

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 6

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD HYGIENE

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REVISION OF THE CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS (CXC 52-2003) AND REVISIONS OF THE SECTION ON SAMPLING, EXAMINATION AND ANALYSIS RELATED TO HISTAMINE FOOD SAFETY

Replies to comments at Step 3 to CL 2018/70-FH

Comments of Argentina, Australia, Brazil, Canada, Colombia, Cuba, Ecuador, European Union, Gambia, Iran, Iraq, Japan, Mexico, Morocco, New Zealand, Norway, Panama, Peru, Senegal, Thailand, United States of America, IUFOST

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2018/70-FH issued in September 2018. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as **Annex I (alignment of Code with histamine control guidance)** and **Annex II (proposed draft amendments to commodity standards)** and are presented in table format.

ANNEX I

GENERAL COMMENTS	
ALIGNMENT OF CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS WITH HISTAMINE CONTROL GUIDANCE	
<p>Argentina appreciates the opportunity to provide comments and commends the Electronic Working Group for its work on this document.</p> <p>Argentina agrees that the newly adopted histamine control guidance should be a separate section in the Code located directly after Section 9 (Processing of Fresh, Frozen and Minced Fish).</p> <p>Argentina agrees with the amendments proposed to Appendix 1, which aligned the Code with the histamine guidance.</p> <p>ii. Sampling Guidance in Commodity Standards</p> <p>Argentina will consider the observations submitted by Morocco on sampling size.</p>	Argentina
<p>Australia would like to thank Japan and the United States of America for leading the eWG. Australia supports that the newly adopted histamine guidance should be a separate section in the Code and located directly after Section 9.</p>	Australia
<p>Cuba appreciates the opportunity to submit its comments and, in principle, supports the document circulated on Alignment of Code with Histamine Control Guidance.</p>	Cuba
<p>Panama agrees with the change</p>	Panama
<p>The United States thanks the electronic working group (EWG) for aligning the complementary sections of the Code of Practice for Fish and Fishery Products with the newly adopted histamine guidance. The U.S. agrees with the alignment edits and supports the insertion of the new Histamine Guidance Section between existing Sections 9 and 10 (with renumbering of the sections and cross-references as needed.)</p> <p>The United States supports advancement of the proposed drafts as is, or with the technical/editorial changes provided above.</p> <p>The United States, as a general comment, would like to suggest changing "micro-organism" to "microorganism" throughout the Code of Practice for Fish and Fishery Products.</p>	USA
<p>IUFOST supports this draft code and urges its adoption as soon as final comments have been considered and included in the code.</p>	IUFOST
ALIGNMENT OF CODE WITH HISTAMINE CONTROL GUIDANCE	
CODE OF PRACTICE – SPECIFIC COMMENTS	
SECTION 2 – DEFINITIONS	
2.1 General definitions	
<i>Disinfection</i> The reduction by means of chemical agents and/or physical methods in the number of micro-organisms in the environment to a level that does not compromise food safety or suitability.	
<p>What about biological disinfection? For more information, the reference entitled "This lab-made probiotic fights off infections from unfriendly bacteria" is available at:</p>	Iran

<p>https://www.theverge.com/2017/4/11/15247748/e-coli-engineered-probiotic-fight-bacteria-infections-antibiotics</p>	
<p>Disinfection The reduction by means of chemical agents and/or physical methods in the number of micro micro-organisms in the environment to a level that does not compromise food safety or suitability.</p> <p>Disinfection The reduction ...to a level that does not compromise ensures food safety or and suitability.</p>	<p>Mexico The definition of disinfection should note that it applies to eliminating pathogenic micro-organisms.</p> <p>It is not clear that it does not compromise safety or suitability.</p>
<p>Disinfection The reduction by means of chemical agents and/or physical methods in the number of micro micro-organisms in the environment to a level that does not compromise food safety or suitability.</p>	<p>Panama Panama agrees with the comment.</p>
<p>4.1 Time and temperature control</p>	
<p>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. <u>Refer to Section 9-bis for further information on control of scombrototoxin.</u></p>	<p>Colombia The wording proposed to the Spanish text simplifies the sentence and makes it clearer.</p>
<p>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. <u>Refer to Section 9-bis for further information on control of scombrototoxin.</u></p>	<p>Mexico Syntax</p>
<p>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. <u>Refer to Section 9-bis for further information on control of scombrototoxin.</u></p>	<p>Iran for as a short time as possible</p>
<p>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. <u>Refer to Section 9-bis for further information on control of scombrototoxin.</u></p>	<p>Panama Panama agrees with the change</p>
<p>5.3.3.1.1 Hazards</p>	
<p>Panama agrees with the change</p>	<p>Panama</p>

<p>... 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. the production of scombrototoxin).</p>	<p>Mexico This example is unclear. It lacks an action.</p>
<p>SECTION 9 – PROCESSING OF FRESH, FROZEN AND MINCED FISH</p>	
<p>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” technical guidance for information on the control of histamine, including guidance for harvest vessel operations.scombrototoxin</p>	<p>Gambia</p>
<p>For fish susceptible to scombrototoxin formation production, 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.</p>	<p>Mexico missing action</p>
<p>Panama agrees</p>	<p>Panama</p>
<p>For “Regarding fish susceptible to scombrototoxin formationscombrototoxin formation, refer to please refer to Section 9-bis “Harvesting, Processing, Storage and Distribution-section 9-bis for Fish and Fishery technical guidance relating to Products at Risk-the control of Scombrototoxin (Histamine) Formation” for information on the control of histamine, including guidance for harvest vessel operations scombrototoxin.”</p>	<p>Senegal Rationale To be more consistent with how guidelines are referenced in other sections of the document.</p>
<p>9.1.1 Raw, fresh or frozen fish reception (Processing Step 1) Potential hazards: <i>microbiological contamination, viable parasites, biotoxins, scombrototoxin¹⁰, chemicals (including veterinary drug residues) and physical contamination.</i></p>	
<p>Potential hazards: <i>microbiological contamination, viable parasites, chemical hazards (biotoxins, scombrototoxin)¹⁰, chemicals (including veterinary drug residues) and physical contamination.</i></p>	<p>Colombia [The first change does not apply to the English text] Colombia asserts that when referring to scombrototoxin, it should be included under hazards or chemical contamination, given that it is a toxin classified as a chemical hazard. We request this change throughout the document, where appropriate.</p>
<p>Methyl mercury and heavy metals are important in marine foods. It is suggested to add them here or somewhere else</p>	<p>Iran</p>
<p>Potential hazards: ——— microbiological contamination, viable parasites, biotoxins, scombrototoxin¹⁰-</p>	<p>Mexico Microbiological hazards should be described as</p>

Potential hazards: pathogenic micro-organisms, viruses, viable parasites, biotoxins, scombrototoxin, ¹⁰ chemicals (including veterinary drug residues) and physical contamination. chemicals (including veterinary drug residues) and physical contamination.	such and should specify whether they are pathogenic bacteria, parasites, viruses, etc., as mentioned in other paragraphs (9.1.5, 9.1.2)
Panama agrees	Panama
9.1.5 Washing and gutting (Processing Steps 6 and 7)	
Potential defects: presence of viscera, bruising, off-flavours , cutting faults, <u>decomposition</u>	Colombia Colombia proposes striking the words "off-flavours" and "decomposition," as these are not defects, rather indications of alteration. This comment is applicable to all relevant parts of the document.
Potential hazards: microbiological contamination, biotoxins and scombrototoxin <i>Gambia recommends that scombrototoxin should be included as an example so that the sentence reads "Potential hazards: microbiological contamination, biotoxins and e.g. scombrototoxin as Scombrototoxin is one of the biotoxins."</i>	Gambia
Panama agrees with the entire content of 9.1.5	Panama
Potential hazards: microbiological contamination, biotoxins and , e.g. scombrototoxin	Senegal
9.2.2 Vacuum or modified atmosphere packaging (Processing Step 11)	
Potential hazards: subsequent microbiological contamination and/or growth and biotoxins formation, subsequent scombrototoxin, physical contamination (metal)	Iran
Potential hazards: subsequent microbiological contamination and biotoxins, <u>subsequent scombrototoxin produced subsequent to packaging</u> , physical contamination (metal)	Mexico improved understanding
Panama agrees with point 9.2.2	Panama
9.3.1 Freezing process (Processing Step 15)	
Panama agrees	Panama
9.4.2 Washing of minced fish (Processing Step 22)	
Panama agrees	Panama
9.4.3 Blending and application of additives and ingredients to minced fish (Processing Steps 23 and 24)	
Potential hazards: physical contamination, chemical contamination, microbiological contamination, non-approved additives and/or ingredients, scombrototoxin	Iran

9.4.4 Wrapping and packaging (Processing Steps 17 and 25)	
Potential hazards: microbiological contamination, scombrototoxin. Chemical hazard is also possible.	Iran
SECTION 10 – PROCESSING OF FROZEN SURIMI	
10.2.1 Raw fresh and frozen fish reception (Processing Step 1)	
Panama agrees with the change	Panama
10.2.2 Chilled storage (Processing Step 2)	
Panama agrees with the change	Panama
10.4 Washing and dewatering process (Processing Step 10)	
Potential hazards: chemical contamination, physical contamination, microbiological contamination, scombrototoxin	Iran
10.5 Refining process (Processing Step 11)	
Technical guidance:	
<ul style="list-style-type: none"> • 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. 	
We noticed that there are no changes to the 2 bullets. Should it include “and scombrototoxin formation” such as the suggestions made in Section 10.7?	Canada
<ul style="list-style-type: none"> • Temperature of the minced fish flesh in the refining process should be adequately controlled to prevent the growth of pathogenic bacteria<u>bacteria and scombrototoxin formation</u>. • Product should be processed promptly to minimize possible pathogenic microbial growth<u>growth and scombrototoxin formation</u>. 	
Temperature of the minced fish flesh in the refining process should be adequately controlled to prevent the growth of pathogenic bacteria <u>micro-organisms</u> .	Colombia The correct word in Spanish is micro-organisms. Please apply this change to the entire document.
Temperature of the minced fish flesh in the refining process should be adequately controlled to prevent the growth of pathogenic bacteria <u>micro-organisms</u> .	Mexico Change the word bacteria to the correct term, micro-organisms, throughout the entire document.
<ul style="list-style-type: none"> • Temperature of the minced fish flesh in the refining process should be adequately controlled to prevent the growth of pathogenic bacteria. <u>and scombrototoxin formation</u>. • Product should be processed promptly to minimize possible pathogenic microbial growth<u>growth and scombrototoxin formation</u>. 	USA Recommend change to be consistent with the proposed change in Subsection 10.7.
10.7 Mixing and addition of adjuvant ingredients process (Processing Step 13)	
Potential hazards: microbiological contamination, scombrototoxin, physical contamination e.g. metal fragments	Iran

10.8 Packaging and weighing (Processing Step 14)	
Potential hazards: physical contamination, microbiological contamination, scombrototoxin <ul style="list-style-type: none"> Product should be packaged promptly to minimize possible pathogenic microbial growth and physical contamination. 	Iran
Packaging should be conducted rapidly to minimize the risk of contamination, <u>pathogenic microbial micro-organism growth, scombrototoxin formation</u> , or decomposition.	Peru
10.9 Freezing operation (Processing Step 15)	
Panama agrees with the change	Panama
SECTION 11 – PROCESSING OF QUICK FROZEN COATED FISH PRODUCTS	
11.3.1 Reception	
11.3.1.1 Fish	
Potential hazards: chemical (<u>scombrototoxin</u>), and biochemical <u>and microbiological</u> contamination, histamine <u>scombrototoxin</u> ¹⁶	Colombia Colombia understands that hazards, by definition, are physical, chemical, and microbiological, and that biochemical are not included.
Panama agrees with the change	Panama
11.3.5.2. Application of additives and ingredients	

<p>Potential defects: <u>incorrect addition of additives</u>, decomposition</p> <p>Potential hazards: <u>incorrect addition of additives</u>, foreign material, microbiological contamination., scombrototoxin</p>	<p>Brazil Rationale: Incorrect addition of additives, either through the addition of an unauthorized additive or in excess of the permitted amount, may be considered a potential hazard rather than a potential defect. An undeclared additive may acutely cause an allergy in susceptible individuals or chronically overexposure to a substance with limited ADI (Acceptable Daily Intake) may cause health damage.</p> <p>Rationale: Incorrect addition of additives, either through the addition of an unauthorized additive or in excess of the permitted amount, may be considered a potential hazard rather than a potential defect. An undeclared additive may acutely cause an allergy in susceptible individuals or chronically overexposure to a substance with limited ADI (Acceptable Daily Intake) may cause health damage.</p>
<p>Potential hazards: physical contamination (foreign material), microbiological contamination., scombrototoxin</p>	<p>Iran</p>
<p>11.3.5.3 Forming</p>	
<p>• Potential hazards: physical contamination, .e.g. foreign material (metal or plastic from machine) and/or microbiological contamination/scombrototoxin (fish mixture only)</p>	<p>Iran</p>
<p>11.3.7.1 Wet coating</p>	
<p>Technical guidance:</p>	
<p><i>Technical guidance:</i></p> <p>• controlled within certain parameters to affect/achieve the proper amount of breeding pick-up.</p>	<p>Iran</p>
<p>controlled within certain <u>temperature, moisture, etc.</u> parameters to effect affect the proper amount of breeding pick-up.</p>	<p>Mexico</p>
<p>SECTION 12 – PROCESSING OF SALTED AND DRIED SALTED FISH</p>	
<p>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 (<i>Gadus morhua</i>), Pacific cod (<i>Gadus macrocephalus</i>), Polar cod (<i>Boreogadus saida</i>), Greenland cod (<i>Gadus ogac</i>), Saithe (<i>Pollachius virens</i>), Ling (<i>Molva molva</i>), Blue ling (<i>Molva dypterygia</i>), Tusk (<i>Brosme brosme</i>), Haddock (<i>Gadus aeglefinus/Melanogrammus aeglefinus</i>), Forkbeard (<i>Phycis blennoides</i>) and Pollock (<i>Pollachius pollachius</i>).</p>	<p>Australia Australia recommends that the sentence regarding the scientific and common names of the species belonging to the Gadidae family be deleted. Rationale: The proposed amendments by the EWG clarifies</p>

	<p>that Section 12 is applicable to all salted and dried salted fish, and listing the scientific and common names of a number of species belonging only to the Gadidae family may still cause confusion.</p>
<p>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 (<i>Gadus morhua</i>), Pacific cod (<i>Gadus macrocephalus</i>), Polar cod (<i>Boreogadus saida</i>), Greenland cod (<i>Gadus ogac</i>), Saithe (<i>Pollachius virens</i>), Ling (<i>Molva molva</i>), Blue ling (<i>Molva dypterygia</i>), Tusk (<i>Brosme brosme</i>), Haddock (<i>Gadus aeglefinus/Melanogrammus aeglefinus</i>), Forkbeard (<i>Phycis blennoides</i>) and Pollock (<i>Pollachius pollachius</i>).</p>	<p>Canada We believe that the edits made in the first paragraph of section 12 changed the intended meaning. The two sentences resulting from this change don't seem to be connected. Was the intent to say that section 12 applies to all salted and dried fish, regardless of the species the fish belongs to (in which case, the second sentence becomes unnecessary), or that it applies only to salted and dried fish made from the species enumerated in the second sentence? Please clarify.</p>
<p>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 (<i>Gadus morhua</i>), Pacific cod (<i>Gadus macrocephalus</i>), Polar cod (<i>Boreogadus saida</i>), Greenland cod (<i>Gadus ogac</i>), Saithe (<i>Pollachius virens</i>), Ling (<i>Molva molva</i>), Blue ling (<i>Molva dypterygia</i>), Tusk (<i>Brosme brosme</i>), Haddock (<i>Gadus aeglefinus/Melanogrammus aeglefinus</i>), Forkbeard (<i>Phycis blennoides</i>) and Pollock (<i>Pollachius pollachius</i>).</p>	<p>Gambia</p>
<p>This Section applies to fresh, all species of fish to be salted and/or dried. of the The following species, all belonging to the Gadidae family, intended for human consumption have the following scientific and common names: Cod (<i>Gadus morhua</i>), Pacific cod (<i>Gadus macrocephalus</i>), Polar cod (<i>Boreogadus saida</i>), Greenland cod (<i>Gadus ogac</i>), Saithe (<i>Pollachius virens</i>), Ling (<i>Molva molva</i>), Blue ling (<i>Molva dypterygia</i>), Tusk (<i>Brosme brosme</i>), Haddock (<i>Gadus aeglefinus/Melanogrammus aeglefinus</i>), Forkbeard (<i>Phycis blennoides</i>) and Pollock (<i>Pollachius pollachius</i>).</p>	<p>Iran</p>
<p>Morocco does not support changing the section's scope to include all species of fish. Rationale: This section as amended changes the scope of Section 12 (Processing of salted and dried salted fish). This modification is not within the EWG terms of reference. The work of the EWG is to align product standards and not to modify the contents of a standard previously developed by another CCFFP committee.</p>	<p>Morocco</p>
<p>We would seek clarification regarding the consequences of broadening of the scope. In our opinion an amendment of the scope, in order to include salted and dried salted fish from all species, might require further discussions and considerations throughout this section. Furthermore, we consider it important to inform that the measures for controlling scombrototoxin is not applicable to the Gadidae family, because scombrototoxin is not a relevant hazard in these species. Therefore we suggest to add the wording "Measures</p>	<p>Norway</p>

<p>to control scrombrotoxin is not relevant for species that are non-susceptible for scrombrotoxin formation, such as species from the Gadidae family”. Unfortunately we have not been able to consider thoroughly whether there is a need for further revision following the broadening of the scope.</p>	
<p>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 (<i>Gadus morhua</i>), Pacific cod (<i>Gadus macrocephalus</i>), Polar cod (<i>Boreogadus saida</i>), Greenland cod (<i>Gadus ogac</i>), Saithe (<i>Pollachius virens</i>), Ling (<i>Molva molva</i>), Blue ling (<i>Molva dypterygia</i>), Tusk (<i>Brosme brosme</i>), Haddock (<i>Gadus aeglefinus/Melanogrammus aeglefinus</i>), Forkbeard (<i>Phycis blennoides</i>) and Pollock (<i>Pollachius pollachius</i>).</p>	<p>Panama Panama agrees with the change</p>
<p>This Section applies to fresh, to all species of salted fish and dried salted 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 (<i>Gadus morhua</i>), Pacific cod (<i>Gadus macrocephalus</i>), Polar cod (<i>Boreogadus saida</i>), Greenland cod (<i>Gadus ogac</i>), Saithe (<i>Pollachius virens</i>), Ling (<i>Molva molva</i>), Blue ling (<i>Molva dypterygia</i>), Tusk (<i>Brosme brosme</i>), Haddock (<i>Gadus aeglefinus/Melanogrammus aeglefinus</i>), Forkbeard (<i>Phycis blennoides</i>) and Pollock (<i>Pollachius pollachius</i>).</p>	<p>Senegal</p>
<p>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 (<i>Gadus morhua</i>), Pacific cod (<i>Gadus macrocephalus</i>), Polar cod (<i>Boreogadus saida</i>), Greenland cod (<i>Gadus ogac</i>), Saithe (<i>Pollachius virens</i>), Ling (<i>Molva molva</i>), Blue ling (<i>Molva dypterygia</i>), Tusk (<i>Brosme brosme</i>), Haddock (<i>Gadus aeglefinus/Melanogrammus aeglefinus</i>), Forkbeard (<i>Phycis blennoides</i>) and Pollock (<i>Pollachius pollachius</i>). <u>Other species, including those that are susceptible to scombrotoxin formation, are covered by this section.</u></p>	<p>USA The introductory paragraph to Section 12 is still somewhat confusing and may lead people to think that fish in the Gadidae family are susceptible to scombrotoxin formation.</p>
<p>12.2.1 Splitting, washing and rinsing (Processing Step 7)</p>	
<p>Potential hazards: physical contamination, unlikely scombrotoxin</p>	<p>Iran</p>
<p>Panama agrees with the change</p>	<p>Panama</p>
<p>12.2.5 Gibbing (Processing Step 11)</p>	
<p>Colombia understands that hazards, by definition, are physical, chemical, and microbiological, and that biochemical are not included.</p>	<p>Colombia</p>
<p>Potential defects: remaining gut content and intestines other than roe or milk <u>gonad</u>, decomposition.</p>	<p>Mexico Both are known as gonads</p>
<p>Panama agrees with the change</p>	<p>Panama</p>
<p>12.4 Salting and maturing</p>	
<p>Two particular conditions that can adversely affect the quality of salted fish are the occurrence of bacteria and mould. Both defects conditions can be combated controlled by maintaining a temperature lower than 8 °C (ideally optimally below 4 °C). Salt produced from marine sources may contain halophilic bacteria, which</p>	<p>Colombia Colombia asserts that the conversation should be about conditions, not defects, to be consistent throughout the paragraph. We propose changing</p>

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.	'combated 'to 'controlled', to enhance understanding. We find optimally to be a more appropriate word, as ideally is ambiguous.
Salted fish should be salt-matured, sound and wholesome. The salting process and the temperature used should be sufficiently controlled to prevent the development of <i>C. botulinum</i> , or the fish should be eviscerated prior to brining.	Iran
<i>Potential hazards:</i> viable parasites, scombrottoxins, botulinum <i>Clostridium botulinum</i> toxin	Peru
13.1 Processing of Smoked Fish	
This Section provides... The sentence is incomplete.	Iran
13.1.2 Salting	
Potential Hazards: microbiological, chemical and physical contamination, scombrottoxins, presence of metal, broken needles. As mentioned before, needles are used just for brine injection not all type of salting. Therefore, Iran suggests removing "broken needle" here.	Iran
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 a temperature <u>between 0 and 12 C, depending on the fish species (e.g. 8-12-0-8°C)</u> , and depending on to the fish species.	Mexico
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. <i>Scombridae</i> , <i>Clupeidae</i> , <i>Engraulidae</i> , <i>Coryphaenidae</i> , <i>Pomatomidae</i> , <i>Scomberesocidae</i>). [Change does not apply to the English text]	Mexico
Panama agrees with the change	Panama
13.1.3 Hanging and racking	
Potential hazards: physical contamination, microbiological contamination, scombrottoxin	Iran
13.1.4 Drying	
Refer also to Section 12.5.2 Potential hazards: microbiological contamination, physical contamination, and histamine formation scombrottoxin formation Potential defects: decomposition, fungal contamination, physical contamination Technical guidance: • Drying should not resulted in involve prolonged exposure to ambient temperature as this may lead to unwanted microbiological growth and the formation of histamine in susceptible species.	Iran

13.1.4 Drying	
Drying should not result in be carried out through the prolonged exposure to ambient temperature as this may lead to unwanted microbiological growth and the formation of histamine in susceptible species.	Mexico
Panama agrees with the change	Panama
13.1.11 Cold smoking	
<i>Potential hazards: Potential hazards: chemical contamination from smoke, growth of Clostridium botulinum, <u>scombrototoxin</u></i>	Mexico [Changes do not apply to the English text]
13.1.13 Slicing	
Potential hazards: physical contamination, microbiological contamination, scombrototoxin	Iran
SECTION 17 – PROCESSING OF CANNED FISH, SHELLFISH AND OTHER AQUATIC INVERTEBRATES	
SECTION 17 – CANNING OF FISH, SHELLFISH AND OTHER AQUATIC INVERTEBRATES. - Canning is a processing itself.	Iran
Morocco suggests clarifying that this statement is valid only for large fish.	Morocco Rationale: For small pelagic fish, a single haul of fish can contain dozens of tons of fish and therefore can be used to manufacture multiple lots. The average quantity of fish fished by coastal fishing boats is on average 40 to 50 tons; it is 300 tons for RSW vessels. When fishing in fish-rich areas, a single haul can contain dozens of tons and therefore can be used to manufacture a single lot.
17.2.1 Hazards A2 Scombrototoxins 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 <u>in fish products</u> .	Mexico Changed for consistency.
Since H histamine is heat stable, its toxicity it remains practically intact in containers following fish processing at high temperatures . 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.	

Panama agrees with the change	Panama
17.3.3 Unwrapping, unpacking (Processing Steps 3 and 4)	
Panama agrees with the change	Panama
17.3.5.1 Fish preparation (gutting, trimming, etc.) Potential hazards	
<u>Gambia recommends to delete the terms “biochemical development” and ‘histamine’ in bracket leaving only the word ‘scombrototoxin’. The sentence will therefore read “microbiological contamination and biochemical development (histamine scombrototoxin”. Similarly modify potential hazards listed in Section 20.1 to read “scombrototoxin and microbiological contamination”</u>	Gambia Provides clarity of the expression since scombrototoxin is the primary food safety hazard of concern.
Panama agrees with the change	Panama
Senegal recommends deleting the terms “biochemical development” and “histamine” in parentheses leaving only the word “scombrototoxin.” The sentence will therefore read: “Microbiological contamination and scombrototoxin.” Senegal also recommends similarly modifying the potential hazards listed in section 20.1 to read: “Scombrototoxin and microbiological contamination.” <i>Potential hazards: microbiological Microbiological, biochemical contamination (histamine, contamination and scombrototoxin) scombrototoxin)</i>	Senegal This change brings clarity to the expression since scombrototoxin is the primary food safety hazard of concern.
17.4.2.1 Filling	
<i>Potential hazards: microbiological contamination, scombrototoxin (waiting period or, after heat processing owing to incorrect filling or defective containers)</i>	Mexico Associates a hazard to a potential defect, not to the step in the process.
Panama agrees with the change	Panama
SECTION 18 – PROCESSING OF FISH SAUCE	
Water Phase Salt concentrations of 20% or higher should be achieved and maintained throughout the fermentation to prevent growth and activity of undesirable microorganisms, including pathogens	Iran
SECTION 10 – TRANSPORTATION	
20.1 For fresh, refrigerated and frozen products	
Potential hazards: scombrototoxin formation, microbiological contamination	Iran
Panamá de acuerdo con la modificación	Panama
SECTION 21 – RETAIL	
21.1.1 Reception of chilled products at retail	
Retailers should ensure that fish are purchased from suppliers that use HACCP or similar control systems to prevent histamine formation. In case the fish being received is likely to be susceptible to scombrototoxin formation, the retailers should measure fish internal temperatures and perform sensory evaluation of representative fish samples before accepting delivery.	Iran

<p><u>For fish susceptible to scombrototoxin formation, retailers should <u>measure fish internal temperatures monitor adequacy of ice or other cooling media when applicable 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.</u></u></p>	<p>Japan Retail is not covered in histamine control guidance adopted by CAC41. To keep fish cold, retailer can easily monitor adequacy of ice or other cooling media when applicable and perform sensory examination before accepting of fish. Measuring fish internal temperatures is not practical in some cases because of the risk of damaging fish body and decreasing the value of fish.</p>
<p>Morocco suggests reviewing these requirements applicable for retail.</p>	<p>Morocco . Requirements inapplicable in practice.</p>
<p>ANNEX I – POTENTIAL HAZARDS ASSOCIATED WITH FRESH FISH, SHELLFISH AND OTHER AQUATIC INVERTEBRATES</p>	
<p>1.2 Bacteria</p>	
<p>Panama agrees with the change</p>	<p>Panama</p>
<p>1.5 Scombrototoxin</p>	
<p>Morocco suggests adding the word mainly before “Enterobacteriaceae;” The sentence thus becomes “Scombrototoxin is attributed mainly to Enterobacteriaceae, which can produce high levels of histamine.” Morocco suggests listing the 6 families of fish predisposed to producing high levels of histamine and not just the clupeid family.</p>	<p>Morocco Psychrophilic and psychrotropic native marine bacteria are also histamine-producing bacteria.</p>
<p>Scombroid intoxication, sometimes referred...symptoms are usually <u>while typically</u> mild, <u>can become severe</u>. Rapid refrigeration after catching and a high standard of handling during processing should prevent the development of the toxin... <u>Refer to Section 9-bis for technical guidelines for control of histamine formation.</u></p>	<p>Colombia Using 'become 'lends greater importance to the severity of intoxication</p>
<p>Scombroid intoxication, sometimes referred to as histamine poisoning <u>or scombrototoxin fish poisoning</u>, results from eating fish that have been incorrectly chilled <u>during and/or</u> after harvesting. Scombrototoxin is attributed mainly to <u>bacteria in the</u> Enterobacteriaceae family...</p>	<p>Mexico</p>
<p>Scombroid intoxication, sometimes referred to as histamine poisoning <u>or scombrototoxin fish poisoning</u>, results from eating fish that have been incorrectly chilled <u>during and/or</u> after harvesting. Scombrototoxin is attributed <u>mainly</u> to Enterobacteriaceae, which can produce high levels of histamine in the fish muscle when products are not immediately chilled after catching <u>and retained in a chilled state</u>.</p>	<p>Morocco Morocco is concerned that there is no safety limit value for fish that have undergone enzymatic maturing. Morocco suggests including a limit of 400 mg/kg following the example of fish sauce. Psychrophilic and psychrotropic native marine bacteria are also histamine-producing bacteria. Morocco suggests listing the 6 families of fish</p>

	predisposed to producing high levels of histamine and not just the clupeid family.
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 harvesting and/or during subsequent processing and handling . Scombrototoxin	USA The first sentence could be interpreted to suggest that histamine formation is only associated with harvesting.

ANNEX II

PROPOSED DRAFT AMENDMENTS TO COMMODITY STANDARDS	
GENERAL COMMENTS	
PROPOSED AMENDMENTS TO COMMODITY STANDARDS: SECTIONS ON SAMPLING, EXAMINATION AND ANALYSIS	
Brazil would like to thank the work carried out by Japan and United States of America. Brazil mainly emphasizes the agreement with the alterations of Annex B, that change histamine units from mg/100g to mg/g and adjust listed level appropriately, throughout standards.	Brazil
Ecuador appreciates the work carried out and is considering supporting the document (at Step 3) for the sections on SAMPLING, EXAMINATION AND ANALYSES RELATED TO HISTAMINE FOOD SAFETY, as it provides broad, detailed information that will contribute to implementation or enhance control systems for fishing activity.	Ecuador
<p>The European Union and its Member States (EUMS) would like to thank the work of the EWG led by Japan and the United States of America. The EUMS have the following comments on the revision of the section on sampling, examination and analyses.</p> <p>The EUMS believe that the criterion of 200 mg of histamine per kg, responding to a pragmatic approach based on the establishment of a three-class attributes plan, should in no way be called into question. The control of histamine is primarily based on the application of good hygiene practices whose effectiveness can be verified by a three-class attributes control plan:</p> <ul style="list-style-type: none"> - Criterion of acceptability or "threshold of decomposition" of 100 ppm (in case of exceeding, measures of correction of the good practices of hygiene must be applied). - 200 ppm safety criterion, in line with the recommendations of the FAO / WHO expert work conducted in 2012. Failure to comply with this safety criterion, validated at the October 2015 CCFFP34, results in the withdrawal from the market of fishery products concerned. <p>Both thresholds had been approved by the Codex Alimentarius Commission pending further data. This validation within the framework of the Codex thus reinforced the 3-class attributes plan. Therefore under 7.1.1 explicit reference should be made to the recommendation of a three class attribute plan.</p> <p>However, the document under discussion seems to suggest an orientation towards a 2-class plan with a M value of 100 mg / kg. This appears in particular in the table provided under point 7.1.2 comparing the level of consumer protection according to the sampling plan chosen. This approach is moving away from risk analysis as defended in the EU by failing to incorporate the notions of acceptability and security. It thus induces the</p>	European Union

<p>possible rejection of products that do not present a health risk. In the absence of any evidence of the added value of adopting a 2-class plan with a single threshold of 100 ppm, the EUMS consider that the 3-class scheme, and the two thresholds it includes, remains the most relevant regulatory approach. Therefore it is proposed to delete the table under point 7.1.2. In case the table is maintained, it should be completed by information on three-class attribute plans.</p> <p>The EUMS consider that the number of samples to be taken (59) for the assessment of GMP / HACCP performance is too high.</p> <p>It is not clear whether it is applicable to each link in the chain. If this were the case, it could not be applied by all operators (due to cost, time, availability of products). Appropriate modalities should therefore be defined. In any case, this can only apply to large lots, the size of which should, moreover, be defined.</p> <p>Therefore, it is proposed to delete under 7.1.1 any reference to the confidence interval and to delete the sentence in the first bullet under 7.1.1 starting with "At minimum, ..."</p> <p>In line with these comments, in the second bullet of 7.1.2., reference to the 95 % confidence and also the specific figure (5%) of maximum percentage given as example should be deleted. Furthermore, it is appropriate to replace the example of 15 mg/kg histamine by "up to 200 mg/kg".</p> <p>3. Referring to the comments made under point 2, it is appropriate to describe for the new Annex [B] additional examples using pooling for less sample units.</p> <p>4- The ML of 400 mg / kg, applicable for fish sauce, should be added to this table with reference to the internationally recognized ISO 19343 method published in July 2017 as applicable method meeting the criteria for the control of the ML of 200 mg/kg.</p> <p>The ISO 19343 method should also be added as applicable method meeting the criteria for the control of the ML of 200 mg/kg.</p> <p>In addition:</p> <ul style="list-style-type: none"> - The abbreviations and terms used in the table should be made explicit, including "ML", "RSDR" and "Recovery"; - For the ML of 100 mg / kg, it is stated "on average", whereas for the ML of 200 mg / kg it is specified "per unit". This distinction should be explained or otherwise the entry should be deleted. 	
<p>This draft needs more help in writing grammatically and typographically. Some examples are indicated here.</p> <ul style="list-style-type: none"> - We suggest changing bullets to continuous numbers to help better tracking. 	Iran
<p>agree with your changes</p>	Iraq
<p>Guyana agrees with the changes and new inclusions in the document. With the proposed changes the document now adequately addresses and identifies detection limits that are more practicable.</p>	Guyana
<p>2. The proposed sampling plan where n=59 and c=0 is impractical, expensive and unwieldy not only for food business operators but also for competent authorities.</p> <p>Rationale:</p>	Morocco

- The proposed sampling plan is not true to the spirit and philosophy of HACCP where safety is ensured by risk prevention upstream and throughout the food chain and not solely by control of the final product.
- The purpose set forth in CX/CAC 16/39/7 was not honored. This document states that developed sampling plans should be risk-based plans that are practical, feasible and do not add a burden to producers and border control authorities.
- The time needed to prepare 59 sample units (opening, draining, blending) is too long and consequently, is incompatible with the urgency that characterizes making a decision about lot compliance on reception.

3. Histamine is scientifically considered and listed as a moderate hazard, and yet the proposed plan (n=59, c=0) is similar to the plan used for severe hazards such as Salmonella (n=60, c=0). Suggested sampling plans must be appropriate for the severity of the hazard.

Morocco suggests using the sampling plans put forward by ICMSF. Using the hazard severity scale, histamine cannot be raised to the level of Salmonella, Listeria monocytogenes and Vibrio cholerae.

Rationale:

The proposed sampling plan (n=59, c=0) is similar to the plan suggested for severe hazards which are life-threatening and produce significant chronic sequelae or long-lasting illnesses, such as Salmonella typhi, Vibrio cholerae, Campylobacter jejuni, enteropathogenic E. coli, Clostridium botulinum, Listeria monocytogenes (n=60, c=0) (1) (2).

ICMSF considers histamine a moderate hazard. For this hazard type, the proposed sampling plans are listed below. In the most conservative scenario, ICMSF suggests a sampling plan where n=10 and c=1. This plan is also used for some microorganisms that are more serious than histamine, such as Clostridium perfringens (type A), Escherichia coli (EPEC, ETEC), staphylococcal toxins (Staphylococcus aureus), Vibrio cholerae non-01 and non-0139, Vibrio parahaemolyticus and the Norwalk virus.

Sampling plans put forward by ICMSF for moderate hazards*

Conditions in which food is expected to be handled and consumed after sampling:

- Conditions reduce hazard: Case 7: 3-class n=5, c=2
- Conditions cause no change in hazard: Case 8: 3-class n=5, c=1
- Conditions may increase hazard: Case 9: 3-class n=10, c=1

* Moderate hazards include Bacillus cereus Clostridium perfringens (type A), Escherichia coli (EPEC, ETEC), staphylococcal toxins (Staphylococcus aureus), Vibrio cholerae non- 01 and non-0139, Vibrio parahemolyticus, Norwalk virus, biogenic amines (histamine).

The plan proposed by the WG (n=59, c=0) is also similar to the plan proposed by the FDA for Salmonella (n=60, c=0) for Category I foods, namely, foods that are not normally subject to a process lethal to

Salmonella between the time of sampling and consumption, and that are intended for consumption by the aged, the infirm, and infants (3).

4. Morocco suggests using only the first sampling plan (7.1.1).

Rationale:

Due to concerns about consistency with the terms of reference of CX/CAC 16/39/7. The purpose of the work is to revise sampling plans in Standards for Fish and Fishery Products related to histamine food safety.”

Work on the sampling plan should be consistent with the terms of reference for the EWG, which state that developed sampling plans should relate to food safety. The second proposed plan involves periodic assessment of the effectiveness of the GMPs/HACCP system implemented by an establishment. This is not within the scope of making a decision about the histamine acceptability and compliance of a lot.

The performance of GMPs/HACCP implementation for histamine control is based on CCP monitoring, compliance with the critical limit set forth in the HACCP plan and compliance with the safety limit for the final product.

Verification is part of HACCP Principle 6: establish verification procedures. Codex guidelines define verification as “the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.” Auditing and verification methods, measuring, including random sampling and analysis, can be used to determine if the HACCP system is working correctly.

Morocco suggests that verification of the HACCP system’s performance be addressed in other Codex documents and not in this document which is specific to histamine compliance for fishery products.

5. The terms of reference are “sampling plans will be developed for different purposes.”

Morocco suggests adopting these two cases for the different purposes:

Enhanced control: for cases with unknown origin, unreliable histamine control, and to settle disputes.

Regular reduced control: for cases with known origin and confirmed histamine control.

6. Morocco supports the proposal to place (right after section 9) the guidelines for histamine control in the Code of Practice for Fish and Fishery Products (CXC 52-2003).

Rationale: for the purpose of consistency and clarity.

CX/FH 18/50/6 Paragraph 15:

To calculate sample size, Morocco suggests using, for small pelagic fish (sardine, mackerel, anchovy), a standard deviation value of 0.4 instead of 0.8

Rationale:

The 0.8 proposed standard deviation is not applicable for small pieces of pelagic fish.

Depending on the measurement method, because these samples will be blended, histamine will be distributed homogeneously in the sample to be tested.

The standard deviation used to calculate the sampling number ($0.8 \log_{10}$) applies to the distribution of microorganisms in non-homogeneous foods, such as solid foods. A standard deviation of $0.2 \log_{10}$ UFC/g is used to describe a food in which microorganisms will be distributed homogeneously within a lot (as with liquid foods). A standard deviation of $0.4 \log_{10}$ UFC/g is assumed for a food of intermediate homogeneity (ground beef) and a standard deviation of $0.8 \log_{10}$ UFC/g for a non-homogeneous food (solid foods) (van Schothorst et al. 2009) (4).

A sampling unit (100g-250g) can contain several pieces of fish. These samples will be fully blended and homogenized; histamine distribution in the sample to be analyzed will be homogeneous. In this case, the standard deviation should be 0.4 or, at least, less than 0.8.

CX/FH 18/50/6 Paragraph 16:

Morocco suggests clarifying the different purposes for a sampling plan here:

1. There is a guarantee that histamine is controlled (adopt a normal or limited (reduced) sampling plan);
2. There is no guarantee that the histamine control system is reliable, in the case of a new origin or initial market access (adopt an enhanced sampling plan).

CX/FH 18/50/6 Paragraph 17:

Morocco suggests clarifying that this statement is valid only for large fish.

Rationale:

For small pelagic fish, a single haul of fish can contain dozens of tons of fish and therefore can be used to manufacture multiple lots.

The average quantity of fish fished by coastal fishing boats is on average 40 to 50 tons; it is 300 tons for RSW vessels. When fishing in fish-rich areas, a single haul can contain dozens of tons and therefore can be used to manufacture a single lot.

CX/FH 18/50/6 Paragraph 18:

Morocco suggests replacing the phrase "Scientific literature" with "according to industry data" and state which countries.

Morocco also suggests replacing the phrase "any scombrototoxin-forming fish" with "some species of fish."

Rationale:

This is not scientific literature, but rather data gathered from industry for some species of fish in a given region.

CX/FH 18/50/6 Paragraph 20:

- Morocco makes the following observation about setting a 50 mg NOAEL. This value comes from two studies conducted on a small number of human volunteers (Motil and Scrimshaw, 1979 (5); van Gelderen et al., 1992)(6). This value was determined statistically because it was the value immediately less than 90 mg, the dose at which a critical effect (congestion, headaches) from histamine was observed (two people out of six). For accuracy and precision, tests should also be conducted between 50 and 90 mg and the NOAEL could be somewhere between those two values. Also, even at doses of 150 mg, only two people out of eight showed critical effects.

- Morocco thinks that protecting sensitive population segments from histamine risk can occur only by informing consumers using labels like what is done for allergens.

CX/FH 18/50/6 Paragraph 24:

Morocco asks what criteria were used to select the sampling plan in Section 2.5.3 - Sampling plans for inspection of critical nonconformities.

Rationale:

This type of sampling plan is specific to cases where the hazard is severe and could cause a serious illness or death. This is not the case for histamine.

CX/FH 18/50/6 Paragraph 25:

Morocco suggests defining the term "large lot" for consistent understanding and greater clarity.

CX/FH 18/50/6 Paragraph 35:

Morocco suggests deleting the 15mg/kg value from the entire document.

Rationale:

The approach adopted by setting a 15 mg/kg level is a prescriptive approach. This approach is not in line with the drafting guidelines for Codex documents.

Increased food safety rests on absolute obligation and not relative obligation.

(1) International Commission for the Microbiological Specifications of Foods (ICMSF). 2002. Microorganisms in Foods 7: Microbiological Testing in Food Safety Management. Kluwer Academic Plenum Publishers. New York.

(2) International Commission on Microbiological Specifications for Foods. 1986. Microorganisms in Foods. 2. Sampling for Microbiological Analysis: Principles and Specific Applications, 2nd ed. University of Toronto Press, Toronto, Ontario, Canada. (<https://seafood.oregonstate.edu/sites/agscid7/files/snic/sampling-for-microbiological-analysis-principles-and-specific-applications-icmsf.pdf>)

(3) FDA BAM Risk Categories in the case of Salmonella (Bacteriological. Analytical Manual Chapter 1. Food Sampling and Preparation of Sample Homogenate, <https://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm063335.htm>)

<p>(4) van Schothorst M., M.H. Zwietering, T. Ross, R.L. Buchanan, M.B. Cole. 2009. International Commission on Microbiological Specifications for Foods (ICMSF) Relating microbiological criteria to food safety objectives and performance objectives. Food Control 20 (2009) 967–979.</p> <p>(5) Motil Kathleen J., Nevin S. Scrimshaw. 1979. The role of exogenous histamine in scombroid poisoning. Toxicology Letters Volume 3, Issue 4, April 1979, Pages 219-223. https://doi.org/10.1016/0378-4274(79)90037-7.</p> <p>(6) van Gelderen C. E. M., T. J. F. Savelkoul, L. A. van Ginkel & W. van Dokkum. (1992) The Effects of Histamine Administered in Fish Samples to Healthy Volunteers, Journal of Toxicology: Clinical Toxicology, 30:4, 585-596, DOI: 10.3109/15563659209017944. To link to this article: http://dx.doi.org/10.3109/15563659209017944</p>	
<p>New Zealand would like to thank the chairs and the electronic working group for developing the revisions to the COP for fish and fishery products (CXC 52-3002) and the section on sampling, examination and analysis related to histamine food safety.</p> <p>It is noted that:</p> <p>the purpose of the proposed sampling plan (Appendix II, section 7.1.1) is to determine lot acceptability at ports of entry and other receiver-oriented situations; and routine (lot by lot) acceptance testing for histamine is not necessary when sufficient past evidence or international agreements adequately ensure that the product is produced with suitable histamine controls; and when a lot is from a source with unknown histamine control, or from a source with unreliable implementation of histamine controls, then histamine testing is the only practical means to provide a margin of assurance that histamine levels in a consignment are safe; and if a definitive sampling plan is to be included for lot acceptance, it must provide adequate consumer protection.</p> <p>The following general comments are made:</p> <p>New Zealand acknowledges the efforts made to limit the application of this sampling plan, but holds the viewpoint that a sampling plan requiring 59 samples (for large lots) is not practical. We consider that such a high sampling rate is likely to result in low adoption rates of the standard, thereby questioning its value.</p> <p>Background, Point 24 refers to the sampling plan in Section 2.5.3 of CXC 50-2004, which is for critical non-conformities that could result in illness or death. The “histamine control guidance” states “Scombrototoxin poisoning is generally a mild disorder where the symptoms disappear quickly after an anti-histamine treatment and where no known long-term sequelae were reported”. Given this, the application of such an intensive sampling regime is questioned.</p> <p>As noted (background point 26) the proposed sampling plan will require significant resource. This resource includes lost product, sampling and testing resource, reinforcing the burdensome nature of sampling at this level. It is not unusual to receive high-priced small products in small lot sizes, or large high-priced products in small lot sizes. The proposed sample size would require a disproportionately large proportion of a small lot to be sampled. How is this to be addressed by the proposed sampling plan?</p>	<p>New Zealand</p>

<p>In response to concerns raised by some members that the plans might be burdensome for small processors, Point 32 states that “commodity standards are used at ports of entry and other receiving-oriented situations, and are not intended for use by processors”. However it should be noted that it is usual practice for costs associated with product clearance be borne by the processor, exporter or importer, and so are a direct burden.</p> <p>If this has not yet occurred, it is suggested that this proposal be reviewed by the Codex Committee on Methods of Analysis and Sampling to ensure that a consistent approach is taken.</p> <p>We found section 7.1.1 difficult to interpret and apply due to the need to refer to CXG 50-2004, and to determine sample size. It may be useful to reproduce 2.5.3 in this document and provide a table of “n” sample sizes for different lot sizes “N”.</p> <p>7.1.1, bullet 6 refers to taking multiple samples for smaller fish. Is it intended that this be the whole fish? The wording in the histamine guidance, section X.2.4.3 uses alternative wording to describe the samples to be taken. It states “Test portions should be cut from the head-end of the lower loin near the gills because that area has the highest probability of elevated histamine in abused raw fish. Sufficient representation of fish muscle should be collected to prepare for analysis (e.g. 100-250 grams). The weight of the representative sample unit may depend on the product and sampling strategy. For smaller fish, in addition to the lower anterior loin portion, the upper anterior loin, and the mid-section of the lower loin, in that order, can also be collected. For very small fish, multiple fish may need to be collected to acquire a representative sample unit”. It is suggested that the wording in these sections be aligned.</p> <p>.1.2. Point [1]. It may be useful to indicate that this refers to histamine levels. i.e. “higher or lower histamine levels”.</p> <p>We welcome the sampling guidance provided in section 7.1.1, and Annex [B] about sample selection, preparation and compositing.</p>	
<p>The United States thanks the electronic working group for their efforts drafting recommended improvements to the histamine sampling guidance in applicable seafood commodity standards. The commodity standards are finished product standards used for lot inspections by wholesale and retail buyers and regulatory authorities. The commodity standards are not intended for use by primary or secondary seafood processors. The Code of Practice for Fish and Fishery Products contains the HACCP and GMP guidance for processors, as well as any related sampling guidance.</p> <p>The Codex Committee on Fish and Fishery Products (CCFFP) struggled for several years with appropriate levels of protection and required sample sizes for histamine sampling plans in commodity standards. Some CCFFP members commented that they did not sample histamine to ensure the safety of isolated lots (the commodity standard model); instead they sampled to assess the performance of systems used to control histamine, using various strategies. To advance work, CCFFP agreed to draft histamine sampling guidance for different purposes, as reflected in the current work plan. The U.S. supports the EWG proposal for two sampling plans for two purposes; Purpose 1) a defined plan to provide a minimum level of consumer protection when determining compliance with the standard of isolated lots with unknown control history;</p>	<p>USA</p>

<p>Purpose 2) a flexible plan to assess the continued performance of histamine control systems that is not intended to ensure the safety of individual lots.</p> <p>The U.S. supports the ‘purpose 1’ defined sampling plan level of protection (95% probability that no more than 5% of the units are over the histamine safety limit) at a minimum. The U.S. does not support use of a weaker sampling plan when determining the safety of isolated lots with unknown control history. Users can achieve the same level of protection with fewer samples by lowering the histamine decision limit. When there is a level of confidence in processor control, importers periodically screen histamine levels using a ‘purpose 2’ plan to evaluate continued performance of the control system. The inclusion of both a defined protective plan and a flexible screening plan is a good approach to meet the needs of different risk management situations.</p>	
<p><u>Sampling sections (new sections 7.1.1 and 7.1.2)</u> 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</p>	
<p>Commodity Standards – Histamine decomposition levels within the Essential Composition and Quality Factors Ten (10) Commodity Standards have a histamine decomposition limit in Section 3 (Essential Composition and Quality Factors). These Commodity Standards are 36-1981, 70-1981, 94-1981, 119-1981, 165-1989, 166-1989, 190-1995, 236-2003, 244-2004 and 311-2013.</p> <p>Codex Standards 119-1981, 165-1989, 166-1989 and 190-1995 also state that the histamine decomposition limit applies only to species of five (5) families.</p> <p>Reference of the EWG, Australia recommends that these histamine decomposition levels should be reviewed prior to progressing/agreeing on the revision. Further to CX-FH 18/50/6 (paragraph 36) that recommends asking the secretary to make the additional changes necessary for the units of measure, at a minimum Australia recommends that the species listed within the decomposition section also be harmonised to those proposed in the Hygiene section, i.e. by ensuring the text applies only to susceptible species (e.g. Scombridae, Clupeidae, Engraulidae, Coryphaenidae, Pomatomidae, Scomberesocidae).</p>	<p>Australia Whilst outside the scope of the Terms of Reference Rationale: Although these decomposition provisions are based on the average of the sample unit tested; there is concern that the decomposition provision are a source of confusion and could become pseudo maximum level. The Codex Procedural Manual specifies that for the Essential Composition and Quality Factors section in Commodity Standards “This section should contain all quantitative and other requirements as to composition including, where necessary, identity characteristics, provisions on packing media and requirements as to compulsory and optional ingredients. It should also include quality factors which are essential for the designation, definition or composition of the product concerned. Such factors could include the quality of the raw material, with the object of protecting the health of the consumer, provisions on taste, odour, colour and texture which may be apprehended by the senses, and basic quality criteria for the finished products, with the object of preventing fraud. This section may refer to</p>

	<p>tolerances for defects, such as blemishes or imperfect material, but this information should be contained in an appendix to the standard or in another advisory text.”</p> <p>It is difficult to see how these existing decomposition levels sustain a quality factor when, the FAO/WHO Expert Report (pg. 50) acknowledged that the correlation between histamine content and odours of decomposition is often inconsistent. The histamine food safety provision of 200 mg/kg under the Section 5 (Hygiene) provides the necessary level of protection for public health.</p>
Unfrozen or thawed sample units should be maintained below 4 °C and analyzed directly to prevent histamine formation and accumulation.	Iran The mean of below sentence cannot be understood.
Refer to <i>General Guidelines on Sampling</i> (CXG 50-2004), Section 2.5.3 (Sampling plans for inspection of critical nonconformities). At a minimum, the sampling plan selected should be 95% reliable in ensuring that no more than 5% of the sample units in the lot exceed 200 mg/kg of histamine. The lot is unacceptable if any sample unit exceeds 200 mg/kg of histamine. [Replace 200 mg/kg with 400 mg/kg for fish sauce, CXS 302-2011]	Mexico Improved wording
Morocco is concerned that there is no safety limit value for fish that have undergone enzymatic maturing. Morocco suggests including a limit of 400 mg/kg following the example of fish sauce.	Morocco
<p>A general comment is that the sampling size (n=59) is large, but Norway supports the suggested risk-based sampling plans “for different purposes”. When the purpose is assessment of control systems for histamine, the risk based plan means that routine histamine testing is not necessary if adequate histamine control has been established. A risk based sampling plan may also result in reduction of sample number and analytical determinations for products and nations able to provide long historic series of safe histamine levels in relevant products.</p> <p>Pooling of samples may result in further reduction of number of samples and determinations needed, while still retaining the appropriate consumer and producer risks. It is positive that a further description regarding composite sampling procedures, is included in a new annex.</p>	Norway
<p>Even though the proposed sampling plan tries to balance between practical sample size and confidence to detect contaminated lots, we are of the opinion that the proposed sampling plan may still not practical for all sizes of business operators and the competent authority.</p> <p>For CXS 302-2011 Standard for Fish Sauce, we are not too sure that the use of binomial attribute plan is appropriate since the final product is homogeneous liquid unlike solid food in the other commodity standards.</p>	Thailand

<p>The different sampling plan for fish sauce might be needed. The Annex [B] Optional composite sampling procedure is also not appropriate for fish sauce since the method suggests dividing the limit 400 mg/kg by 5 units equalling 80 mg/kg. The composite sample is unlikely to contain less than 80 mg/kg histamine which is the nature of the fish sauce. As a result, all samples are subject to individually determined.</p>	
<p>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. In those instances where the history of the product is known (e.g., the product is produced under a HACCP system), alternate sampling criteria may be feasible. 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.</p>	<p>Thailand For 7.1.1 Sampling for lot acceptance, the flexible sampling plan for the lot with known or reliable histamine control should be added in order to ease the stringency of the plan proposed in 7.1.1. The suggested sentence is similar to the note appeared in the microbiological criteria found in Annex I of Code of Hygienic Practice for Powdered Formulae for Infants and Young Children.</p>
<p>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.</p>	<p>Morocco Morocco suggests providing detailed information in the paragraph about lot acceptability and compliance with safety provisions. Morocco suggests providing for two types of sampling plans:</p> <ul style="list-style-type: none"> <input type="checkbox"/> An enhanced plan for cases with unknown origin, unreliable control, and to settle disputes. <input type="checkbox"/> A second reduced sampling plan: for cases with known origin and confirmed histamine control.
<p>Lot size “N” (used to determine sample size in GL 50, Section 2.5.3) is the total number of sample units sampling units available in the lot, and is calculated by dividing the total lot net weight by the test unit weight.</p>	<p>Morocco Morocco asks whether it is useful to define the term relative to lot size N when it has not been used in the document.</p>
<p>The test unit (blended for analysis) should weigh at least 400-50 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 400-50-250-gram sample unit. [For CXS 302-2011, this bullet should be: The test unit (blended for analysis) should weigh at least 400-50 grams,</p>	<p>Morocco</p> <ul style="list-style-type: none"> <input type="checkbox"/> Morocco suggests adding a new section that provides details about collecting and sampling methods for greater clarity and consistent understanding. <input type="checkbox"/> Morocco suggests that the “sampling unit” be the market unit for products whose weight is

<p>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.]</p>	<p>less than 100g. <input type="checkbox"/> Morocco recalls that some market units can have a weight of up to 2 to 5 kg (products used in the food service industry). Morocco suggests taking these sizes into account and providing for the number of sample units to take. Rationale: The CX/CAC 16/39/7 terms of reference to revise the sampling plans recommended including sampling guidelines for proper sample handling to prevent histamine formation.</p>
<p>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.</p>	<p>Morocco The term “routinely low” is subjective and may be confusing. Morocco suggests replacing this term with clearer, objective data. Also, if there is no history, how to know if the rate is routinely low?</p>
<p>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.</p>	<p>Morocco Morocco suggests deleting the second sampling plan (7.1.2), Rationale: Due to concerns about consistency with the terms of reference of CX/CAC 16/39/7, Morocco suggests discussing only the first sampling plan (7.1.1) because the second is not within the terms of reference. “The purpose of the work is to revise food safety control guidance for histamine in the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003), and to revise sampling plans in Standards for Fish and Fishery Products related to histamine food safety.”</p>
<p>Flexible plans appropriate for periodic assessment of GMP/HACCP systems.</p>	<p>Morocco</p>
<p>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]).</p>	<p>Morocco</p>
<p>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)</p>	<p>Morocco</p>

<p>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].-L</p>	<p>Morocco</p>
<p>[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).-]</p>	<p>Morocco</p> <ul style="list-style-type: none"> - Codex documents are intended for international application. The 15 mg/kg value applies to a single region, a given species. A specific example should not be included in a Codex standard as a general value and proposed as a reference value. - Setting a 15 mg/kg level is a prescriptive approach. - HACCP system implementation hinges on professionals setting a histamine critical limit. This limit is used to control histamine in the raw material upon reception. The critical limit is a preventive measure determined so as to not exceed the safety limit for the final product, which is 200 mg/kg. - The HACCP system verification uses the regulatory safety limit.
<p>[2] According to the the FAO/WHO (2013), when food business operators apply GHPs and HACCPs, an achievable level of histamine in fish products was reported to be lower than 15 mg/kg, based on data provided by the 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)</p>	<p>Mexico</p>
<p>ANNEX [B] – OPTIONAL COMPOSITE SAMPLING PROCEDURE FOR HISTAMINE SCREENING</p>	
<p>Morocco wonders what scientific method was used to set a 40 mg/kg level?</p>	<p>Morocco</p> <p>Morocco requests additional explanations and more details about the calculation method for the composite sample analytical value (40 mg/kg).</p>
<p>Standard for Quick Frozen Finfish, Uneviscerated and Eviscerated (CXS 36-1981)</p>	
<p>Morocco suggests expanding the list of families responsible for scombrototoxin poisoning to include the Istiophoridae family. In their systematic review and meta-analysis of histamine food poisoning, Colombo et al. (2016) (*) concluded that fish involved in histamine poisoning was mainly tuna or Istiophoridae species. Fresh or frozen fish, diversely prepared and cooked, and fish products differently processed (not canned) were the cause of poisoning in 79 episodes. The species or the family mainly reported were (number, % of 79): tuna (26, 32.9%); scombridae other than tuna (7, 8.8%); mahi mahi (3, 3.8%); species of the family Istiophoridae (total 8, 10.1%) such as Makaira spp (5), Tetrapturus spp (2), sailfish (1); swordfish (2); others species (12,</p>	<p>Morocco</p>

15.2%). (*) Colombo Fabio M., Patrizia Cattaneo, Enrica Confalonieri & Cristian Bernardi. (2016). Histamine food poisonings: A systematic review and meta-analysis, Critical Reviews in Food Science and Nutrition, DOI	
Panama agrees with the change	Panama
Standard for Canned Tuna and Bonito (CXS 70-1981) Standard for Canned Sardines and Sardine-Type Products (CXS 94-1981) Standard for Canned Finfish (CXS119-1981) Standard for Quick Frozen Blocks of Fish Fillet, Minced Fish Flesh and Mixtures of Fillets and Minced Fish Flesh (CXS165-1989) Standard for Quick Frozen Fish Sticks (Fish Fingers), Fish Portions and Fish Fillets - Breaded or in Batter (CXS166-1989) Standard for Quick Frozen Fish Fillets (CXS 190-1995) Standard for Boiled Dried Salted Anchovies (CXS 236-2003) Standard for Salted Atlantic Herring and Salted Sprat (CXS 244-2004) Standard for Fish Sauce (CXS 302-2011) Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish (CXS 311-2013)	
Panama agrees with the change	Panama
DETERMINATION OF HISTAMINE	
In the last table entitled "Methods meeting the following method performance criteria may be used", LOQ is 2 times more than LOD. But, in analytical chemistry, LOQ is usually 3 times more than LOD not 2 times.	Iran
<p>The numbers in the first column with criteria for «minimum applicable range» are rounded off (ML 100 and ML 200). On the other hand, is RSDR (%) given in 3 significant numbers.</p> <p>We suggest the following amendments: Specific comments Sampling guidance in commodity standards Comment to the table regarding method performance criteria: The criterias for «minimum applicable range» are rounded off (ML 100 and ML 200). On the other hand RSDR (%) is given in 3 significant numbers. We suggest the following amendments to the table:</p> <p>For ML = 100 mg/kg: Minimum applicable range from 76 mg/kg to 124 mg/kg. RSDR: 16 For ML = 200 mg/kg: Minimum applicable range from 157 mg/kg to 243 mg/kg. RSDR: 14</p>	Norway
AOAC 977.13 NMKL 99, 2013 2013 Elisa assay with LD 2	Mexico Add the direct competitive enzyme-linked immunoabsorbent assay (Elisa), in keeping with AOAC. RI 070703