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World Health Organization

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Agenda Item 5 **CX/FH 17/49/6**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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

PROPOSED DRAFT GUIDANCE FOR HISTAMINE CONTROL IN THE *CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS* (CAC/RCP 52-2003)

Prepared by the Electronic Working Group led by Japan and the United States of America

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL 2017/70-FH available on the Codex webpage/Circular Letters 2017:

http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/. Comments will only be accepted through the online commenting system within the deadline indicated in CL 2017/70-FH.

Background

1. During the 48th Session of the Committee on Food Hygiene, the CCFH agreed to develop separate guidance on histamine control and to decide at a later stage on the final format in the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003)[1].

2. The Committee agreed to establish an electronic working group (EWG), co-chaired by Japan and the United States of America, working in English, with the following terms of reference:

a. Revise control guidance of the Code of Practice for Fish and Fishery Products for the "hazard of scombrotoxin fish poisoning", using histamine as the marker biogenic amine for control, and using a GHP and HACCP-based approach, for circulation for comments at Step 3.

b. Ensure that the guidance covers the entire food chain (harvesting, storage, handling, processing, and distribution).

c. Include, where appropriate, scientific information about histamine formation with the purpose of informing on the importance of time/temperature controls.

d. Consider if any products covered by the Code of Practice for Fish and Fishery Products need specialized or revised control guidance.

e. Consider based on the review of scientific literature by FAO/WHO, the inclusion of Salmonidae in the list of susceptible species in the table which will be adopted from the FAO/WHO Table 2.3[2].

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3. 28 member countries (Argentina, Australia, Brazil, Canada, Chile, China, Costa Rica, Ecuador, France, Germany, India, Japan, Malaysia, Morocco, Mexico, New Zealand, Norway, Peru, Philippines, Poland, Portugal, Singapore, Spain, Switzerland, Thailand, United Kingdom, United States, and Uruguay), one member organization (European Union) and three international organizations (FAO, WHO and ICMSF), and one NGO (NHF) participated in the EWG. A complete list of participants is attached as Appendix II.

4. The proposed draft document was initially drafted by the co-chairs, circulated twice for participant comments, and revised twice based on comments received.

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[1] Code of Practice for Fish and Fishery Products. Link ftp://ftp.fao.org/codex/Publications/Booklets/Practice_code_fish/CCFFP_2012_EN.pdf

[2] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome. Link: http://www.fao.org/fileadmin/user_upload/agns/pdf/Histamine/Histamine_AdHocfinal.pdf

5. The EWG did not consider Item d in the terms of reference ("Consider if any products covered by the Code of Practice for Fish and Fishery Products need specialized or revised control guidance"). This item may be better considered when aligning the existing Code with the draft section.

6. The following were significant EWG discussion points:

7. One participant commented that all content relating to the application of HACCP principles on fishing vessels should be removed from the document. In their viewpoint, fishing vessels in developing countries only box and ice fish and these are primary production activities that should be excluded. And, that the FAO/WHO Expert Meeting concluded that histamine formation and SFP can be easily controlled, and the risk from SFP is best mitigated by applying basic GHPs and, where feasible, a HACCP system. In response to these comments, several changes were made to clarify that the draft guidance applies to vessels that use basic GMPs, and to vessels that use basic GMPs and HACCP systems. The Draft recommends that when establishments receive fish from vessels that apply basic GMPs without a HACCP system (i.e. without a documented structure and monitoring records), then the receiving establishment should monitor histamine levels in the fish.

8. Several participants asked about the relationship between draft section X.2.4 (Histamine testing), and the work to be done later on sampling guidance. It was discussed that the later work was a revision of eleven Codex commodity standards that contain histamine safety limits, and that these standards were determined by CCFFP to have inconsistent, and possibly inadequate, sampling guidance for determining compliance of lots in trade with the histamine safety limit listed in the standard. *The Code of Practice for Fish and Fishery Products* serves a different purpose and contains guidance for producers on how to produce safe products with acceptable quality that will meet the end-product requirements of the Codex commodity standards.

9. One participant asked where the new histamine section would fit in the code. It was discussed that the proposed draft was designed to be a separate section within the Code, and that it is analogous to existing sections because it covers a subset of fish and fishery products, and contains control guidance at production steps. It was noted that the Introduction to the Code (How to use this Code) explains the aim and layout of the Code, and that the Proposed Draft can be added within sections 10-19 (Processing of specific fish and shellfish products).

10. One participant recommended revising an existing section of the adopted Code in order to reference the proposed draft section. It was discussed that significant editing to several sections of the existing Code will be required in order to reference the proposed draft section and to assure alignment of the existing guidance with the new guidance, and that work on aligning the existing Code should not begin until it is agreed to advance the proposed new section forward.

11. Several participants asked if the EWG was considering inclusion of Salmonidae in the table of at-risk species as listed in the terms of reference. It was noted that the FAO/WHO review was not completed, and inclusion of salmon, and the title of the table, would need to be considered after completion of the FAO/WHO review.

Recommendations

12. The working group recommends that the Committee:

a. Consider advancing the proposed draft (Appendix I) as a new section in the Code.

b. Consider when to begin an EWG for aligning the existing Code with the draft new section, taking into consideration that this work may lead to significant revisions of the adopted Code, and that it will rely on overall CCFH agreement on the content of the draft new section.

c. 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).

Appendix I

PROPOSED DRAFT REVISION OF THE *CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS* (CAC/RCP 52-2003)
NEW SECTION [X] FOR FISH AT RISK FOR SCOMBROTOXIN FORMATION

(for comments at Step 3 through https://ocs.codexalimentarius.org)

SECTION [X] – HARVESTING, PROCESSING, STORAGE AND DISTRIBUTION OF FISH AND FISHERY PRODUCTS AT RISK FOR SCOMBROTOXIN (HISTAMINE) FORMATION

Preamble

This section complements other sections of the Code by providing detailed control recommendations for the prevention of scombrotoxin fish poisoning (SFP). This section only applies to specific marine finfish species (listed in Annex [Z]) at risk of developing hazardous levels of histamine. This section contains specific guidelines for preventing SFP; however, within the scope of this Code, it is not possible to provide all the appropriate controls and alternatives that may apply to every operation because these will vary with each particular operation.

Scombrotoxin fish poisoning (SFP) is a worldwide food safety challenge that, in some parts of the world, accounts for the largest proportion of fish-borne illness cases. Individuals suffering from SFP may show one or more symptoms including flushing, swelling, rash, itching, headache, heart palpitations, abdominal cramps, diarrhoea, and vomiting. In some cases, exacerbation of asthma and more serious cardiac manifestations may occur. Symptoms typically develop rapidly (from 5 minutes to 2 hours after ingestion of implicated fish), with a usual duration of 8–12 hours, although symptoms may persist for up to several days. SFP is rarely fatal.

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.

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.

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 enzymes (HDC), which convert naturally present histidine into the toxic metabolite histamine.

Rapid multiplication of histamine-producing bacteria can be prevented by chilling fish immediately after death and maintaining the fish in a chilled, or frozen, state from harvest to consumption. However, once sufficient bacterial multiplication has occurred to produce histidine decarboxylase, enzymatic activity can continue to produce histamine slowly at refrigeration temperatures.

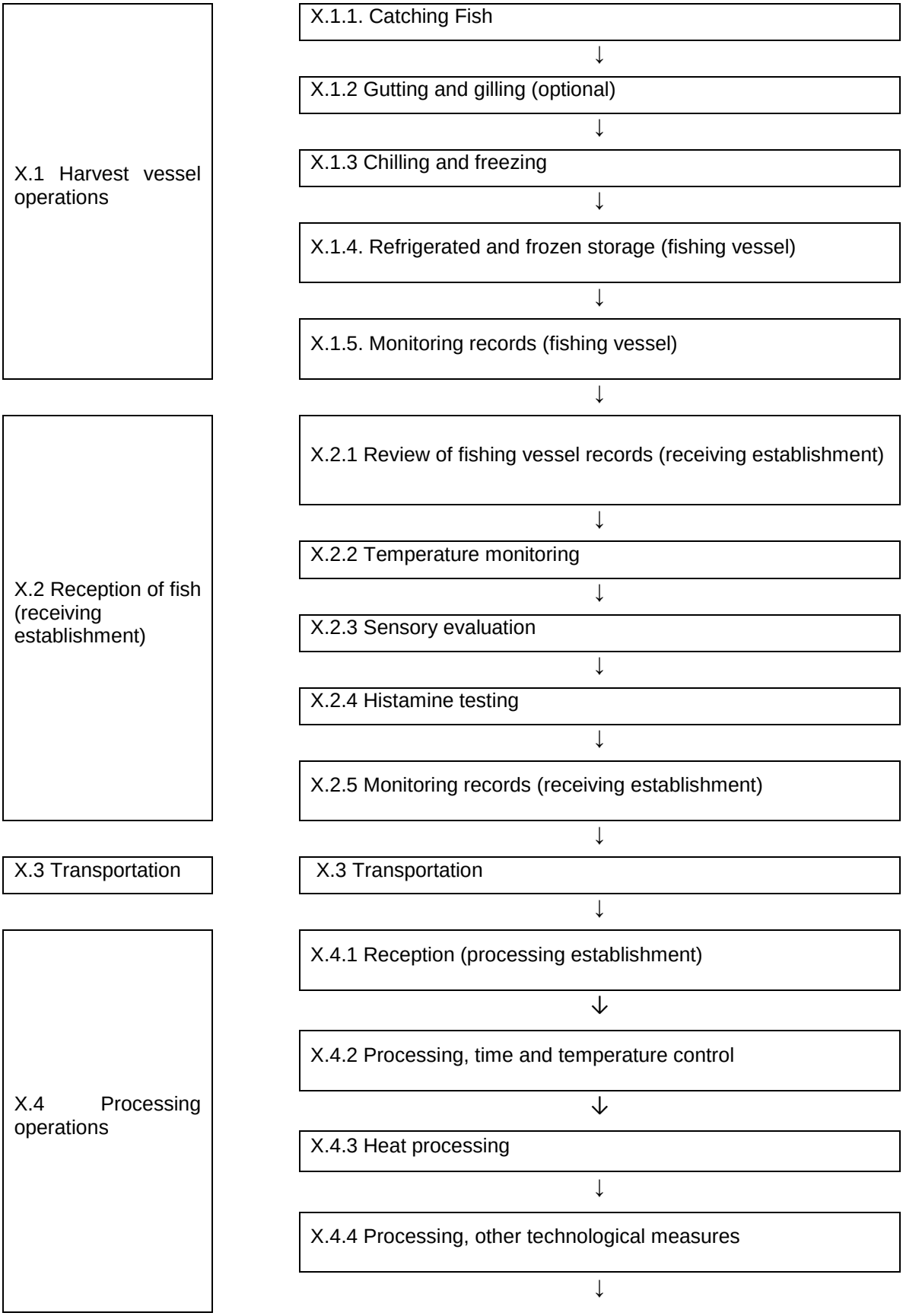
Histamine formation is effectively controlled by adherence to good manufacturing practices to maintain hygienic quality of fish, and by using HACCP principles to control detrimental fish time-temperature exposure.

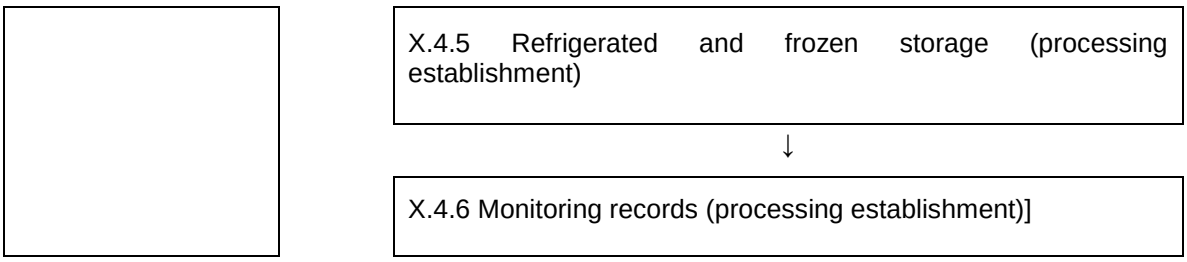
The following subsections contain technical guidance for the control of histamine formation at key steps in the food chain (harvesting, receiving, transportation, and processing operations).

The relevant guidelines in subsection X.1 (Harvest vessel operations) also apply to the harvest of aquacultured fish.

Figure X.1. Example flow chart for the production of fish at risk of scombrotoxin formation.

This flow chart is for illustrative purposes only. For implementation of HACCP principles, a complete and comprehensive flow chart has to be drawn up for each product.





X.1 Harvest vessel operations

Fishers use many different harvesting methods throughout the world, employing hooks, nets, and traps. Water and environmental temperatures vary depending on geographic location and season. In all cases, live retrieval or quick retrieval of dead fish, rapid chilling of the fish in a timely manner, and maintenance of the fish at cold temperatures, are critical to prevent histamine formation.

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.

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 understand their importance, and responsible crew members should be trained in HACCP principles used to control histamine formation, where possible.

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.

X.1.1 Catching fish

- The time period that nets or hooks are left in the water, and the number and rate of fish caught, should be optimized to allow live landing of fish where practical.
- If captured fish are held in the sea for too long following death, decomposition commences, and 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 contamination of fish (see Section 3.4 Hygiene control program), and the chilling medium should be ready and at the target temperature.
- Fish should be removed from nets and hooks as quickly as possible to prevent death or to minimize the period from death until chilling of the fish.
- 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.
- 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)[3] for further guidance on establishing time-temperature critical limits for fish after death.

[3] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1.1 Chilling.) Link: http://www.fao.org/fileadmin/user_upload/agns/pdf/Histamine/Histamine_AdHocfinal.pdf

- 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 maintain critical limits for cooling media temperature, or sufficiency of ice.
- 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.

X.1.2 Gutting and gilling (optional)

- Histamine-producing bacteria are universally present in the gut, gills, and skin of fish at the point of capture. Rapid removal of guts and gills, and rinsing of the gut cavity, significantly delays histamine formation in the muscle.
- 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.
- Care should be taken and hygienic practices should be maintained during gutting and gilling in order to minimize the spread of bacteria from the guts, gills, skin, and other contamination sources, into the muscle tissue.

X.1.3 Chilling and freezing

Rapid chilling as soon as possible after death is the most crucial aspect of histamine control because bacterial growth and histamine formation accelerate exponentially with time under unrefrigerated conditions. Few prolific histamine-producing bacteria will grow and multiply at refrigeration temperatures, and the growth rates of those that do are much reduced.

- Sufficient ice to completely surround each fish, or preferably, ice/seawater slurries or refrigerated seawater (RSW) should be used to bring the internal temperature of fish to below 4°C as quickly as possible after death to slow bacterial growth and enzymatic activity.
- Freezing is more effective than refrigerated chilling and maintaining chilled temperatures in preventing 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.
- Note that freezing does not detoxify preformed histamine, nor does it effectively eliminate histamine-producing bacteria and enzymes, which can become active when temperatures increase again, such as during processing or meal preparation.
- 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.
- 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.
- Refrigeration and other chilling equipment should be in good repair, and operated in a manner that quickly chills fish without physical damage. For example, fish should be packed loosely in ice slurries, RSW, and brine tanks to allow good circulation and rapid cooling.
- Where ice is used, fishing vessels should have sufficient ice for the amount of fish that could be caught and for the potential length of the fishing trip. For further information see FAO Fisheries Technical Paper 436 (The use of ice on small fishing vessels)[4].
- 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.
- 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[5] of fish.

X.1.4 Refrigerated and frozen storage (fishing vessel and transfer vessel)

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[4] *FAO Fisheries Technical Paper 436* ("The use of ice on small fishing vessels.") Link: http://www.fao.org/docrep/006/Y5013E/y5013e00.htm#Contents

[5] A "set" means the fish from one set net, or the fish from one set long-line, etc.

- Fish should be stored at a temperature as close as possible to 0°C (4°C or below) until off-loading.
- Refrigerated storage at 4°C or below will inhibit growth and enzyme production for most histamine-producing bacteria, and will slow the growth of the less prolific histamine-producing bacteria that can grow at refrigerated temperatures.
- Ice, where used, should completely surround the stored fish and be regularly monitored throughout the trip and replenished as necessary.
- Refrigerated seawater and/or brine temperature should be monitored and carefully controlled in order to help maintain inhibitory temperatures.
- Continuous temperature recording devices should be used where practical in refrigerated and frozen storage compartments to enable inadequate conditions to be identified and appropriate actions taken to minimize consumer risk.

X.1.5 Monitoring records (fishing and transfer vessel)

- Records of histamine control monitoring activities should be maintained in a way that they can be readily retrieved for trace-back to possible causes if elevated levels of histamine are detected later.
- 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.
- 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.
- The records kept depend on the operation and may include:
    - Ocean water temperature and air temperature
    - Dates and times of earliest fish death, and times to get fish into appropriate chilling media
    - Initial RSW and/or brine tank temperatures
    - 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.
- A responsible crew member should review the monitoring records daily to confirm that critical limits were met, and that appropriate corrective actions were taken when necessary.
- 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.
- 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.

X.2 Reception of fish (receiving establishment)

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.

Reception controls may need to be specific to both the harvest vessels as well as to any collection/transfer vessels that deliver the fish to the receiving establishment.

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.

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.

X.2.1 Review of fishing vessel controls and records (receiving establishment)

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.

- Refer to Section X.1.5 Monitoring records (fishing vessel).
- Vessel records applicable to histamine control should be requested and reviewed by the receiving personnel to determine if they are complete and reflect appropriate harvest and onboard handling practices, and that all applicable fishing vessel critical limits were met.
- 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.
- Sometimes the 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) and if the affected fish can be 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.
- 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.)

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.
- 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.
- 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.
- 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.

X.2.3 Sensory evaluation

Sensory evaluation of fish at reception is a useful screening method to identify fishing vessel delivery lots that have been mishandled or subjected to time - temperature abuse and, hence, are at risk of elevated histamine levels. Neither histamine formation nor decomposition occurs in the absence of time-temperature abuse. However, the correlation between histamine level and sensory evidence of decomposition is not absolute, and histamine formation often occurs without readily detectable sensory indicators of decomposition. Therefore, sensory evaluation should not be used as the only or final assurance that the histamine level is acceptable, and reliable vessel control records or histamine testing, along with temperature monitoring, should be part of a complete receiving control system.

- 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.

- 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.
- Evidence of abuse that may be conducive to histamine formation is indicated when the fish sensory attributes indicate marginal quality, not only when the sensory attributes show advanced decomposition. See FAO "Sensory Assessment of Fish Quality"[6] and Codex "Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories"[7] for guidance on sensory evaluation of fish.
- 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.

X.2.4 Histamine testing

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 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 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 notified and the cause determined and corrected. In addition, the affected fishing vessel delivery lot should be rejected.

The histamine testing guidance in this subsection is also applicable to 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.

X.2.4.1 Histamine testing, achievable histamine level

- Freshly harvested scombrotoxin-forming fish typically have histamine levels below 2 mg/kg, and food business operators that apply HACCP principles can achieve a histamine level lower than 15 mg/kg[8].
- 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.
- 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.

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[6] FAO/Torry Advisory Note No. 91, "Sensory Assessment of Fish Quality." Link: http://www.fao.org/wairdocs/tan/x5989e/x5989e00.htm

[7] CAC/GL 31-1999, "Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories." Link: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B31-1999%252FCXG_031e.pdf

[8] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1 Management of histamine production in fish and fishery products.)

X.2.4.2 Histamine testing, sampling strategies

- 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[9] is a useful application designed for this purpose.
- 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)[10], or it can be estimated when 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)[11] suggests 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.
- More sample units should be tested whenever vessel records, sensory analysis, or fish temperatures indicate possible lapses in time - temperature control that could result in elevated histamine.

X.2.4.3 Histamine testing, analytical methods

- 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.
- Several reliable test methods exist for determining histamine levels in fish. The FAO/WHO Expert Report (Section 2.5 Analytical methods for histamine)[12] lists some of the available methods.
- The receiving establishment should confirm that the testing method used is properly validated for the detection limits used. The staff responsible for the sampling and testing should receive training in the procedures used.
- The part of the fish selected for testing will significantly affect the test results. Test portions should be cut from the head-end of the lower loin near the gills because that area has the highest probability of elevated histamine in abused raw fish. Sufficient representation (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.
- 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 portion (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 divided by 3 in order to ensure detection of one unit exceeding the critical limit within the composite sample. If the lower critical limit is exceeded, further analysis of the retained individually ground portions from each of the 3 sample units making up the composite may be performed to determine if any sample unit exceeds 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.

X.2.5 Monitoring records (receiving establishment)

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[9] *FAO/WHO Histamine Sampling Tool*. Link: http://www.fstools.org/histamine/

[10] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Table 5.1 Parameters of the Normal distribution fitted to the logarithm of the concentration of histamine, and probability of exceeding the limit of 200 mg/kg for each survey referenced in Table 3.2.)

[11] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.2.2.2 Using the known standard deviation and the derived mean to design a sampling plan.)

[12] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 2.5 Analytical methods for histamine.)

- Histamine control records should be maintained at the receiving establishment for trace-back to possible causes if elevated histamine is discovered further along the distribution chain.
- Receiving establishment monitoring records may include, but are not limited to:
    - Relevant information about vessel delivery lot (e.g. vessel name and type, captain's name, date/time of offloading, type and volume (weight) of fish off-loaded)
    - Copies of the fishing vessel's monitoring records that were reviewed (refer to Section X.1.5, Monitoring records (fishing vessel)
    - Sensory evaluation results
    - Internal temperatures at the time of offloading
    - Histamine test results, when applicable.
- A responsible person should examine, as a part of verification activity, the monitoring records before product release to confirm that critical limits were maintained, and that appropriate corrective actions were taken when necessary.

X.3 Transportation

- Refer to Section 20 (Transportation)
- Refer to Section X.1.4 (Refrigerated and frozen storage)
- Transport vehicles or vessels should be adequately equipped to keep fish cold by mechanical refrigeration or by completely surrounding the fish with ice or other cooling media.
- Vehicles or vessels should be pre-chilled before loading fish where applicable.
- Refrigerated compartment temperatures, or cooling media such as ice slurries, should be monitored during transportation between locations (e.g. receiving establishment, processing establishment, distributor, market, etc.) using continuous temperature recording devices (where practical), and the receiving establishment should review the temperature record from the device. Devices should be periodically calibrated for accuracy.
- At delivery, internal temperatures of a representative sample of fish, and adequacy of ice or other cooling media when applicable, should be monitored by receiving personnel as described in Section X.2.2 Temperature monitoring.
- If a temperature control critical limit is exceeded, the cause of the problem should be identified and corrected by the operator of the vehicle or vessel. 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 the histamine critical limit (See subsection X.2.4).

X.4 Processing operations

This section applies to processing on land or at sea (e.g.

, factory vessel, mother ship)

X.4.1 Reception (processing establishment)

- If fish are delivered directly from the fishing vessel to the processing establishment, then refer to Section X.2 Reception (receiving establishment).
- If fish are delivered by transport vehicle or vessel, then refer to Section X.3 Transportation.
- 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 that the primary processor uses HACCP or a similar control system designed to prevent formation of hazardous levels of histamine.
- When it is impractical for the initial receiving establishment to conduct all the appropriate histamine 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 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).

X.4.2 Processing, time and temperature control

When fish undergo processing (e.g., thawing, cutting, re-chilling, salting, drying, pickling, 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 levels.

- Scientific studies and microbial growth models[13] may be used to estimate the exposure times and temperatures that result in elevated histamine levels.
- 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 critical limits.
- The acceptable maximum histamine level used to establish processing time-temperature critical limits should take into consideration any further handling, processing, storage, and preparation that may lead to further histamine formation before consumption.
- The measure used for time-temperature critical limits should be the cumulative product non-refrigerated time-temperature exposure over all processing steps.
- Processing room temperature should be maintained as cool as practical during processing operations, and product exposure times should be minimized. For example, fish should be iced, or returned to refrigerated storage, during production breaks or production flow slow-downs.
- Controlled product flow and batch monitoring is an effective strategy to ensure product is not subjected to unacceptable time-temperature exposures. For example, periodically measure the ambient temperature and the time for a marked batch to begin and complete the processing step.
- Air thawing of raw material should occur at refrigerated temperatures to prevent excessive warming of the surface of the fish. Immersion in circulating cold water or spraying with cold water may be used to shorten thawing time. For re-chilling and refreezing, see Subsection X.1.3.
- When time-temperature critical limits are exceeded, the cause should be determined and corrected. 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

- 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).
- Once formed, however, histamine itself is heat stable and is not destroyed by heat. Therefore, histamine controls during harvesting, and during other steps prior to thermal processing, are critical to prevent inclusion of previously formed histamine in the finished product.
- If the product is exposed to bacterial contamination and temperature abuse after initial heating, histamine formation may start again. Thus, for products such as hot smoked fish, care should be taken to avoid contamination after smoking. Additionally, refrigerated storage is essential unless the water activity is reduced sufficiently or some other means is used to prevent bacterial growth.
- For commercially sterile canned or pouched products, the 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.

X.4.4 Processing, other technological measures

Time and temperature control is the recommended method for preventing histamine formation in fresh, frozen, and refrigerated processed fish products.

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[13] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1.9 Microbiological modelling.)

Some products and processes (e.g. fermenting, smoking, salting, drying, pickling, acidifying, preserving, modified atmosphere packaging) introduce other technological factors that may inhibit the introduction and/or growth of histamine-producing bacteria. The interaction of these factors is complex and often unpredictable. For example, increased salt content, or increased acidity, may decrease or increase histamine production, depending on conditions.

Thorough scientific studies, and proper establishment and validation of control parameters for each specific process and product, are imperative to ensure the safe manufacture of foods that incorporate other technological measures as an element of histamine control. (See Guidelines for the Validation of Food Safety Control Measures, CAC/GL 69 - 200.)

The safe application of any of these treatments is dependent on the rapid chilling and 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 the treatments have been achieved. And, depending on the treatment, the finished product may need to remain chilled until consumed to ensure safety.

X.4.5 Refrigerated and frozen storage (processing establishment)

- Refer to Section X.1.4 Refrigerated and frozen storage (fishing vessel).
- For products whose preparation does not include a heating step or other means to eliminate histamine-producing bacteria and their enzymes, the presence of histamine-producing bacteria means that refrigerated storage will continue to be a critical control point for the inhibition of histamine formation throughout the shelf-life of the products until consumed.

X.4.6 Monitoring records (processing establishment)

- Processing establishment monitoring records may include, but are not limited to:
    - Transport vehicle or transport vessel temperature log or adequacy of ice, and fish internal temperatures
    - Temperatures and exposure times of product during unrefrigerated processing steps
    - Critical control point monitoring records for other validated methods used to control histamine formation in processed fish
    - Refrigerated storage temperature logs.
- A responsible person should examine the monitoring records before product release to confirm that critical limits were maintained, and that appropriate corrective actions were taken when necessary.

The processing facility should use histamine testing to periodically verify that histamine controls are working properly (Refer to section X.2.4).

Appendix II

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