



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

Thirty-fourth Session

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DISCUSSION PAPER ON HISTAMINE

Comments of Brazil, Kenya, Morocco, Nigeria, Senegal, Thailand and African Union

BRAZIL

Brazil agrees to consult the CCCF for comments on appropriate health-based limits based on adverse event thresholds and uncertainty.

Also, in recommendation 4, Brazil supports option 3 which is the most appropriate for introducing a harmonized sampling plan considering the different purposes; however the sampling plan can only be established after setting the maximum level. The harmonization is essential to avoid disputes, because sampling is, among others, procedures utilized to assess whether foods in trade are compliant with particular specifications.

The first and the second option do not require a harmonized sampling for verification of parameters related to risks to health and may lead to disputes. The absence of defined, scientifically valid procedures could lead to *ad hoc* practices being used, resulting in inconsistent decisions and an increased occurrence of disputes.

Parts of the fish that will compose the sample and the weight of the sample are key points to be considered in the establishment of the sampling plan, taking into account the histamine inhomogeneous distribution in fish.

The sampling plans should also consider if there is a control system or whether sampling is done in lots of unknown quality.

It is important include the sampling plan in all standards of products subject to histamine formation after it be defined.

KENYA

Terminology

1. This paper follows the usage of the terms 'histamine' and 'scombrototoxin' found in the *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* (FAO/WHO Expert Report), which states in Section 2.3,

SFP [scombrototoxin fish poisoning] is a worldwide food safety problem and is a common cause of fish poisoning that occurs in humans. The food poisoning is caused by heat-stable scombrototoxins, presumably arising from bacterial action in fish. Although detailed components of scombrototoxins have not been identified, it is generally accepted that biogenic amines, especially histamine, play an important role in the pathogenesis of SFP.

Comment:

We have observed that “SFP [scombrototoxin fish poisoning]” was not agreed on EWG. We agree with the term and therefore propose to open the brackets.

I. CONTROL GUIDANCE

Recommendation 1) Form a dedicated EWG to revise and elaborate guidance in the *Code of Practice for Fish and Fishery Products* with the following terms of reference:

The CCFFP should:

- a) Revise, where necessary, control guidance for scombrototoxin fish poisoning, using histamine as the marker biogenic amine for control.
- b) Include where appropriate scientific information about histamine formation with the purpose of informing on the importance of time/temperature controls.
- c) Ensure that applicable sections of the Code cover the entire food chain (harvesting, storage, handling, processing and distribution.)
- d) Incorporate into the Code, and revise if necessary, Table 2.3 (Scientific names, free histidine levels and mean annual production levels for fish associated with SFP or high free histidine levels) from the FAO/WHO Expert Report (See Recommendation 2 below.)
- e) Consider if any products with greater risk for histamine formation because of unique processing methods need specialized or revised control guidance.

Comment

We have gone through the recommendations 1 mentioned above and we support the proposals therein.

II. SUSCEPTIBLE SPECIES LIST

(Table 2.3 “Scientific names, free histidine levels and mean annual production levels for fish associated with SFP or high free histidine levels” in FAO/WHO Expert Report)

Recommendation 2) Incorporate Table 2.3 (Scientific names, free histidine levels and mean annual production levels for fish associated with SFP or high free histidine levels) from the FAO/WHO Expert Report into the *Code of Practice for Fish and Fishery Products*, revising the list where necessary. Consider how the table should be formatted, and if specific data fields (e.g. histidine levels, production levels, market names) or specific species (e.g. salmon) should be included or excluded. Consider how to integrate the Table with existing susceptible species lists in fish and fishery product commodity standards. See Recommendation 1(d) (above.)

Comment

1. This second recommendation mentioned above is the duplication of ‘recommendation 1 ‘d’ ’ that states ‘Table 2.3 (Scientific names, free histidine levels and mean annual production levels for fish associated with SFP or high free histidine levels) from the FAO/WHO Expert Report’ . We therefore agree to that recommendation to that effect.

2. While revising table 2.3 we propose a separate list of susceptible species to be included.

III. SAFETY LIMIT

Recommendation 3) EWG participants did not reach consensus on support for a lower limit (i.e. 100 mg/kg) or support for the current limit of 200 mg/kg. The EWG recommends that CCFFP consider these two options for the Hygiene section of standards (other than the *Standard for Fish Sauce*.)

Comment

We noted that there was no consensus on the limits for histamine in fish species other than fish sauce. We do not support neither lower limit of 100mg/kg nor support for the current limit of 200 mg/kg proposed by EWG. We also noted that 15mg/kg can be achieved as stated FAO/WHO Expert Report 23-27th July 2012’.

We therefore propose 10mg/kg as the maximum limit for histamine which we have been achieving for some years without any trade issues.

26. The EWG also recommends that CCFFP consider consulting the Codex Committee on Contaminants in Foods (CCCF) for advice on appropriate health-based limits based on adverse event thresholds and uncertainty presented in the FAO/WHO Expert Report.

IV. SAMPLING PLANS

Recommendation 4)

For the Hygiene section of standards

- The wording for the health-based histamine safety limit should be consistent among standards unless different limits apply for specific commodities.

For the Methods of Analysis and Sampling section of standards

- Reference the *General Guidelines on Sampling* (CAC/GL 50-2004).

O Further expert review may be needed to determine if any particular approach within the *General Guidelines on Sampling* (CAC/GL 50-2004) should be referenced or explained in standards.

- Clarify that “AQL of 6.5” does not apply to histamine.
- Clarify the use of the defined sampling plan listed in the *Standard for Frozen Blocks of Fish Fillet, Minced Fish Flesh and Mixtures of Fillets and Minced Fish Flesh* (Codex STAN 165-7989) that may not be intended for the histamine safety limit.
- Include additional sampling guidance; such as what constitutes a lot, which part of the fish to sample, weight of the sample unit, pooling samples, etc.
- Options for sampling plan information:

Option 1: No change. Countries can select appropriate sampling plans using existing Codex guidance (considered above.) Most CCFFP standards do not include specific sampling plans for health-based, or quality, limits. Codex procedure recommends including a sampling plan. However, in order to be included in the commodity standard, the reference sampling plan used to determine acceptance of a lot (or settle disputes) should provide a measurable degree of confidence about the safety of a lot with unknown exposure history.

Option 2: Include the following reference to the FAO/WHO Histamine Sampling Tool: SAMPLING, EXAMINATION AND ANALYSIS

Sampling of lots for examination of the final product shall be in accordance with the *General Guidelines on Sampling* (CAC/GL 50-2004). The FAO/WHO Sampling Tool for Histamine (<http://www.fstools.org/histamine/Default.aspx>) provides useful information about the performance of sampling plans⁷ under various decision parameters that may be applicable under some sampling plan strategies.

This is optional guidance that was designed for Codex histamine sampling by FAO/WHO experts. Option 3: Include a defined sampling plan or more than one sampling plan for different purposes.

37. In order to design justified sampling plans in a transparent manner, it is necessary to first establish an agreed health-based safety limit (discussed in Section III.) Because a health-based safety limit has not been agreed, the EWG cannot properly propose specific sampling plans. After the health-based safety limit is agreed, CCFFP may consider establishing an EWG devoted to sampling plans and related guidance.

COMMENT ON SAMPLING PLAN ABOVE

We have gone through table 1, 2, and 3 provided in the sampling plan and observed the following information missing:

- 2. The agreed method of sampling indication, batch and lot number**,***
- 3. The position where the sample will be obtained and***
- 4. The weight of the sample to be obtained.***
 - ***We therefore suggest that sampling to be 9 samples per batch.***
 - ***Concerning Sampling position- the cut to be obtained on the back of the fish just next to the head down to the backbone (can be “V” shaped or straight parallel cut).***
 - ***We propose the weight of the sample to range between 150-200g.***

MOROCCO

I. CONTROL GUIDANCE

Background

7. Histamine is a bacterial metabolite that is generated by spoilage microbe enzymatic decomposition of histidine, primarily at elevated temperatures, after fish death. It is recognized that properly harvested, stored, handled, and distributed fish results in little to no histamine accumulation. In Section 6.1 of the FAO/WHO Expert Report, the experts state:

Freshly harvested scombrotoxin-forming fish typically have histamine levels below 2 mg/kg (Frank et al., 1981; Staruszkiewicz et al., 2004). ~~In addition, food business operators that apply GHP and HACCP can achieve a histamine level lower than 15 mg/kg in fish products, based on data made available by industry (using a test method with a lower detection limit of 15 mg/kg).~~

Discussion

Morocco propose that the following sentence should be removed from this paragraph of "background"

"In addition, food business operators apply GHP and HACCP That can accomplish achieve a level lower than histamine 15 mg / kg in fish products, based on data made available by industry (using a test method with a lower detection limit of 15 mg / kg) . "

Rationale:

This value of 15 mg / 100 kg is biased because several variables were not taken into account when setting this value such as:

- Fishing Area
- The fishing season and the ambient temperature at the time of catch
- The species of fish concerned by this study
- the processing mode of this species of fish
- The number of samples taken
- Duration of the study
-etc

Or to add at this paragraph :

In addition, food business operators that apply GHP and HACCP can, in xx % of the instances, achieve a histamine level lower than 15 mg/kg in fish products, based on data made available by industry (using a test method with a lower detection limit of 15 mg/kg).

Reason: because databases are available and have been used for these conclusions, it is possible to have the percentages of the samples found with less than 15 mg / kg.

Recommendation

Recommendation 1) Form a dedicated EWG to revise and elaborate guidance in the *Code of Practice for Fish and Fishery Products* with the following terms of reference:

The CCFFP should:

- a) Revise, where necessary, control guidance for scombrotoxin fish poisoning, using histamine as the marker biogenic amine for control.
- b) Include where appropriate scientific information about histamine formation with the purpose of informing on the importance of time/temperature controls.
- c) Ensure that applicable sections of the Code cover the entire food chain (harvesting, storage, handling, processing and distribution.)
- d) Incorporate into the Code, and revise if necessary, Table 2.3 (Scientific names, free histidine levels and mean annual production levels for fish associated with SFP or high free histidine levels) from the FAO/WHO Expert Report (See Recommendation 2 below.)
- e) Consider if any products with greater risk for histamine formation because of unique processing methods need specialized or revised control guidance.
- f) Consider making a call to a database to collect the results of histamines at the establishment processing fishery products for accurate and updated data on the levels of histamine at international level)
- e) Consider making a call to a database to collect histamine results of official controls (at the borders and for national productions)
- h) Use risk ranger tool or any pertinent risk assessment tool, when appropriate, to ascertain histamine risk, based on the data collected.

Morocco agree to form an electronic working group dedicated to revise and develop the guidelines in the Code of Practice for fish and fishery products by adding in the terms of reference the following:

f) Consider making a call to a database to collect the results of histamines at the establishment processing fishery products for accurate and updated data on the levels of histamine at international level

g) Consider making a call to a database to collect histamine results of official controls (at the borders and for national productions)

h) Use risk ranger tool or any pertinent risk assessment tool, when appropriate, to ascertain histamine risk, based on the data collected

Rationale:

The Codex Alimentarius and its subsidiary bodies, acting as responsible for risk management as was adopted in "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius were adopted by the Commission Codex Alimentarius in 2003. "

The working principles are:

- The risk management process should be transparent, consistent and fully documented.
- Risk management decisions should take into account the uncertainty of the outcome of the risk assessment.
- To avoid creating unjustified trade barriers, risk management should ensure transparency and consistency in the decision making process in all cases. Examination of the full range of risk management options includes, to the extent possible, an assessment of their potential advantages and disadvantages. When choosing among the various risk management options, which are equally effective in the protection of consumer health, the Commission and its subsidiary bodies should seek and take into consideration the potential impact of such measures on trade among its Member countries and select measures that are no more trade restrictive than necessary.
- Risk management should take into account the economic consequences and the possibility of implementation of risk management options. Risk management should also recognize the need for alternative options in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumer health. Taking this into consideration, the Commission and its subsidiary bodies should give particular attention to the situation of developing countries.
- Those responsible for risk management must ensure that the risk assessment conclusions are made before formulating proposals or make final decisions about the options available for management, especially regarding the standards and maximum limits

Therefore these databases will be of great importance and pertinence for risk management of histamine in accordance with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius were adopted by the Commission Codex Alimentarius in 2003.

II. SUSCEPTIBLE SPECIES LIST (Table 2.3 “Scientific names, free histidine levels and mean annual production levels for fish associated with SFP or high free histidine levels” in FAO/WHO Expert Report)

Recommendation

Recommendation 2) Incorporate Table 2.3

Morocco agree with this recommendation

III. SAFETY LIMIT

Background

14. ... CCFFP is the risk management body responsible for recommending the appropriate histamine safety limit in seafood standards by considering the risk assessment and uncertainty discussed in the FAO/WHO Expert Report, along with other legitimate and **well-founded** factors and options for public protection.

Rational: in the working paper on histamine, little attention has been paid to other legitimate factors. It is proposed to add a separate paragraph for these factors in the final draft of the document.

24. There was some EWG discussion on histamine limits for products consumed in small portions; however, it remains apparent that CCFFP should first consider the appropriate limit for normal portions (as examined in the FAO/WHO Expert Report.) It should be noted that only the *Standard for Fish Sauce* would appear affected by further consideration of small portion sizes. It was discussed that histamine limits should not be raised based on portion size alone; and CCFFP should also consider the “need” for a higher limit based on the process and application of good manufacturing practices.

~~Decomposition limits: If the safety limit is lowered to 100 mg/kg or below, then the provisions set for decomposition and for safety would conflict and become a potential source of confusion if the established decomposition limit is not lowered or removed in conjunction with the safety provision change.~~

Rational: because the discussions have not yet reached consensus, it is early to talk about the merger of the two limits

Recommendation

Recommendation 3) EWG participants did not reach consensus on support for a lower limit (i.e. 100 mg/kg) or support for the current limit of 200 mg/kg. The EWG recommends that CCFFP consider these two options for the Hygiene section of standards (other than the *Standard for Fish Sauce*.)

26. The EWG also recommends that CCFFP consider consulting the Codex Committee on Contaminants in Foods (CCCF) for advice on appropriate health-based limits based on adverse event thresholds and uncertainty presented in the FAO/WHO Expert Report.

IV. SAMPLING PLANS

35. Page 8. First paragraph: Table 2: SD = 0.88 (log₁₀ scale). SD = 0.88 is the average SD (log₁₀ scale) of the 39 surveys listed in Table 5.1 of the FAO/WHO Expert Report. SD = 0.88 also agrees with the ICMSF recommended standard deviation assumption for inhomogeneous food such as solid foods⁶.

Rational: It is proposed to add the word inhomogeneous in the sentence because this is the reason why a SD of 0.8 is to be used. Solid food is given as an example.

We quote the paper cited « ... a standard deviation = 0.2 log₁₀ CFU g⁻¹ is used to describe a food in which microbes would be expected to be rather homogeneously distributed within a batch (e.g., for liquid food with a high degree of mixing). A standard deviation of 0.4 log₁₀ CFU g⁻¹ is assumed for a food of intermediate homogeneity (e.g., ground beef) and a standard deviation = 0.80 log₁₀ CFU g⁻¹ for an inhomogeneous food (e.g., solid food) ».

Rational: It is proposed to change the reference number 6 by the following because the paper has already been published :

M. van Schothorst, M.H. Zwietering, T. Ross, R.L. Buchanan, M.B. Cole, International Commission on Microbiological Specifications for Foods (ICMSF). 2009. Relating microbiological criteria to food safety objectives and performance objectives. Food Control 20 : 967–979 (page 970, §8).

NIGERIA AND AFRICAN UNION

POSITION: Nigeria and African Union supports the review and update of the List of Species in order to include the other species with histamine producing capability.

1. Inform and educate consumers by indicating in the label that the product might contain histamine.
2. Keep the current approach, with the two limits; 100mg/kg as an indicator of alteration and 200mg/kg for public health.
3. Ensure implementation of GHP, GMP and HACCP to prevent histamine risk contamination and improve practices by avoiding the break of cold chain (sampling is used to verify that these practices and systems are adequate).
4. Study the contribution of other biogenic amines, and other compounds and use risk analysis for evaluation of histamine risk.

SENEGAL

COMMENTAIRES : Nous soutenons la révision et la mise à jour de la Liste des espèces en vue d'y inclure d'autres espèces ayant une capacité de production d'histamine.

Nous recommandons de :

- Faire un plan de communication pour sensibiliser les populations sur les risques liés à l'histamine
- Maintenir l'approche actuelle, avec deux limites; 100 mg/kg comme indicateur d'altération et 200 mg/kg pour la santé publique.
- S'assurer de l'application des BPH, BPF et du HACCP dans la prévention du risque de contamination à l'histamine et améliorer les pratiques en évitant la rupture de la chaîne du froid.
- Etudier la contribution d'autres amines biogènes.

JUSTIFICATIONS: Le traitement par saumurage, avec de l'eau, le lavage, etc entraîne un lessivage du produit avec une diffusion des substances nitrogènes dans la solution. Ceci entraîne une diminution des composés azotés du produit. Les composés azotés pourraient ainsi servir d'indicateur de qualité surtout en ce qui concerne la semi-conserve.

THAILAND

General comments

We agree with the document in principle.

Specific comments

Our comments on specific sections are as follows:

- **I. CONTROL GUIDANCE**

- **Recommendation: c) Ensure that applicable sections of the Code cover the entire food chain (harvesting, storage, handling, processing and distribution.)**

We would like to request for clarification that the term “the entire food chain” will be applied to the whole document of Code of Practice for Fish and Fishery Products or the individual code for the specific processing of products.

- **II. SUSCEPTIBLE SPECIES LIST**

- **Table 2.3 “Scientific names, free histidine levels and mean annual production levels for fish associated with SFP or high free histidine levels” in FAO/WHO Expert Report**

From our point of view, some information in Table 2.3 is incomprehensive and not up-to-date, e.g. histidine levels. And, histidine levels are not directly relevant with histamine levels, so only its levels cannot be used to suggest the levels of histamine.

Therefore, it is however recommended that information from Table 2.3 should be incorporated into commodity standards for fish and fishery products, including market name and scientific name, meanwhile histidine levels and annual production should be excluded, as they are unnecessary.

- **III. SAFETY LIMIT**

It is agreed to support retaining the current limit of histamine level of 200 mg/kg, because the level is calculated on a basis of NOAEL and consumption data. And, it was considered and agreed by the FAO/WHO experts.

- **IV. SAMPLING PLANS**

It is proposed that a sampling plan for histamine should be based on option 1, because individual country can select appropriate sampling plans based on Codex guidance. Besides, it is practical and has no disadvantage in the implementation.