

Standard Management Rule 14b: Fish - selected species that are susceptible to the production of histamine

From the 1st July 2009 NZFSA replaced this SMR with a standardised format for all Imported Food Requirements.

For the current version refer to the Imported Food Requirement for fish species susceptible to production of histamine.

Recent Updates:

Date	Location	Information
1 July 2009	All	Made obsolete refer to the Imported Food Requirement for fish species susceptible to production of histamine.
15 September 2008	Section 2.1	Removal of Singapore Pathology Laboratory, Singapore General Hospital, for testing purposes.
10 March 2008	Section 3.3.2	Method of analysis updated to include methods recognised in LAS as acceptable testing methods.
20 July 2007	Section 3.4	Sampling and Inspection costs have been updated
24 November 2005	Section 2.1	New certification option for products from the European Union.
30 March 2005	Section 3.2.7	Changes to sampling and release criteria
10 January 2007	Section 1.0	Tariff Codes updated to reflect changes made by World Customs Organisation.

Background Information:

SUMMARY OF HAZARD:

Selected species of fish (e.g. species of finfish of the Scombridae, Scombresocidae, Clupeidae, Coryphaenidae and Pomatomidae families) are more susceptible to microbiological spoilage and the production of histamine. Histamines are heat stable and cause illness; as a result the Standard Management Rule applies to canned, pouch and frozen products.

Amines, including histamines, are only produced during temperature abuse or spoilage. The enzymes which produce histamines, once produced, may still be active even if the bacteria which produced them are subsequently controlled. Vacuum packing and salting are not effective in delaying the production of amines.

Not all species in these families are targeted at present due to limitations in the tariff codes. The NZFSA is currently investigating ways of targeting risk species in the tariff code system.

All fish pastes are tested regardless of the fish species stated on the packaging. This is because fish pastes are usually prepared from a variety of fish types and are likely to contain species that are more susceptible to the production of histamines.

GENERAL INFORMATION ON AGENCY ROLES:

The following descriptions have been included to clarify the roles of the New Zealand Food Safety Authority and Ministry of Agriculture and Forestry in imported food.

New Zealand Food Safety Authority (NZFSA):

NZFSA was established on 1 July 2002 as a semi-autonomous body attached to the Ministry of Agriculture and Forestry (MAF). The Authority has responsibility for the food functions previously managed by MAF and the Ministry of Health. Establishment of the NZFSA provides a more integrated approach to food safety in New Zealand. NZFSA is the controlling authority for imports of food and sets policies, criteria and procedures to monitor the safety of imported food for human consumption and for food containers (see www.nzfsa.govt.nz).

- **Auckland Central Clearing House (ACCH):**

ACCH is part of the Auckland Regional Public Health Service, and is contracted by the NZFSA to carry out day to day operational procedures. The ACCH provides the initial point of contact for information to importers and customs brokers throughout New Zealand. It facilitates the inspection and clearance services of identified imported products.

- **Public Health Units (PHU):**

Food and Health Protection Officers (Food/HPOs) employed by the various public health services are responsible for the inspection and sampling of high-risk imported foods under the coordination of the ACCH.

Biosecurity New Zealand:

Biosecurity NZ is the lead agency in New Zealand's biosecurity system. 'Biosecurity' is the protection of New Zealand's economy, environment and people's health from pests and diseases. It includes trying to prevent new pests and diseases arriving. Established in November 2004 (replacing MAF Biosecurity), it has been tasked with a 'whole of system' leadership role, encompassing economic, environmental, social and cultural outcomes. Importers should contact Biosecurity NZ directly to check their requirements <http://www.biosecurity.govt.nz/>.

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Import Criteria Applying to Selected Species of Fish that are Susceptible to the Production of Histamine

1.0 Products targeted:

Prescribed foods are targeted at the border using the New Zealand Customs tariff code system. Products classified with the following tariff codes are captured under this rule:

<i>Tariff codes targeted for histamine susceptible fish</i>	
<i>0302 Fish, fresh or chilled, excluding fish fillets and other fish meat of heading 03.04</i>	
0302.31.00.01L	Whole Albacore Or Longfinned Tunas Fresh Or Chilled
0302.31.00.11H	Headed And Gutted Albacore Or Longfinned Tunas Fresh Or Chilled
0302.31.00.19C	Albacore Or Longfinned Tunas Fresh Or Chilled Other Than Whole Headed And Gutted
0302.32.00.01E	Whole Yellowfin Tunas Fresh Or Chilled
0302.32.00.11B	Headed And Gutted Yellowfin Tunas Fresh Or Chilled
0302.32.00.19H	Yellowfin Tunas Fresh Or Chilled Other Than Whole Headed And Gutted
0302.33.00.01K	Whole Skipjack Or Stripe-Bellied Bonito Fresh Or Chilled
0302.33.00.11G	Headed And Gutted Skipjack Or Stripe-Bellied Bonito Fresh Or Chilled
0302.33.00.19B	Skipjack Or Stripe-Bellied Bonito Fresh or Chilled Other Than Whole Headed And Gutted
0302.34.00.10C	Whole Bigeye Tunas Fresh Or Chilled
0302.34.00.12K	Headed And Gutted Bigeye Tunas Fresh Or Chilled
0302.34.00.19G	Bigeye Tunas Fresh Or Chilled Other Than Whole Headed And Gutted
0302.35.00.10H	Whole Bluefin Tunas Fresh Or Chilled
0302.35.00.12D	Headed And Gutted Bluefin Tunas Fresh Or Chilled
0302.35.00.19A	Bluefin Tunas Fresh Or Chilled Other Than Whole Gutted And Headed
0302.36.00.10B	Whole Southern Bluefin Tunas Fresh Or Chilled
0302.36.00.12J	Headed And Gutted Southern Bluefin Tunas Fresh Or Chilled
0302.36.00.19F	Southern Bluefin Tunas Fresh Or Chilled Other Than Whole Headed And Gutted

0302.39.00.10F	Whole Other Tuna Fresh Or Chilled
0302.39.00.12B	Headed And Guttled Other Tunas Fresh Or Chilled
0302.39.00.18A	Other Tunas Fresh Or Chilled Other Than Whole Headed And Guttled
0302.40.00.01K	Whole Herrings Fresh Or Chilled
0302.40.00.11G	Headed And Guttled Herrings Fresh Or Chilled
0302.40.00.19B	Herrings Fresh Or Chilled Other Than Whole Headed And Guttled
0302.64.00.01E	Whole Mackerel Fresh Or Chilled
0302.64.00.11B	Headed And Guttled Mackerel Fresh Or Chilled
0302.64.00.19H	Mackerel Fresh Or Chilled Other Than Whole Headed Or Guttled
0302.69.01.55C	Whole Fresh Or Chilled Yellowtail Kingfish
0302.69.11.51F	Headed And Guttled Fresh Or Chilled Yellowtail Kingfish
0302.69.19.51G	Other Fresh Or Chilled Yellowtail Kingfish

<i>0303 Fish, frozen, excluding fish fillets and other fish meat of heading 03.04</i>	
0303.41.00.01B	Whole Frozen Albacore Or Longfinned Tunas
0303.41.00.11K	Headed And Guttled Frozen Albacore Or Longfinned Tunas
0303.41.00.19E	Frozen Albacore Or Longfinned Tunas Other Than Whole Headed Or Guttled
0303.42.00.01G	Whole Frozen Yellowfin Tunas
0303.42.00.11D	Headed And Guttled Frozen Yellowfin Tunas
0303.42.00.19K	Frozen Yellowfin Tunas Other Than Whole Headed Or Guttled
0303.43.00.01A	Whole Frozen Skipjack Or Stripe-Bellied Bonito
0303.43.00.11J	Headed And Guttled Frozen Skipjack Or Stripe-Bellied Bonito

0303.43.00.19D	Frozen Skipjack Or Stripe-Bellied Bonito Other Than Whole Or Headed And Guttled
0303.44.00.10E	Whole Frozen Bigeye Tunas
0303.44.00.12A	Headed And Guttled Frozen Bigeye Tunas
0303.44.00.19J	Frozen Bigeye Tunas Other Than Whole Or Headed And Guttled
0303.45.00.10K	Whole Frozen Bluefin Tunas
0303.45.00.12F	Headed And Guttled Frozen Bluefin Tunas
0303.45.00.19C	Frozen Bluefin Tunas Other Than Whole Or Headed And Guttled
0303.46.00.10D	Whole Frozen Southern Bluefin Tunas
0303.46.00.12L	Headed And Guttled Frozen Southern Bluefin Tunas
0303.46.00.19H	Frozen Southern Bluefin Tunas Other Than Whole Or Headed And Guttled
0303.49.00.10H	Whole Frozen Other Tuna

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0303.49.00.12D	Headed And Guttled Frozen Other Tuna
0303.49.00.18C	Frozen Other Tuna Other Than Whole Or Headed And Guttled
0303.51.00.01A	Whole Frozen Herrings
0303.51.00.11J	Headed And Guttled Frozen Herrings
0303.51.00.19D	Frozen Herrings Other Than Whole Or Headed And Guttled
0303.74.00.02E	Whole Frozen Blue Mackerel
0303.74.00.08D	Whole Frozen Other Mackerel (Excluding Jack)
0303.74.00.11D	Headed And Guttled Frozen Blue Mackerel
0303.74.00.19K	Headed And Guttled Frozen Other Mackerel (Excluding Jack)
0303.74.00.21A	Frozen Blue Mackerel Other Than Whole Or Headed And Guttled
0303.74.00.29G	Frozen Other Mackerel (Excluding Jack) Other Than Whole Or Headed And Guttled
0303.79.01.23G	Whole Frozen Jack Mackerel
0303.79.01.85G	Whole Frozen Yellowtail Kingfish
0303.79.11.23B	Frozen Headed And Guttled Jack Mackerel
0303.79.11.81K	Headed And Guttled Frozen Yellowtail Kingfish
0303.79.19.23C	Other Frozen Jack Mackerel
0303.79.19.91H	Other Frozen Yellowtail Kingfish
<i>0304 Fish fillets and other fish meat (whether or not minced), fresh, chilled or frozen</i>	
0304.19.00.66L	Southern Bluefin Tuna Fillets
0304.19.00.68G	Other Tuna Fillets Etc
0304.19.00.76H	Yellowtail Kingfish Fillets Fresh Or Chilled
0304.29.00.41J	Frozen Blue Mackerel Fillets
0304.29.00.42G	Jack Mackerel Fillets Frozen
0304.29.00.66D	Frozen Southern Bluefin Tuna Fillets
0304.29.00.68L	Frozen Other Tuna Fillets

<i>0305 Fish, dried, salted or in brine; smoked fish, whether or not cooked before or during the smoking process; flours, meals and pellets of fish, fit for human consumption</i>	
0305.42.00.00E	Smoked Herrings
0305.61.00.00H	Salted Herrings
<i>1604 Crustaceans, molluscs and other aquatic invertebrates, prepared or preserved</i>	
1604.12.00.01J	Herrings Prepared In Cans or Jars
1604.12.00.09D	Herrings Prepared Otherwise Packed
1604.14.01.00F	Tunas Skipjack And Bonito Prepared In Cans Or Jars
1604.14.09.00G	Tunas Skipjack And Bonito Prepared Packed Otherwise Than In Cans Or Jars
1604.15.01.00L	Mackerel Prepared In Cans Or Jars
1604.15.09.00A	Mackerel Prepared Otherwise Packed
1604.19.01.01G	Pilchards Prepared In Cans Or Jars
1604.19.01.09B	Sild And Saury Prepared In Cans Or Jars
1604.19.09.19L	Other Fish Prepared In Cans Or Jars Other
1604.20.01.00A	Fish Pastes
1604.20.09.01L	Fish Pate
1604.20.09.09F	Fish Fingers
1604.20.09.11H	Prepared Dinners Containing Fish
1604.20.09.19C	Fish Cakes
1604.20.09.29L	Other Fish Preparations Such As Sausages Etc
1604.20.29.11J	Tuna Otherwise Prepared In Cans Or Jars

INADVERTENT CAPTURES:

As the tariff classification system is not designed specifically around the imported food regime, some food products may be inadvertently captured by the targeted tariff codes above. If this is the case, products will not be subject to the sampling and testing protocol outlined in this rule.

2.0 Clearance options:

The following 3 options are available to clear consignments captured under this rule:

2.1 Acceptance of recognised certification:

Where the NZFSA (or Ministry of Health prior to July 2002) has negotiated certification arrangements with other governments or specific manufacturers then approved certification may be accepted for a prescribed food. Importers should check specific certification requirements with their local PHU prior to importing a prescribed product.

For histamine susceptible fish approved certification may be accepted from:

- Australian Quarantine Inspection Service (AQIS)
- Department of Pathology, Singapore General Hospital
- Canadian Food Inspection Agency (previously the Dept. of Fisheries and Oceans)
- Thailand Department of Fisheries
- Thailand Centre of Export Inspection and Certification for Agricultural Products (CEICAP)
- EU - Animal and Public Health Certificate: New Zealand has a Veterinary Agreement with the European Union (EU) to facilitate trade of live animal and animal products. The standard verification testing rate outlined below does not apply in this case; a reduced level of sampling/testing of 2% applies. Importers must obtain an MRP in order for this reduced rate to be implemented. Refer to <http://www.nzfsa.govt.nz/imported-food/eu-nz-vet/index.htm> for more information.

PRODUCTS FROM THE USA:

USA products will not be accompanied by any certification and are to be monitored at the rate of 1 in every 10 shipments as they are covered by a Mutual Recognition Arrangement between New Zealand and USA.

In all cases certification is required with **each consignment**.

Consignments imported under certification are required to be tested at intervals. The standard testing rate used to verify certification which applies to most prescribed foods is 1 in every 20 where consignments are more frequent than 20 in a six month period. Where consignments are less than 20 in a six month period, they are tested every six months.

2.2 Multiple Release Permits (MRPs):

MRPs are issued on a case by case basis to importers with the technical skill and experience to manage a quality imports system. They are specific to importer, broker, product and supplier and are issued for a defined time period. MRPs enable importers to bypass the normal import clearance procedure for prescribed foods saving time and clearance costs. Where testing is required, the sampling and testing protocol applied is specified below, unless a different protocol is a specific condition of the MRP.

MRPs are issued for imported food products that are:

- Inadvertently captured by the tariff codes monitored by the NZFSA
- From particular suppliers under an arrangement agreed to by the importer and NZFSA. This includes the importer maintaining an agreed imported food surveillance programme for the products covered by the MRP.

Importers wishing to apply for a MRP for this product should contact the NZFSA to discuss their situation prior to completing a MRP application form. For fish that is susceptible to histamines, importers applying for MRPs will need to demonstrate knowledge of their suppliers, time and temperature processes through the supply chain. The importer must also have an established history of testing compliance of these products to be considered for an MRP.

2.2 Clearance sampling and testing on arrival in New Zealand:

In the absence of approved certification or a MRP, fish susceptible to histamines are sampled and tested in New Zealand according to the sampling and testing protocol in the table below.

3.0 Sampling and testing protocol:

3.1 Toxicological criteria:

In order to ascertain if a consignment is safe the consignment is inspected and samples taken for laboratory testing. The following criteria are used when deciding if a consignment captured by this rule is safe to be released:

- Presence of histamine to a level not exceeding 100mg/kg

3.2 Sampling requirements:

3.2.1 When to sample consignments:

ACCH identifies which consignments are to be sampled and tested. Sampling frequencies depend on whether certification or a MRP are used as clearance options:

In the absence of certification or a MRP:

The frequency of sampling is based on the sampling and testing history developed by each importer for a specific product. A “specific product” means a product that is exactly the same i.e. the same size bottle/packet, variety, brand, and is manufactured by the same company. As a compliant history is developed, the frequency of sampling and inspection is reduced for the importer for that specific product. This reduction is governed by the “switching rule”, which follows the steps below:

- Sampling initially starts out at the *tightened* level (where 100% or every consignment is sampled and tested) until 5 compliant consignments have been cleared, when:
- Sampling is then lowered to the *normal* level (where 20% or 1 consignment in 5 is sampled and tested), until another 5 compliant consignments have been cleared, when:
- Sampling is then lowered to the *reduced* level (where 10% or one consignment in 10 is sampled and tested).

The frequency of sampling returns back to the *tightened* when a product is tested and found not to comply.

ACCH selects the frequency of sampling that is to apply to an imported product at any particular time using the *Switching Rule*. However, application of the *Switching Rule* may also be affected by the difficulty of managing the hazards applying to particular food products e.g. peanuts & pistachios are not able to be tested at a *reduced* level. Importers can contact their local PHU to discuss application of switching rules.

Certification:

Where testing is required to verify certification the sampling frequency does not follow the *Switching Rule* but is 1 in 20 consignments – see point 1 under “Clearance Options” above.

MRPs:

Where sampling is a requirement of a MRP, the MRP will specify the sampling frequency.

3.2.2 Who samples consignments:

Sampling must be carried out by PHUs, who will arrange for one of their Food/HPOs to inspect and sample any consignment identified as requiring testing.

3.2.3 Products to be sampled:

Samples should be taken for each specific type of product (e.g. same type of product, size packet, variety, brand, and is manufactured by the same company).

3.2.4 Number of lots to be sampled per consignment:

Food/HPOs select the lot(s) to be inspected and sampled. Where a consignment contains more than one lot, the number of lots to be sampled is calculated using the table below. This table is standard for all prescribed foods.

Number of lot codes in consignment	Number of lots to sample	Reject lots if n samples fail
1	1	$n = 1$
2 -8	2	$n = 1$
9 -15	3	$n = 1$
16 – 25	5	$n = 1$
> 26	8	$n = 1$

3.2.5 Number of samples to take per lot:

Each product has its own sample requirements. For fish susceptible to histamines the number of samples to take per lot is shown below:

Number of samples to be taken per lot = 5

Samples from within the same lot shall be identified by the same sampling officer sample number, with each of these samples being identified by a letter (A - E) e.g. where an officer has the sample number 751, the first sample from within the same lot will be identified as 751A, the second 751B, and so on.

3.2.6 Sample weight

- Each sample should be at least 100g.
- Individual units or packets should be sampled if these are available.

3.2.7 Release of product being sampled:

- All canned, fresh, chilled and frozen fish should be **SAMPLED AND HELD** until the laboratory results become available. (HPOs please see FoodNet for more details and exceptions).

3.3 Testing requirements:

3.3.1 NZFSA approved laboratories:

Samples of imported food can only be tested by laboratories approved by the NZFSA. At present only laboratories that are accredited by International Accreditation New Zealand (IANZ) to do the relevant test are approved by the NZFSA. NZFSA is currently updating its list of approved laboratories.

3.3.2 Methodology to be applied by laboratories:

- The preferred method for HISTAMINE ANALYSIS is described in the *Official Methods of Analysis of AOAC International 16th Edition, 1995*.
- Laboratories can use another method, as long as the laboratory is approved under NZFSA Laboratory Approval Scheme (LAS) to perform histamine analysis using that method.

3.3.3 Compositing Samples:

- Histamine results from composite samples are acceptable if the analysis methodology is sufficiently sensitive to demonstrate compliance for each individual sample.
- Each sample shall be entirely homogenised before compositing.

3.4 Sampling and testing costs:

All sampling and testing is at the importers expense. Permit and sampling costs are listed below, are in New Zealand dollars and include GST:

- Permit application assessment : \$48 per line assessment + \$96/hour
- Sampling and inspection: \$96 per hour payable in 15-minute units

For laboratory costs, contact NZFSA approved laboratories.

3.5 Reject criteria:

PHUs will apply the following criteria to lots after inspection and sampling:

REJECT lots where test results indicate the presence of histamine to a level exceeding 100mg/kg (based on the average).

REJECT lots when test results indicate the presence of histamine in a single sample exceeds 200mg/kg

- When lots fail the import criteria, those lots and any untested lots in the same consignment are rejected.
- Lots that fail the import criteria are not re-tested.
- Importers have the option of having any untested lots sampled and tested, and if any of these lots pass they can be cleared. Any untested lots in the same consignment of a reject lot must be sampled for clearance at the rate detailed in *Inspection Requirements and Testing Requirements* above.

Where a consignment of fresh or chilled tuna fails, the importer should take steps to recall any product still in the market place. Any untested fish in the products that are recovered must be sampled before being cleared and released **or** all recovered product needs to be disposed of.

Once an importer has had a consignment that fails, they need to establish a history of compliance over the next five imported shipments and their product should be **sampled and frozen or chilled** before being released for sale. The importer should be reminded to make specific arrangement with the laboratory to ensure samples are processed in a prompt manner.

3.6 Special conditions that may apply:

In unique or out of the ordinary situations, the NZFSA reserves the right to either stop trade or replace the above sampling regime with a special elevated programme of testing in order to regain confidence in a product.