

1 **CCFH Histamine EWG 2017**

2 **Second draft of Proposed Draft Revision of the Code of Practice for Fish and Fishery Products**
3 **New section [X] for fish at risk for scombrototoxin formation**

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30 Proposed draft:

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

35 **Preamble**

36 This section complements other sections of the Code by providing detailed control
37 recommendations for the prevention of scombrototoxin fish poisoning (SFP). This section only
38 applies to specific marine finfish species (listed in Annex [Z]) at risk of developing hazardous
39 levels of histamine.

41 Hazard Analysis and Critical Control Point (HACCP) systems and their prerequisite programmes
42 are used to control the SFP hazard. Refer to Section 5 and Section 3 of this Code for guidelines
43 on developing and using HACCP and prerequisite programmes. On fishing vessels that have not
44 adopted HACCP, equivalently effective good manufacturing practices (GMPs) may be used. This

45 section contains specific guidelines for preventing SFP; however, within the scope of this Code,
46 it is not possible to provide all the appropriate controls and alternatives that may apply to every
47 operation because these will vary with each particular operation.

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

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58 Scombrototoxin fish poisoning is caused by the ingestion of certain species of marine fish (listed
59 in Annex [Z]) that have been allowed to develop biogenic amines such as histamine. These
60 species generally contain high levels of free histidine in their musculature and are more likely to
61 form hazardous levels of histamine after death when subjected to time-temperature abuse.

62

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

72

73 Histamine is produced in fish and fishery products by spoilage bacteria that are part of the
74 natural microflora of the skin, gills, and gut of freshly caught fish. After the fish die, these
75 bacteria migrate into the previously sterile fish musculature where they multiply if time and
76 temperature are not controlled. When histamine-producing bacteria multiply in fish flesh, they
77 produce the enzyme histidine decarboxylase, which converts naturally present histidine into
78 the toxic metabolite histamine.

79

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

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

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

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94 **X.1 Harvest vessel operations**

95 Fishers use many different harvesting methods throughout the world, employing hooks, nets,
96 and traps in waters at different temperatures. In all cases, live retrieval or quick retrieval of
97 dead fish, rapid chilling of the fish in a timely manner, and maintenance of the fish at inhibitory
98 cold temperatures, are critical to inhibit histamine formation in freshly harvested fish.

99

100 Time for histamine formation can vary substantially at the same temperature because different
101 histamine-producing bacteria with different histamine-producing activity may be present. Time
102 and temperature critical limits should account for the potential of histamine production under
103 the worst case conditions for the particular operation.

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105 The fishing boat, equipment, and methods used should be designed or adapted to control
106 histamine formation for the catch sizes, fish sizes, fish species, and air and water temperatures
107 encountered. Vessel crews should be trained in the hygienic practices and temperature control
108 methods and understand their importance, and responsible crew members should be trained in
109 HACCP principles used to control histamine formation.

110

111 Use of HACCP principles to control fish time-temperature exposure on the harvest vessel is an
112 effective means to prevent hazardous levels of histamine formation, and preferable to testing
113 for histamine after delivery. Where onboard record-keeping is impractical, such as for small
114 artisanal day boats, the operation that receives the fish from the day boat may be able to
115 obtain the appropriate fishing trip information in order to monitor histamine control for the
116 boat.

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118 **X.1.1 Catching fish**

119 • The time period that nets or hooks are left in the water, and the number and rate of fish
120 caught, should be optimized to allow live landing of fish where practical.

121 • If captured fish are held in the sea for too long following death, decomposition
122 commences, and histamine can begin to form. The warmer the seawater, the more
123 rapid the decomposition and the greater the risk of histamine formation. Dead fish that
124 exhibit marginalized quality attributes consistent with deleterious time/temperature
125 exposures should not be brought on board the vessel, or, if retained, should be
126 segregated and labelled to allow testing and proper disposition when off-loaded. In
127 addition, the harvesting methods should be modified in a way that no dead fish with
128 marginal quality will be brought on board.

129 • Before landing fish, the deck area and equipment should be hygienically cleaned to
130 avoid contamination of fish (see Section 3.4 Hygiene control program), and the chilling
131 medium should be ready and at the target temperature.

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- 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 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 and the actual time of death is not observed or truly known.
 - 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)¹ for further guidance on establishing time/temperature critical limits for fish after death.
 - The rate or volume of catch should not exceed the ability of the crew to quickly initiate chilling, and should not exceed the capability of the vessel's chilling 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.

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151 **X.1.2 Gutting and gilling**

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- 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.

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162 **X.1.3 Chilling and freezing**

163 Rapid chilling as soon as possible after death is the most crucial aspect of histamine control

164 because bacterial growth and histamine formation accelerate exponentially with time under

165 unrefrigerated conditions. Few prolific histamine-producing bacteria will grow and multiply at

166 refrigeration temperatures and the growth rates of those that do are much reduced.

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- 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.

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

- 171 • Freezing is more effective than refrigerated chilling and holding in preventing histamine
172 formation. It is good practice to gut the fish before freezing. Freezing to -18 °C, or
173 below, will stop the growth of histamine-producing bacteria and will prevent any
174 preformed histidine decarboxylase enzymes from producing additional histamine.
- 175 • Note that freezing does not detoxify preformed histamine, nor does it effectively
176 eliminate histamine-producing bacteria and enzymes, which can become active when
177 temperatures increase again during such things as processing or meal preparation.
- 178 • Crew members responsible for chilling should provide feedback to the catching
179 operation to assure that the rate or volume of incoming fish does not exceed the ability
180 to rapidly chill the fish within established time/temperature critical limits and maintain
181 the fish in a chilled state.
- 182 • Care should be taken to manage the chilling of dead fish to ensure that none are
183 inadvertently left exposed on deck past the critical time limit for the conditions.
- 184 • Refrigeration and other chilling equipment should be in good repair, and operated in a
185 manner that quickly chills fish without physical damage. For example, fish should be
186 packed loosely in ice slurries, RSW, and brine tanks to allow good circulation and rapid
187 cooling.
- 188 • Where ice is used, fishing vessels should have sufficient ice for the amount of fish that
189 could be caught and for the potential length of the fishing trip. For further information
190 see FAO Fisheries Technical Paper 436 (The use of ice on small fishing vessels)².
- 191 • For larger fish, evisceration is recommended and the belly cavity should be packed with
192 ice, or other cooling media, to ensure rapid chilling of this critical area of the fish and to
193 aid internal muscle cooling.
- 194 • Critical limits and monitoring methods and frequencies should be established for the
195 onboard chilling/freezing process. For example, limits may be established for maximum
196 loading volumes and rates, maximum starting temperature for RSW and/or brine tanks,
197 and monitoring frequencies to ensure an adequate chilling environment is maintained
198 for the duration of the chilling operation for each harvested set of fish.

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200 **X.1.4 Refrigerated and frozen storage (fishing vessel)**

- 201 • After chilling, fish should be stored at the lowest temperature possible (e.g., below 4°C)
202 until off-loading.
- 203 • Refrigerated storage at 4°C or below will inhibit growth and enzyme production for most
204 histamine-producing bacteria, and will slow the growth of the less prolific histamine-
205 producing bacteria that can grow at refrigerated temperatures.
- 206 • Ice, where used, should completely surround the stored fish and be regularly monitored
207 throughout the trip and replenished as necessary.
- 208 • Refrigerated seawater and/or brine temperature should be monitored and carefully
209 controlled in order to help maintain inhibitory temperatures.
- 210 • Continuous temperature recording devices should be used where practical in
211 refrigerated and frozen storage compartments.

² FAO Fisheries Technical Paper 436 (“The use of ice on small fishing vessels.”) Link:
<http://www.fao.org/docrep/006/Y5013E/y5013e00.htm#Contents>

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X.1.5 Monitoring records (fishing vessel)

- Records of histamine control monitoring activities should be maintained where 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 harvest vessel operation.
- 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 and/or at delivery, to confirm that critical limits were met, and that appropriate corrective actions were taken when necessary.
- For small artisanal day boats that have difficulty maintaining records, the operation receiving the fish may be able to record most, if not all, of the histamine control parameters for the boat, such as time of departure and return, adequacy of ice at departure and return, air and water temperature, etc., as applicable.
- 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 identified, segregated and labeled in order to allow targeted testing and proper disposition at the receiving establishment.

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

254 future deliveries from the fishing vessel are considered. In addition, appropriate corrective
255 actions regarding the delivered fish should be taken and recorded.

256
257 During offloading of fish from the harvest vessel (and at any point of transfer in the supply
258 chain), care should be taken that the cold chain is maintained. For example, fish should be
259 offloaded quickly, fish totes should not be left exposed to elevated temperatures, and fish
260 should be re-iced or placed under refrigeration in a timely manner.

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

263 Review of fishing vessel histamine control systems and monitoring records, when available, is
264 an effective method to ensure that appropriate strategies were followed to help control
265 histamine formation in the fish while on the fishing vessel.

- 266 • Refer to Section X.1.5 Monitoring records (fishing vessel).
- 267 • Vessel records applicable to histamine control should be requested and reviewed by the
268 receiving personnel to determine if they are complete and reflect appropriate harvest
269 and onboard handling practices, and that all applicable fishing vessel critical limits are
270 met.
- 271 • If vessel records are incomplete, or a required corrective action is missing or unclear,
272 reception personnel should verify that fishing vessel personnel have identified the
273 problem and taken appropriate corrective actions. If future actions are required, such as
274 equipment repairs, then reception personnel should follow-up to ensure these
275 corrections are made.
- 276 • Sometimes the impact of a critical limit deviation on the fishing vessel may be
277 minimized if the records clearly show that only part of a delivery was affected (e.g., one
278 brine well or one specific fishing set during the fishing trip) and if the affected fish can
279 be effectively segregated from the rest of the delivery when the vessel is unloaded.
280 Precautions should be taken to ensure none of the other fish in the delivery have been
281 affected.
- 282 • Histamine testing can be used when vessel records are not available. However, this
283 testing can be less reliable because histamine may be unevenly distributed within and
284 between fish, and fish with high histamine are difficult to find using limited or small
285 sample sizes. Sampling and testing that is statistically meaningful in terms of
286 appropriate consumer protections can be resource intensive. Histamine testing at
287 fishing vessel reception is therefore best used as verification of the effectiveness of a
288 properly implemented and documented histamine control system on the fishing vessel.
289 (Refer to Section X.2.4 Histamine testing.)

290

291 **X.2.2 Temperature monitoring**

- 292 • Fish internal temperatures should be measured at reception to ensure that fish were
293 properly stored onboard the fishing vessel.
- 294 • For fish stored in ice, the adequacy of ice surrounding the fish should also be observed
295 and recorded at the time of offloading the fishing vessel, along with internal
296 temperature measurements. More fish should be monitored when the quantity or

297 distribution of ice appears inadequate. Temperatures near the surface of exposed un-
298 iced portions should be measured, as well as deep core temperatures of the fish, to
299 ensure all edible portions of the fish are taken into consideration in the assessment.

- 300 • Fish should be randomly selected from throughout the fishing vessel delivery lot. The
301 number of fish temperatures monitored and recorded should be sufficient to provide
302 reasonable assurance that temperatures appeared to be controlled by the vessel crew.
303 Variations in species, morphologies, and sizes of fish should be considered and captured
304 in selection of fish monitored for temperature.
- 305 • If an internal temperature in a sample fish exceeds 4°C, then the entire fishing vessel
306 delivery lot should be considered at risk for elevated histamine. Higher deep core
307 temperatures may need to be accounted for when larger fish have been delivered soon
308 after harvest such that the core temperatures have not yet chilled to 4°C or below
309 despite implementation of appropriate chilling procedures. Science-based cooling
310 curves applicable for the specific fishing sector are useful to ascertain proper
311 temperature critical limits for fish at receiving in these circumstances. If a deviation
312 from the temperature critical limits occurs, the cause should be determined and
313 corrected, and thorough risk-based histamine testing performed, or the vessel lot
314 rejected.

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316 **X.2.3 Sensory evaluation**

- 317 • Sensory evaluation of fish at reception is a useful screening method to identify fishing
318 vessel delivery lots that have been mishandled or subjected to time-temperature abuse
319 and, hence, are at risk of elevated histamine levels. Neither histamine formation nor
320 decomposition occurs in the absence of time-temperature abuse. However, the
321 correlation between histamine level and sensory evidence of decomposition is not
322 absolute, and histamine formation often occurs without readily detectable sensory
323 indicators of decomposition. Therefore, sensory evaluation should not be used as the
324 only or final assurance that the histamine level is acceptable, and reliable vessel control
325 records or risk-based histamine testing, along with temperature monitoring, should be
326 part of a complete receiving control system.
- 327 • Fish for sensory examination should be chosen randomly from throughout the fishing
328 vessel delivery lot. Deliveries of multiple species with different compositions,
329 morphologies, and sizes should be taken into account in the sampling strategy. It may
330 be appropriate to select more fish from portions of the delivery identified by vessel
331 records or temperature examination to be at greater risk for histamine formation.
- 332 • The number of fish examined should be sufficient to provide assurance that the fishing
333 vessel crew appear to have been vigilant about time-temperature exposures of the fish.
334 The number of samples should be increased when conditions or fishing methods are
335 more likely to introduce variable time-temperature exposures of fish, e.g., longlining,
336 unusually warm weather, unusually large catch size, limited remaining ice, etc.
- 337 • Evidence of abuse that may be conducive to histamine formation is indicated when the
338 fish sensory attributes indicate marginal quality, not only when the sensory attributes
339 show advanced decomposition.

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- 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 risk-based 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.

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350 **X.2.4 Histamine testing**

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

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362 When a fishing vessel delivering fish has not implemented a histamine control system based on
363 HACCP principles, then histamine testing becomes a critical control point at reception rather
364 than a verification procedure, and testing should be applied to every vessel delivery lot. If
365 histamine levels do not meet the testing criteria, the vessel should be notified and the cause
366 determined and corrected. In addition, the affected fishing vessel delivery lot should be
367 rejected.

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369 **X.2.4.1 Histamine testing, acceptable histamine level**

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- Histamine acceptance levels at vessel reception should be lower than the acceptable levels in product further along the distribution chain because histamine is likely to increase with time and exposure to non-refrigerated temperatures during further processing and handling.
 - 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/kg³.
 - Marginally elevated histamine levels indicate poor implementation of hygienic processes and HACCP controls, and a significant risk that some fish in a lot will have unacceptable histamine levels.

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 Management of histamine production in fish and fishery products.)

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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 tools 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 Tool⁴ is useful 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)⁵, or it can be estimated when adequate 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)⁶ 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.

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)⁷ lists some of the available methods.
- The receiving establishment should confirm that the testing method used is properly validated for the detection limits used and is reliable for the species. 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, or typical serving size) of fish muscle, should be collected to prepare for analysis. For smaller fish, in addition to the lower

⁴ FAO/WHO Histamine Sampling Tool. Link: <http://www.fstools.org/histamine/>

⁵ 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.)

⁶ 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.)

⁷ 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.)

415 anterior loin portion, the upper anterior loin, and the mid-section of the lower loin, in
416 that order, can also be collected, and for very small fish, multiple fish may need to be
417 collected to acquire a representative sample unit of fish muscle. The entire sample unit
418 should be thoroughly blended so that the smaller aliquot used for the analytical method
419 is representative of the entire sample unit.

- 420 • To screen deliveries more economically when histamine levels are consistently low,
421 sample units from different fish can be combined (composite sample) to reduce the
422 number of histamine analyses required, provided that the histamine level critical limit is
423 lowered proportionately. For example, 3 sample units can be blended together and used
424 for a single analysis. In this case, the critical limit must be divided by 3 in order to ensure
425 detection of one unit exceeding the critical limit within the composite sample. If the
426 lower critical limit is exceeded, further analysis may be required to determine if any
427 sample unit actually exceeds the normal critical limit. Note, the ability to composite
428 multiple sample units is limited by the lowest histamine level that is accurately
429 quantified by the analytical method in use.

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431 **X.2.5 Monitoring records (receiving establishment)**

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

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447 **X.3 Transportation**

- 448 • Refer to Section 20 (Transportation)
- 449 • Refer to Section X.1.4 (Refrigerated and frozen storage)
- 450 • Transport vehicles or vessels should be adequately equipped to keep fish cold by
451 mechanical refrigeration or by completely surrounding the fish with ice or other cooling
452 media.
- 453 • Vehicles or vessels should be pre-chilled before loading fish where applicable.
- 454 • Refrigerated compartment temperatures, or cooling media such as ice slurries, should
455 be monitored during transportation between locations (e.g., receiving establishment,
456 processing establishment, distributor, market, etc.) using continuous temperature
457 recording devices (where practical), and the receiving establishment should review the

458 temperature record from the device. Devices should be periodically calibrated for
459 accuracy.

- 460 • At delivery, internal temperatures of a representative sample of fish, or adequacy of ice
461 or other cooling media, should be monitored by receiving personnel as described in
462 Section X.2.2 Temperature monitoring.
- 463 • If a temperature critical limit is exceeded, the cause of the problem should be identified
464 and corrected by the operator of the vehicle or vessel. The affected lot may be rejected
465 by the receiving personnel, or the receiver may perform risk-based histamine analysis
466 on representative fish collected throughout the lot, and the lot rejected if any fish are
467 over the histamine critical limit.

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469 **X.4 Processing operations**

470 This section applies to processing on land or at sea (e.g., factory vessel, mother ship)

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472 **X.4.1 Reception (processing establishment)**

- 473 • If fish are delivered directly from the fishing vessel to the processing establishment,
474 then refer to Section X.2 Reception (receiving establishment).
- 475 • If fish are delivered by transport vehicle or vessel, then refer to Section X.3
476 Transportation.
- 477 • If the processing establishment is a secondary processor receiving product from a
478 primary processor (e.g., receiving establishment, factory vessel), then the secondary
479 processor should ensure that the primary processor uses HACCP or a similar control
480 system designed to prevent formation of hazardous levels of histamine.
- 481 • At times, it may be impractical or unreliable for the initial receiving establishment to
482 conduct all the appropriate histamine controls listed in Section X.2 (Reception (receiving
483 establishment)). In these cases, the processing establishment may conduct these
484 activities, but should ensure that the controls and decisions are applied to intact fishing
485 vessel lots that are not comingled with other lots. However, fish internal temperature
486 should be monitored both at vessel delivery (to evaluate vessel control), and at
487 processing establishment reception (to evaluate transport cooling).

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489 **X.4.2 Processing, time and temperature control**

490 When fish undergo processing (e.g., thawing, cutting, re-chilling, salting, drying, pickling,
491 smoking, canning) it is important that they are not held at temperatures for sufficient time that
492 histamine-producing bacteria can grow and produce histamine to hazardous levels.

- 493 • Scientific studies and microbial growth models⁸ may be used to estimate the exposure
494 times and temperatures that result in elevated histamine levels.
- 495 • Histamine formation is quite variable and strongly depends on the previous handling of
496 the raw material and the different species of histamine-producing bacteria that are
497 present; therefore, the worst case scenario should be considered when establishing
498 critical limits.

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 6.1.9 Microbiological modelling.)

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- 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 and temperature critical limits should be the cumulative product 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 and temperature exposures. For example, periodically measure the 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 and temperature critical limits are exceeded, the cause should be determined and corrected. In addition, risk-based histamine testing should be performed before releasing affected product for human consumption. Alternatively, product should be rejected.

522 **X.4.3 Heat processing**

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- Proper heat treatment (e.g., cooking, hot smoking) can kill histamine-producing bacteria and inactivate the enzyme histidine decarboxylase. The food business operator should ensure that an adequate heat treatment is carried out in order to avoid the development of histamine-producing bacteria.
 - 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 unrefrigerated temperature 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 again commence without proper preventative controls.

541 **X.4.4 Processing, other technological measures**

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

544
545 Some products and processes (e.g., fermenting, smoking, salting, drying, pickling, acidifying,
546 preserving, modified atmosphere packaging) introduce other technological factors that may
547 inhibit the introduction and/or growth of histamine-producing bacteria. The interaction of
548 these factors is complex and often unpredictable. For example, increased salt content, or
549 increased acidity, may decrease or increase histamine production, depending on conditions.

550
551 Thorough scientific studies, and proper establishment and validation of control parameters for
552 each specific process and product, are imperative to ensure the safe manufacture of foods that
553 incorporate other technological measures as an element of histamine control. (See Guidelines
554 for the Validation of Food Safety Control Measures, CAC/GL 69 - 200.)

555
556 The safe application of any of these treatments is dependent on the rapid chilling and
557 maintenance of chilled temperatures of the raw fish material from the time of death of the fish
558 until the proper inhibitory or destructive control attributes contributed by the treatments have
559 been achieved. And depending on the treatment, the finished product may need to remain
560 chilled until consumed to ensure safety.

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562 **X.4.5 Refrigerated and frozen storage (processing establishment)**

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

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570 **X.4.6 Monitoring records (processing establishment)**

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

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584 **GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS**

585

586 In order to facilitate the compilation and prepare a more useful comments document and further
587 revision of the draft CoP, Members and Observers, which are not yet doing so, are requested to
588 provide their comments under the following headings:

589 (i) General Comments

590 (ii) Specific Comments

591

592 Specific comments should include a reference to the relevant section and/or line number of the
593 document that the comments refer to.

594 When changes are proposed to specific paragraphs and lines, Members and Observers are
595 requested to provide their proposal for amendments accompanied by the related rationale. New
596 texts should be presented in **underlined/bold** font and deletion in ~~strikethrough~~ font.

597

598 In order to facilitate the work of the EWG Secretariats to compile comments, Members and
599 Observers are requested to refrain from using colour font/shading as documents are printed in
600 black and white and from using track change mode, which might be lost when comments are
601 copied / pasted into a consolidated document.

602

603 In order to reduce the translation work and save paper, Members and Observers are requested not
604 to reproduce the complete document but only those parts of the texts for which any change
605 and/or amendments is proposed.