



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

#### Fiftieth Session

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### REVISION OF THE CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS (CXC 52-3002) AND REVISIONS OF THE SECTION ON SAMPLING, EXAMINATION AND ANALYSES RELATED TO HISTAMINE FOOD SAFETY

Prepared by the Electronic Working Group chaired by Japan and co-chaired by the United States of America

Codex members and Observers wishing to submit comments at Step 3 on the draft (Appendices I and II) should do so as instructed in CL 2018/70-FH available on the Codex webpage/Circular Letters 2018:

<http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/>.

#### **Background**

1. The *Code of Practice for Fish and Fishery Products* (CXC 52-2003) contains GMP and HACCP guidance intended for use by processors to produce safe and wholesome products.
2. Fish and fishery product commodity standards contain food safety and quality specifications intended for end-product lot acceptance inspection at ports of entry, and other receiver-oriented situations.

#### Code of Practice for Fish and Fishery Products (processor histamine control guidance)

3. At the 49<sup>th</sup> session, CCFH agreed to forward the histamine control guidance for adoption by CAC41 at Step 5/8 and noted that the guidance would be published only once consequential alignment amendments to relevant sections of CXC 52-2003, if any, were finalized and adopted by the Commission.
4. For the 50<sup>th</sup> session, the terms of reference for the histamine EWG were to identify an appropriate place for the control guidance in CXC 52-2003, and to consider whether the inclusion of the new guidance would require amendment of other sections of CXC 52-2003, which contain technical guidance on histamine.

#### Fish and Fishery Product Commodity Standards (trade lot sampling guidance)

5. The format of commodity standards is covered in the *Codex Procedural Manual*, which indicates that the sampling section of standards should provide the information necessary to determine lot compliance with the provisions listed in the standards.
6. Eleven seafood commodity standards have a histamine safety provision in Section 5 (Hygiene) indicating that no sample unit may exceed 200 mg/kg histamine when tested by appropriate methods of sampling and examination prescribed by the Codex Alimentarius Commission. The Codex Committee on Fish and Fishery Products (CCFFP) noted that Section 7 (Sampling) of these standards lacked guidance, or contained unclear guidance, for determining lot compliance with the histamine safety provision. CCFFP discussed possible options to improve the sampling sections (33<sup>rd</sup> and 34<sup>th</sup> sessions), and the work moved forward with project document CX/CAC 16/39/7.
7. At the 49<sup>th</sup> session, CCFH recalled that further work was still needed on the revision of sampling, examination and analyses sections in standards for fish and fishery products related to histamine food safety according to project document in CX/CAC 16/39/7.

#### CX/CAC 16/39/7 Terms of Reference

The revision of standards will provide the necessary alignment of sampling plans and related sampling guidance across relevant standards for fish and fishery products. Sampling plans will be developed for different purposes. The work will bear in mind that sampling plans should be practical and feasible while still ensuring food safety using a risk-based approach.

Applicable commodity standards include:

CXS 36-1981. Standard for Quick Frozen Finfish, Uneviscerated and Eviscerated

CXS 70-1981. Standard for Canned Tuna and Bonito

CXS 94-1981. Standard for Canned Sardines and Sardine-Type Products

CXS 119-1981. Standard for Canned Finfish

CXS 165-1989. Standard for Quick Frozen Blocks of Fish Fillet, Minced Fish Flesh and Mixtures of Fillets and Minced Fish Flesh

CXS 166-1989. Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets - Breaded or in Batter

CXS 190-1995. Standard for Quick Frozen Fish Fillets

CXS 236-2003. Standard for Boiled Dried Salted Anchovies

CXS 244-2004. Standard for Salted Atlantic Herring and Salted Sprat

CXS 302-2011. Standard for Fish Sauce

CXS 311-2013. Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish

Main aspects to be covered

- Align histamine sampling guidance across the relevant Standards for Fish and Fishery product.
- Design risk-based sampling plans for the Sampling Section of Standards for different purposes that are practical, feasible and not adding a burden to producers while still ensuring food safety.
- Include appropriate supplemental sampling guidance such as:
  - 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.

**EWG Process**

8. Thirty-eight member countries, one member organization, and three observer organizations joined the EWG that was led by Japan and the United States of America. Appendix III contains the list of participants.

9. Proposed draft amendments were prepared by Japan and the United States of America. The proposed draft amendments to the *Code of Practice for Fish and Fishery Products* were circulated once for comment and revision. The proposed draft amendments to the commodity standards were circulated twice for comment and revision. Comments were received from 14 countries: Argentina, Australia, Brazil, Canada, France, Iran, Ireland, Japan, Morocco, Mexico, Norway, Spain, Thailand, and the United States of America.

**Discussion – Amendments to Code of Practice for Fish and Fishery Products**

10. EWG members agreed that the newly adopted histamine guidance should be a separate section in the Code located directly after Section 9 (Processing of Fresh, Frozen and Minced Fish).

11. The EWG agreed with proposed 1<sup>st</sup> draft amendments. Further amendments proposed in comments are included in the final draft (Appendix I), which is expected to be generally well accepted.

12. Regarding *Section 12 - Processing of Salted and Dried Salted Fish*, two comments revealed potential confusion about the scope of this section. The section title and specific guidance indicate that Section 12 covers all salted fish, including herring, fatty fish, and scombrotoxin-forming species. However, a paragraph added during the final (34<sup>th</sup>) meeting of the Codex Committee on Fish and Fishery Products (CCFFP) may be misinterpreted to mean that the guidance applies only to species of the Gadidae family (which do not have a scombrotoxin risk). The EWG co-leads recall that CCFFP decided to stop work on certain appendices for “optional final product requirements” that were “under development” within the *Code of Practice for Fish and Fishery Products*. CCFFP members were asked to comment on which, if any, information in the unfinished appendices should be retained by moving it to appropriate sections in the Code body. One delegation (to CCFFP) proposed that the table of English and Latin names in *Appendix 6 (Optional Final Product Requirements – Salted Fish)* should be retained because it contained useful market name information for commonly salted fish. This was presented as a simple movement of published information from one section of the Code to another, and CCFFP agreed<sup>1</sup> without seeing or discussing the actual revision in plenary. CCFFP did not intend to change the scope of the Section 12, which would have required discussion of that intention and further revisions throughout the section. A proposed amendment in the EWG draft clarifies that Section 12 applies to all salted and dried salted fish. Control of salting and drying hazards is important for all species.

#### **Conclusion and Recommendations – Amendments to Code of Practice for Fish and Fishery Products**

13. The draft amendments align the Code with the newly adopted histamine guidance, and are expected to be well received by members of CCFH.

14. The EWG recommends that CCFH review the amendments in Appendix I for advancement.

#### **Discussion – Sampling Guidance in Commodity Standards**

15. For an overall perspective, Table 1 shows the statistical protection provided by example 2 and 3-class sampling plans with different limits and acceptance numbers. The relative protection is determined based on a log-normal histamine distribution with standard deviation (SD) of  $0.8 \log_{10}$  (the average SD from FAO/WHO Expert Report survey data, and the ICMSF default SD used for solid foods.)

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<sup>1</sup> REP16/FFP, para. 66a and Appendix VIII

Table1. Relative consumer protection provided by sampling plans.

“Level of protection” is the fraction of sample units in a lot exceeding the 200 mg/kg histamine safety limit for which the sampling plan would have a 95% probability of generating a signal (when the distribution of histamine is log-normal with SD = 0.8 log<sub>10</sub>); (“n” = sample size; “m” = histamine limit (mg/kg); “M” = upper maximum (mg/kg); “c” = acceptance number).

Level of protection	n	m	M	c	Comment
1 in 1,000	64	15	na	0	Justifiable consumer protection; m = expected GHP level
1 in 890	59	15	na	0	Reasonable sample number; m = expected GHP level
1 in 303	30	15	na	0	Small sample number; m = expected GHP level
1 in 212	59	35	na	0	Reasonable sample number; m = lenient GHP level
1 in 83	30	35	na	0	Small sample number; m = lenient GHP level
1 in 26	18	50	na	0	US, processor raw material HACCP (minimum # samples)
1 in 21	24	50	500	1	US, border inspection, processed fish
1 in 20	59	200	na	0	EWG proposal for isolated lot acceptance
1 in 20	28	100	na	0	Similar protection to EWG proposal using less samples
1 in 14	18	50	500	1	US, border inspection, fresh and frozen fish
1 in 3.8	9	100	200	2	EU, border inspection (minimum # samples)

#### Rationale for the EWG proposed sampling plans in Appendix II

##### *Purpose for sampling and testing*

16. During previous work, CCFFP had difficulty agreeing on a histamine safety sampling plan for standards that provided adequate consumer protection. For this reason, the terms of reference for this work included designing risk-based sampling plans “for different purposes”. The two sampling purposes discussed were 1) lot acceptance (the commodity standard model), and 2) periodic assessment of control systems. These two purposes are reflected in proposed draft sections 7.1.1 and 7.1.2, respectively.

1) Lot acceptance: Sampling and testing is used to determine lot acceptability at ports of entry, and other receiver-oriented situations. Routine (lot-by-lot) acceptance testing for histamine is not necessary when sufficient past evidence or international agreements adequately insure that the product is produced with suitable histamine controls. However, when a lot is from a source with unknown histamine control (e.g. new source with no test history), or from a source with unreliable implementation of histamine controls (e.g. poor past test results, unavailable documentation), then histamine testing is the only practical means to provide a margin of assurance that histamine levels in a consignment are safe. This is the purpose for the sampling plan in draft Section 7.1.1.

2) System assessment: If adequate histamine control has been established, then routine histamine testing is not necessary. However, it may be prudent to periodically sample susceptible products to assess the continued performance of the histamine control system. System assessment test results are not used to determine lot acceptance, except if they exceed the 200 mg/kg safety limit. However, they may be used to adjust the frequency of system assessment testing, or, if necessary, to discuss with the producer to avert a possible hazardous situation. This is the purpose for the sampling plan in draft Section 7.1.2.

##### *Selection of a binomial attribute plan*

17. The proposed plans are attribute plans based on the binomial (or hypergeometric) distribution. Alternative approaches that assume histamine follows a log-normal distribution with known standard deviation are inappropriate for border lot inspections because international shipments often contain fish sourced from different harvest vessels, and sometimes processed in different facilities, such that lots may contain sub-parts with different histamine levels and different standard deviations. Therefore, a plan based on an assumed distribution can lead to erroneous lot acceptance decisions (excess consumer or producer risk). Attribute

sampling plans based on the binomial (or hypergeometric) distribution are independent of histamine distribution and can be used when product with different histamine profiles is mixed.

#### *Selection of a two-class plan*

18. The proposed plans are two-class attribute plans. A two-class plan is appropriate when a third marginal range has not been identified. When a three-class plan is used for a safety provision, the level of “little m” should reflect the level readily attainable under GHP (ICMSF 2018)<sup>2</sup>. Scientific literature indicates that histamine levels below 15 mg/kg histamine are readily achievable and maintained for any scombrotoxin-forming fish that is chilled soon after death of the fish. However, it is difficult to agree on a science-based value for “little m”, therefore a two-class sampling plan was selected.

19. The terms of reference for this work were to consider sampling guidance for the histamine safety provision listed in Section 5 (Hygiene). The terms intentionally precluded consideration of sampling plans for the decomposition provision listed in Section 3 (Essential Composition and Quality Factors) because the sampling plan for the safety provision should be developed independently for clarity, and because the level of histamine that indicates excess decomposition is not in current agreement. If a single three-class sampling plan were used for both safety and quality, the contribution of each element to the plan would be ambiguous, and updating based on new science would be difficult.

#### *Critical histamine level*

20. The FAO/WHO Joint Expert Meeting Report<sup>3</sup> indicated that a 250-gram serving of fish containing 200 mg/kg histamine provides a histamine dose equal to the no-observed-adverse-effect-level (NOAEL) determined from a histamine challenge study in eight healthy adults. Therefore, the 200 mg/kg histamine safety limit reflects only the value of the NOAEL, and does not include a margin of safety for inter-individual variability, for members of certain segments of the population who may have an increased sensitivity (e.g. metabolic differences, physiological conditions, drug therapies, age), for increased consumption per body weight by children, and for the presence of other biogenic amines in fish thought to potentiate histamine absorption. Therefore, as indicated in the standards, any sample unit found above 200 mg/kg should result in lot rejection. This indicates a zero-acceptance number sampling plan (i.e., “c” = 0) when “m” = 200 mg/kg in a two-class plan.

#### *Selection of plan methodology*

21. The *General Guidelines on Sampling* (CXG 50-2004), Section 2.5.3, “Sampling plans for inspection of critical nonconformities” contains the appropriate guidance for zero-tolerance (“c” = 0) attribute plans to use for the 200 mg/kg histamine safety limit. The formula listed uses the hypergeometric distribution, which adjusts the sample size based on lot size. The hypergeometric distribution is similar to the binomial distribution for larger lots, and begins to differ when the sample size exceeds 10% of the lot size. Zero-acceptance-number plans are also ideal for system assessment because they use fewer samples for a given level of protection, and, for system assessment, lot acceptance is not being determined.

#### *Selection of plan performance*

22. The appropriate level of consumer protection for a food safety hazard, such as scombrotoxin fish poisoning, is typically one illness per ten thousand, or per million, servings. This is readily achievable for histamine with application of GMPs and HACCP by harvesters and processors. However, the level of protection practically achievable by histamine testing alone (using the safety limit as the decision point) is much lower and depends on the number of test units examined.

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<sup>2</sup> *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*, 2<sup>nd</sup> edition. International Commission on Microbiological Specifications for Foods. 2018. Section 8.7 “Determining values for m and M”.

<sup>3</sup> *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July 2012, Rome.

Link: [http://apps.who.int/iris/bitstream/10665/89216/1/9789240691919\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/89216/1/9789240691919_eng.pdf?ua=1)

23. Table 2 (below) shows the number of sample units required for a zero-acceptance number sampling plan to provide specified levels of protection based on the binomial formula for the probability of observing no non-compliant sample units (Equation 1)<sup>4</sup>:

$$\beta = (1 - p)^n \quad \text{(Equation 1)}$$

$p$  = incidence of non-compliant sample units in the lot (expressed as a fraction)

$\beta$  = probability of failing to find at least one non-compliant sample unit (expressed as a fraction)

$n$  = sample size (number of sample units drawn)

**Table 2.** Number of randomly selected samples required for a given probability of finding at least one non-compliant sample unit in a lot, for a given incidence of non-compliant units in the lot (based on binomial distribution).

Incidence of non-compliant units ( $p$ ) in the lot by ratio and percentage:		Minimum number of samples required to detect a non-compliant unit with a probability of $(1-\beta)$ :		
Ratio	Percentage	95%	99%	99.9%
1:1,000	0.1%	2,995	4,603	6,905
1:500	0.2%	1,497	2,301	3,451
1:200	0.5%	598	919	1,379
1:100	1.0%	299	459	688
1:50	2.0%	149	228	342
1:20	5.0%	59	90	135
1:10	10.0%	29	44	66

24. The *General Guidelines on Sampling* (Section 2.5.3, Sampling plans for inspection of critical nonconformities) indicates that the incidence of nonconforming items that can result in illness is usually taken as less than or equal to 0.2%, and that the probability of detection is usually chosen at 99.9% or better. However, this would require a prohibitive number of samples for histamine testing of fish lots. Therefore, the proposed plan performance parameters are a considerable compromise away from ideal consumer protection.

25. Proposed Section 7.1.1 specifies that plans should signal with 95% probability when 5% of the units in a lot contain histamine over 200 mg/kg (59 samples for large lots). Reliable detection of lots containing 5% unsafe product is difficult to justify for consumer safety. However, 90 additional samples are needed to gain reliable detection of lots containing 2% non-compliant product, which becomes less practical under normal lot surveillance circumstances.

26. When used, the proposed plan for isolated lot acceptance, still requires significant resources; however, after resources are expended to stage and randomly sample a lot, it is important that the sampling effort provides worthwhile, meaningful results. Rapid test kits (see FAO/WHO Expert Report, Table 2.2) and composite samples (see proposed Annex [B]) ease the burden of histamine analysis relative to microbiological analyses.

#### *Assessment of histamine control systems*

27. Under some country and industry strategies, the primary purpose for sampling is to assess the performance of the producer's food safety control system, and not to assure the safety and acceptability of individual lots.

28. Assessing the performance of a control system by periodically inspecting an isolated lot requires a rigorous sampling plan. To be efficient and effective, system assessment plans use a criterion level that is lower than

<sup>4</sup> Common binomial formula, such as found in *Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLS* (CXG 33-1999)

the safety limit, and that corresponds to the histamine level expected from implementation of GMP/HACCP systems. The lower level is not used to determine lot acceptance because the examined lot may still meet the safety limit in the standard. Instead, if a sample unit exceeds the level expected from GMP/HACCP systems (but is below the safety limit), then precautionary actions are taken, such as increasing the sampling frequency and discussing findings with the producer.

29. The proposed sampling plan for system assessment is a user-flexible plan. It lists an example level of detection and an example histamine level to show how to use the plan. However, the user decides the appropriate parameters to use for specific product and risk management needs. A table is included with the plan to help select plan performance and sample size for a 2-class binomial attribute plan.

#### Other proposed amendments in standards

30. The hygiene sections of standards (that contain the histamine safety provision) are not within the EWG terms of reference, however some amendments related to sampling are proposed in the hygiene sections.

#### Issues discussed

31. In the viewpoint of several EWG members, the number of samples required in the sampling plans might be burdensome. It was discussed that the first sampling plan (Sec. 7.1.1) was intended for determining acceptance of isolated lots with unknown control history against the commodity standard, where the plan must provide a justifiable measure of consumer protection. While the second sampling plan (Sec 7.1.2) for system assessment has a flexible sample size and is appropriate to use when there is reason to believe that controls are in place, and the safety of the individual lot is not the primary purpose for sampling. Generally regulatory authorities assume controls are in place and do not inspect every lot for acceptance. Using both plans appropriately can provide an efficient means to attain the food safety objective.

32. Some members thought that the plans might be burdensome for small processors. It was discussed that commodity standards are used at ports of entry and other receiving oriented situations, and are not intended for use by processors, who are covered by the *Code of Practice for Fish and Fishery Products*.

33. Some members were interested in further guidance on use of composite samples ("pooled samples" in the Terms of Reference), therefore a composite sampling example was added as Annex [B].

34. One member questioned if histamine analytical methods could adequately measure the 40 mg/kg histamine level used in the composite sample example. Therefore the 40 mg/kg level was added to the "Determination of Histamine" subsection of standards with method criteria determined from the Codex Procedural Manual, "*Working Instructions for the Implementation of the Criteria Approach in Codex*".

35. Some members were concerned that the example histamine criterion listed in section 7.1.2 ("e.g. 15 mg/kg") could be mistaken as a limit. Therefore, revisions were included to further clarify that the example is an example. Also, Section 7.1.2 clearly indicates that lower histamine levels used for system assessment are not used to determine lot acceptance, therefore any level may be used (up to 200 mg/kg) without violating the standard. Note that the 15 mg/kg example is based on the FAO/WHO Expert Meeting Report, which states: "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)." The FAO/WHO Report also indicates that gross temperature abuse is necessary for histamine levels to reach 15 mg/kg.

36. Some members noted that the histamine units (mg/kg) in the amendments differed from the units (mg/ 100 g) used in the standards. It was noted that "mg/kg" is more current, eliminates the need for confusing decimals, and is used in the FAO/WHO Expert Report. Therefore "mg/kg" was used in the working drafts, and the EWG recommends asking if the secretary can make the additional change necessary in the decomposition sections.

#### **Conclusion and Recommendations – Sampling Guidance in Commodity Standards**

37. Members generally agreed with most of the sampling guidance amendments. Some members may continue to express concern with the sample sizes required for the lot acceptance sampling plan, which could prevent a definitive sampling plan from moving forward. If a definitive sampling plan is included for lot acceptance, it must provide adequate consumer protection for questionable lots, and be suitable in cases of dispute. Revisions to the current draft address EWG comments and concerns. Taking into considerations the

purpose for commodity standards (compared to the Code) and the practical reason for including two sampling plans for different purposes, general agreement should be possible.

38. The EWG recommends that CCFH consider Appendix II for advancement.

## ALIGNMENT OF CODE WITH HISTAMINE CONTROL GUIDANCE

(for comments at Step 3 through CL 2018/70-FH)

Edits shown in **bold underline** and ~~strike through~~ font.

CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS

CAC/RCP 52-2003

### SECTION 2 – DEFINITIONS

#### 2.1 General definitions

**Disinfection** The reduction by means of chemical agents and/or physical methods in the number of ~~miree~~ micro-organisms in the environment to a level that does not compromise food safety or suitability.

### SECTION 4 – GENERAL CONSIDERATIONS FOR THE HANDLING OF FRESH FISH, SHELLFISH AND OTHER AQUATIC INVERTEBRATES

#### 4.1 Time and temperature control

Temperature is the single most important factor affecting the rate of fish and shellfish deterioration and multiplication of micro-organisms. For species prone to scombrototoxin production, time and temperature control ~~may be~~ **is** the most effective method for ensuring food safety. It is therefore essential that fresh fish, fillets, shellfish and their products that are ~~to be~~ chilled, be **chilled rapidly and** held at a temperature as close as possible to 0 °C. **Refer to Section 9-bis for further information on control of scombrototoxin.**

### SECTION 5 – HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) AND DEFECT ACTION POINT (DAP) ANALYSIS

#### 5.3.3.1.1 Hazards

...However, as with all foods, there are some health risks associated with the consumption of certain products, which may be increased when the catch is mishandled **during and** after harvest (**e.g. scombrototoxin**).

### SECTION 9 – PROCESSING OF FRESH, FROZEN AND MINCED FISH

...As in the further processing of fresh fish in a MAP product, or minced or frozen fish, the section labelled “Fish preparation” is used as the basis for all the other fish-processing operations (Sections **9-bis**, 10, 12, 13, 17 and 21), where appropriate.

**For fish susceptible to scombrototoxin formation, refer to Section 9-bis “Harvesting, Processing, Storage and Distribution of Fish and Fishery Products at Risk for Scombrototoxin (Histamine) Formation” for information on the control of histamine, including guidance for harvest vessel operations.**

#### 9.1.1 Raw, fresh or frozen fish reception (Processing Step 1)

*Potential hazards: microbiological contamination, viable parasites, biotoxins, scombrototoxin<sup>10</sup>, chemicals (including veterinary drug residues) and physical contamination.*

<sup>10</sup>**Refer to Section 9-bis for scombrototoxin control guidance.**

#### 9.1.5 Washing and gutting (Processing Steps 6 and 7)

*Potential hazards: microbiological contamination, biotoxins and scombrototoxin*

*Potential defects: presence of viscera, bruising, off-flavours, cutting faults, **decomposition***

#### 9.2.2 Vacuum or modified atmosphere packaging (Processing Step 11)

*Potential hazards: subsequent microbiological contamination and biotoxins, **subsequent scombrototoxin**, physical contamination (metal)*

*Potential defects: subsequent decomposition*

#### 9.3.1 Freezing process (Processing Step 15)

*Potential hazards: viable parasites, **scombrototoxin***

Potential defects: *texture deterioration, development of rancid odours, freezer burn, **decomposition***

#### 9.4.2 Washing of minced fish (Processing Step 22)

Potential hazards: *microbiological contamination and scombrototoxin*

Potential defects: *poor colour, poor texture, excess of water, **decomposition***

#### 9.4.3 Blending and application of additives and ingredients to minced fish (Processing Steps 23 and 24)

Potential hazards: *physical contamination, **microbiological contamination**, non-approved additives and/or ingredients, **scombrototoxin***

Potential defects: *physical contamination, incorrect addition of additives, **decomposition***

#### 9.4.4 Wrapping and packaging (Processing Steps 17 and 25)

Potential hazards: *microbiological contamination, **scombrototoxin***

Potential defects: *subsequent dehydration, decomposition*

### **SECTION 9-bis – HARVESTING, PROCESSING STORAGE AND DISTRIBUTION OF FISH AND FISHERY PRODUCTS AT RISK FOR SCOMBROTOXIN (HISTAMINE FORMATION)**

[Placeholder for newly adopted histamine control guidance]

### **SECTION 10 – PROCESSING OF FROZEN SURIMI**

#### 10.1.1 Hazards

If scombrototoxin-forming fish such as tuna or mackerel, or tropical reef fish that may accumulate ciguatera toxin, are utilized for surimi, appropriate controls for these hazards should be developed<sup>14</sup>.

**<sup>14</sup> Refer to Section 9-bis for scombrototoxin control guidance.**

#### 10.2.1 Raw fresh and frozen fish reception (Processing Step 1)

Potential hazards: *~~unlikely when using marine groundfish as the raw material~~ **scombrototoxin***

Potential defects: *decomposition, protein denaturation*

#### 10.2.2 Chilled storage (Processing Step 2)

Potential hazards: *~~unlikely~~ **scombrototoxin***

Potential defects: *protein denaturation, **decomposition***

#### 10.4 Washing and dewatering process (Processing Step 10)

Potential hazards: *microbiological contamination, **scombrototoxin***

Potential defects: *decomposition, protein denaturation, residual water-soluble protein*

#### 10.5 Refining process (Processing Step 11)

Potential hazards: *microbiological contamination, **scombrototoxin**, metal fragments*

Potential defects: *objectionable matter, protein denaturation, **decomposition***

Technical guidance:

- Temperature of the minced fish flesh in the refining process should be adequately controlled to prevent the growth of pathogenic bacteria.
- Product should be processed promptly to minimize possible pathogenic microbial growth.

#### 10.6 Final dewatering process (Processing Step 12)

Potential hazards: *microbiological contamination, **scombrototoxin***

Potential defects: *decomposition, protein denaturation*

#### 10.7 Mixing and addition of adjuvant ingredients process (Processing Step 13)

Potential hazards: *microbiological contamination, **scombrototoxin**, metal fragments*

Potential defects: *improper use of food additives, protein denaturation, **decomposition***

*Technical guidance:*

- Temperature of the product in the mixing process should be adequately controlled to avoid the growth of pathogenic bacteria **and scombrotoxin formation**.
- Product should be processed promptly to minimize possible pathogenic microbial growth **and scombrotoxin formation**.

#### 10.8 Packaging and weighing (Processing Step 14)

*Potential hazards:* *microbiological contamination, **scombrotoxin***

*Potential defects:* *foreign matter (packaging), incorrect net weight, incomplete packaging, denaturation of protein, **decomposition***

*Technical guidance:*

- Temperature of the product should be adequately controlled during packaging to avoid the growth of pathogenic bacteria **and scombrotoxin formation**.
- Product should be packaged promptly to minimize possible pathogenic microbial growth.
- Packaging should be conducted rapidly to minimize the risk of contamination, **pathogenic microbial growth, scombrotoxin formation**, or decomposition.

#### 10.9 Freezing operation (Processing Step 15)

*Potential hazards:* *~~unlikely~~ **scombrotoxin***

*Potential defects:* *protein denaturation, decomposition*

*Technical guidance:*

- After packaging and weighing, the product should be promptly frozen to maintain the quality of the product, **and to prevent scombrotoxin formation**.
- Procedures should be established that specify maximum time limits from packaging to freezing.

#### 10.13 Frozen storage (Processing Step 19)

*Potential hazards:* *~~unlikely~~ **scombrotoxin***

*Potential defects:* *decomposition, protein denaturation*

*Technical guidance:*

### SECTION 11 – PROCESSING OF QUICK-FROZEN COATED FISH PRODUCTS

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#### 11.3.1 Reception

##### 11.3.1.1 Fish

*Potential hazards:* *chemical, ~~and~~ biochemical **and microbiological** contamination, ~~histamine~~ **scombrotoxin**<sup>16</sup>*

*Potential defects:* *tainting, block irregularities, water and air pockets, packaging material, foreign matter, parasites, dehydration, decomposition*

<sup>16</sup> **Refer to Section 9-bis for scombrotoxin control guidance.**

##### 11.3.5.2. Application of additives and ingredients

*Potential hazards:* *foreign material, microbiological contamination, **scombrotoxin***

*Potential defects:* *incorrect addition of additives, **decomposition***

*Technical guidance:*

- The temperature of the product in the mixing process should be adequately controlled to avoid the growth of pathogenic bacteria, **and scombrotoxin formation**.

##### 11.3.5.3 Forming

*Potential hazards:* *foreign material (metal or plastic from machine) and/or microbiological contamination/**scombrotoxin** (fish mixture only)*

*Potential defects:* *poorly formed fish cores, cores subjected to too much pressure (mushy, rancid), **decomposition***

### 11.3.7.1 Wet coating

*Technical guidance:*

- controlled within certain parameters to effect **affect** the proper amount of breeding pick-up.

## **SECTION 12 – PROCESSING OF SALTED AND DRIED SALTED FISH**

This Section applies to fresh, **all species of** salted and dried salted fish, of the **The** following species, all belonging to the Gadidae family, intended for human consumption **have the following scientific and common names:** Cod (*Gadus morhua*), Pacific cod (*Gadus macrocephalus*), Polar cod (*Boreogadus saida*), Greenland cod (*Gadus ogac*), Saithe (*Pollachius virens*), Ling (*Molva molva*), Blue ling (*Molva dypterygia*), Tusk (*Brosme brosme*), Haddock (*Gadus aeglefinus/Melanogrammus aeglefinus*), Forkbeard (*Phycis blennoides*) and Pollock (*Pollachius pollachius*).

### 12.1 General

Refer also to Section 9.1 for general handling prior to processing and Figure 12.1 for an example flow chart of a salted and dried salted fish-processing line. **Refer to Section 9-bis for technical guidelines for the control of scombrototoxin.**

### 12.2 Preparing for salting

#### 12.2.1 Splitting, washing and rinsing (Processing Step 7)

*Potential hazards:* ~~unlikely~~ **scombrototoxin**

*Potential defects:* *improper splitting, **decomposition***

#### 12.2.4 Nobbing (Processing Step 10)

*Potential hazards:* ~~unlikely~~ **scombrototoxin**

*Potential defects:* *remaining gut content and intestines other than roe or milt, decomposition*

#### 12.2.5 Gibbing (Processing Step 11)

*Potential hazards:* ~~unlikely~~ **scombrototoxin**

*Potential defects:* *remaining gut content, decomposition*

*Technical guidance:*

### 12.4 Salting and maturing

Salted fish should be salt-matured, sound and wholesome. The salting process, including the temperature, should be sufficiently controlled to prevent the development of *C. botulinum*, or the fish should be eviscerated prior to brining. **The temperature should also be sufficiently controlled to prevent the formation of histamine in susceptible species.**

Salting of fish either by brining, brine injection, wet-salting, dry-salting or pickling should be carried out with full understanding of their effects on the quality of the final product and should be done under strict hygienic conditions and temperature control.

Two particular conditions that can adversely affect the quality of salted fish are the occurrence of bacteria and mould. Both defects can be combated by maintaining a temperature lower than 8 °C (**ideally below 4 °C**). Salt produced from marine sources may contain halophilic bacteria, which continue to live in the salt and salted fish. In order to minimize such microbial contamination of salted fish, previously used and/or contaminated salt should be removed from the plant.

#### 12.4.1 Brining (Processing Step 14)

*Potential hazards:* *viable parasites, scombrototoxins, botulinum toxin*

#### 12.4.2 Brine injection (Processing Step 15)

*Potential hazards:* *viable parasites, scombrototoxins, injection needle fragment, botulinum toxin*

#### 12.4.3 Wet-salting (Processing Step 16)

*Potential hazards:* *viable parasites, scombrototoxins, botulinum toxin*

#### 12.4.4 Dry-salting (Processing Step 17)

*Potential hazards:* *viable parasites, scombrototoxins, botulinum toxin*

**12.4.5 Pickling (Processing Step 18)**

*Potential hazards: viable parasites, scombrottoxins, botulinum toxin*

*Potential defects: decomposition*

*Technical guidance:*

- The amount of salt must be adjusted to the quality of the fatty (primary) fish (fat content). Salt, sugar and spices should be weighed/measured and be evenly distributed.
- Cured fatty fish should be kept in brine or pickle.
- Fatty fish should always be covered with pickle during curing.
- Pickling is primarily used for fatty fish. Under certain conditions, dry-salting of small fatty fish, such as anchovy and small herring, may be used.

**12.4.6 Maturing (Processing Step 19)**

*Potential hazards: viable parasites, **microbiological contamination**, scombrottoxins, botulinum toxin*

*Potential defects: decomposition, rancidity and discolouring of the flesh or surface bacteria and mould*

*Technical guidance:*

- The first part of curing period for fish that accumulate histamine should be done at temperatures between 0 °C and 5 °C to prevent **growth of microbial pathogens and** development of histamine.
- Fatty fish such as herring may be kept in a temperature range of 5–10 °C during the maturing period **provided the salt concentration is sufficient to inhibit scombrotxin formation**. The length of this period will vary from weeks to several months depending on the specific products. If the containers are to be held at lower temperatures, the maturing period will increase.

**12.5.2 Drying (Processing Step 21)**

*Potential hazards: ~~unlikely~~ **scombrotxin***

**12.5.3 Weighing, wrapping and packaging (Processing Step 22)**

*Technical guidance:*

- Barrels in which fatty fish are ready to be marketed should be clean, whole and hygienic.

**SECTION 13 – SMOKED FISH, SMOKE-FLAVOURED FISH AND SMOKE-DRIED FISH****13.1 Processing of Smoked Fish**

This Section provides...

The recommendations made for the production of fresh fishery products in Section 9 are valid for the preparation of fish used as raw material for the production of fish products covered by this section.

**For fish at risk for scombrotxin formation, the times of product exposure between refrigerated and hot smoking temperatures should be monitored to control histamine formation (refer to Section 9-bis for technical guidelines on histamine control).**

If raw material...

**13.1.1 Reception of raw materials**

Refer to Section 9.1.1. **Refer to Section 9-bis.1 for fish susceptible to scombrotxin.**

**13.1.2 Salting**

*Potential Hazards: microbiological, chemical and physical contamination, scombrottoxins, presence of metal, broken needles*

*Potential Defects: decomposition, physical contamination, undesired texture, physical damage*

*Technical guidance:*

- Fish for cold smoking are dry salted, wet salted, combined salted or salted by brine injection of a medium-strength salt brine to enhance flavour and for safety purposes. To ensure a uniform salt distribution throughout the fish, it can be left for up to 24 hours under refrigeration to equilibrate. The equilibration time should be adapted to the salting technique used, to the temperature (e.g. 8-12 °C), and depending on the fish species.
- Salting time and temperature and fish temperature should be selected so as to control the development of histamine, where fish of susceptible species are concerned (e.g. *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryphaenidae*, *Pomatomidae*, *Scomberesocidae*).

**13.1.3 Hanging and racking**

*Potential hazards: microbiological contamination, scombrotoxin*

*Potential defects: physical damage, drying/smoking defects due to inadequate separation, decomposition*

**13.1.4 Drying**

Refer also to Section 12.5.2

*Potential hazards: microbiological contamination, physical contamination, and ~~histamine formation~~ scombrotoxin*

*Potential defects: decomposition, fungal contamination, physical contamination*

*Technical guidance:*

- Drying should not result in prolonged exposure to ambient temperature as this may lead to unwanted microbiological growth and the formation of histamine in susceptible species.

**13.1.10 Hot smoking**

*Potential hazards: parasites and microbiological contamination, scombrotoxin, chemical contamination from smoke*

*Potential defects: physical contamination (tar, ash), poor colour, flavour and texture, decomposition*

*Technical guidance:*

- Time and temperature of the smoking process should be monitored to achieve the desired colour, taste and texture, and to ensure control of microbiological contamination, and scombrotoxin formation in susceptible species. Continuous monitoring devices are recommended to ensure that time and temperature conditions are met.

**13.1.11 Cold smoking**

*Potential hazards: chemical contamination from smoke, growth of *Clostridium botulinum*, scombrotoxin*

*Potential defects: physical contamination (tar, ash), poor colour, flavour and texture, decomposition*

*Technical guidance:*

- In the cold smoking process the temperature of the products is kept below the coagulation temperature for the proteins of the flesh of the fish, usually under 30 °C, but can vary between 27 °C and 38 °C. Time and temperature of the smoking process should be monitored to achieve the desired colour, taste and texture. Continuous monitoring devices are recommended to ensure that time and temperature conditions are met.

**13.1.12 Cooling**

*Potential hazards: microbiological contamination, scombrotoxin*

*Potential defects: poor taste and texture, decomposition*

*Technical Guidance:*

- Following smoking, the fish should be cooled rapidly and thoroughly to a temperature that minimizes microbiological growth over the determined shelf-life.

**13.1.13 Slicing**

Potential hazards: *microbiological contamination, scombrotoxin*

Potential defects: *physical contamination, poor slices, decomposition*

Technical guidance:

- The flow of products should be maintained to avoid undue accumulation of products along the processing line.

**13.1.14 Packaging**

Potential hazards: *microbiological, chemical and physical contamination, scombrotoxin*

Potential defects: *physical contamination, decomposition*

**13.1.15 Cooling or freezing**

Potential hazards: *microbiological contamination, scombrotoxin, survival of parasites*

Potential defects: *poor taste and texture, decomposition*

**13.1.16 Storage**

Potential hazards: *microbiological contamination, scombrotoxin*

Potential defects: *poor taste and texture, decomposition, freezer burn*

**13.3.1 Pre-drying**

Potential hazards: *microbiological and physical contamination, scombrotoxin*

Potential defects: *decomposition, physical contamination*

**13.3.2 Smoke-drying**

Potential hazards: *parasites and microbiological contamination, scombrotoxin, chemical contamination from smoke*

Potential defects: *physical contamination (filth), burnt parts, poor texture, decomposition*

## **SECTION 17 – PROCESSING OF CANNED FISH, SHELLFISH AND OTHER AQUATIC INVERTEBRATES**

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**17.2.1 Hazards****A2 Scombrotoxins***Histamine*

Since ~~H~~histamine is heat stable, ~~its toxicity~~ it remains ~~practically~~ intact in containers. Good practices for the conservation and handling from capture to heat processing are essential to prevent histamine production. Refer to Section 9-bis for further information about histamine control. In its standards for some fish species, Codex adopted maximum levels for histamine.

**17.3.1.1 Fish and shellfish (Processing Step 1)**

Potential hazards: *chemical and biochemical contamination (DSP, PSP, scombrotoxin, heavy metals, etc.)*

Potential defects: *species substitution, decomposition, parasites*

Technical guidance:

Refer to Section 9.1.1 (and Section 9-bis.4.1 for scombrotoxin-forming fish), and other relevant sections; and also:

**17.3.3 Unwrapping, unpacking (Processing Steps 3 and 4)**

Potential hazards: *unlikely scombrotoxin*

Potential defects: *foreign matter, decomposition*

Technical guidance:

- During unwrapping and unpacking operations, precautions should be taken to limit product contamination and the introduction of foreign matter into the product. To avoid microbial proliferation, waiting periods before further processing should be minimized.

**17.3.5.1 Fish preparation (gutting, trimming, etc.)**

Potential hazards: *microbiological contamination, biochemical development (histamine scombrototoxin)*

Potential defects: *objectionable matter (viscera, skin, scales, etc. in certain products), off-flavours, decomposition, presence of bones, parasites, etc.*

Technical guidance:

Refer to Sections 9.1.5 and 9.1.6, **and 9-bis** and:

**17.4.1 Precooking**

Potential hazards: *chemical contamination (polar components of oxidized oils), microbiological or biochemical (~~scombrototoxin~~) contamination, scombrototoxin*

Potential defects: *water release in the final product (for products canned in oil), abnormal flavours, decomposition*

**17.4.2.1 Filling**

Potential hazards: *microbiological contamination, scombrototoxin (waiting period or, after heat processing owing to incorrect filling or defective containers)*

Potential defects: *incorrect weight, foreign matter, decomposition*

**17.4.3 Handling of containers after closure – staging before heat processing (Processing Step 9)**

Potential hazards: *microbiological contamination, scombrototoxin (waiting period or owing to damaged containers)*

Potential defects: *unlikely, decomposition*

**SECTION 18 – PROCESSING OF FISH SAUCE**

Salt is an essential ingredient in fish sauce production in order to support the growth of halophilic ~~micro~~ **micro**-organisms that produce effective fermentation, and prevent growth of bacterial pathogens and other undesirable microbial activity, yielding a high quality, safe fish sauce product.

**General considerations of hazards and defects****Hazards**

The raw material used in the fermentation to make fish sauce may include both freshwater and marine fish. Some marine fish, such as mackerel, sardines or anchovies, pose a risk of scombrototoxin formation; **for these it is necessary to refer to Section 9-bis of this Code**. Fish may be contaminated with undesirable ~~micro~~ **micro**-organisms, including pathogenic bacteria, thus it is necessary to control raw material on the harvest vessel in compliance with Sections 3, **and 4, and 9-bis** of this Code.

Water Phase Salt concentrations of 20 percent or higher should be achieved and maintained throughout the fermentation to prevent growth and activity of undesirable ~~micro~~ **micro**-organisms, including pathogens.

**SECTION 20 – TRANSPORTATION****20.1 For fresh, refrigerated and frozen products**

Potential hazards: *biochemical development (~~histamine~~ scombrototoxin), microbiological contamination*

Potential defects: *decomposition, physical damage, chemical contamination (fuel)*

Technical guidance:

**Refer to Section 9-bis.3 for fish at risk of scombrototoxin formation.**

- Check product temperature before loading.

**SECTION 21 – RETAIL****21.1.1 Reception of chilled products at retail**

Potential hazards: *microbiological contamination, chemical and physical contamination, scombrototoxin formation, C. botulinum toxin formation*

*Potential defects: spoilage (decomposition), contaminants, filth*

*Technical guidance:*

- Product temperature should be taken from several locations in the shipment and recorded. Chilled fish, shellfish and their products should be maintained at or below 4 °C (40 °F). MAP product, if not frozen, should be maintained at or below 3 °C (38 °F).
- **For fish susceptible to scombrototoxin formation, retailers should measure fish internal temperatures and perform sensory examination of representative fish before accepting delivery, and retailers should ensure that fish are purchased from suppliers that use HACCP or similar systems to prevent histamine formation.**

## ANNEX I — POTENTIAL HAZARDS ASSOCIATED WITH FRESH FISH, SHELLFISH AND OTHER AQUATIC INVERTEBRATES

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### 1.2 Bacteria

...Examples of indigenous bacteria that may pose a health hazard are *Aeromonas hydrophila* **hydrophila**, *Clostridium botulinum*, *Vibrio parahaemolyticus*, *Vibrio cholerae*, *Vibrio vulnificus* and *Listeria monocytogenes*.

...Other species that cause foodborne illness and that have occasionally been isolated from fish are *Edwardsiella tarda*, *Plesiomonas shigelloides* **Plesiomonas shigelloides** and *Yersinia enterocolitica*.

### 1.5 Scombrototoxin

Scombroid intoxication, sometimes referred to as histamine poisoning **or scombrototoxin fish poisoning**, results from eating fish that have been incorrectly chilled **during and/or** after harvesting. Scombrototoxin is attributed mainly to Enterobacteriaceae, which can produce high levels of histamine and other biogenic amines in the fish muscle when products are not immediately chilled after catching **and retained in a chilled state**. The main susceptible fish are the scombroids such as tuna, mackerel and bonito, although it can be found in other fish families such as Clupeidae. The intoxication is rarely fatal and symptoms ~~are usually~~ **while typically** mild, **can be severe**. Rapid refrigeration after catching and a high standard of handling during processing should prevent the development of the toxin. The toxin is not inactivated by ~~normal~~ heat processing. In addition, fish may contain toxic levels of histamine without exhibiting any of the usual sensory parameters characteristic of spoilage. **Refer to Section 9.bis for technical guidelines for control of histamine formation.**

**Proposed Draft Amendments to Commodity Standards  
(for comments at Step 3 through CL 2018/70-FH)**

Sampling sections (new sections 7.1.1 and 7.1.2)

**7. SAMPLING, EXAMINATION AND ANALYSES** [For CXS 302-2011, Section 9.3.5 will be replaced by the following provisions]

**7.1 Sampling**

**7.1.1 Sampling of lots for the examination of histamine for compliance with the safety provision listed in Section 5**

- Refer to the *General Guidelines on Sampling* (CXG 50-2004), Section 2.5.3 (Sampling plans for inspection of critical nonconformities). At minimum, the sampling plan selected should provide 95% confidence that no more than 5% of the available sample units in the lot exceed 200 mg/kg histamine. The lot is unacceptable if any sample unit exceeds 200 mg/kg histamine. **[Replace 200 mg/kg with 400 mg/kg for fish sauce, CXS 302-2011]**
- Plan is intended for end-product lot acceptance inspections at ports of entry and other receiver-oriented situations.
- Plan is appropriate for determining acceptability of lots with unknown history, from sources with unknown or unreliable implementation of histamine controls, or to settle disputes. Refer to Section 7.1.2 if acceptable histamine controls for the product and source have been established and the purpose for sampling is periodic assessment of source controls.
- Lot size “N” (used to determine sample size in GL 50, Section 2.5.3) is the total number of sample units available in the lot, and is calculated by dividing the total lot net weight by the test unit weight.
- Unfrozen or thawed sample units should be maintained below 4 °C and analyzed directly to prevent histamine accumulation.
- The test unit (blended for analysis) should weigh at least 100 grams, but not more than 250 grams. The test unit should be cut from the anterior-ventral portion of the fish loin when this portion is discernable in the market form sampled. For small fish and market forms weighing less than 100 grams (e.g., small cans, portions), multiple smaller units may be required to attain a 100-250-gram sample unit. **[For CXS 302-2011, this bullet should be: The test unit (blended for analysis) should weigh at least 100 grams, but not more than 250 grams. For market forms weighing less than 100 grams (e.g. small bottles), multiple smaller units may be required to attain a 100-250-gram sample unit.]**
- When histamine levels are routinely low, composite samples may reduce the number of analyses required. Refer to Annex [B] for optional composite sample screening procedure.
- Before testing, any liquid packing media, e.g., water, broth, oil, and flavored sauces, should be drained and, when necessary, the meat rinsed. **[Add this bullet for canned products only: CXS 70-1981, CXS 94-1981, CXS 119-1981]**
- Before testing, breading and/or batter should be removed. **[Add this bullet for CXS 166-1989 only.]**
- The product shall also comply with the histamine decomposition provision listed in section [3.X].

7.1.2. Sampling of lots to assess the performance of Good Manufacturing Practices (GMPs) and Hazard Analysis and Critical Control Point (HACCP) systems for histamine.

- Flexible plans appropriate for periodic assessment of GMP/HACCP systems.
- The sampling plan selected should provide 95% confidence that no more than a maximum percentage (e.g. 5%) of the available sample units in the lot contain more histamine than expected from a GMP/HACCP system (e.g. 15 mg/kg histamine <sup>[1][2]</sup>).

Examples of number of samples required to detect one deviating unit (with 95% probability) in lots with different hypothetical percentages of deviating units (based on binomial distribution; applicable to large lots)	
% deviating	No. samples
2.0%	149
5.0%	59
10.0%	29
15.0%	19

- System assessment results may be used to adjust sampling frequency or as a signal for follow-up, however the lot tested is acceptable regardless of test results, unless the histamine levels do not comply with the safety provision in section 5, or the decomposition provision in section [3.X].

[1] Higher or lower levels may be selected as a sign that GMP/HACCP systems are performing properly.

[2] FAO/WHO (2013) reported that 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). (Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and other Biogenic Amines from Fish and Fishery Products. Meeting Report 2013).

#### New Annex [B] for standards

#### Annex [B] – Optional composite sampling procedure for histamine screening

Example for lot acceptance against the 200 mg/kg histamine limit using 59 x 100 g sample units and 12 composite samples):

1. Blend (homogenize) each of the 59 X 100-gram sample units independently.
2. Take 50 grams from each of 5 blended 100-gram units and thoroughly blend (homogenize) together to make a composite sample. Analyze the histamine level in a test aliquot drawn from the composite sample.
3. Divide the histamine criterion being used by the number of units composited (in this case, divide 200 mg/kg by 5 units equaling 40 mg/kg). If the composite contains less than 40 mg/kg histamine, then all 5 units in the composite must contain less than 200 mg/kg histamine. If the composite sample contains more than 40 mg/kg histamine, then one or more samples may contain over 200 mg/kg histamine, or they may all be under 200 mg/kg histamine; in this case, analyze the retained 50-gram portions individually to determine the exact histamine level in each of the 5 sample units.
4. Apply the composite procedure to all the sample units. In this case, analyze 11 composites of 5 units, and one composite of 4 units (for the 4-unit composite, divide 200 mg/kg by 4, giving 50 mg/kg as the maximum level to assure that all 4 samples meet the 200 mg/kg limit).

The number of sample units that can be composited for a single analysis depends on the histamine criterion and the performance of the analytical method used. For lot acceptance sampling, refer to the Codex Procedural Manual, "*General Criteria for the Selection of Methods of Analysis using the Criteria Approach*".

Hygiene section amendments (changes in **bold underline** and ~~strikethrough~~)

#### **Standard for Quick Frozen Finfish, Uneviscerated and Eviscerated (CXS 36-1981)**

5.3 When tested by appropriate methods of sampling and examination prescribed by the Codex Alimentarius Commission, the product:

- i) shall be free from microorganisms or substances originating from microorganisms in amounts which may present a hazard to health in accordance with standards established by the Codex Alimentarius Commission;

ii) shall not contain histamine that exceeds ~~20 mg/100 g~~ **200 mg/kg in any sample unit**. This applies only to **susceptible** species of **(e.g. Scombridae, Clupeidae, Engraulidae, Scombridae, Coryphaenidae, Scomberesocidae, Pomatomidae, and Coryphaenidae Scomberesocidae)** families.

iii) shall not contain any other substance in amounts which may present a hazard to health in accordance with standards established by the Codex Alimentarius Commission.

#### **Standard for Canned Tuna and Bonito (CXS 70-1981)**

When tested by appropriate methods of sampling and examination as prescribed by the Codex Alimentarius Commission, the product:

- (i) shall be free from micro-organisms capable of development under normal conditions of storage;
- (ii) no sample unit shall contain histamine that exceeds ~~20 mg per 100 g~~ **200 mg/kg**;
- (iii) shall not contain any other substance including substances derived from microorganisms in amounts which may represent a hazard to health in accordance with standards established by the Codex Alimentarius Commission;
- (iv) shall be free from container integrity defects which may compromise the hermetic seal.

#### **Standard for Canned Sardines and Sardine-Type Products (CXS 94-1981)**

When tested by appropriate methods of sampling and examination as prescribed by the Codex Alimentarius Commission, the product:

- (i) shall be free from micro-organisms capable of development under normal conditions of storage;
- (ii) no sample unit shall contain histamine that exceeds ~~20 mg per 100 g~~ **200 mg/kg**;
- (iii) shall not contain any other substance including substances derived from microorganisms in amounts which may represent a hazard to health in accordance with standards established by the Codex Alimentarius Commission;
- (iv) shall be free from container integrity defects which may compromise the hermetic seal.

#### **Standard for Canned Finfish (CXS119-1981)**

When tested by appropriate methods of sampling and examination prescribed by the Codex Alimentarius Commission, the product:

- (i) shall be free from micro-organisms capable of development under normal conditions of storage; and
- (ii) no sample unit shall contain histamine that exceeds ~~20 mg per 100 g~~ **200 mg/kg**. This applies only to **susceptible** species of **the families (e.g. Scombridae, Clupeidae, Engraulidae, Coryphaenidae, Scomberesocidae and Pomatomidae, Scomberesocidae)**.
- (iii) shall not contain any other substance including substances derived from microorganisms in amounts which may represent a hazard to health in accordance with standards established by the Codex Alimentarius Commission; and
- (iv) shall be free from container integrity defects which may compromise the hermetic seal.

#### **Standard for Quick Frozen Blocks of Fish Fillet, Minced Fish Flesh and Mixtures of Fillets and Minced Fish Flesh (CXS165-1989)**

When tested by appropriate methods of sampling and examination prescribed by the Codex Alimentarius Commission, the product:

- (i) shall be free from microorganisms or substances originating from microorganisms in amounts which may represent a hazard to health in accordance with standards established by the Codex Alimentarius Commission;
- (ii) shall not contain histamine that exceeds ~~20 mg/100 g~~ **200 mg/kg** in any sample unit. This applies only to **susceptible** species of **(e.g. Scombridae, Clupeidae, Scombridae, Engraulidae, Coryphaenidae, Scomberesocidae, Pomatomidae, and Coryphaenidae Scomberesocidae)** families;

(iii) shall not contain any other substances in amounts which may represent a hazard to health in accordance with standards established by the Codex Alimentarius Commission.

**Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets - Breaded or in Batter (CXS166-1989)**

When tested by appropriate methods of sampling and examination prescribed by the Codex Alimentarius Commission, the product:

(i) shall be free from microorganisms or substances originating from microorganisms in amounts which may present a hazard to health in accordance with standards established by the Codex Alimentarius Commission;

(ii) shall not contain histamine that exceeds ~~20 mg/100 g~~ **200 mg/kg in any sample unit**. This applies only to **susceptible** species of (**e.g., Scombridae, Clupeidae, Scombridae, Engraulidae, Coryphaenidae, Scomberesocidae, Pomatomidae, and Coryphaenidae Scomberesocidae**) families;

(iii) shall not contain any other substance in amounts which may present a hazard to health in accordance with standards established by the Codex Alimentarius Commission.

**Standard for Quick Frozen Fish Fillets (CXS 190-1995)**

When tested by appropriate methods of sampling and examination prescribed by the Codex Alimentarius Commission, the product:

(i) shall be free from microorganisms or substances originating from microorganisms in amounts which may present a hazard to health in accordance with standards established by the Codex Alimentarius Commission;

(ii) shall not contain histamine that exceeds ~~20 mg/100 g~~ **200 mg/kg in any sample unit**. This applies only to **susceptible** species of (**e.g., Scombridae, Clupeidae, Scombridae, Engraulidae, Coryphaenidae, Scomberesocidae, Pomatomidae, and Coryphaenidae Scomberesocidae**) families;

(iii) shall not contain any other substance in amounts which may present a hazard to health in accordance with standards established by the Codex Alimentarius Commission.

**Standard for Boiled Dried Salted Anchovies (CXS 236-2003)**

5.3 No sample unit shall contain histamine that exceeds ~~20 mg/100g~~ **200 mg/kg**.

**Standard for Salted Atlantic Herring and Salted Sprat (CXS 244-2004)**

5.5 Histamine

No sample unit shall contain histamine that exceeds ~~20 mg per 100g~~ **200 mg/kg** fish muscle.

**Standard for Fish Sauce (CXS 302-2011)**

6.4 The product shall not contain more than ~~40 mg histamine /100g~~ **400 mg histamine/kg** of fish sauce in any sample unit tested.

9.1 Sampling of lots for **Sensory and Physical** examination of the final product shall be in accordance with the *General Guidelines on Sampling* (CXG 50-2004). A sample unit is the individually packed product (bottle) or a 1l portion from bulk containers.

~~9.1.19.2~~ Sensory and Physical Examination Samples taken for...

**Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish (CXS 311-2013)**

6.6 Histamine

The product shall not contain histamine that exceeds ~~20 mg/100g~~ **200 mg/kg** fish flesh in any sample unit tested. This applies only to susceptible species (e.g. Scombridae, Clupeidae, Engraulidae, Coryphaenidae, Pomatomidae, Scomberesocidae).

Determination of Histamine subsection amendment (changes in **bold underline** and ~~strikethrough~~)

### DETERMINATION OF HISTAMINE

Methods meeting the following method performance criteria may be used:

ML (mg/100 <del>kg</del> )	Minimum applicable range (mg/100 <del>kg</del> )	LOD (mg/100 <del>kg</del> )	LOQ (mg/100 <del>kg</del> )	RSDR (%)	Recovery	Applicable methods that meet the criteria
10 <del>0</del> (average)	8 <del>0</del> – 12 <del>0</del>	1 <del>0</del>	2 <del>0</del>	16.0	90 – 107	AOAC 977.13   NMKL 99, 2013 NMKL 196, 2013
20 <del>0</del> (each unit)	16 <del>0</del> – 24 <del>0</del>	2 <del>0</del>	4 <del>0</del>	14.4	90 – 107	AOAC 977.13   NMKL 99, 2013 NMKL 196, 2013
<b><u>40</u></b> <b><u>(composite)</u></b>	<b><u>29 – 51</u></b>	<b><u>4</u></b>	<b><u>8</u></b>	<b><u>18.4</u></b>	<b><u>80 -110</u></b>	<b><u>AOAC</u></b> <b><u>977.13</u></b>

#### Additional edits in standards

Change histamine units from “mg/100 g” to “mg/kg”, and adjust listed level appropriately, throughout standards.

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