

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Items 6

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

Fiftieth Session

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#### REVISION OF RELATED CODEX FISH AND FISHERY PRODUCT COMMODITY STANDARD

##### *Revision of appendix II. Proposed draft amendments to commodity standard sampling sections*

Prepared by the EWG chairs

EWG Co-lead revision based on comments received at Step 3 (CL 2018/70-FH)

New sections 7.1.1 and 7.1.2 under Section 7.1 in eleven adopted standards (CRD changes shown in strikethrough and **bold underline**.)

#### 7. SAMPLING, EXAMINATION AND ANALYSES

##### 7.1 Sampling

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

~~Plan~~ Section 7.1.1 is appropriate **intended** for determining acceptability of lots with unknown history, ~~or from sources with unknown or unreliable implementation of histamine controls, or to settle~~ **for settling** disputes. The plan is intended for end-product lot ~~acceptance~~ inspections at ports of entry and other receiver-oriented situations.

Refer to Section 7.1.2 if acceptable histamine controls ~~for the product and source~~ have been established **(e.g., produced under adequate GMPs and HACCP)**, and the purpose for sampling is ~~periodic assessment of source~~ **to confirm that histamine levels remain indicative of adequate** controls.

- ~~Refer to the *General Guidelines on Sampling* (CXG 50-2004), Section 2.5.3 (Sampling plans for inspection of critical nonconformities).~~

~~1. At minimum,~~The sampling plan selected should provide 95% confidence that no more than **shall be able to detect at least one sample unit over 200 mg/kg histamine (with 95% probability) when 1 in 20 (5%)** of the available sample units in the lot exceed ~~the~~ 200 mg/kg histamine **safety limit**.

**2. For large lots the number of sample units required is 59, and** the lot is unacceptable if any sample unit **tested** exceeds 200 mg/kg histamine. **[Replace 200 mg/kg with 400 mg/kg for fish sauce, CXS 302-2011]**

**3.** The ~~product~~ **lot** shall also comply with the histamine decomposition provision listed in section [3.X].

**4. For small lots (where 59 sample units represent more than 10% of the lot net weight),** refer to the *General Guidelines on Sampling* (CXG 50-2004), Section 2.5.3.1 **(e) (first bullet point)**, ~~(Sampling plans for inspection of critical nonconformities)~~ **for an optional formula that may be used to calculate a reduced number of samples.**

- ~~Lot size "N" (used in formula for 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 lot net weight by the test unit weight.~~
- ~~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.

- Unfrozen or thawed sample units should be maintained below 4 °C and analyzed directly to prevent histamine accumulation.

**5.** The ~~test~~ **sample** unit (blended for analysis) should weigh at least 100 grams, but not more than 250 grams.

**6.** The ~~test~~ **sample** 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 **whole fish** may be required to attain a 100-250-gram sample unit. **[For CXS 302-2011, this bullet should be: The test sample 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.]**

**7.** Unfrozen or thawed sample units should be maintained below 4 °C and analyzed directly **as soon as possible** to prevent histamine accumulation **formation**.

- 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.

**8.** 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]**

**9.** Before testing, breading and/or batter should be removed. **[Add this bullet for CXS 166-1989 only.]**

**10.** When histamine levels are routinely low, composite samples may reduce the number of analyses required. Refer to Annex [B] for **an** optional composite sample screening procedure.

- The product shall also comply with the histamine decomposition provision listed in section [3.X].

**7.1.2. Sampling histamine in lots from sources with established GMPs and HACCP controls to assess the confirm that histamine levels remain indicative of adequate control. performance of Good Manufacturing Practices (GMPs) and Hazard Analysis and Critical Control Point (HACCP) systems for histamine.**

**1.** Flexible plans appropriate **Different sampling strategies (e.g., variable sampling frequency, variable sample size, different histamine indicator levels, 2 or 3-class plans) may be selected to assess histamine levels at ports of entry and other receiver-oriented situations.** for periodic assessment of GMP/HACCP systems.

**2.** System assessment results **Effective sampling strategies use histamine levels below the safety limit (indicative of application of GMPs and HACCP<sup>(1)</sup>) to** may be used to adjust sampling frequency, **sample size,** or as a signal to follow-up **make other risk management decisions.**

**3.** Regardless of **the sampling strategy used** test results, **the** lot tested is acceptable unless the histamine levels do not comply with the safety provision in section 5 **a sample unit exceeds 200 mg/kg histamine,** or **histamine levels do not meet** the decomposition provision in section [3.X].

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

<b>Table 1</b>	
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] ~~[footnote] [1] According to~~ 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 (CRD changes shown in ~~striketrough~~ and **bold underline**)

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

Example for lot acceptance testing ~~against the 200 mg/kg histamine limit~~ under Section 7.1.1 using 59 sample units × of 100 grams each, sample units and 12 composite samples):

**This example uses sets of 5 sample units for compositing, however fewer units (e.g., 3) may be used. 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 testing, refer to the Codex Procedural Manual, “General Criteria for the Selection of Methods of Analysis using the Criteria Approach”.**

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) **the 5 portions** 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 **being** composited **to determine the composite histamine limit (the maximum histamine level in the composite that assures all the sample units in the composite meet the 200 mg/kg limit.)**
  - a. ~~(in this case~~ **For the example**, divide **the** 200 mg/kg **histamine limit** by **the** 5 units **composited** ~~equaling~~ **giving a** 40 mg/kg **composite histamine limit**).
  - b. 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.
  - c. 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~~ **59** sample units. In this ~~case~~ **example**, 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 **composite histamine limit** ~~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 ~~striketrough~~)

### **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, Scombresocidae, 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 **not** contain histamine that exceeds ~~20 mg per 100 g~~ **200 mg/kg in any sample unit**;

(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 **not** contain histamine that exceeds ~~20 mg per 100 g~~ **200 mg/kg in any sample unit**;

(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 **not** contain histamine that exceeds ~~20 mg per 100 g~~ **200 mg/kg in any sample unit**. This applies only to **susceptible** species of the families (e.g. Scombridae, Clupeidae, Engraulidae, Coryphaenidae, Scombresocidae 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, Scombresocidae, 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, Scombresocidae, 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.

**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
<u>100</u> (average)	<del>8 – 12</del> <b><u>76-124</u></b>	<u>10</u>	<u>20</u>	16.0	90 – 107	AOAC 977.13   NMKL 99, 2013 NMKL 196, 2013 <b><u>AOAC-RI No. 070703</u></b>
<u>200</u> (each unit)	<del>16 – 24</del> <b><u>157-243</u></b>	<u>20</u>	<u>40</u>	14.4	90 – 107	AOAC 977.13   NMKL 99, 2013 NMKL 196, 2013 <b><u>AOAC-RI No. 070703</u></b>
<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 977.13</u></b>

Additional general edits in standards

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

Align lists of susceptible family names throughout standards.