

# CODEX ALIMENTARIUS COMMISSION





Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 5

CX/FH 17/49/6-Add.1 Rev

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

49th Session

Chicago, Illinois, United States of America, 13 - 17 November 2017

PROPOSED DRAFT GUIDANCE FOR HISTAMINE CONTROL IN THE CODE OF FISH AND FISHERY PRODUCTS (CAC/RCP 52-2003)

Comments at Step 3 (Replies to CL 2017/70-FH)

Comments of Argentina, Brazil, Canada, Ecuador, European Union, Kenya, Morocco, New Zealand, Paraguay, USA

## **Background**

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2017/70-FH issued in July 2017. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.

### Explanatory notes on the appendix

2. The comments submitted through the OCS are, hereby attached as **Annex I** and are presented in table format.

# ANNEX I

# Comments on the proposed draft guidance for histamine control in the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)

GENERAL COMMENT	MEMBER/OBSERVER
Argentina agrees with the structure and content of the document and has no comments on the wording. It agrees with considering advancing the proposed draft (Appendix I) as a new section in the Code.	Argentina
Regarding the table of at-risk species for the Code derived from Table 2.3 in the FAO/WHO Expert Meeting Report:	
i. Consider the inclusion of Salmonidae in the table based on the FAO/WHO review;	
ii. Consider the appropriate title for the table, which may depend on if Salmonidae are included;	
iii. Confirm where the table will be located (e.g. as a new annex in the Code).	
Argentina understands that it is necessary to wait for the FAO report on the review of the at-risk species list to define the inclusion or exclusion of Salmonidae.	
Category: SUBSTANTIVE	
Brazil is against the inclusion of the Salmonidae family in the list of fish species susceptible to histamine production, considering that it is a family with low histidine content and that the results contributed for salmon refer to a species that is not of the Salmonidae family.	Brazil
Category: TECHNICAL	
Ecuador commends the work conducted by Japan and the United States of America as part of this Electronic Working Group.	Ecuador
Following analysis of this latest proposal, Ecuador believes that the document issues clear guidelines to avoid contamination of fish with histamine.	
Ecuador, thus, supports the inclusion of this section in the Code of Practice for Fish and Fishery Products.	
Category: TECHNICAL	
Kenya would like to propose that the standards be given an introductory page of table of contents and should cover each section in details such as Harvesting vessels and personnel; harvesting fish; processing of fish that will give the diagram given as an example. This diagram should be annexed to the standard for clarity etc.	Kenya
Category: SUBSTANTIVE	
Morocco thanks Japan and the United States for chairing the EWG and for drafting this document.	Morocco
Several proposals made by Morocco were not taken into account, including:	
a. The required application of HACCP for all categories of fishing vessels:	
Providing guidelines for histamine control, cold chain compliance, use of good hygiene practices and training of fishers are the best means of controlling the histamine hazard;	
Morocco thanks the co-chairs, who made several edits to the document, but other comments still stand, including the application of HACCP and adoption of critical limits.	
Proposal: All sections and mentions relating to the application of HACCP to fishing vessels should be removed from the document.	
Any possibility that HACCP may be applied to fishing vessels must be eliminated given that this predominately involves traditional fishing and primary production.	

GENERAL COMMENT	MEMBER/OBSERVER
However, HACCP principles may be implemented on factory vessels (fishing vessels on which specific processing occurs onboard to increase value).	
Rationale:	
For fishing vessels in developing countries, the only onboard actions are catching, sorting (on trawlers), boxing and icing. In this case, fishing is primary production. This document should bar the application of HACCP on vessels engaged in primary production as is sanctioned in most international regulations.	
Morocco does not accept adding the "time" factor as a main histamine producing parameter and reiterates that the two key factors behind histamine production are:	
- Temperature non-compliance: break in the cold chain.	
- Non-compliance with good hygiene practices which produces bacterial contamination, whether of internal or external origin.	
Proposal: Throughout the document, do not use the "time-temperature" pairing, keep only "temperature."	
Rationale: "Many conditions can affect the growth of biogenic amine producers. Temperature is the main determinant. Biogenic amine concentrations thus depend on the combined influence of time and temperature: longer times and higher temperatures will lead to greater microbial growth and biogenic amine formation. Other important factors can be involved, including pH, salt, oxygen availability and competition with other spoilage microorganisms." As stated in Expert Report on page 6:	
"Many conditions can affect the growth of biogenic amine products. Temperature is the main determinant; admittedly, time and temperature are closely related with regards to histamine production, but there are other parameters that also affect histamine formation. In this document, the "time" factor alone should not be added, but rather all factors that affect histamine production, including pH, salt concentration, Aw, fish species, histidine content, whether or not fish are eviscerated, oxygen availability and competition with other spoilage microorganisms." As stated in the Expert Report on page 6.	
It is necessary to await the FAO report regarding the review of the list of species at risk which will determine whether or not to include the Salmonidae.	Paraguay
The United States thanks the electronic working group (EWG) for their efforts in drafting the Proposed Draft Guidance for Histamine Control.	USA
Although two EWG revisions attempted to address member's concerns with the difficulty of applying HACCP principles on artisanal day boats, we believe that additional changes may be needed. The use of HACCP principles on any fishing boat and training crew members on HACCP is optional; however, this may not be clear. Recording certain harvest vessel activities can provide evidence of adequate histamine control, and is preferable to burdening the shore-based operator with less effective histamine testing of each delivery, but we recognize that for certain harvest vessels this may not be practical. See our specific comments for suggested revisions that may clarify this issue.	
We feel that the draft is ready to advance as is; however, we continue to notice opportunities for small improvements, which we offer in the specific comments below.	
Category: SUBSTANTIVE	

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
Preamble		
Scombrotoxin fish poisoning is caused by the ingestion of certain species of marine fish (listed in Annex [Z]) that have been allowed to develop biogenic amines such as histamine. These species generally contain high levels of free histidine in their musculature and are more likely to form hazardous levels of histamine after death when subjected to time-temperature abuse.		
Replace "hazardous levels" with "high levels"	Morocco	
	Replace "death when subjected to time-temperature abuse" with "catching due to bacterial decomposition."	
	Category: EDITORIAL	
Scombrotoxin fish poisoning is caused by the ingestion of certain species of marine fish (listed in Annex [Z]) that have been allowed to develop biogenic amines such as histamine. These species generally contain high levels of free histidine in their musculature muscle tissue and are more likely to form hazardous unacceptable levels of histamine after death when subjected to time-temperature abuse. Generally this takes place at a temperature of more than 25°C over a period of more than 6 hours or longer at lower temperatures.	New Zealand Provide an indication of the times and temperatures of concern. FAO Fisheries Technical Paper 436 ("The use of ice on small fishing vessels.") Link: http://www.fao.org/docrep/006/Y5013E/y5013e00.htm#Contents . Exectuive summary. Consistent terminology. Category: EDITORIAL	
Scombrotoxin fish poisoning is caused by the ingestion of certain species of marine fish (listed in Annex [Z]) that have been subjected to time-temperature abuse and allowed to develop biogenic amines such as histamine. These species generally contain high levels of free histidine in their musculature and are more likely to form hazardous levels of histamine after death when subjected to time-temperature abuse.scombrotoxin  Although detailed components of scombrotoxin have not been identified, it is generally as	USA Rationale: For clarity, and to avoid inappropriate consideration of histidine levels. The roll of histidine is discussed in the following paragraph.  Category: SUBSTANTIVE	

Although detailed components of scombrotoxin have not been identified, it is generally accepted that biogenic amines produced by spoilage bacteria, especially histamine, play an important role in the pathogenesis of SFP. Other biogenic amines that are also produced during fish spoilage, such as cadaverine and putrescine, are thought to increase the toxicity of histamine. However, in most epidemiological studies, SFP is associated with high histamine levels in the implicated fish, and the controls used to inhibit histamine-producing bacteria and enzymes are also expected to be effective at preventing the formation of other biogenic amines. Therefore, histamine serves as a useful indicator compound for scombrotoxin, and histamine is monitored for scombrotoxin control purposes.

Although detailed components of scombrotoxin have not been identified, it is generally accepted that biogenic amines produced by spoilage bacteria, especially histamine, play an important role in the pathogenesis of SFP. Other biogenic amines that are also produced during fish spoilage, such as cadaverine and putrescine, are thought to increase the toxicity of histamine. However, in most epidemiological studies, SFP is associated with high histamine levels in the implicated fish, and the controls used to inhibit histamine-producing bacteria and enzymes are also expected to be effective at preventing the formation of other biogenic amines. Therefore, histamine serves as a useful indicator compound for scombrotoxin, and histamine is monitored for scombrotoxin control purposes. Although detailed

#### Morocco

In fact, a systematic review and meta-analysis of histamine poisoning outbreaks that occurred between 1959 and 2013 showed that the mean concentration in poisoning samples was 1107.21 mg/kg with confidence interval of 422.62 to 2900.78 mg/kg (Colombo et al., 2016).

Reference: Fabio M. Colombo, Patrizia Cattaneo, Enrica Confalonieri & Cristian Bernardi (2016): Histamine food

#### **SPECIFIC COMMENTS**

#### Section / paragraph

components of scombrotoxin have not been identified, it is generally accepted that biogenic amines produced by spoilage bacteria, especially histamine, play an important role in the pathogenesis of SFP. Other biogenic amines that are also produced during fish spoilage, such as cadaverine and putrescine, are thought to increase the toxicity of histamine. However, in most epidemiological studies, SFP is associated with high histamine levels in the implicated fish.

#### Member/Observer/rationale

poisonings: A systematic review and meta-analysis, Critical Reviews in

Food Science and Nutrition, DOI:

10.1080/10408398.2016.1242476.

The controls used to inhibit histamine-producing bacteria and enzymes are also expected to be effective at preventing the formation of other biogenic amines.

Therefore, histamine serves as a useful indicator compound for scombrotoxin, and histamine is monitored for scombrotoxin control purposes.

Revise the paragraph as follows: Although detailed components of scombrotoxin have not been identified, it is generally accepted that biogenic amines produced by spoilage bacteria, especially histamine, play an important role in the pathogenesis of SFP. Other biogenic amines that are also produced during fish spoilage, such as cadaverine and putrescine, are thought to increase the toxicity of histamine. However, in most epidemiological studies, SFP is associated with high histamine levels in the implicated fish.

In fact, a systematic review and meta-analysis of histamine poisoning outbreaks that occurred between 1959 and 2013 showed that the mean concentration in poisoning samples was 1107.21 mg/kg with confidence interval of 422.62 to 2900.78 mg/kg (Colombo et al., 2016).

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The controls used to inhibit histamine-producing bacteria and enzymes are also expected to be effective at preventing the formation of other biogenic amines. Therefore, histamine serves as a useful indicator compound for scombrotoxin, and histamine is monitored for scombrotoxin control purposes.

Category: SUBSTANTIVE

Section / paragraph	Member/Observer/rationale
Histamine is produced in fish and fishery products by spoilage bacteria that are part of the natural I After the fish die, these bacteria migrate into the previously sterile fish musculature where they mulhistamine-producing bacteria multiply in fish flesh, they produce histidine decarboxylase enzymes toxic metabolite histamine	Itiply if time and temperature are not controlled. When
Histamine is produced in fish and fishery products by spoilage bacteria that are part of the natural microflora of the skin, gills, and gut of freshly caught fish. After the fish die, these bacteria migrate into the previously sterile fish musculature where they multiply if time and temperature are not controlled. When histamine-producing bacteria multiply in fish flesh, they produce histidine decarboxylase (HDC) enzymes (HDC), which that convert naturally present histidine (naturally present in the flesh of at-risk fish) into the toxic metabolite histamine.	USA  Editorial, and to indicate that histidine is present in at-risk fish  Category: EDITORIAL / SUBSTANTIVE
Replace "if time and temperature are not controlled" with "when conditions are conducive to the	Morocco.
multiplication of histamine-producing bacteria"	Category: TECHNICAL
from harvest to consumption. However, once sufficient bacterial multiplication has occurred to produce histamine slowly at refrigeration temperatures  Add mesophilic in the first sentence: "mesophilic bacteria."	
Add mesophilic in the first sentence: "mesophilic bacteria."	Morocco
Replace "immediately" with "as soon as possible."	Category: TECHNICAL
Add "and processing (heat processing or other types of processing)" before however.	
Add after however: "However, chilling cannot prevent the multiplication of histamine-producing	
psychrotrophic bacteria, which are not well understood."	
psychrotrophic bacteria, which are not well understood."  Histamine formation is effectively controlled by adherence to good manufacturing practices to main to control detrimental fish time-temperature exposure.	 ntain hygienic quality of fish, and by using HACCP principles
Histamine formation is effectively controlled by adherence to good manufacturing practices to main	ntain hygienic quality of fish, and by using HACCP principles  Canada
Histamine formation is effectively controlled by adherence to good manufacturing practices to main to control detrimental fish time-temperature exposure.	
Histamine formation is effectively controlled by adherence to good manufacturing practices to main to control detrimental fish time-temperature exposure.	Canada
Histamine formation is effectively controlled by adherence to good manufacturing practices to main to control detrimental fish time-temperature exposure.  Define the HACCP acronym.  Histamine formation is effectively controlled by adherence to good manufacturing practices to maintain hygienic quality of fish, and by using HACCP principles to control detrimental fish time-temperature exposure. If fish are harvested under temperature conditions that are not likely to lead to histaime	Canada Category: EDITORIAL  New Zealand If fish are harvested in areas with colder climates that controls required maybe much reduced. The document should signal this. Category: TECHNICAL
Histamine formation is effectively controlled by adherence to good manufacturing practices to main to control detrimental fish time-temperature exposure.  Define the HACCP acronym.  Histamine formation is effectively controlled by adherence to good manufacturing practices to maintain hygienic quality of fish, and by using HACCP principles to control detrimental fish time-temperature exposure. If fish are harvested under temperature conditions that are not likely to lead to histaime formation, the controls may be tailored to reflect those conditions.  The following subsections contain technical guidance for the control of histamine formation at key	Canada Category: EDITORIAL  New Zealand If fish are harvested in areas with colder climates that controls required maybe much reduced. The document should signal this. Category: TECHNICAL

SPECIFIC COMMENTS	
Section / paragraph	Member/Observer/rationale
It is unclear why only the harvest vessel operations section X.1 applies to aquaculture. All relevant	New Zealand
guidelines could apply".	Category: TECHNICAL
FIGURE X.1	
Replace "Chilling and freezing" with "Chilling and/or freezing."	Morocco
Replace "X.1.4. Refrigerated and frozen storage" with "X.1.4. Refrigerated and/or frozen storage."	Only steps that are part of the
Replace "X.1.5. Monitoring records (fishing vessel)" with "Vessel transportation to the establishment"	harvesting/production/manufacturing process should be
Replace "X.2 Reception of fish" with "X.2 Interim storage of fish."	included.  Rationale: analyses, testing and controls must be listed on the
Replace X.2.2 "Temperature monitoring" with "Storage and shipping"	margin and not within the manufacturing diagram because they
Add (optional) to "X.2.4 Histamine testing."	are not part of the process
Delete "X.2.3 Sensory evaluation."	Category: SUBSTANTIVE
Delete "X.2.4 Histamine testing (optional)."	
Delete "X.2.5 Monitoring records (receiving establishment)."	
Delete "time and temperature control" from section X.4.2	
Delete "X.4.3 Heat processing" and "X.4.4 Processing, other technological measures"	
Replace section "X.4.5 Refrigerated and frozen storage" with "Refrigerated and/or frozen storage."	
Delete "X.4.6 Monitoring records (processing establishment)."	
Delete steps in the flow chart that are not process steps e.g. X.1.5, X.2.1, X.2.2, X.2.3, X.2.4, X.2.5,	New Zealand
X.4.6.	Category: TECHNICAL / EDITORIAL
Section headings should align with chart references	
Remove "and freezing" from box X.1.3.	USA
	Confusing title. The section covers chilling of freshly caught fish to frozen temperatures, or to un-frozen refrigerated temperatures. Also change heading of section X.1.3.
	Category: SUBSTANTIVE
X.1 Harvest vessel operations	
Fishers use many different harvesting methods throughout the world, employing hooks, nets, and on geographic location and season. In all cases, live retrieval or quick retrieval of dead fish, rapid fish at cold temperatures, are critical to prevent histamine formation.	
Delete the phrases "Water and environmental temperatures vary depending on geographic location and	Morocco
season" and "live retrieval or dead fish."	Category: EDITORIAL
Add "of fish" after "quick retrieval."	

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
Time for histamine formation can vary substantially at the same temperature because different histamine-producing bacteria with different histamine-producing activity may be present. Time-temperature critical limits should take into account the potential for histamine production under the worst case conditions for the particular operation.		
Delete this paragraph	Morocco	
	Category: EDITORIAL	
The fishing vessel and equipment, and the methods used, should be designed or adapted to	USA	
prevent histamine formation for the catch sizes, fish sizes, fish species, and air and water temperatures encountered. Time for histamine formation can vary substantially at the same temperature because different histamine-producing bacteria with different histamine-producing activity may be present. Time-temperature One effective means to prevent hazardous levels of histamine formation is by use of HACCP principles to control fish time-temperature exposure on the harvest vessel. When HACCP is applied on harvest vessels, time-temperature critical limits should take into account the potential for histamine production under the worst-case worst-case conditions for the particular operation.	Category: SUBSTANTIVE	
species, and air and water temperatures encountered. Vessel crews should be trained in hygienic putheir importance, and responsible crew members should be trained in HACCP principles used to co		
	Delete these two phrases: "and air and water temperatures encountered" and "and responsible crew members should be trained in HACCP principles used to control histamine formation, where possible."	
	Category: SUBSTANTIVE	
The fishing vessel and equipment, and the methods used, should be designed or adapted to prevent	New Zealand	
histamine formation for the catch sizes, fish sizes, fish species, and air and water temperatures encountered. Vessel crews should be trained in hygienic practices and temperature control methods and understand their importance importance for histamine control. Where HACCP prinicples are applied, and persons responsible erew members for developing HACCP documentation should also be trained in HACCP principles used to control histamine formation, where possible.	Category: TECNICAL	
The fishing vessel and equipment, and the methods used, should be designed or adapted to prevent histamine formation for the catch sizes, fish sizes, fish species, and air and water temperatures encountered. Vessel crews should be trained in hygienic practices and temperature control methods and in order to understand their importance, and . Consideration should be given to training responsible crew members should be trained in HACCP principles used to control histamine formation, where possiblepracticable.	USA Category: SUBSTANTIVE	

	SPECIFIC COMMENTS	
Section / paragraph	Member/Observer/rationale	
Use of HACCP principles to control fish time-temperature exposure on the harvest vessel is an effective means to prevent hazardous levels of histamine formation, and provides better consumer protection than the alternative approach of testing histamine levels in fish after delivery.		
Delete this paragraph	Morocco	
	Category: EDITORIAL	
Use of HACCP principles <u>and good manufacturing practices</u> to control fish time-temperature exposure on the harvest vessel is an effective means to prevent hazardous levels of histamine formation, and provides better consumer protection than the alternative approach of testing histamine levels in fish after delivery	New Zealand Category: TECHNICAL	
Use of HACCP principles to control fish time-temperature exposure on the harvest vessel is an effective	USA	
means to prevent hazardous levels of histamine formation, and provides better consumer protection than the alternative approach of testing histamine levels in fish after delivery.	Clarify that HACCP and HACCP training are not required on harvest vessels.	
	Category: SUBSTANTIVE	
• If captured fish are held in the sea for too long following death, decomposition commences, and I more rapid the decomposition and the greater the risk of histamine formation. Dead fish that exhib time-temperature abuse, should not be retained on board the vessel, or, if retained, should be segr disposition when off-loaded. In addition, the harvesting methods should be modified in a way that	it marginalized quality attributes, consistent with exposure to egated and identified properly to allow testing and proper	
Delete this paragraph	Morocco	
	Category: EDITORIAL	
If captured fish are held in the sea for too long following death, decomposition commences, and	Category: EDITORIAL  New Zealand	
histamine can begin to form. The warmer the seawater, the more rapid the decomposition and the greater the risk of histamine formation. Dead fish that exhibit marginalized quality attributes, consistent with		
histamine can begin to form. The warmer the seawater, the more rapid the decomposition and the greater the risk of histamine formation. Dead fish that exhibit marginalized quality attributes, consistent with exposure to time-temperature abuse, should not be retained on board the vessel, or, if retained, should	New Zealand Testing would only be expected if product were to be retained.	
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histamine can begin to form. The warmer the seawater, the more rapid the decomposition and the greater the risk of histamine formation. Dead fish that exhibit marginalized quality attributes, consistent with exposure to time-temperature abuse, should not be retained on board the vessel, or, if retained, should be segregated and identified properly to allow testing and proper disposition when off-loaded. In addition, the harvesting methods should be modified in a way that no dead fish with marginal quality will be brought	New Zealand Testing would only be expected if product were to be retained. Using the words proper disposition should cover this Category: EDITORIAL Testing only required if product to be retained – determining proper disposition should address this. TECHNICAL	
histamine can begin to form. The warmer the seawater, the more rapid the decomposition and the greater the risk of histamine formation. Dead fish that exhibit marginalized quality attributes, consistent with exposure to time-temperature abuse, should not be retained on board the vessel, or, if retained, should be segregated and identified properly to allow testing and proper disposition when off-loaded. In addition, the harvesting methods should be modified in a way that no dead fish with marginal quality will be brought on board.  • Before landing fish, the deck area and equipment should be hygienically cleaned to avoid contains.	New Zealand Testing would only be expected if product were to be retained. Using the words proper disposition should cover this Category: EDITORIAL Testing only required if product to be retained – determining proper disposition should address this. TECHNICAL amination of fish (see Section 3.4 Hygiene control program),  Morocco	
histamine can begin to form. The warmer the seawater, the more rapid the decomposition and the greater the risk of histamine formation. Dead fish that exhibit marginalized quality attributes, consistent with exposure to time-temperature abuse, should not be retained on board the vessel, or, if retained, should be segregated and identified properly to allow testing and proper disposition when off-loaded. In addition, the harvesting methods should be modified in a way that no dead fish with marginal quality will be brought on board.  • Before landing fish, the deck area and equipment should be hygienically cleaned to avoid contained the chilling medium should be ready and at the target temperature.	New Zealand Testing would only be expected if product were to be retained. Using the words proper disposition should cover this Category: EDITORIAL Testing only required if product to be retained – determining proper disposition should address this. TECHNICAL amination of fish (see Section 3.4 Hygiene control program),	
histamine can begin to form. The warmer the seawater, the more rapid the decomposition and the greater the risk of histamine formation. Dead fish that exhibit marginalized quality attributes, consistent with exposure to time-temperature abuse, should not be retained on board the vessel, or, if retained, should be segregated and identified properly to allow testing and proper disposition when off-loaded. In addition, the harvesting methods should be modified in a way that no dead fish with marginal quality will be brought on board.  • Before landing fish, the deck area and equipment should be hygienically cleaned to avoid contained the chilling medium should be ready and at the target temperature.  Add "and icing" after chilling	New Zealand Testing would only be expected if product were to be retained. Using the words proper disposition should cover this Category: EDITORIAL Testing only required if product to be retained – determining proper disposition should address this. TECHNICAL amination of fish (see Section 3.4 Hygiene control program),  Morocco Category: EDITORIAL	

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
• Critical limits should be established for the time period between death of the fish and the start of chilling that will effectively prevent histamine production.  Time of death of the fish may be the time slaughtered onboard, or where the actual time of death is not observed or truly known, an estimated time based on an observable event, such as the time of deployment of a longline when some of the fish are landed dead.		
Delete the paragraph     Critical limits (ie. parameters for time and temperature) should be established for the time period between death of the fish and the start of chilling that will effectively prevent minimise histamine production. Time of death of the fish may be the time slaughtered onboard, or where the actual time of	Morocco Category: EDITORIAL  New Zealand Category: TECHNICAL	
death is not observed or truly known, an estimated time based on an observable event, such as the time of deployment of a longline-when some of the first dead fish are landed deadlanded.		
• Critical limits should be established for the time period between death of the fish and the start of chilling that will effectively prevent histamine production. Time of death of the fish may be the time slaughtered onboard, or where the actual time of death is not observed or truly known, an estimated time based on an observable event, such as the time of deployment of a longline when some of the fish are landed dead.	USA To combine redundant language in the 5th and 6th bullets.  Category: SUBSTANTIVE / EDITORIAL	
There shall appear on the label either in conjunction with, or in close proximity to, the name of the food, specific information related to processing or treatment it has undergone the physical condition of the food; for example: dried, concentrated, reconstituted, smoked.	New Zealand Category: EDITORIAL	
• The time period between death of fish and chilling that will effectively prevent histamine formation can vary based on the ocean and air temperatures encountered, the sizes and species of fish caught, and other relevant factors particular to the harvesting operation. See the FAO/WHO Expert Report (Section		
6.1.1 Chilling) <sup>[1]</sup> for further guidance on establishing time-temperature critical limits for fish after dec		
• The time period between death of fish and chilling that will effectively prevent_minimise_histamine formation can vary based on the ecean_water_and air temperatures encountered, the sizes and species of fish caught, and other relevant factors particular to the harvesting operation. See the The FAO/WHO	New Zealand Created by merging other changes together Category: TECHNICAL	
Expert Report (Section 6.1.1 Chilling) <sup>[1]</sup> for further provides the following guidance on establishing time-temperature critical limits for fish after death.		
• <u>Critical limits should be established for tThe-he</u> time period between death of fish and <u>start</u> of chilling that will effectively prevent histamine formation. These can vary based on the ocean and air temperatures encountered, the sizes and species of fish caught, and other relevant factors particular to the harvesting operation. See-For some examples based on medium to large fish, see the FAOWHO Expert Report (Section 6.1.1 Chilling) <sup>[1]</sup> for further guidance on establishing time-	USA  To combine redundant language, and to provide information about the examples in the Expert Report  Category: SUBSTANTIVE	
temperature critical limits for fish after death.  The rate or volume of catch should not exceed the ability of the crew to quickly initiate chilling,	and should not exceed the capability of the vessel's chilling	
<ul> <li>system to maintain critical limits for cooling media temperature, or sufficiency of ice.</li> <li>The rate or volume of catch should not exceed the ability of the crew to quickly initiate chilling, and should not exceed the capability of the vessel's chilling system to <u>achieve and</u> maintain <u>critical limits</u> for cooling media temperature, or sufficiency of icechilled temperatures.</li> </ul>	New Zealand	

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
	Chilling regime should be managed by good manufacturing practice and therefore does not need critical limits. Chiling is a routine requirement on vessels and is essenatial for GMP.	
	Chilling regime does not need to have critical limits, should just be managed by GMP. Is a routine requirement on vessels and is essential GHP.	
	Category: TECHNICAL	
Rough handling, overcrowding and over stacking of fish should be avoided where practical because crushing, bruising, and lacerations of the skin accelerate the spread of histamine-producing bacteria from the gut, gills, and skin into the fish musculature.		
Rough handling, overcrowding and over stacking of fish should be avoided where practical because	New Zealand	
crushing, bruising, and lacerations of the skin accelerate the spread of histamine-producing bacteria from the gut, gills, and skin into the fish musculaturemuscle.	Category: EDITORIAL	
X.1.2 Gutting and gilling (optional)		
□□For large fish, removing the gut aids chilling by allowing chilling media (e.g. ice, refrigerated seawater) access to the visceral cavity, resulting in more rapid chilling of this bacteria-laden region of the fish.		
Replace "region" with "part"	Morocco	
	Category: EDITORIAL	
X.1.3 Chilling and freezing		
X.1.3 Chilling and freezing Chilling	USA	
	Category: SUBSTANTIVE	
<ul> <li>Sufficient ice to completely surround each fish, or preferably, ice/seawater slurries or refrigeratemperature of fish to below 4°C as quickly as possible after death to slow bacterial growth and enables.</li> </ul>		
Replace this paragraph with "Sufficient ice to completely surround the fish, or preferably, ice/seawater	Morocco	
slurries or refrigerated seawater should be used for effective chilling that slows bacterial growth and enzymatic activity."	Category: SUBSTANTIVE	
Freezing is more effective than refrigerated chilling and maintaining chilled temperatures in preventing histamine formation. It is good practice to gut the fish pefore freezing. Freezing to -18 °C, or below, will stop the growth of histamine-producing bacteria and will prevent any preformed histidine decarboxylase enzymes from producing additional histamine.		
• Freezing is more effective than refrigerated chilling and maintaining chilled temperatures in preventing	New Zealand	
histamine formation. It is good practice to gut the fish before freezing. Freezing to -18 °C, or below, will stop the growth of histamine-producing bacteria and will prevent any preformed histidine decarboxylase enzymes from producing additional histamine.	Category: EDITORIAL	
• Freezing <u>fish</u> is more effective <u>in preventing histamine formation</u> than <del>refrigerated chilling and</del>	USA	
maintaining chilled temperatures in preventing histamine formation fish near 4°C. It is good practice to gut the fish before freezing. Freezing to -18 °C, or below, will stop the growth of histamine-producing	Category: SUBSTANTIVE	

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
bacteria and will prevent any preformed histidine decarboxylase enzymes from producing additional histamine.		
□□Note that freezing does not detoxify preformed histamine, nor does it effectively eliminate histamactive when temperatures increase again, such as during processing or meal preparation.	nine producing bacteria and enzymes, which can become	
Replace "does not detoxify" with "does not eliminate."	Morocco	
Add "completely" to the phrase "completely eliminate histamine producing bacteria and enzymes."	Category: EDITORIAL	
• Crew members responsible for chilling should provide feedback to the catching operation to assu the ability to rapidly chill the fish within established time-temperature critical limits and maintain the		
Crew members responsible for chilling should provide feedback to the catching operation to assure that	New Zealand	
the rate or volume of incoming fish does not exceed the ability to rapidly chill the fish within established	Chilling should be managed by good manufacturing practice.	
time-temperature critical limits and maintain the fish in a chilled state.	Category: SUBSTANTIVE	
Crew members responsible for chilling should provide feedback to the catching operation	USA	
to assure ensure that the rate or volume of incoming fish does not exceed the ability to rapidly chill the	Category: EDITORIAL	
fish within established time-temperature critical limits and maintain the fish in a chilled state.		
Crew members responsible for chilling should provide feedback to the catching operation to assure that the rate or volume of incoming fish does not exceed the ability to rapidly chill the fish within established time-temperature critical limits and maintain the fish in a chilled state.		
Delete "within established time-temperature critical limits and maintain the fish in a chilled state."	Morocco	
	Category: EDITORIAL	
• Care should be taken to manage the chilling of dead fish to ensure that none are inadvertently left conditions.	exposed on deck past the critical time limit for the	
Care should be taken to manage the chilling of dead fish to ensure that none are inadvertently left	New Zealand	
exposed on deck past the critical time limit <u>established</u> for the <u>temperature</u> conditions.	Category: TECHNICAL	
□□Care should be taken to manage the chilling of dead fish to ensure that none are inadvertently left exposed on deck past the critical time limit for the conditions.		
Delete "on deck past the critical time limit for the conditions."	Morocco	
	Category: EDITORIAL	
• Refrigeration and other chilling equipment should be in good repair, and operated in a manner that fish should be packed loosely in ice slurries, RSW, and brine tanks to allow good circulation and ra		
Refrigeration and other chilling equipment should be in good repair, and operated in a manner that	USA	
quickly chills fish without physical damage. For example, fish should be packed loosely in ice slurries, RSW, RSW and brine tanks to allow good circulation and rapid cooling.	Category: EDITORIAL	
□□For larger eviscerated fish, the belly cavity should be packed with ice, or other cooling media, for more rapid chilling of this bacteria-laden region of the fish.		
Replace "region" with "part."	Morocco	

SPECIFIC COMMENTS	
Section / paragraph	Member/Observer/rationale
	Category: EDITORIAL
• Critical limits and monitoring methods and frequencies should be established for the onboard chi established for maximum loading volumes and rates, maximum starting temperature for RSW and/o adequate chilling environment is maintained for the duration of the chilling operation for each harve	or brine tanks, and monitoring frequencies to ensure an
• Critical limits and Monitoring methods and frequencies should be established for the onboard chilling/freezing process. For example, limits may be established for maximum loading volumes and rates, maximum starting temperature for RSW and/or brine tanks, and monitoring frequencies to ensure an adequate chilling environment is maintained for the duration of the chilling operation for each harvested set <sup>[3]</sup> of fish.	Morocco
	Category: SUBSTANTIVE
	Edit the first sentence as follows: "Critical limits, freezing guidelines and monitoring methods and frequencies should be established for the onboard freezing process."
	Delete the following: "maximum starting temperature for RSW and/or brine tanks" and "for the duration of the chilling operation" Replace chilling with freezing in this phrase "to ensure an adequate chilling environment is maintained."
	Category: EDITORIAL
• <u>MCritical limits and monitoring onitoring</u> methods and frequencies should be established for the onboard chilling/freezing process. For example, limits <u>Parameters</u> may be established for maximum loading volumes and rates, <u>and</u> maximum starting temperature for RSW and/or brine tanks, and monitoring frequencies tanks to ensure an adequate chilling environment is maintained for the duration of the chilling operation for each harvested set <sup>5</sup> https://ocs.codexalimentarius.org/Reports/ReviewerReconcileReport.aspx?reviewid	New Zealand Category: TECHNICAL
<u>=413&amp;reporttype=consolidated - ftn3</u> of fish.	
X.1.4 Refrigerated and frozen storage (fishing vessel and transfer vessel)	
• Fish should be stored at a temperature as close as possible to 0°C (4°C or below) until off-loading	
• Fish should be stored at a temperature as close as possible to <del>0°C (4°C or below)</del> <u>0°C. The storage</u> temperature should be kept bellow 4°C until off-loading.	Brazil We emphasize that the storage temperature of the fish in the vessels should be as close as possible to O ° C, with temperatures up to 4 ° C allowed.  Category: TECHNICAL
• Fish should be stored at a temperature as close as possible to 0°C (4°C or below) until off-loading-, and	Colombia
the maximum amount of time it may be stored on the vessel at this temperature should be defined.	Colombia suggests including the proposed paragraph, given that there needs to be a time limit on storage prior to off-loading, to prevent histamine formation.
	Category: TECHNICAL

	T
Section / paragraph	Member/Observer/rationale
• Refrigerated fFish-ish should be stored at a temperature as close as possible to 0°C (4°C or below) until off-loading.	USA
	To differentiate from frozen fish
	Category: SUBSTANTIVE
<ul> <li>Refrigerated storage at 4°C or below will inhibit growth and enzyme production for most histamine prolific histamine-producing bacteria that can grow at refrigerated temperatures.</li> </ul>	e-producing bacteria, and will slow the growth of the less
• Refrigerated storage-Storage at 4°C or below these temperatures will inhibit or slow the growth and	New Zealand
enzyme production for most histamine-producing bacteria, and will slow the growth of the less prolific	Also combine with previous bullet.
histamine-producing bacteria that can grow at refrigerated temperatures.	Category: TECHNICAL
<ul> <li>Refrigerated seawater and/or brine temperature should be monitored and carefully controlled in o</li> </ul>	rder to help maintain inhibitory temperatures.
Refrigerated seawater and/or brine temperature should be <u>regularly</u> monitored <u>throughout the</u>	New Zealand
trip and carefully controlled in order to help maintain inhibitory storage temperatures.	Category: EDITORIAL
<ul> <li>Continuous temperature recording devices should be used where practical in refrigerated and fro to be identified and appropriate actions taken to minimize consumer risk.</li> </ul>	zen storage compartments to enable inadequate conditions
Continuous temperature recording devices should be used where practical in refrigerated and frozen	Colombia
storage compartments to enable inadequate conditions to be identified and appropriate actions taken to	Colombia suggests striking the text, as it is imperative to have
minimize consumer risk.	devices to measure and verify temperature on a periodic basis.
	Category: TECHNICAL
Add this phrase to the beginning of the paragraph "• For vessels with freezing equipment"	Morocco
Delete "refrigerated and" from the phrase "in refrigerated and frozen storage compartments"	Category: EDITORIAL
• Continuous temperature recording devices should can be used where practical in refrigerated and	New Zealand
frozen storage compartments to enable inadequate conditions to be identified and appropriate actions taken to minimize consumer risk.	Category: EDITORIAL
Continuous temperature recording devices should be used where practical in refrigerated and frozen	USA
storage compartments to enable ensure that inadequate holding conditions to be are identified and appropriate actions taken to minimize consumer risk.	Category: EDITORIAL
X.1.5 Monitoring records (fishing and transfer vessel)	
X.1.5 Monitoring <u>and records (fishing and transfer vessel)</u>	New Zealand
	This section includes information about records and monitoring
	Category: EDITORIAL
Monitoring and recording critical histamine controls on the harvest vessel can ensure histamine	USA
is under control and eliminate the need for histamine testing of every lot delivered to the shore-	Add following introductory sentence (non-bulleted) to explain
based receiving establishment.	the benefits of record keeping as follows:
	To explain the benefits of recordkeeping

SPECIFIC COMMENTS		
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	Category: SUBSTANTIVE	
• Records should be made available to the receiving establishment that offloads the fish from the vessel to provide evidence that histamine controls were implemented properly and effectively by the fishing and transfer vessel.		
• Records should be made available to the receiving establishment that offloads the fish from the vessel	New Zealand	
to provide evidence that histamine controls were implemented <del>properly and effectively by the fishing and transfer</del> -vessel.	Where referring to both fishing and transfer vessels, for simplicity can use the term vessel.	
	Category: EDITORIAL	
• Vessel records should include documentation of actual observed activities and times pertinent to onboard controls for all histamine-forming fish harvested from each fishing set on each fishing trip.		
Vessel records should include documentation of <del>actual</del> -observed activities <del>and times</del> -pertinent to	New Zealand	
onboard controls for all histamine-forming fish harvested from each fishing set on each fishing trip.	Category: EDITORIAL	
The records kept depend on the operation and may include:		
• The records kept of histamine control monitoring activities depend on the operation and may	New Zealand	
include:	Category: EDITORIAL	
Ocean water temperature and air temperature		
Delete this sentence	Morocco	
	Category: EDITORIAL	
<u>W</u> Ocean water temperature ater and air temperature	New Zealand Category: EDITORIAL	
Ocean water temperature and air temperature	USA	
	Category: SUBSTANTIVE	
Dates and times of earliest fish death, and times to get fish into appropriate chilling media		
Delete this sentence	Morocco Category: EDITORIAL	
Brine, RSW, or storage compartment refrigeration temperature monitoring records or checks for adequacy of ice during the chilling operation and during holding of the fish for the duration of the fishing trip.		
Delete "brine, RSW, or storage compartment refrigeration temperature"	Morocco	
Add to the same paragraph: FAO document no. 436: "The Use of Ice on Small Fishing Vessels" is an extremely important tool because it includes several mathematical formulas that can be used to calculate the amount of ice needed for a fishing trip.	Category: TECHNICAL	
Add the following paragraph: For proper onboard ice use, recommendations include:		
- comply with the fish/ice ratio;		

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
<ul><li>use finely crushed ice to prevent large pieces from damaging the fish;</li><li>the ice and fish must be evenly and carefully spread out;</li></ul>		
- add a thick layer of ice between the last layers of fish.		
Brine, RSW, or storage compartment refrigeration temperature monitoring records or checks for adequacy of ice during the chilling operation and during <a href="https://example.com/helding-storage">helding-storage</a> of the fish for the duration of the fishing trip.	New Zealand Category: EDITORIAL	
Brine, RSW, or storage compartment refrigeration temperature monitoring records or checks for	USA	
adequacy of ice during the chilling operation and during holding of the fish for the duration of the fishing trip.	For clarity and simplicity. Initial temperatures are included when monitoring temperature. Time from death to chilling moved to top.	
- Ocean water temperature and air temperature.	Category: SUBSTANTIVE	
• Where onboard record keeping is impractical, such as for small artisanal day boats, the operation receiving the fish may be able to monitor and record all the parameters necessary to assure histamine control (e.g. time of departure and return, air and water temperature, adequacy of ice and fish internal temperature, etc.), and avoid the need to test histamine levels at receipt.		
Edit this paragraph as follows: "For small artisanal day boats, where onboard record keeping is	Morocco	
impossible, all the parameters necessary to assure histamine control (e.g. time of departure and return, adequacy of ice) may be monitored and recorded and avoid the need to test histamine levels at receipt."	Category: SUBSTANTIVE	
Add "Unloading and" to point "X.2 Reception of fish."	Morocco	
	Category: EDITORIAL	
Replace "Where onboard record keeping is impractical, such as for small artisanal day boats" with "• For small artisanal day boats,"  Delete "air and water temperature," and "and fish internal temperature."	Morocco Category: SUBSTANTIVE	
• Where onboard record keeping is impractical, such as for small artisanal day boats, the operation receiving the fish may be able to monitor and record all the parameters necessary to assure histamine control (e.g. time of departure and return, air and water temperature, adequacy presence of ice and fish internal temperature, visual assessment of the fish etc.), and avoid the need to test histamine levels at receipt.	New Zealand Category: TECHNICAL	
• Where enboard record keeping is impractical, such as for small artisanal For day boats, the operation receiving the fish may be able to monitor and record all the parameters necessary to assure-ensure histamine control (e.g. time of departure and return, air and water temperature, adequacy of ice and fish internal temperature, etc.), and avoid the need to test histamine levels at receipt. In some cases, a day boat may need to record the time that fishing started in order to determine that there was adequate histamine control for the trip.	"Small" or "artisanal" is less relevant than the time period from death to chilling that, in the case of day boats, may be short enough to use shore-based monitoring. The simple recording of the start of fishing can allow a longer day trip (without the need for temperature monitoring) when it takes some time to get to the fishing area.  Category: EDITORIAL / SUBSTANTIVE	

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
• If some of the fish stored on the vessel are at risk for histamine formation because critical limits were exceeded, then these fish should be segregated and identified in order to allow targeted testing and proper disposition at unloading.		
• If some of the fish stored-on the vessel are at risk for histamine formation because critical limits were	New Zealand	
exceeded, then these fish should be segregated and identified in order to allow targeted testing and assessment and/or proper disposition at unloading.	Category: EDITORIAL	
X.2 Reception of fish (receiving establishment)		
Edit section as follows: "X.2 Unloading and reception of fish (receiving establishment)"	Morocco	
	Category: EDITORIAL	
Fish reception (at the establishment where the fish are offloaded from the fishing or transfer vessel) is an important control point for histamine because this is where vessel records, fish temperatures, signs of decomposition, and histamine levels are best monitored and decisions are made as to whether the fish are safe to accept for processing or to proceed in commerce.		
Edit this paragraph as follows: "Fish reception (at the establishment where the fish are offloaded from the	Morocco	
fishing or transfer vessel or road transport vehicle) is an important control point for histamine because this is where decisions are made to accept fish lots for processing or to proceed in commerce."	Category: EDITORIAL	
Fish reception (at the establishment where the fish are offloaded from the fishing or transfer vessel) is an	New Zealand	
important control point for histamine because this is where vessel records,	Category: EDITORIAL	
fish temperatures, temperatures and signs of decomposition, and histamine levels are best monitored and verified, and decisions are made as to whether the fish are safe to accept for processing or to		
proceed in commerce.		
Reception controls may need to be specific to both the harvest vessels as well as to any collection establishment.	transfer vessels that deliver the fish to the receiving	
Delete this paragraph	Morocco	
	Category: EDITORIAL	
If deficiencies in fishing vessel controls are found at receiving, feedback should be provided to the vessel operator, and the cause(s) of the problem should be evaluated and corrected before future deliveries from the fishing vessel are considered. In addition, appropriate corrective actions regarding the delivered fish should be taken and recorded.		
If deficiencies in fishing-vessel controls are found at receiving, feedback should be provided to the vessel	New Zealand	
operator, and the cause(s) of the problem should be evaluated and corrected before future deliveries from	Category: TECHNICAL	
the fishing vessel are considered corrected. In addition, appropriate corrective actions regarding the delivered fish should be taken and recorded.		
During offloading of fish from the harvest vessel (and at any point of transfer in the supply chain), care should be taken that the cold chain is maintained. For example, fish should be offloaded quickly, fish totes should not be left exposed to elevated temperatures, and fish should be re-iced or placed under refrigeration in a timely manner. Frozen fish should be handled in a manner to maintain the frozen state.		
During offloading of fish from the harvest-vessel (and at any point of transfer in the supply chain), care	New Zealand	
should be taken that the cold chain is maintained. For example, fish should be offloaded quickly, fish totes should not be left exposed to elevated temperatures, and fish should be re-iced or placed under	Category: EDITORIAL	

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
refrigeration in a timely manner. Frozen fish should be handled maintained in a manner to maintain the frozen state.		
During offloading of fish from the harvest vessel vessels (and at any point of transfer in the supply chain), care should be taken that the cold chain is maintained. For example, fish should be offloaded quickly, fish totes should not be left exposed to elevated temperatures, and fish should be re-iced or placed under refrigeration in a timely manner. Frozen fish should be handled in a manner to maintain the frozen state.	USA To include both harvest and transfer vessels Category: SUBSTANTIVE	
X.2.1 Review of fishing vessel controls and records (receiving establishment)		
X.2.1 Review Reception checks, review of fishing vessel controls and records (receiving establishment)  Review of fishing vessel histamine control systems and monitoring records, when available, is an efollowed to help control histamine formation in the fish while on the fishing vessel.	New Zealand  Better reflect content  Category: TECHNICAL  ffective method to ensure that appropriate procedures were	
Edit the first sentence as follows: "Vessel records applicable to histamine control should be requested and reviewed by the receiving personnel"  Replace "complete" with "compliant."  Delete "and that all applicable fishing vessel critical limits were met."	Morocco Category: EDITORIAL	
Review of fishing-Reception checks should give confidence that vessel histamine control systems and monitoring records controls are affective. If a receiver has concern about the adequacy of histamine controls on a vessel, the vessel records can be requested and reviewed when available, is as this can be an effective method to ensure that appropriate procedures were followed to help control histamine formation in the fish while on the fishing vessel.	New Zealand  Records from the vessel would generally be reviewed if concerns were identified during the reception checks. The reciever can then request the vessel records to determine were there may have been a loss of control. Otherwise the reciever should be able to rely on the actions of the vessel operator and that the appropriate controls and procedures have been implemented.  Category: TECHNICAL	
Review of fishing vessel histamine control systems and monitoring records, when available, is an effective method to ensure that appropriate procedures were followed to help control histamine formation in the fish while on the fishing vessel, and is more effective than routine histamine testing.	USA  To indicate the benefit of documenting control of histamine on fishing vessels.  Category: SUBSTANTIVE	
• If vessel records are incomplete and the receiving establishment cannot reliably ensure that the specific delivery of fish was harvested, handled, and stored in a manner that prevents histamine formation, such as by intensified histamine sampling and testing, the delivery should be rejected.		
Delete "are incomplete and the receiving establishment cannot reliably ensure that the specific delivery of fish was harvested, handled and stored in a manner that prevents histamine formation, such as by intensified sampling and."  Delete "the delivery should be rejected."	Morocco Category: EDITORIAL	

SPECIFIC COMMENTS	
Section / paragraph	Member/Observer/rationale
• If vessel records are <u>reviewed and found to be</u> incomplete and the receiving establishment cannot reliably ensure that the specific delivery of fish was harvested, handled, and stored in a manner that prevents histamine <u>formation</u> , <u>formation by other means</u> such as by intensified histamine sampling and testing, the delivery should be rejected. <u>(Refer to Section X.2.4 Histamine testing).</u>	New Zealand Category: EDITORIAL
• If vessel records are incomplete and the receiving establishment cannot reliably ensure that the specific delivery of fish was harvested, handled, and stored in a manner that prevents histamine formation, such as by intensified histamine sampling and testingtesting(refer to Section X.2.4 Histamine testing), the delivery should be rejected.	USA Category: SUBSTANTIVE
	USA
	Moved up from 5th bullet because we suggest moving the 5th bullet to the histamine testing section.
	Category: EDITORIAL
• Sometimes the <u>The</u> impact of a critical limit deviation on the fishing vessel may be minimized if the records clearly show that only part of a delivery was affected (e.g. one brine well or one specific fishing set during the fishing trip) set) and if the affected fish can be were effectively segregated from the rest of the delivery when the vessel is unloaded. Precautions should be taken to ensure none of the other fish in the delivery have been affected.	New Zealand Category: EDITORIAL
<ul> <li>Histamine testing can be used when vessel records are not available or unclear. However, this test distributed within and between fish, and fish with high histamine are difficult to find using limited or meaningful in terms of appropriate consumer protections can be resource intensive. Histamine test verification of the effectiveness of a properly implemented and documented histamine control syste testing.)</li> </ul>	r small sample sizes. Sampling and testing that is statistically ing at fishing vessel reception is therefore best used as
Delete this paragraph "However, this testing can be less reliable because histamine may be unevenly	Morocco
distributed within and between fish, and fish with high histamine are difficult to find using limited or small sample sizes. Sampling and testing that is statistically meaningful in terms of appropriate consumer protections can be resource intensive. Histamine testing at fishing vessel reception is therefore best used as verification of the effectiveness of a properly implemented and documented histamine control system on the fishing vessel. (Refer to Section X.2.4 Histamine testing.)"	Category: SUBSTANTIVE
• Histamine testing can be used when vessel records are not available or unclear. However, this testing	New Zealand
can be less reliable because histamine may be unevenly distributed within and between fish, and fish with high histamine are difficult to find using limited or small sample sizes. Sampling and testing that is statistically meaningful in terms of appropriate consumer protections can be resource intensive.	Category: EDITORIAL
Histamine testing at fishing vessel reception is therefore best used as verification of the effectiveness of a	

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
properly implemented and documented histamine control system on the fishing vessel. (Refer to Section X.2.4 Histamine testing.)		
• Histamine testing can be used when vessel records are not available or unclear. However, this testing can be less reliable because histamine may be unevenly distributed within and between fish, and fish with high histamine are difficult to find using limited or small sample sizes. Sampling and testing that is statistically meaningful in terms of appropriate consumer protections can be resource intensive. Histamine testing at fishing vessel reception is therefore best used as verification of the effectiveness of a properly implemented and documented histamine control system on the fishing vessel. (Refer to Section X.2.4 Histamine testing.)	Agree with Morocco that this information does not fit well in the section about review of vessel records. Move to Histamine testing section (see comment in section X.2.4).  Category: SUBSTANTIVE	
X.2.2 Temperature monitoring		
• Fish internal temperatures should be measured at reception to help ensure that fish were properly	stored onboard the fishing and transfer vessel.	
• Fish internal temperatures should be measured at reception to help ensure provide confidence that fish were properly stored onboard the fishing and transfer vessel, and that the reception temperatures are met.	New Zealand Checking internal temperature will not ensure that vessel controls were properly implemented, but will provide a degree of confidence that that is the case.  Category: TECHNICAL	
internal temperature measurements. More fish should be monitored when the quantity or distribution of ice appears inadequate. Temperatures near the surface of exposed un-iced portions should be measured, as well as deep core temperatures of the fish, to ensure all edible portions of the fish are taken into consideration in the assessment.		
• For fish stored in ice, the adequacy of ice surrounding the fish should also be observed and recorded at the time of offloading the fishing vessel, along with internal temperature measurements. More fish should be monitored when the quantity or distribution of ice appears inadequate. Temperatures near the surface of exposed un-iced portions should be measured, as well as deep core temperatures of the fish, to ensure all edible portions of the fish are taken into consideration in the assessment.	USA  "Also" is redundant with "along with internal temperature measurements."  Category: EDITORIAL	
• Fish should be randomly selected from throughout the fishing vessel delivery lot. The number of fish temperatures monitored and recorded should be sufficient to provide reasonable assurance that temperatures appeared to be controlled by the vessel crew. Variations in species, morphologies, and sizes of fish should be considered and captured in the selection of fish monitored for temperature.		
• Fish should be randomly selected from throughout the fishing vessel delivery lot. The number of fish temperatures monitored and <u>results</u> recorded should be sufficient to provide reasonable assurance that <u>the</u> temperatures appeared to be controlled by the vessel crew. Variations in species, morphologies, and sizes of fish should be considered and captured in the selection of fish monitored for temperature taken into account when taking samples.	New Zealand Category: EDITORIAL	
• If an internal temperature in a sample fish exceeds 4°C, then the entire fishing vessel delivery lot should be considered at risk. Higher temperatures usually correspond to higher histamine risk, however, higher deep core temperatures may need to be accounted for when larger fish have been delivered soon after harvest such that the core temperatures have not yet chilled to 4°C or below despite implementation of appropriate chilling procedures. Cooling curves based on studies applicable to the specific fishing sector are useful to ascertain proper temperature critical limits for fish at receiving in these circumstances. If a		

SPECIFIC COMMENTS	
Section / paragraph	Member/Observer/rationale
deviation from the temperature critical limits occurs, the cause should be determined and corrected lot rejected.	, and intensified histamine testing performed, or the vessel
Edit the first sentence as follows: "Sensory evaluation of fish at reception involves a sensory evaluation to determine fish quality to determine the sensory quality of fish. Neither"  Replace "reliable" with "compliant."  Delete "or histamine testing," then the paragraph reads: "Therefore, sensory evaluation should not be used as the only or final assurance that the histamine level is acceptable, and compliant vessel control records, along with temperature monitoring, should be part of a complete receiving control system."	Morocco Category: TECHNICAL
• If an internal temperature in a sample fish exceeds 4°C, then the entire fishing-vessel delivery lot should be considered at risk. Higher, as higher temperatures usually correspond to higher histamine risk. However, however, higher deep core-internal temperatures may need to be accounted allowed for when larger in fish that have been delivered soon after harvest such that the core temperatures and have not yet chilled to 4°C or below despite implementation of appropriate chilling procedures. Cooling curves based on studies applicable to the specific fishing sector are useful to ascertain proper temperature critical limits for fish at receiving reception temperatures in these circumstances. If a deviation from the established fish reception temperature critical limits occurs exceeded, the cause should be determined and corrected, and intensified histamine testing performed, or the vessel lot rejected.	New Zealand Category: EDITORIAL
• If an internal temperature in a sample fish exceeds 4°C, then the entire fishing vessel delivery lot should be considered at risk. Higher temperatures usually correspond to higher histamine risk, however, higher deep core temperatures may need to be accounted for when larger fish have been delivered soon after harvest such that the core temperatures have not yet chilled to 4°C or below despite implementation of appropriate chilling procedures. Cooling curves based on studies applicable to the specific fishing sector are useful to ascertain proper temperature critical limits for fish at receiving in these circumstances. If a deviation from the temperature critical limits occurs, the cause should be determined and corrected, and intensified histamine testing performed, or the vessel lot rejected.	Per previous comment, concept moved to the previous (4th) bullet for a better fit.  Category: EDITORIAL / SUBSTANTIVE
• Fish on the vessel should be stored at a temmperature as close as possible to 0°C (4°C or below). If an internal temperature in a sample fish exceeds 4°C, (or the target temperature based on elapsed time from death and the prevention of histamine formation), then this indicates a lapse in histamine control. The cause of the deviation should be determined and corrected, and intensified histamine testing of the entire fishing-vessel delivery lot should be considered at risk. performed, or the delivery rejected. Higher temperatures usually correspond to higher histamine risk, however, higher deep core temperatures may need to be accounted for when larger fish have been delivered soon after harvest such that the core temperatures have not yet chilled to 4°C or below despite implementation of appropriate chilling procedures. Cooling curves based on studies applicable to the specific fishing sector are useful to ascertain proper temperature critical limits for fish at receiving in these circumstances. If a deviation from the temperature critical limits occurs, the cause should be determined and corrected, and intensified histamine testing performed, or the vessel lot rejected.	To clarify how a temperature deviation is indicative of loss of control and greater risk of elevated histamine. The second line was moved up from the following bullet for a better fit. Added text about this applying to fish expected to have a temperature of 4°C or below to account for recently caught fish that are in the process of being chilled.  Category: SUBSTANTIVE
X.2.3 Sensory evaluation	

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
• Fish for sensory evaluation should be chosen randomly from throughout the fishing vessel delivery lot. Deliveries of multiple species with different compositions, morphologies, and sizes should be taken into account in the sampling strategy. It may be appropriate to select more fish from portions of the delivery identified by vessel records or temperature examination to be at greater risk for histamine formation.		
• Fish for sensory evaluation should be chosen randomly from throughout the fishing vessel delivery lot.  Deliveries of multiple species with different compositions, morphologies, and sizes should be taken into account in the sampling strategyplan. It may be appropriate to select more fish from portions of the delivery lot identified by the reception checks, vessel records or temperature examination to be at greater risk for histamine formation.	New Zealand  Category: EDITORIAL	
• The number of fish examined should be sufficient to provide assurance that the fishing vessel crew appear to have been vigilant about time-temperature exposures of the fish. The number of samples should be increased when conditions or fishing methods are more likely to introduce variable time-temperature exposures of fish, e.g. longlining, unusually warm weather, unusually large catch size, limited remaining ice, etc.		
Delete the following: "that the entire vessel lot is at risk for elevated histamine" and "time-temperature,"	Morocco	
	Category: SUBSTANTIVE	
• The number of fish examined should be sufficient to provide assurance that the fishing-vessel crew appear to have been vigilant about time-temperature exposures of the fish. The number of samples taken should be increased when conditions or fishing methods are more likely to introduce variable time-temperature exposures of fish, e.g. longlining, unusually warm weather, unusually large catch size, limited remaining ice, etc.	New Zealand Category: EDITORIAL	
• If sensory evidence of decomposition is detected at reception, it indicates that controls on the fishing vessel may be inadequate and that the entire vessel lot is at risk for elevated histamine. The cause of the decomposition should be determined and the necessary procedural corrections, or equipment repairs, verified. It is justifiable to reject the entire delivery based on inadequate time-temperature control; however, if further evaluation is used to determine if some of the fish are suitable for human consumption, then intensified histamine sampling and testing should be performed on the delivery. The testing should also include the decomposed fish to determine if the decomposition was conducive to histamine formation.		
Delete the following: "that the entire vessel lot is at risk for elevated histamine" and "time-temperature,"	Morocco	
	Category: SUBSTANTIVE	
• If sensory evidence of decomposition is detected at reception, it indicates that controls on the fishing-vessel may be-have been inadequate and that the entire vessel lot is at risk for elevated histamine. The cause of the decomposition should be determined and the necessary procedural correctionschanges, and improvements to facilities or equipment repairsequipment, verified. It If there is justifiable to reject the entire delivery based on evidence of inadequate time-temperature control; however, if further evaluation is can be used to determine if some of the fish are suitable for human consumption, then intensified. Intensified histamine sampling and testing should be performed on the delivery. The testing should also include the decomposed of at risk fish to determine if the decomposition was conducive to histamine formation can be performed on the delivery (Refer to Section X.2.4 Histamine testing).	New Zealand Category: EDITORIAL	
X.2.4 Histamine testing		

#### **SPECIFIC COMMENTS**

Section / paragraph

Member/Observer/rationale

When a fishing vessel delivering fish has implemented a histamine control system based on HACCP principles, and review of vessel records is one of the controls used by the receiving establishment, then histamine testing is only used as a periodic verification procedure to assess if the vessel control system is adequate and working properly. The number and frequency of the verification tests carried out depend on the number of vessel suppliers and the type of fishery from which the receiving establishment receives fish. If verification test results signal potential lapses in care of the fish, then the frequency of verification testing should be increased until testing and other evidence suggest that the vessel operators have implemented effective corrective measures (e.g. a series of consecutive problem-free deliveries).

When a fishing vessel delivering fish has implemented a histamine control system based on HACCP principles, and review of **fishing** vessel records is **used as** one of

the <u>histamine</u> controls <u>used</u> by <u>the a</u> receiving establishment, then histamine testing <u>is only used should</u> <u>be performed periodically</u> as a <u>periodic-verification procedure to assess if that</u> the <u>vessel-control</u> system is <u>adequate and working properlycontinuing to work effectively</u>. The number and frequency of the verification tests <u>carried out depend should be dependent</u> on the number of vessel suppliers and the type of fishery from which the receiving establishment receives fish. If <u>verification test results signal</u> potential lapses in care of the fish, then the frequency of verification testing should be increased until testing and other evidence suggest that the vessel operators have implemented effective corrective measures (e.g., a series of consecutive problem-free deliveries).

· When fishing vessel records are inadequate, or when past histamine test results from the vessel signal potential lapses in care of the fish, then risk-based sampling should be applied to future deliveries from that vessel until testing and other evidence suggest that the vessel operators have implemented effective corrective measures (e.g., a series of consecutive problem-free deliveries).

Add to the beginning of the paragraph "For vessels with freezing equipment:"

When a fishing vessel delivering fish has implemented a If histamine control system based is implemented on HACCP principles, and review of a fishing vessel records is one of and the reception checks give confidence that vessel histamine controls used by the receiving establishmentare effective, then is is sufficient that histamine testing is enly used as a periodic verification procedure to assess if the vessel control system is adequate and working properlyprocedure. The number and frequency of the verification tests carried out depend on the number of vessel suppliers and the type of fishery from which the receiving establishment receives fish. If verification test results signal potential lapses in care of the fishindicate elevated histamine levels, then the frequency of verification testing should be increased until testing results and other evidence suggest that the vessel operators have control systems are being effectively implemented effective corrective measures (e.g. a series of consecutive problem-free deliveries).

#### Canada

The text used in the previous draft version (that did not include HACCP terminology) was better and we suggest reverting to it.

Rationale: We find that the new text uses HACCP language that is not consistent with some of the concepts currently discussed in the revision of the "General Principles of Food Hygiene (GPFH) and its annex on HACCP". The new text dictates histamine testing as a CCP at receiving when the fishing vessel is not following HACCP or HACCP-based controls, and "only" has GHPs. As discussed while working on the revision of the GPFH and HACCP, CCPs are not control measures but steps at which control measures are applied. Also, lot by lot testing to determine acceptability of the product is typically not in line with the HACCP approach, so it is confusing to see it being recommended as a "CCP".

Category: SUBSTANTIVE

Morocco

Category: SUBSTANTIVE

#### **New Zealand**

Simplify the wording. If the histamine controls, whether HACCP or GMP based are effective, histamine testing should be used for verification.

Category: TECHNICAL

When a fishing vessel delivering fish uses GMPs, but has not implemented a histamine control system based on HACCP principles using monitoring and establishing its records that provide assurance and evidence of control, then histamine testing becomes a critical control point at reception rather than a

SPECIFIC COMMENTS	
Section / paragraph	Member/Observer/rationale
verification procedure, and testing should be applied to every vessel delivery lot. If histamine levels do not meet the required limit, the vessel should be noti and the cause determined and corrected. In addition, the affected fishing vessel delivery lot should be rejected.	
Define the GMP acronym in the first sentence.  The text used in the previous draft version (that did not include HACCP terminology) was better and we suggest reverting to it.	Canada  We find that the new text uses HACCP language that is not consistent with some of the concepts currently discussed in the revision of the "General Principles of Food Hygiene (GPFH) and its annex on HACCP". The new text dictates histamine testing as a CCP at receiving when the fishing vessel is not following HACCP or HACCP-based controls, and "only" has GHPs. As discussed while working on the revision of the GPFH and HACCP, CCPs are not control measures but steps at which control measures are applied. Also, lot by lot testing to determine acceptability of the product is typically not in line with the HACCP approach, so it is confusing to see it being recommended as a "CCP"  Category: SUBSTANTIVE
Add to the beginning of the paragraph: "* For fishing vessels with refrigeration equipment:"  Delete ", but has not implemented a histamine control system based on HACCP principles using monitoring and establishing."  Edit the sentence at the end of the paragraph as follows: "In addition, the affected fishing vessel delivery lot with non-compliant receiving tests should be rejected."	Morocco Category: EDITORIAL
When If a fishing vessel delivering fish uses GMPs, but has not implemented a histamine control system based on HACCP principles using including monitoring and establishing its records that provide assurance and evidence of control, then histamine testing becomes a critical control point at reception rather than a verification procedure, and testing should be applied to every vessel delivery lot. However, histamine testing can be less reliable because histamine may be unevenly distributed within and between fish, and fish with high histamine are difficult to find using limited or small sample sizes. Sampling and testing that is statistically meaningful in terms of appropriate consumer protections can be resource intensive.	New Zealand This bullet can then address those operations that don't implement adequate histamine controls.  Category: TECHNICAL
If histamine levels do not meet exceed the required-limit, the vessel should be notified and the cause determined and corrected. In addition, the affected fishing vessel delivery lot should be rejected.  When a fishing vessel delivering fish uses GMPs, but has not implemented a histamine control system based on HACCP principles using monitoring and establishing its records record keeping that provide assurance and evidence of control, then histamine testing becomes a critical control point at reception an important monitoring procedure rather than a verification procedure, at the reception critical control point, and testing should be applied to every vessel delivery lot. If histamine levels do not meet the required limit, the vessel should be notified and the cause determined and corrected. In addition, the	USA  Paragraph moved here from "review of fishing vessel controls and records" section for a better fit.  Category: SUBSTANTIVE / EDITORIAL

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
affected fishing vessel delivery lot should be rejected.  Note that histamine testing can be less reliable than receipt of appropriate vessel control records because histamine may be unevenly distributed within and between fish, and fish with high histamine are difficult to find using limited or small sample sizes. Sampling and testing that is statistically meaningful in terms of appropriate consumer protection can be resource intensive. Histamine testing at fishing vessel reception is therefore best used as verification of the effectiveness of a properly implemented and documented histamine control system on the fishing vessel.  The histamine testing guidance in this subsection is also applicable to periodic verification of histamine.	mine controls used during later production, storage and	
transportation steps, as well as for testing to determine product disposition when critical limits are		
The histamine testing guidance in this subsection is <u>can</u> also <u>applicable</u> to <u>intensified</u> <u>sampling or</u> periodic verification of histamine controls used during later production, storage and transportation steps, as well as for testing to determine product disposition when critical limits are exceeded throughout the supply chain.	New Zealand Category: EDITORIAL	
X.2.4.1 Histamine testing, achievable histamine level		
Brazil understands that the numerical limits of histamine and the reference cited in this paragraph should be in a footnote. The way proposed in the text may be confusing, since this information is from a FAO / WHO report and was not based in a safety limit.	Brazil Category: SUBSTANTIVE	
Delete the section	Morocco	
	Category: SUBSTANTIVE	
• Freshly harvested scombrotoxin-forming fish typically have histamine levels below 2 mg/kg, and fachieve a histamine level lower than 15 mg/kg <sup>8</sup>	food business operators that apply HACCP principles can	
Delete this paragraph	Morocco	
	Category: SUBSTANTIVE	
• Freshly harvested scombrotoxin-forming fish typically have histamine levels below 2 mg/kg, and food	New Zealand	
business operators that apply HACCP principles histamine controls can achieve a histamine level lower than 15 mg/kg <sup>8</sup> .	Consider adding "in the final product after 15mg/kg so that it is clear ar which point this applies.	
	Category: TECHNICAL	
• Marginally elevated histamine levels indicate poor implementation of hygienic processes and histamine controls during harvest, chilling and/or on-vessel storage, and a significant risk that some fish in a lot will have unacceptable histamine levels.		
	New Zealand	
	To be helpful and indication what marginally elevated levels is needed.	
	Category: TECHNICAL	

SPECIFIC COMMENTS	
Section / paragraph	Member/Observer/rationale
<ul> <li>Marginally elevated histamine levels indicate poor implementation of hygienic processes and histamine controls during harvest, chilling and/or on-vessel storage, and a significant risk that some fish in a lot will have unacceptable histamine levels. In addition, they indicate that elevated levels of histamine decarboxylase are present that can contribute to more rapid histamine formation during exposure to elevated temperatures further along the food chain.</li> <li>Histamine achievable levels at vessel reception should be lower than the achievable levels in proception of histamine-forming enzymes, as evidenced by histamine levels approaching 15 mg/kg, it exposure to non-refrigerated temperatures during further processing and handling.</li> </ul>	
<u>Achievable h</u> Histamine achievable istamine levels at vessel reception should be lower than the achievable levels in product further along the distribution chain because chain. This is due to the presence of histamine-forming enzymes, as evidenced by which continue to produce histamine levels appreaching 15 mg/kg, is likely at a slow rate despite the use of proper temperature control measures or to result in additional increases increased histamine concentrations with time and exposure to non-refrigerated temperatures during further processing and handling.	Canada Category: EDITORIAL
Histamine achievable levels at vessel reception should be lower than the achievable levels in product further along the distribution chain because the presence of histamine-forming enzymes, as evidenced by histamine levels approaching 15 mg/kg, is likely to result in additional increases with time and exposure to non-refrigerated temperatures during further processing and handling.	Morocco Delete: "as evidenced by histamine levels approaching 15 mg/kg," Replace "achievable levels" with "achieved levels" Delete: "as evidenced by histamine levels approaching 15 mg/kg," Category: SUBSTANTIVE
Histamine achievable levels at vessel reception should be lower than the achievable levels Additional increases in product further along the distribution chain because the presence of histamine-forming enzymes, as evidenced by histamine levels approaching 15 mg/kg, is are likely to result in additional increases with time and exposure to non-refrigerated temperatures during further processing and handling.	New Zealand  Deletion as is repeating earlier statements.  Category: EDITORIAL
• <u>A</u> Histamine achievable <u>chievable</u> levels <u>of histamine</u> at vessel reception <u>should may</u> be lower than the achievable levels in product further along the distribution chain because the presence of histamine-forming enzymes, as evidenced by histamine levels approaching 15 mg/kg, is likely to result in additional increases with time and exposure to non-refrigerated temperatures during further processing and handling.	USA  Editorial and to further emphasize that it is not just the level of histamine ther emphasize that it is not just the level of histamine that is a concern, but also the high level of enzymes formed.  Category: EDITORIAL
X.2.4.2 Histamine testing, sampling strategies	
Delete this section because sampling plans will be discussed later	Morocco Category: SUBSTANTIVE

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
• Sampling plans for histamine should be selected based on statistical performance parameters to be effective. Statistical tables and computer programs provide the information needed to design a sampling plan based on the histamine limits, the degree of protection, and the confidence in results desired. The FAO/WHO Histamine Sampling Tool <sup>9</sup> is a useful application designed for this purpose.		
FAO/WHO Histamine Sampling Tool. Link:	European Union	
http://tools.fstools.org/histamine/ http://www.fstools.org/histamine/	The link in the footnote 9 should be corrected.	
	Category: EDITORIAL	
Sampling plans for <u>testing</u> histamine <u>levels</u> should be selected based on statistical	New Zealand	
performance parameters to be effective parameters. Statistical tables and computer programs can provide the information needed to design a sampling plan based on the histamine limits,	Category: TECHNICAL	
the degree of protection, and the confidence in results desired. The FAO/WHO Histamine Sampling		
Tool9https://ocs.codexalimentarius.org/Reports/ReviewerReconcileReport.aspx?reviewi		
<u>d=413&amp;reporttype=consolidatedftn7</u> is <del>a useful an example of an </del> application <del>designed that</del>		
is particularly useful for this purpose intensified sampling.		
• Determining sampling plan performance usually requires an estimate of the standard deviation of the level being measured. The standard deviation of the histamine levels can be estimated from the global data provided in the FAO/WHO Expert Report (Table 5.1) <sup>10</sup> , or it can be estimated when appropriate data have been collected, including worst case scenarios, at the receiving location.		
Determining sampling plan performance usually requires an estimate of the standard deviation of the	USA	
level being measured. The standard deviation of the histamine levels can be estimated from the global data provided in the FAO/WHO Expert Report (Table 5.1) 10, or it can be	Category: EDITORIAL	
estimated when after appropriate data have been collected, including worst case scenarios, at the		
receiving location.		
• Because histamine is distributed unevenly in lots (has a high standard deviation), hazardous fish are statistically difficult to find using small sample numbers. The FAO/WHO Expert Report (Section		
6.2.2.2) <sup>11</sup> https://ocs.codexalimentarius.org/Reports/ReviewerReconcileReport.aspx?reviewerReconcileReport.aspx.aspx.aspx.aspx.aspx.aspx.aspx.aspx		
using histamine accept/reject levels ("value for m") that are lower than the target acceptable limit in order to reduce the number of samples required to achieve a given level of confidence in the testing results.		
Because histamine is distributed unevenly in lots (has a high standard deviation), hazardous fish are	New Zealand	
statistically difficult to find using small sample numbers. The FAO/WHO Expert Report (Section	Category: EDITORIAL	
6.2.2.2) <sup>[9]</sup> suggests using histamine accept/reject levels ("value for m") that are lower than the target the acceptable limit in order to reduce the number of samples required to achieve a given level of		
confidence in the testing results.		
Samples taken should be representative of the lot.		
X.2.4.3 Histamine testing, analytical methods		

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
• It is best to test the raw fish material upon arrival from the fishing vessels, where individual loin sections can be identified. As the fish get processed into various market forms, or product from different vessel lots gets comingled, assessments of the suitability and safety of the fish from the individual fishing vessels becomes more difficult and less effective.		
<ul> <li>The part of the fish selected for testing will significantly affect the test results. It is best to test the raw fish material upon arrival from the fishing vessels, where in a form that individual loin sections can be identified. As the fish get processed into various market forms, or product from different vessel lots gets comingled, assessments of the suitability and safety of the fish from the individual fishing vessels becomes more difficult and less effective.</li> <li>The receiving establishment should confirm that the testing method used is properly validated for sampling and testing should receive training in the procedures used.</li> </ul>	New Zealand  Moved from bullet 4.  Category: EDITORIAL  the detection limits used. The staff responsible for the	
Delete "properly"	Morocco	
Delete "for the detection limits used."	Category: SUBSTANTIVE	
• The receiving establishment should confirm that the testing method used is should be properly	New Zealand	
validated for the detection limits used. The staff responsible for the sampling and testing-should receive training in the procedures used.	The laboratory is responsible for ensuring they have a valid test method and trained staff.	
	Category: TECHNICAL	
• The part of the fish selected for testing will significantly affect the test results. Test portions should because that area has the highest probability of elevated histamine in abused raw fish. Sufficient re should be collected to prepare for analysis. For smaller fish, in addition to the lower anterior loin pollower loin, in that order, can also be collected, and for very small fish, multiple fish may need to be muscle (e.g. approximately 250 grams). The entire sample unit should be thoroughly blended so that representative of the entire sample unit.	epresentation (e.g. approximately 250 grams) of fish muscle, ortion, the upper anterior loin, and the mid-section of the collected to acquire a representative sample unit of fish	
• The part of the fish selected for testing will significantly affect the test results. Test portions should be	Canada	
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 (e.g. approximately 250 grams) of fish muscle, should be collected to prepare for analysis. 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, and for very small fish, multiple fish may need to be collected to acquire a representative sample unit of fish muscle (e.g. approximately 250 grams). The entire sample unit should be thoroughly blended so that the smaller aliquot used for the analytical method is representative of the entire sample unit.	We suggest splitting the recommendation in two sentences.  Category: EDITORIAL	
Edit the second sentence as follows: "Sufficient representation of fish muscle should be collected to	Morocco	
prepare for analysis (e.g. approximately 250 grams)."	Category: TRANSLATION	
• The part of the fish selected for testing will significantly affect the test results. Test portions should be	New Zealand	
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 (e.g. approximately 250 grams) of fish muscle, should be collected to prepare for analysis. For smaller fish, in addition to the lower anterior loin	Move under first bullet.	
	Category: EDITORIAL	

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
portion, the upper anterior loin, and the mid-section of the lower loin, in that order, can also be collected, and for very small fish, multiple fish may need to be collected to acquire a representative sample unit of fish muscle (e.g. approximately 250 grams). The entire sample unit should be thoroughly blended so that the smaller aliquot used for the analytical method is representative of the entire sample unit.		
<ul> <li>The part of the fish selected for testing will can 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 (e.g. appreximately 100 - 250 grams) of fish muscle, should be collected to prepare for analysis. 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, and for very small fish, multiple fish may need to be collected to acquire a representative sample unit of fish muscle (e.gmuscle). appreximately 250 grams). The entire sample unit should be thoroughly blended so that the smaller aliquot used for the analytical method is representative of the entire sample unit.</li> <li>To screen deliveries more economically, sample units from different fish can be optionally combinanalyses required, provided that the histamine level critical limit is lowered proportionately. For exa sample units, a portion (e.g. 100 grams from each of the 250 gram ground units) can be further blend analysis. In this case, the critical limit must be divided by 3 in order to ensure detection of one unit of the lower critical limit is exceeded, further analysis of the retained individually ground portions from the performed to determine if any sample unit exceeds the non-composited critical limit. Note, the ablowest histamine level that is accurately quantified by the analytical method in use.</li> <li>To screen deliveries more economically, sample units from different fish can be optionally combined (composite sample) to reduce the number of histamine analyses required, provided that the histamine level critical limit is lowered proportionately. For example, after independently grinding each of 3 individual sample units, a pertion (e.g. 100 grams from each of the 250 gram ground units) can be further blended together and used for a single composite sample analysis. In this case, the critical limit must be</li></ul>	mple, after independently grinding each of 3 individual ded together and used for a single composite sample exceeding the critical limit within the composite sample. If a each of the 3 sample units making up the composite may	
the non-composited critical limit. Note, the ability to composite multiple sample units is limited by the lowest histamine level that is accurately quantified by the analytical method in use.		

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
multiple sample units is limited by the lowest histamine level that is accurately quantified by the analytical method in use.		
X.2.5 Monitoring records (receiving establishment)		
X.2.5 Monitoring and records (receiving establishment)	New Zealand	
	Section covers both monitoring and records.	
	Category: TECHNICAL	
☐ Histamine control records should be maintained at the receiving establishment for trace-back to along the distribution chain.	possible causes if elevated histamine is discovered further	
Delete "histamine control"	Morocco	
	Category: EDITORIAL	
• Relevant information about vessel delivery lot (e.g. vessel name and type, captain's name, date loaded)	time of offloading, type and volume (weight) of fish off-	
Relevant information about vessel delivery lot (e.g. vessel name and typeidentifer, captain's	New Zealand	
name, date/time of offloading, type and volume (weight) of fish off-loaded)	Category: EDITORIAL	
Copies of the fishing vessel's monitoring records that were reviewed (refer to Section X.1.5, Monito	oring records (fishing vessel)	
Copies of the any fishing vessel's monitoring records that were reviewed (refer to Section X.1.5,	New Zealand	
Monitoring records (fishing vessel)	Review of vessel histamine control records generall only needed if reception checks indicate a need to do so.	
	Category: TECHNICAL	
• If a temperature control critical limit is exceeded, the cause of the problem should be identified an affected lot may be rejected by the receiving personnel, or the receiver may perform intensified his the lot, and the lot rejected if any fish are over the histamine critical limit (See subsection X.2.4).	tamine analysis on representative fish collected throughout	
• If a the established fish reception temperature control critical limit is exceeded, the cause of the	New Zealand	
problem should be identified and corrected by the operator of the vehicle or vessel. The If the journey was such that temperature abuse leading to elevated histamine levels could have occured, the affected lot may be rejected by the receiving personnel, or the receiver may perform intensified histamine analysis on representative fish collected throughout the lot, and the lot rejected if any fish are over exceed the histamine critical limit (See (Refer to subsection X.2.4)4 Histamine testing).	The lot should be rejected or subject to intensified testing if there is reason to believe that there may be elevated histamine levels. In some cases this may not be the case.	
	Category: TECHNICAL	
<ul> <li>If the processing establishment is a secondary processor receiving product from a primary processor secondary processor should ensure that the primary processor uses HACCP or a similar control shistamine.</li> </ul>		
The notion of similar control system is not defined in the document; a receiving establishment or a factory	European Union	
vessel should have in place a control system based on HACCP.		

SPECIFIC COMMENTS	
Section / paragraph	Member/Observer/rationale
• If the processing establishment is a secondary processor receiving product from a primary processor (e.g. receiving establishment or factory vessel), then the secondary processor should ensure confirm that the primary processor uses HACCP principles or a similar control system designed to prevent minimise formation of hazardous unacceptable levels of histamine.	New Zealand Category: EDITORIAL
• When it is impractical for the initial receiving establishment to conduct all the appropriate histami review, temperature monitoring, sensory evaluation, and histamine testing), then the processing establishment that the controls and decisions are applied to intact fishing vessel lots that are not comingle adequacy of ice, where applicable) should always be monitored at vessel delivery (to evaluate vessel valuate transport control).	stablishment should conduct these activities, and should ed with other lots. However, fish internal temperatures (and
Replace "When it is impractical for the initial receiving establishment to conduct all the appropriate	Morocco
histamine controls listed in subsection X.2" with "When the initial receiving establishment has not conducted conducted all the appropriate histamine controls listed in subsection X.2."	Category: EDITORIAL
When it is impractical for the initial receiving establishment to conduct all	New Zealand
the appropriate necessary histamine checks and controls listed in subsection X.2 (i.e. vessel records review, temperature monitoring, sensory evaluation, and histamine testing), then the processing establishment should conduct these activities, and should ensure that where practical, the controls and decisions are applied to intact fishing vessel lots that are not comingled with other lots. However, fish internal temperatures (and adequacy of ice, where applicable) should always be monitored at vessel delivery (to evaluate vessel control), as well as at the processing establishment (to evaluate transport control).	The necessary reception checks and controls will depend on the operation and procedures in place. Not all controls listed in X.2 will be necessary in all cases. It is also only when the necessary checks cannot be completed by the receiver that these would need instead to be carried out by the processor.  Temperature checks on vessel reception are covered under x.2.5. so do not need to be repeated here.
If lots are co-mingled and there may be unacceptable levels of histamine in fish, the entire lot must be considered when making decisions on diposition.	Category: TECHNICAL
X.4.2 Processing, time and temperature control	
Delete "time and temperature control."	Morocco
	Category: SUBSTANTIVE
When fish undergo processing (e.g. thawing, cutting, re-chilling, salting, drying, pickling, smoking, temperatures for sufficient time that histamine-producing bacteria can grow and produce histamine	
When fish undergo processing (e.g., thawing, cutting, re-chilling, salting, drying, pickling, smoking,	Canada
canning) it is important that they are not held at temperatures for sufficient subjected to	We suggest the following modifications for clarity.
<u>temperature</u> time <u>that-conditions where</u> histamine-producing bacteria can grow and produce histamine to hazardous levels.	Category: EDITORIAL
When fish undergo processing (e.g. thawing, cutting, re-chilling, salting, drying,	New Zealand
pickling, <b>cooking</b> , smoking, canning) it is important that they are not held at temperatures for sufficient time that histamine-producing bacteria can grow and produce histamine to hazardous unacceptable levels.	Category: EDITORIAL

		SPECIFIC COMMENTS
server/rationale		Section / paragraph
		• Histamine formation is quite variable and strongly depends on the previous handling of the raw r bacteria that are present; therefore, the worst case scenario should be considered when establish
		Delete this paragraph
DITORIAL		
1		• Histamine formation is quite variable and strongly depends on the previous handling of the raw material and the different species of histamine-producing bacteria that are present; therefore, the worst case scenario should be considered when establishing <a href="mailto:any.critical.limits">any.critical.limits</a> .
sing critical limits.	case	
ECHNICAL.		
ke into consideration any further handling,		• The acceptable maximum histamine level used to establish processing time-temperature critical processing, storage, and preparation that may lead to further histamine formation before consumptions.
		Delete this paragraph.
DITORIAL		
1		• The acceptable maximum histamine level used to establish processing time-temperature eritical
CHNICAL		limits parameters should take into consideration the point in the supply chain and any further handling processing, storage, and preparation that may lead to further histamine formation before consumption.
mperature exposure over all processing steps.	non-refriger	• The measure used for time-temperature critical limits should be the cumulative product non-refri
		Delete this paragraph.
DITORIAL		
1		• The measure used for time-temperature critical limits maximum exposure to detrimental times and
ay not be managed as critical limits. This is more anaged under GMP.		<u>temperatures</u> should be the cumulative product non-refrigerated time-temperature exposure over all processing steps.
CHNICAL		
		• Controlled product flow and batch monitoring is an effective strategy to ensure product is not example, periodically measure the ambient temperature and the time for a marked batch to begin a
	ires."	Delete "effective to ensure product is not subjected to unacceptable time-temperature exposures."
DITORIAL		
		• When time-temperature critical limits are exceeded, the cause should be determined and corrected performed (see section X.2.4.2) before releasing affected product for human consumption. Alternative
i		When time-temperature critical limits are exceeded, the cause should be determined and
CHNICAL		corrected. Procedures should be reviewed where necessary to ensure that the problem does not recur. In addition, intensified histamine testing should be performed (see section X.2.4.2) before releasing affected product for human consumption. Alternatively, product should be rejected.
		X.4.3 Heat processing
		asing affected product for human consumption. Alternatively, product should be rejected.

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
• Adequate heat treatment (e.g. cooking, hot smoking) can kill histamine-producing bacteria and inactivate probably the most heat resistant of the histamine-producing bacteria, and in Australian salmon/ kahawai at these bacteria and their associated HDC enzymes were between 15 and 1.5 minutes (FAO/WHO 2012).		
• Adequate heat treatment (e.g. cooking, hot smoking) can kill histamine-producing bacteria and inactivate histidine decarboxylase enzymes.—. Morganella morganii is probably the most heat resistant of the histamine-producing bacteria, and in Australian salmon/ kahawai at temperatures between 58 and 62°C, the D-values for eliminating these bacteria and their associated HDC enzymes were between 15 and 1.5 minutes (FAO/WHO 2012).	Brazil  Transfer the deleted sentence to a footnote, since although it is a reference for checking the heat treatment parameter, it is very specific for a fish type and uses a bacterium that "may be" the most thermally resistant. Therefore, it is a measure fraught with uncertainties.  Category: SUBSTANTIVE	
Replace "/ kahawai" with "(Kahawai)."	Morocco	
	Category: TECHNICAL	
• Adequate heat treatment (e.g. cooking, hot smoking) can kill histamine-producing bacteria and inactivate histidine decarboxylase enzymes. <i>Morganella morganii</i> is probably the most heat resistant of the histamine-producing bacteria, and in Australian salmon/kahawai (Arriis trutta) at temperatures between 58 and 62°C, the D-values for eliminating these bacteria and their associated HDC enzymes were between 15 and 1.5 minutes (FAO/WHO 2012).	USA  The fish "Australian salmon/ kahawai" is not a true salmon, nor a member of the Salmonidae family. Suggest referring to the fish by its scientific name – Arripis trutta – to clarify that it is not a salmon. Including a reference to salmon in the code of practice will suggest that salmon are prone to histamine formation.	
	Category: SUBSTANTIVE	
• Once formed, however, histamine itself is heat stable and is not destroyed by heat. Therefore, hist prior to thermal processing, are critical to prevent inclusion of previously formed histamine in the fi		
• Once formed, however, histamine itself is heat stable and is not destroyed by heat. Therefore, histamine	Canada	
controls during harvesting, and during other steps prior to thermal processing, are critical to prevent inclusion of previously formed minimize the presence of histamine in the finished product.	Category: EDITORIAL	
Delete "during harvesting and"  The entire sentence reads as follows: "Therefore histamine controls during other steps prior to thermal processing."	Morocco Category: SUBSTANTIVE	
• For commercially sterile canned or pouched products, the container protects the product from back when stored at ambient temperatures. However, once the product package is opened, histamine for the absence of preventative time-temperature controls.		
• For commercially sterile canned or pouched products products in consumer ready packaging, the	New Zealand	
container protects the product from bacterial recontamination, and no further histamine is produced when stored at ambient temperatures. However, once the product package is opened, histamine formation can occur again if the product is recontaminated in the absence of preventative time-temperature controls.	That is, product that is not repackaged prior to sale.  Category: TECHNICAL	

SPECIFIC COMMENTS		
Section / paragraph	Member/Observer/rationale	
X.4.4 Processing, other technological measures		
Time and temperature control is the recommended method for preventing histamine formation in fr	esh, frozen, and refrigerated processed fish products.	
Delete this paragraph	Morocco	
	Category: EDITORIAL	
The safe application of any of these treatments is dependent on the rapid chilling and maintenance of death of the fish until the proper inhibitory or destructive control attributes contributed by the treatment, the finished product may need to remain chilled until consumed to ensure safety.		
The safe application success of any of these treatments is dependent on the rapid chilling and	Canada	
maintenance of chilled temperatures of the raw fish material from the time of death of the fish-until the proper-inhibitory or destructive control attributes contributed by effects from the treatments have	We propose a modification because the paragraph is not clear.	
been are achieved. And addition, depending on the treatment, the finished product may need to	Category: EDITORIAL	
remain chilled until consumed to ensure safety.		
Refer to Section X.1.4 Refrigerated and frozen storage (fishing vessel).		
• Refer to Section X.1.4 Refrigerated and frozen storage (fishing vessel and transfer vessel).	New Zealand	
	Category: EDITORIAL	
<ul> <li>For products whose preparation does not include a heating step or other means to eliminate hista histamine-producing bacteria means that refrigerated storage will continue to be a critical control p shelf-life of the products until consumed.</li> </ul>		
• For products whose preparation does not include a heating step or other means to eliminate histamine-	Canada	
producing bacteria and their enzymes, the presence of histamine-producing bacteria means	We propose a modification to simplify the sentence.	
that-refrigerated storage will continue to be a critical control point for the inhibition of to prevent histamine formation throughout the shelf-life of the products until consumed products.	Category: EDITORIAL	
X.4.6 Monitoring records (processing establishment)		
Transport vehicle or transport vessel temperature log or adequacy of ice, and fish internal temperature	tures	
Delete this paragraph.	Morocco	
	Category: SUBSTANTIVE	
Transport vehicle or transport-vessel temperature log-records or adequacy of ice, and fish internal temperatures	New Zealand	
	Category: EDITORIAL	
The processing facility should use histamine testing to periodically verify that histamine controls a	re working properly (Refer to section X.2.4).	
The processing facility should use histamine testing to periodically verify that histamine controls are working properly (Refer to section X.2.4)4 Histamine testing).	New Zealand	
	Category: EDITORIAL	