SECTION 2 – DEFINITIONS

2.1 General definitions

**Disinfection** The reduction by means of chemical agents and/or physical methods in the number of microorganisms 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 scombrotoxin 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 scombrotoxin.

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

5.3.3.1 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. scombrotoxin).

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 scombrotoxin formation, refer to Section 9-bis “Harvesting, Processing, Storage and Distribution of Fish and Fishery Products at Risk for Scombroid-Toxin (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, scombrotoxin, chemicals (including veterinary drug residues) and physical contamination.

Refer to Section 9-bis for scombrotoxin control guidance.

9.1.5 Washing and gutting (Processing Steps 6 and 7)

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

**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 scombrotoxin, physical contamination (metal)

**Potential defects:** subsequent decomposition

9.3.1 Freezing process (Processing Step 15)

**Potential hazards:** viable parasites, scombrotoxin
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 scombrotxin
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, scombrotxin
Potential defects: physical contamination, incorrect addition of additives, decomposition

9.4.4 Wrapping and packaging (Processing Steps 17 and 25)
Potential hazards: microbiological contamination
Potential defects: subsequent dehydration, decomposition

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

[Placeholder for newly adopted histamine control guidance]

SECTION 10 – PROCESSING OF FROZEN SURIMI

10.1 Hazards
If scombrotxin-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. Refer to Section 9-bis for scombrotxin control guidance.

10.2 Raw fresh and frozen fish reception (Processing Step 1)
Potential hazards: unlikely when using marine groundfish as the raw material
Potential defects: decomposition, protein denaturation

10.2.2 Chilled storage (Processing Step 2)
Potential hazards: unlikely scombrotxin
Potential defects: protein denaturation, decomposition

10.4 Washing and dewatering process (Processing Step 10)
Potential hazards: microbiological contamination, scombrotxin
Potential defects: decomposition, protein denaturation, residual water-soluble protein

10.5 Refining process (Processing Step 11)
Potential hazards: microbiological contamination, scombrotxin, 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, scombrotxin
Potential defects: decomposition, protein denaturation

10.7 Mixing and addition of adjuvant ingredients process (Processing Step 13)
Potential hazards: microbiological contamination, scombrotxin, 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

11.3.1 Reception

11.3.1.1 Fish

Potential hazards: chemical, and biochemical and microbiological contamination, histamine scombrotoxin

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

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 affect the proper amount of breading 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 following species, all belonging to the Gadidae family, intended for human consumption:

- Cod (Gadus morhua),
- Pacific cod (Gadus macrocephalus),
- Polar cod (Boreogadus saida),
- Greenland cod (Gadus ogac),
- Saithe (Pollachius virens),
- Blue ling (Molva dypterygia),
- Tusk (Brosme brosme),
- Haddock (Gadus aeglefinus/Melanogrammus aeglefinus),
- Forkbeard (Phycis blennoides),
- 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 scombrotoxin.

12.2 Preparing for salting

12.2.1 Splitting, washing and rinsing (Processing Step 7)

Potential hazards: unlikely scombrotoxin

Potential defects: improper splitting, decomposition

12.2.4 Nobbing (Processing Step 10)

Potential hazards: unlikely scombrotoxin

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

12.2.5 Gibbing (Processing Step 11)

Potential hazards: unlikely scombrotoxin

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, scombrotoxins, botulinum toxin

12.4.2 Brine injection (Processing Step 15)

Potential hazards: viable parasites, scombrotoxins, injection needle fragment, botulinum toxin

12.4.3 Wet-salting (Processing Step 16)

Potential hazards: viable parasites, scombrotoxins, botulinum toxin

12.4.4 Dry-salting (Processing Step 17)

Potential hazards: viable parasites, scombrotoxin, botulinum toxin
12.4.5 Pickling (Processing Step 18)
Potential hazards: viable parasites, scombrototoxins, 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, scombrototoxins, 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 scombrototoxin 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 scombrototoxin

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 scombrototoxin 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 scombrototoxin.

13.1.2 Salting
Potential Hazards: microbiological, chemical and physical contamination, scombrototoxins, 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, scombrotxin
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, scombrotxin
Potential defects: physical contamination, decomposition

13.1.15 Cooling or freezing
Potential hazards: microbiological contamination, scombrotxin, survival of parasites
Potential defects: poor taste and texture, decomposition

13.1.16 Storage
Potential hazards: microbiological contamination, scombrotxin
Potential defects: poor taste and texture, decomposition, freezer burn

13.3.1 Pre-drying
Potential hazards: microbiological and physical contamination, scombrotxin
Potential defects: decomposition, physical contamination

13.3.2 Smoke-drying
Potential hazards: parasites and microbiological contamination, scombrotxin, 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

17.2.1 Hazards

A2 Scombrotoxins

Histamine

Histamine is heat stable, its toxicity 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, scombrotxin, heavy metals, etc.)
Potential defects: species substitution, decomposition, parasites
Technical guidance:
Refer to Section 9.1.1 (and Section 9-bis.4.1 for scombrotxin-forming fish), and other relevant sections; and also:

17.3.3 Unwrapping, unpacking (Processing Steps 3 and 4)
Potential hazards: unlikely scombrotxin
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 scombrotoxin)

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 (scombrotoxin) contamination

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

17.4.2 Filling

Potential hazards: microbiological contamination, scombrotoxin (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, scombrotoxin (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 microorganisms 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 scombrotoxin formation; for these it is necessary to refer to Section 9-bis of this Code. Fish may be contaminated with undesirable microorganisms, 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 microorganisms, including pathogens.

SECTION 20 – TRANSPORTATION

20.1 For fresh, refrigerated and frozen products

Potential hazards: biochemical development (histamine scombrotoxin), microbiological contamination

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

Technical guidance:

Refer to Section 9-bis.3 for fish at risk of scombrotoxin 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, scombrotoxin 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

1.2 Bacteria

...Examples of indigenous bacteria that may pose a health hazard are \textit{Aeromonas hydrophyla}, \textit{Clostridium botulinum}, \textit{Vibrio parahaemolyticus}, \textit{Vibrio cholerae}, \textit{Vibrio vulnificus} and \textit{Listeria monocytogenes}.

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

1.5 Scombrotoxin

Scombroid intoxication, sometimes referred to as histamine poisoning or \textit{scombrotoxin fish poisoning}, results from eating fish that have been incorrectly chilled \textit{during and/or} after harvesting. Scombrotoxin is attributed mainly to \textit{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 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. \textit{Refer to Section 9.bis for technical guidelines for control of histamine formation.}

Appendix II

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 \textit{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 [1][2]).

<table>
<thead>
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<th>% deviating</th>
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<tr>
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</tr>
<tr>
<td>5.0%</td>
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</tr>
<tr>
<td>10.0%</td>
<td>29</td>
</tr>
<tr>
<td>15.0%</td>
<td>19</td>
</tr>
</tbody>
</table>

• 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 compositing (in this case, divide 200 mg/kg by 5 units equalling 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, Scombridae, 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 microorganisms 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 microorganisms 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 microorganisms 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, Scombridae 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/100g 200 mg/kg in any sample unit. This applies only to susceptible species of (e.g., Scombridae, Clupeidae, Engraulidae, Coryphaenidae, Scombersocidae, Pomatomidae, and Coryphaenedae 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/100g 200 mg/kg in any sample unit. This applies only to susceptible species of (e.g., Scombridae, Clupeidae, Engraulidae, Coryphaenidae, Scombersocidae, Pomatomidae, and Coryphaenedae 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/100g 200 mg/kg in any sample unit. This applies only to susceptible species of (e.g., Scombridae, Clupeidae, Engraulidae, Coryphaenidae, Scombersocidae, Pomatomidae, and Coryphaenedae 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:

<table>
<thead>
<tr>
<th>ML (mg/100 kg)</th>
<th>Minimum applicable range (mg/100 kg)</th>
<th>LOD (mg/100 kg)</th>
<th>LOQ (mg/100 kg)</th>
<th>RSD (%)</th>
<th>Recovery</th>
<th>Applicable methods that meet the criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 (average)</td>
<td>80 – 120</td>
<td>10</td>
<td>20</td>
<td>16.0</td>
<td>90 – 107</td>
<td>AOAC 977.13</td>
</tr>
<tr>
<td>200 (each unit)</td>
<td>160 – 240</td>
<td>20</td>
<td>40</td>
<td>14.4</td>
<td>90 – 107</td>
<td>AOAC 977.13</td>
</tr>
<tr>
<td>40 (composite)</td>
<td>29 – 51</td>
<td>4</td>
<td>8</td>
<td>18.4</td>
<td>80 – 110</td>
<td>AOAC 977.13</td>
</tr>
</tbody>
</table>

**Additional edits in standards**

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