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PROPOSED DRAFT GUIDANCE FOR HISTAMINE CONTROL IN THE *CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS (CAC/RCP 52-2003) (REVISED)*

Prepared by the EWG chairs

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*

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 scombrototoxin 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.

Scombrototoxin 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.

Scombrototoxin 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 scombrototoxin. ~~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.~~ [US]

Although detailed components of scombrototoxin 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 scombrototoxin, and histamine is monitored for scombrototoxin 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 (**HDC**) enzymes, ~~that which~~ convert histidine (naturally present in muscle tissue flesh of at risk fish) into the toxic metabolite histamine. [US, NZ]

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.

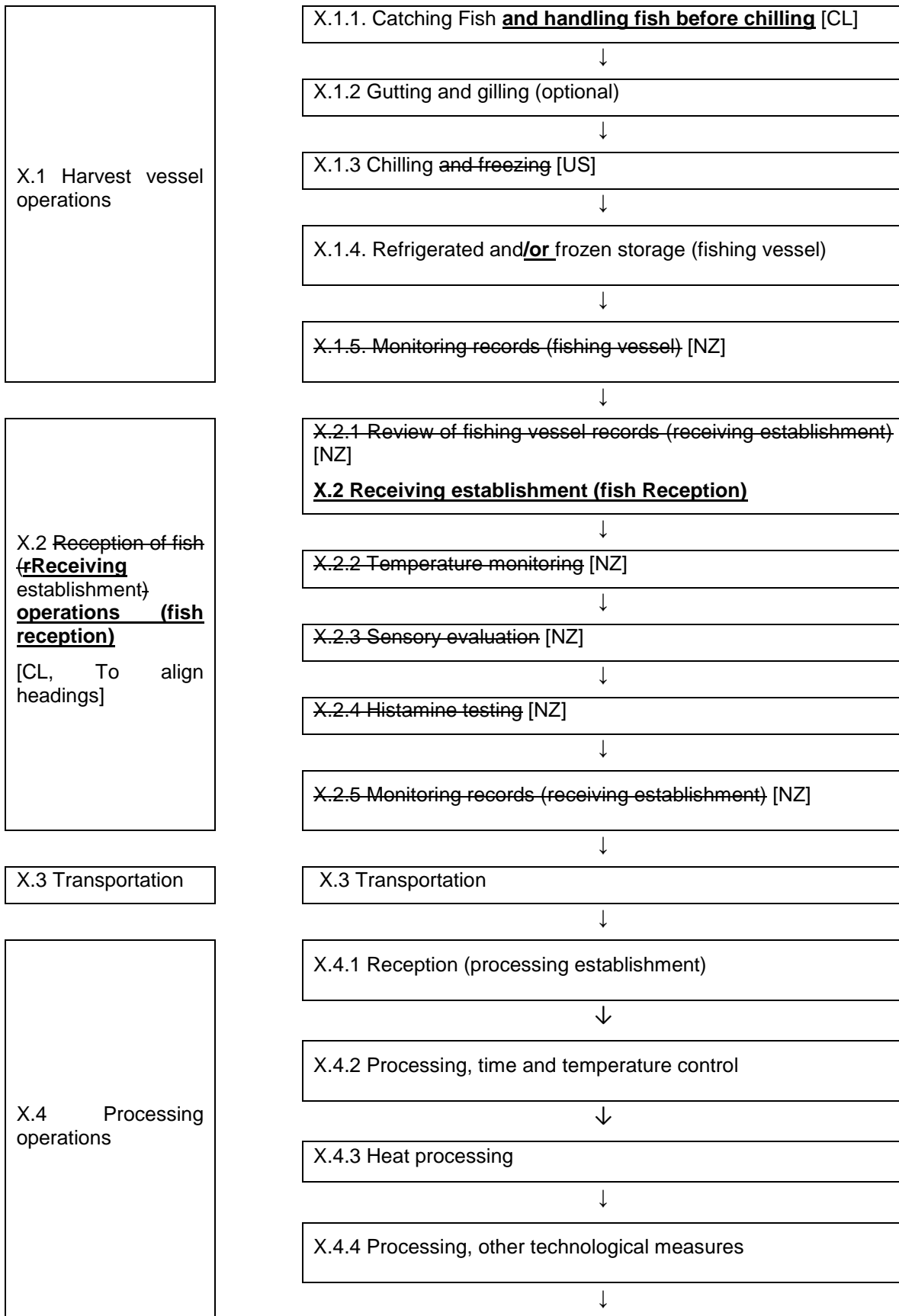
~~Histamine formation is effectively controlled by adherence to good manufacturing practices to maintain hygienic quality of fish, and by using HACCP principles to control detrimental fish time-temperature exposure. [CL (co-lead), use of GMPs and HACCP is explained in "Introduction, "How to use this Code"]~~

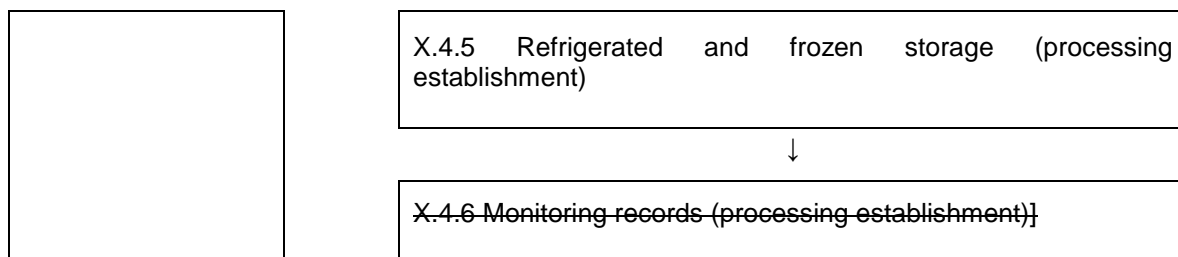
The following subsections contain technical guidance for the control of histamine formation at key steps in the food chain (harvesting, receiving, transportation, and processing operations).

The relevant guidelines in **this** section X.1 ~~(Harvest vessel operations)~~ also apply to ~~the harvest of~~ aquacultured fish. [NZ]

Figure X.1. Example flow chart for the production of fish at risk of scombrototoxin 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.~~ [MAR] 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.~~ [CL moved to X.1.1]

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 **for histamine control.** ~~and~~ **Where HACCP principles are used, persons** responsible crew members **for developing HACCP documentation** should be trained in HACCP principles used to control histamine formation, ~~where possible.~~ [NZ]

Traditionally, vessel operations use GMPs to control histamine, in which case the shore-based receiving establishment should perform histamine testing on each vessel delivery to monitor and document acceptable histamine levels in the raw material received. If vessel operations use a HACCP approach that provides documented evidence that histamine was controlled on the vessel, then the receiving establishment may choose to examine the vessel monitoring records as an alternative to testing each lot. [CL clarification] **The use of HACCP principles to control fish time-temperature exposure on the harvest vessels is an effective means to prevent hazardous levels of histamine formation, and provides better more reliable consumer protection than the alternative approach of testing histamine levels in fish after delivery.** [US]

X.1.1 Catching and handling fish before chilling [CL clarification of key control period, bullets rearranged in time order]

- ~~Critical limits~~ should be established for the time period between death of the fish and the start of chilling that will effectively prevent **minimize** [NZ, CL] histamine production. This time period **may be adjusted according to water and air temperatures encountered, the size and species of fish caught, and other relevant factors of the operation. The types of histamine-producing bacteria present and how rapidly they produce histamine can also change, therefore established critical limits should take into account the worst-case scenario. The FAO/WHO Expert Report (Section 6.1.1 Chilling)**¹ **provides examples of time-temperature limits from fish death to chilling for medium to large fish.** [US] for further guidance on establishing time-temperature critical limits for fish after death. 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. [US, CL]
- **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.** [US]
- 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.

¹ 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 **achieve and** [NZ] maintain **critical established** limits for cooling media temperature, or sufficiency of ice. [CL]
- 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.
- 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 **muscle musculature**. [NZ]
- 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** [NZ] 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 **in the future**. [CL]
- 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.
- ~~The time period between death of fish and chilling that will effectively **minimize** prevent histamine formation can vary based on the ocean **water** 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)² for further guidance on establishing time-temperature critical limits for fish after death. [US (CL) concept incorporated above]~~

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~~ **part** [MAR] 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~~. [CL]

X.1.3 Chilling and freezing [US, CL, bullets rearranged in time order]

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.

- ~~Critical **Temperature** 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, **and** 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 set³ of fish. [NZ, MAR, CL]~~
- Sufficient ice to completely surround ~~each~~ **the** [MAR] 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.

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 (Section 6.1.1 Chilling.) Link: http://www.fao.org/fileadmin/user_upload/agns/pdf/Histamine/Histamine_AdHocfinal.pdf

³ A "set" means the fish from one set net, or the fish from one set long-line, etc.

- 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 **part** region [MAR] of the fish.
- Freezing **fish** is more effective **in preventing histamine formation** than ~~refrigerated~~ chilling and maintaining **fish near 4°C** ~~chilled temperatures in preventing histamine formation~~. [US,NZ] 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 **ensure** ~~assure~~ [US] that the rate or volume of incoming fish does not exceed the ability to rapidly chill the fish within established time-temperature ~~critical~~ [CL] limits and maintain the fish in a chilled state. (US)
- Care should be taken to manage the chilling of dead fish to ensure that none are inadvertently left exposed on deck past the ~~critical~~ [CL] time limit **established** for the **temperature** conditions. [NZ]
- Refrigeration ~~and other chilling~~ [US] 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)⁵.~~
- ~~For larger eviscerated fish, the belly cavity should be packed with ice, or other cooling media, for more rapid chilling of this bacteria-laden **part** region [MAR] of the fish.~~

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

- **Refrigerated** Fish [US] should be stored at a temperature as close as possible to 0°C (4°C or below). **The storage temperature should be kept below 4°C** until off-loading. [BRA] Refrigerated ~~s~~Storage at 4°C or below **these temperatures** will inhibit **or slow the** 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. [NZ]
- 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 **regularly** monitored **throughout the trip** and ~~carefully~~ controlled in order to ~~help~~ maintain inhibitory **storage** temperatures. [NZ]
- Continuous temperature recording devices, **or thermometers**, should be used ~~where practical~~ in refrigerated and frozen storage compartments to ~~enable~~ **ensure that** inadequate **holding** conditions ~~to be~~ **are** identified and appropriate actions taken to minimize consumer risk. [COL, NZ, US, CL]

X.1.5 Monitoring records (fishing and transfer applicable to vessels using HACCP principles) [CL]

- 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. [NZ]
- Vessel records should include **real-time** 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. [NZ, CL]

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

- The records kept **of histamine control monitoring activities** [NZ] depend on the operation and may include:
 - ~~Ocean water temperature and air temperature [US]~~
 - Dates and times of earliest fish death, and times to get fish into appropriate chilling media
 - ~~Initial RSW and/or brine tank temperatures [US]~~
 - Brine, RSW, or storage compartment refrigeration temperature monitoring records or checks for adequacy of ice during the chilling operation and during **holding storage** of the fish for the duration of the fishing trip. [NZ]
 - ~~Ocean w~~**Water temperature** and air temperature [NZ]
- 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. [CL]~~
- If some of the fish stored on the vessel are **determined based on monitoring records to be** at risk for **unacceptable histamine levels** formation because critical limits were exceeded, then these fish should be segregated and identified in order to allow targeted testing and/or proper disposition at unloading. [NZ, CL]

X.2 Reception of fish (r Receiving establishment) operations (fish reception) [CL, alignment of section headings]

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 and/or vessel records are best should be monitored, and decisions are made as to whether the fish are safe to accept for processing or to proceed in commerce.** [CL, (NZ)]

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** [NZ] 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~~**ed in** the frozen state. [NZ]

X.2.1 Review of fishing vessel controls and records (receiving establishment) [CL, section moved down]

~~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.2.21 Temperature monitoring

- Fish internal temperatures should be measured at reception to **ensure reception temperature limits are met, and to help ensure provide confidence** that fish were properly stored onboard the fishing and transfer vessel. [NZ, CL]
- For fish stored in ice, the adequacy of ice surrounding the fish should **also** [US] 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 **results** recorded should be sufficient to provide reasonable assurance that **the** 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**. [NZ]
- **Fish on the vessel should have been stored at a temperature as close as possible to 0°C (4°C or below)**. If an internal temperature in a sample fish exceeds 4°C, **(or the established temperature limit based on elapsed time from death)**, 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**. [US]
- ~~If an internal temperature in a sample fish exceeds 4°C, then the entire fishing vessel delivery lot should be considered at risk.~~ [US] Higher temperatures usually correspond to higher histamine risk; however, higher deep core temperatures may need to be ~~accounted~~ **allowed** for ~~when in~~ larger 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 **establish** ~~ascertain~~ proper temperature critical limits for fish at receiving **reception temperatures** 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.~~ [US]

X.2.32 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~~ **plan**. It may be appropriate to select more fish from portions of the delivery **lot** identified by vessel records or temperature examination to be at greater risk for histamine formation. [NZ]
- 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. [NZ]

- 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 **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 ~~corrections~~ **changes, and improvement to facilities** or equipment ~~repairs~~, verified. It is justifiable to reject the entire delivery **lot** based on **evidence of** 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 **entire** delivery **lot**. The testing should also include the decomposed fish **found** to determine if the **type of** decomposition **detected** was conducive to histamine formation. [NZ, CL clarification]

X.2.43 Review of fishing vessel controls and records (receiving establishment) [CL (NZ)]

If vessel operators use HACCP principles, ~~R~~review of fishing vessel histamine control ~~systems and monitoring~~ records, when available, is an effective **control** method **at receipt** to ensure that appropriate procedures were followed on the vessel to ~~help control~~ **minimize** histamine formation in the fish while on the fishing vessel [CL] **and is more effective than routine histamine testing.** [US]

- 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 **reviewed and found to be** 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 **by other means**, such as by intensified histamine sampling and testing, the delivery should be rejected. **(Refer to Section X.2.4 Histamine testing).** [NZ]
- ~~Sometimes t~~**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~~ **were** effectively segregated from the rest of the delivery when the vessel is **was** unloaded. ~~Precautions should be taken to ensure none of the other fish in the delivery have been affected.~~ [NZ]
- ~~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.)~~ [US, MAR, NZ (moved)]

X.2.4 Histamine testing

When a fishing vessel delivering fish has implemented a histamine control system based on HACCP principles, and review of **fishing** vessel **histamine control** records is **used as** one of the **histamine** controls used by the **a** receiving establishment, then histamine testing ~~is only used~~ **should be performed periodically** as a periodic verification procedure to assess if **that** the vessel control system is adequate and working properly **continuing to work effectively.** [CAN] ~~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.~~ [NZ] If verification test results signal potential lapses in care of the fish **indicate elevated histamine levels**, then **the vessel control system should be reviewed and corrected, and 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). [NZ, CL clarification]

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%252FBGL%252B31-1999%252FCXG_031e.pdf

When a fishing vessel delivering fish **operation** uses GMPs, but has not implemented a histamine control system based on HACCP principles using **including** monitoring and establishing its records **record keeping** that provide assurance and **documented** evidence of control, then histamine testing becomes a critical control point **is an important monitoring procedure at the reception critical control point, rather than a verification procedure**, and testing should be applied to every vessel delivery lot. If histamine levels do not meet **exceed** the required **established critical** limit, the vessel should be notified and the cause determined and corrected. In addition, the affected fishing vessel delivery lot should be rejected. [NZ, CL clarification]

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. [US, NZ]

The histamine testing guidance in this subsection is **can** also applicable **be applied** to **intensified sampling or** 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**. [NZ]

X.2.4.1 Histamine testing, achievable histamine levels [CL]

- Freshly harvested scombrototoxin-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/kg⁸.
- Marginally elevated histamine levels **[e.g., > 15 mg/kg]** [for NZ] indicate poor implementation of hygienic processes and histamine controls during harvest, chilling and/or on-vessel storage, and **an significant elevated** risk that some fish in a lot will have unacceptable histamine levels. **In addition, they indicate that histamine decarboxylase enzymes are present that can contribute to histamine formation during exposure to elevated temperatures further along the food chain, even without growth of histamine-forming bacteria.** [US]
- Histamine achievable levels of at vessel reception should ~~may 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, **and this should be considered when establishing acceptable histamine levels.** [NZ, CL clarify intent]

X.2.4.2 Histamine testing, sampling strategies

- Sampling plans for **testing** histamine **levels** should be selected based on statistical performance parameters ~~to be effective~~. Statistical tables and computer programs **can** 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 Tool⁹ is ~~a useful~~ **an example of an** application designed for this purpose. [NZ]
- 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 after** [US] 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** [NZ] acceptable limit in order to reduce the number of samples required to achieve a given level of confidence in the testing results.

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.)

⁹ FAO/WHO Histamine Sampling Tool. Link: <http://tools.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.)

- 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.
- It is best to ~~test~~ **sample** the raw fish material upon arrival from the fishing vessels, where individual loin sections can be identified, ~~and for trace back to vessel lots~~. 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. [CL, moved from below with clarification]
- **Samples taken should be representative of the lot.** [NZ]

X.2.4.3 Histamine testing, analytical methods

- ~~It is best to test~~ **sample** the raw fish material upon arrival from the fishing vessels, where individual loin sections can be identified, ~~and for trace back to vessel lots~~. [CL] 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. [CL moved up]
- 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 **should be** properly validated for the detection limits used. The staff responsible for the sampling and ~~testing for sample analysis~~ **analysis** should receive training in the procedures used. [NZ, CL]
- The part of the fish selected for testing ~~will~~ **can** 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 (e.g. approximately **100-250 grams**). 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~~ **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. [US, CAN, MAR]
- 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.~~ [NZ]

X.2.5 Monitoring records (receiving establishment)

- 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

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 test results, when applicable.
 - Copies of the fishing vessel's monitoring records ~~that were reviewed~~, **when applicable** (~~refer to Section X.1.5, Monitoring records (fishing vessel)~~) [CL (NZ)]
- 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 **established fish reception or vehicle compartment** temperature control ~~critical limits~~ **is are** exceeded, the cause of the problem should be identified and corrected by the operator of the vehicle or vessel. **If evidence indicates that temperature abuse leading to elevated histamine could have occurred**, ~~The 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 **established** histamine ~~critical~~ limit (See **Refer to** subsection X.2.4 **Histamine testing**). [NZ]

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 **also** refer to Section X.2 Reception (receiving establishment). [CL]
- If fish are delivered by transport vehicle or vessel, then **also** refer to Section X.3 Transportation. [CL]
- 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 **a** HACCP ~~or a similar control~~ system designed to prevent formation of ~~hazardous~~ unacceptable levels of histamine. [EU, NZ]
- When it is impractical for the initial receiving establishment to conduct all the ~~appropriate~~ **necessary** histamine controls listed in subsection X.2 (i.e., ~~vessel records review~~, temperature monitoring, sensory evaluation, **vessel records review**, and/or 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. **Note**, however, **that** fish internal temperatures (and adequacy of ice, where applicable) should always be monitored at vessel delivery **by the receiving establishment** (to evaluate vessel control), as well as at **receipt to** the processing establishment (to evaluate **land-transportation** control). **If lots are comingled and there may be unacceptable levels of histamine in fish, the entire lot must be considered when making decisions on disposition.** [NZ, CL]

X.4.2 Processing_i time and temperature control [CL - comma not needed]

When fish undergo processing (e.g., thawing, cutting, re-chilling, salting, drying, pickling, **cooking**, smoking, canning) it is important that they are not ~~held at temperatures for sufficient~~ **subjected to time-temperature conditions** ~~that~~ **where** histamine-producing bacteria can grow and produce histamine to ~~hazardous~~ **unacceptable** levels. [CAN, NZ]

- Scientific studies and microbial growth models¹³ 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 **the point in the supply chain and** any further handling, processing, storage, and preparation that may lead to further histamine formation before consumption. [NZ]
- 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 (*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). [US]
- 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~~ **minimize the presence of** histamine in the finished product. [CAN]
- 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.

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

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.)

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~~ **success** 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~~ **effects from** the treatments ~~have been~~ **are** achieved. And **In addition**, depending on the treatment, the finished product may need to remain chilled until consumed to ensure safety. [CAN]

X.4.5 Refrigerated and frozen storage (processing establishment)

- Refer to Section X.1.4 Refrigerated and frozen storage (fishing **vessel and transfer** vessel). [NZ]
- 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~~ **to prevent** histamine formation throughout the shelf-life of the products ~~until consumed~~. [CAN]

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~~ **records** or adequacy of ice, and fish internal temperatures [NZ]
 - 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 **Histamine testing**). [NZ]