market fish in Japan or canned tuna imports to Canada). For surveys in which no high concentration of histamine was detected, the standard*

deviations are comparatively low (about 0.5 or less) but the associated means are comparatively high (greater than 1.0). This is probably due to the limited sample size of these surveys.

Example values for the standard deviation (SD) were selected as follows:

- SD = 1.3 (represents lots with high histamine)
- SD = 0.88 (average SD for the 39 surveys listed in Table 5.1)
- SD = 0.5 (represents lots with no high histamine)
- SD = 0.3 (represents an industry lenient SD)

For the 39 surveys listed in Table 5.1, the SD range was 0.05 to 2.79, and the median was 0.72.

Suggested sampling plans with 'M' = 200, 'm' = 50, and C= 1 or 2 cannot be designed using the most lenient 'level of protection' and 'confidence limits' available in the FAO/WHO Sampling Tool, and are not listed because they could not be assigned a practical statistical basis.

Different Limits for Different Products Based on Consumption Levels and product characteristics

- Since members of the EWG expressed different views, the EWG has no specific recommendations applicable to existing standards.
- The EWG recommends that the appropriate histamine limit for products consumed at normal levels should be considered first, because this would affect limits for smaller portions.

The Histamine Decomposition Limit

The EWG has the following recommendations:

- Finalize consideration of the histamine safety limit before reviewing histamine as an indicator of decomposition.
- If the histamine safety limit is changed to be lower, or equal to, the decomposition limit in a standard, then only a provision for the safety limit may be necessary because if the safety limit is met the decomposition limit will also be met.
- If the decomposition limit remains a concern after review of the safety limit, then the Committee should consider forming an electronic working group to assess indicators of decomposition and appropriate decomposition provisions for histamine standards.

Histamine Control Guidance

- The EWG recommends that the Committee considers forming an electronic working group to review the existing histamine related guidance in the Code of Practice on Fish and Fishery Products and propose any needed revised or new guidance based on information in the Expert Report and comments received.
- Any new work should take into consideration that histamine is easily controlled under GMPs and/or HACCP and that revised or new guidance should not become an unnecessary burden beyond what is required to protect public health.
- The EWG recommends that any work on histamine control guidance should be started after any further work on the histamine limit is completed.

Susceptible Species List

The EWG recommends that the list of species contained in Table 2.3 of the Expert Meeting Report should be reviewed for inclusion in the CoP during the work recommended above for "Histamine Control Guidance".

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