Histamine

A Guideline for the Seafood Industry

Particular Reference: European Union OMAR

New Zealand Seafood Standards Council

Version 2, October 2013

1.0 Purpose

This guideline aims to clarify the legislative requirements associated with histamine in seafood. It provides particular reference to compliance with the EU OMAR.

2.0 Scope

This resource applies to:

- Species of seafood that are susceptible to histamine formation and therefore have the potential to cause histamine poisoning, as identified in Section 5.0.

It is intended as a guide only.

3.0 Background

Histamine is a toxin that can form in fish species that contain naturally high amounts of free histidine in their tissue (susceptible species). When conditions are favourable, bacteria multiply and convert histidine to histamine and the histamine toxin if present in high enough levels causes food poisoning when the fish are consumed. Cooking does not destroy the histamine toxin once it has formed.

The formation and rate of formation of histamine is affected by temperature and time. Generally this takes place at a temperature of more than 25°C over a period of more than 6 hours or over longer timeframes if at lower abuse temperatures (anything kept at 7°C or warmer for extended periods of time should be considered temperature abused).

4.0 Regulatory Requirements

4.1 New Zealand Legislation

The following New Zealand legislation is relevant to operators with respect to contaminants and fish:

- Animal Products Regulations
- Animal Products (Specifications for Products Intended for Human Consumption) Notice

AP Reg 6

Taking into consideration it intended use, animal product must be free from –

(a) Biological, chemical and physical hazards in amounts that may be directly or indirectly harmful to humans or animals:

AP Reg 7

(1) All RMP operators, must ensure that the composition of the animal product complies with any relevant composition levels and requirements set out in the specifications:

HC Spec103 Handling and Processing

(2) The level of histamine in fish or fish product must not exceed 200 mg/kg

4.2 Overseas Market Access Requirements

The EU has specific requirements relating to Histamine:

EU OMAR

1.6 Process Hygiene & Food Safety Criteria for Foodstuffs

1.6.2 Operators must decide the appropriate sampling frequencies if these are not otherwise specified, taking into account their RMP, good hygiene practice and the instructions for use of the foodstuff. The frequency of sampling may be adapted to the nature and size of the food business provided the safety of the foodstuffs will not be endangered.

1.6.5 Operators must have a programme in place capable of meeting the food safety criteria for the products described below:

(j) Fishery products – refer to Part 6

6.8 Food Safety Criteria

6.8.1 Operators must have procedures in place to meet the following food safety criteria:

(c) Fishery products from fish species associated with high amounts of histidine (particularly fish species of the families *Scombriae, Clupeidae, Engraulidae, Coryphaenidae, Pomatomidae, Scombresosidae*)

- Histamine n = 9, c = 2, m = 100mg/kg, M = 200mg/kg

(d) Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with high amounts of histidine

- Histamine n = 9, c = 2, m = 200mg/kg, M = 400mg/kg

Note:
There is no expectation that species susceptible to histamine formation would be tested for histamine on a consignment basis. Operators should focus their attention on assessing the risk of histamine formation, taking into account their specific operation and the susceptible species processed, and identifying appropriate controls to manage the risk as assessed. Testing is likely to only be required when monitoring indicates a potential abuse problem or for verification purposes.

In New Zealand, the risk of histamine is highly likely to be controlled by the normal acceptable time/temperature criteria applied during catching, transport and processing operations.

5.0 Susceptible Fish Species

While processors of all fish should be concerned with temperature abuse for a variety of reasons, it is only those who process species with high levels of free histidine, i.e. susceptible species that need to be concerned with histamine. In New Zealand, the following table includes the species of fish caught commercially that have been identified (either internationally or domestically) as being histamine susceptible species:

Histamine Susceptible Species

Family	Common Name	Scientific Name
Scombridae	Albacore	Thunnus alalunga
	Bigeye Tune	Thunnus obesus
	Pacific Bluefin Tuna	Thunnus orientalis
	Southern Bluefin Tuna	Thunnus maccoyii
	Yellowfin Tuna	Thunnus albacares
	Skipjack Tuna	Katsuwonus pelamis
	Slender Tuna	Allothunnus fallai
	Blue Mackerel	Scomber australasicus
Arripidae	Kahawai	Arripis trutta Arripis xylabion
Carangidae	Yellowtail Kingfish	Seriola lalandi
Carangidae	Trevally	Pseudocaranx dentex
Carangidae	Jack Mackerel	Trachurus spp (Trachurus murphyi, Trachurus declivis, Trachurus novazelandiae)
Clupeidae	Pilchard	Sardinops sagax
	Sprat	Sprattus spp, Sprattus antipodum, Sprattus muelleri
Engraulidae	Anchovy	Engraulis australis

Note:
The EU also refers to species from the following families as being susceptible to histamine. There are no species from these families caught commercially in New Zealand.

Family	Comment
Coryphaenidae	No species caught commercially in NZ
Pomatomidae	No species caught commercially in NZ
Scombresosidae	No species caught commercially in NZ

6.0 Risk of Histamine Formation

When freshly caught, fish will be around the temperature of the seawater from which they are caught, in some areas, such as in the far North of New Zealand in the height of summer this could be as warm as 20°C. However, the temperature of seawater in the South Island in the middle of winter will be lucky to be above 10 °C, particularly the lower South Island. These are the kinds of considerations that should be taken into account when assessing the risk of histamine formation in susceptible species.

However, temperature alone is not the only parameter that should be considered, time is also an important criterion, along with the post-harvest practices. If the fish is brought on board (after catching), placed in ice to ensure rapid chilling, maintained in a chilled state and is processed quickly then conditions are not favourable for histamine formation. However, if the product is not adequately chilled and is held for extended periods of time, then this creates a risk of histamine formation. The method of catching may also be a factor that needs to be considered, any fish that dies and then spends time in warm waters before being bought on board could be at risk.

7.0 Control of Histamine Formation

Regardless of where and when fish is caught, it is important that the susceptible species are iced or chilled by other means such as use of refrigerated seawater or brine, as soon as possible once bought on board so that it will begin to reduce in temperature.

Post catching handling practices are most important in order to control the formation of histamine in susceptible species. Ensuring chilling to 4.4°C[1] or below without delay and maintaining the cold chain from point of catch through to processing will prevent the formation of high levels of histamine.

[1] According to the FDA Fish and Fishery Products, Hazards and Controls Guidance, Fourth Edition, 2011
http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM251970.pdf

According to the MPI Hazard Scombroid Fact Sheet[2], the following storage temperature and times are appropriate controls:

Susceptible Fish	Temperature (fish)	Time
Store Fish At:	-18°C 0°C 4.4°C 10°C 21°C	No limit Up to 14 days Up to 7 days Up to 3 days 0 days

[2] MPI Scombroid Fact Sheet can be found at:
http://www.foodsafety.govt.nz/elibrary/industry/Scombroid_Histamine-Science_Research.pdf

Given that vessel handling practices are one of the key controls, receivers of susceptible species may consider providing information on handling practices to their fishers and/or requiring supplier guarantees in order to ensure that appropriate handling of susceptible species takes place on-board the vessel.

8.0 Monitoring and Sampling Programmes

The activities included in the monitoring programme should be based on the risk as assessed by the operator. As a result the operator will need to decide what parameters they monitor such as time/ temperature parameters and any other factors appropriate for their operation.

The key control to prevention of histamine formation is temperature reduction and maintenance of the cold chain, the key aspect of any monitoring programme should also focus on temperature and condition of fresh (unfrozen) fish on arrival.

Monitoring programmes should include documentation of the following:

- Monitoring
- Corrective Action
- Verification

Monitoring

To determine the monitoring required, consider the range of susceptible species received and processed. Initial checks at reception are likely to include:

- Evidence that the product has been adequately chilled, this could include:

- assessing whether sufficient ice is present; or
- taking a sample temperature

- Condition of the fish
  - Sensory checks (visual, smell etc) for signs of spoilage that may indicate temperature abuse has occurred

If product is received in an acceptable condition with no evidence to suggest temperature abuse has occurred, then no further action is necessary.

However, if not, each operator will need to apply a decision making process to determine if any further action is required. Decisions should take into account all of the relevant factors, which may include:

- Temperature
- Time since capture
- Condition of fish (signs of spoilage or not)
- Evidence that may be provided by the fisher, such as vessel/product temperature records or other forms of guarantees

For susceptible species consider the following examples:
Fish that arrives at 15°C was caught 48 hours earlier and shows signs of spoilage are a probable candidate for histamine formation and samples should be sent for histamine analysis.

Fish that arrives at 10°C, was caught within the past 6 hours, is well iced and shows no signs of spoilage, is likely to be still in the temperature reduction phase and there has not been sufficient time for significant histamine formation, so no further action required.

Corrective Action
Action to take will depend on what is found but essentially, if the operators pre-determined acceptability parameters are not met, then samples should be sent to a laboratory for histamine analysis (see below for further details on laboratories, methods and sampling plans) to ensure the fish is within safe limits.

Other action will of course include, following up with the vessel or supplier and/or transporter to determine the root cause, and implementing preventative measures as appropriate.

Verification
It is good practice to build in verification activities for any monitoring programme, in order to confirm that the parameters being monitored are controlling the risk.

In this case, as a verification activity, it is suggested that once per year, select the most susceptible species that is received and processed and test it for histamine, unless operators can justify through their risk assessment, that appropriate controls and monitoring are in place to adequately manage the risk.

9.0 Laboratories, Methods and Sampling Plans

When testing occurs operators need to identify the appropriate sampling plan to use. This will depend on the reason for testing, which could be:

- As part of corrective action to confirm product meets the New Zealand standard
- As part of corrective action to confirm product meets the EU standard
- A verification activity to confirm compliance to the New Zealand standard
- A verification activity to confirm compliance to the EU standard.

9.1 Sampling Plans

New Zealand Standard

If you are carrying out analysis as part of corrective action to confirm product meets the New Zealand standard, i.e. after initial monitoring criteria was not met, the following sampling plan is recommended:

- n = 5, c = 0, M = 200mg/kg

If you are carrying out analysis as a verification activity only to confirm the New Zealand standard is met or for the operator's own purposes, then the following sampling plan may be sufficient:

- n = 1, c = 0, M = 200mg/kg

Note:
There are no prescribed sampling plans in the New Zealand standard and therefore the operator can determine the number of samples to test.

EU Standard

However, if you are carrying out analysis to confirm the EU OMAR is met, either as a result of corrective action or as a verification activity the following sampling plan **must** be used:

- n = 9, c = 2, m = 100mg/kg, M = 200mg/kg

9.2 Laboratories and Methods

When testing samples for official purposes – i.e. to confirm the New Zealand or the EU standard is met, the laboratory must be approved under the MPI Laboratory Approval Scheme (LAS) and the method used for analysis must also be an approved test under LAS.

The numerical reference for the approved test method for histamine is 11.5.8. Attached is a list of laboratories approved under LAS to carry out histamine analysis using approved test method 11.5.8.

Note:
You must inform the laboratory that the analysis is for official purposes and the method must comply with the LAS, i.e method reference 11.5.8. If the analysis is also for confirming EU compliance as per the above, inform the laboratory of this so they can report the sampling as n = 9 on the laboratory report.

Appendix 1:

Laboratories Approved for Histamine Analysis as at 1 August 2013

Laboratory Name	Postal Address	Physical Address	Approved Tests	Authorised Representative
AsureQuality Limited, Laboratory Services-Auckland Laboratory	P O Box 41 AUCKLAND 1140	131 Boundary Road, Blockhouse Bay AUCKLAND	3.1.2, 3.1.4, 3.1.3, 3.1.1, 4.02, 4.03, 4.04, 2.6, 1.1, 1.2, 1.3, 2.4.3, 1.4, 2.4.2, 2.1.1, 2.1.2, 2.2.2, 2.3, 2.4.1, 11.8.5, 1.6.1, 22.1, 2.8, 2.9, 2.1.4, 1.1.1, 1.5.1, 11.1.1, 11.1.2, 11.5.3, 11.5.4, 11.6.2, 11.6.3, 11.8.1, 11.8.2, 11.8.3, 7.04, 6.15, 6.31, 7.03, 7.10, 11.7.2, 11.7.4, 6.18, 11.5.7, 5.17, 5.18, 5.19, 5.20, 5.22, 5.23, 5.26, 5.28, 5.29, 5.32, 5.33, 6.16, 23.1, 23.2 interim, 6.02, 6.03, 6.04, 6.05, 6.10, 6.13, 6.17, 5.03, 6.28, 6.29, 6.30, 5.02, 7.01, 7.02, 7.06, 7.09, 5.04, 6.01, 6.06, 6.11, 6.12, 6.26, 6.27, 5.13, 5.14, 5.10, **11.5.8**, 11.5.9, 6.24, 6.25, 5.24, 5.25, 5.27, 5.30, 5.31, 6.14, 6.19, 6.20, 6.21, 6.22, 6.23, 5.21, 6.32	Vijaya Naidu
Institute of Environmental Science & Research Limited, Christchurch Science Centre	PO Box 29-181 CHRISTCHURCH 8540	27 Creyke Road CHRISTCHURCH	**11.5.8**, 4.01	Christina Bir
The Cawthron Institute Trust Board	Private Bag 2 Nelson 7042	98 Halifax Street East NELSON	11.7.2, 8.43, 11.7.1, 8.42, 11.7.7, 11.7.6, 11.7.5, 11.7.4, 11.7.3, 11.8.6, 2.4.1, 2.1.6, 2.10.1, 2.5, 2.9, 11.3.3, 1.3, 1.4, 1.1.1, 11.1.1, 11.1.2, 11.2.1, 11.2.3, 11.3.1, 11.4.1, 11.4.2, 11.5.3, 11.5.4, 11.5.6, 11.6.1, 11.6.3, 11.6.4, 11.8.1, 11.8.2, 11.8.3, 11.8.5, 11.6.2, 11.5.10, 11.5.11, 1.1, 11.5.12, 1.2, 2.8.1, 11.6.7, 5.01, 5.02, 5.03, 5.04, 6.21, 6.22, 6.23, 6.24, 6.25, 11.5.7, 11.6.6, 6.14, 6.20, 6.19, 6.16, 6.15, **11.5.8**, 11.5.9	Nicolaas Gijsbert van Loon

Laboratories can be found here:
http://www.foodsafety.govt.nz/registers-lists/laboratory-scope-list/index.htm?setup_file=authorised-representative-laboratory.setup.cgi&session_file=&rows_to_return=10000&LaboratoryName=&Location=&ApprovedTest=11.5.8&submit_search=Search