

Imported food risk statement
Fish and fish products from the families specified and histamine

Commodity: Fish and fish products of the families specified in the table below. This includes fresh, frozen, dried and canned fish, and fish products (e.g. fish sauce) containing more than 30% fish.

ORDER	FAMILY
PERCIFORMES (perches and allies)	SCOMBRIDAE (tuna, mackerel and bonito)
	CORYPHAENIDAE (mahi-mahi)
	POMATOMIDAE (bluefish)
	CARANGIDAE (<i>Trevallies, Jacks & pompanos</i>)
CLUPEIFORMES (Herrings)	CLUPEIDAE (herrings, sardines)
	ENGRAULIDAE (anchovy)
BELONIFORMES (needle fishes)	SCOMBERESOCIDAE (King Gars, saury)

Analyte: Histamine

Recommendation and rationale
<p>Is histamine in fish and fish products of the families specified in the table above, a medium or high risk to public health:</p> <p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> <i>Uncertain, further scientific assessment required</i></p> <p>Rationale:</p> <ul style="list-style-type: none"> Histamine poisoning (also known as Scombrotxin Fish Poisoning [SFP] or scombroid fish poisoning) may occur following consumption of fish which has not been appropriately preserved following capture. Unsafe levels of histamine in fish have been commonly associated with fish in the families of <i>Scombridae, Coryphaenidae, Pomatomidae, Carangidae, Clupeidae, Engraulidae</i> and <i>Scomberesocidae</i>. There have been recalls in Australia of fish and fish products (fish sauce) with high histamine concentrations and the kinds of fish in the recalled products were anchovy, herring, tuna, mackerel and sardines.

General description
<p>Nature of the analyte:</p> <p>Histamine is a biogenic amine endogenous in human tissue and is released in response to a variety of immunologic and non-immunologic signals. The release of histamine induces a variety of vascular changes resulting in acute symptoms such as rhinitis, cramping, diarrhoea, bronchoconstriction, headache and flushing of the face (Taylor 1986; EFSA 2011; FAO/WHO 2013).</p> <p>Histamine, together with other as yet undefined biogenic amines, may form in foods such as fish and can lead to histamine poisoning (also known as Scombrotxin Fish Poisoning [SFP] or scombroid fish poisoning)</p>

depending on individual sensitivity. Histamine in this context is produced by the bacterial decarboxylation of histidine, an amino acid present at varying concentrations in fish muscle. In general, histamine production is higher in decomposing fish or fish that have been inappropriately stored (Kim et al. 2000; Economou et al. 2007; Vusilovic et al. 2008; Visciano et al. 2012). Histamine is heat stable and remains unaffected by temperature (Lee et al. 2013) and therefore canned fish has also been associated with SFP (Prester 2011).

Fish types, such as those of the *Scombridae* family (e.g. tuna and mackerel) and *Scomberesocidae* (e.g. saury) are commonly associated with histamine poisoning; however other fish families have also been implicated (Lehane and Olley 2000; Guillier et al. 2011; EFSA 2011; FDA 2011; FAO/WHO 2013).

Adverse health effects:

Given histamine is endogenous in the human body, low doses are unlikely to be toxic. It is when individuals are exposed to histamine levels at doses in excess of their individual tolerance that histamine may become toxic. Excess histamine can effect the cardiovascular system (tachycardia, headache, hypotension, rash and flushing), gastrointestinal tract (cramps, nausea, vomiting diarrhea) and neurological functions (pain and itching). Other symptoms include burning sensation in the mouth, swelling of the tongue and a peppery flavour to the fish (Whittle and Gallacher 2000; Lehane and Olley 2000; EFSA 2011; FAO/WHO 2013).

The onset of symptoms following the consumption of fish with high levels of histamine varies amongst individuals from minutes to hours. Symptoms generally persist for approximately 8-12 hours and resolve with either no or limited medication (e.g. anti-histamines) within 24 hours post-consumption (EFSA 2011; FAO/WHO 2013). An individual's sensitivity to histamine exposure varies and is usually dependent on additional factors including susceptibility to asthma, metabolic differences and drug therapies (Lehane and Olley 2000; Hungerford 2010; EFSA 2011; FAO/WHO 2013). From human challenge studies, a no observed adverse effect level (NOAEL) of 50 mg has been determined in healthy histamine-sensitive individuals. The application of Benchmark Dosing analysis (i.e. the BMDL₁₀ - 95 percent lower bound confidence limit) with a Weibull model to the same data yielded the almost identical no effect dose level (49.7 mg). The threshold or lowest observed adverse effect level (LOAEL) was considered to be 90 mg, however some uncertainty around this value exists due to the limited data available. Given the consumption of fish is variable, a serving size of 250 gms was considered reasonable to establish a Maximum Level (ML) for histamine in fish at 200 mg/kg (FAO/WHO 2013).

Consumption patterns:

In the 2007 Australian National Children's Nutrition and Physical Activity Survey, 17% children aged 2-16 years consumed fish (includes fresh, frozen, smoked, battered, crumbed and packed)(DOHA 2008).

In the 2011-2012 Nutrition and physical activity survey (part of the 2011-2013 Australian Health Survey), 8% of children aged 2-16 years, 14 % of adults aged 17-69 years and 18% for adults aged 70+ years reported consumption of fish. These data included fresh, frozen, smoked, battered, crumbed and packed forms of fish. The reported percentages are based on a single day of consumption information from each nutrition survey and do not indicate the frequency of consumption of fish (ABS 2014).

Key risk factors:

There are a number of factors related to histamine levels in fish. These include:

- Endogenous histidine levels in fish
- Bacterial presence
- Handling and storage procedures.

Risk mitigation:

In Australia [Schedule S19—6 Maximum levels of contaminants and natural toxicants](#) of the Australia New Zealand Food Standards Code (the Code), currently specifies a ML of histamine in fish and fish products of 200 mg/kg.

[Standard 2.2.3 \(Fish and fish products\)](#), [3.2.2 \(Food safety practices and general requirements – Australia only\)](#) and [4.2.1 \(Primary production and processing standard for seafood – Australia only\)](#), also contain relevant guidance in relation to labelling, general and specific seafood food safety requirements, to ensure good hygienic practices and temperature control.

A range of education measures have been undertaken to improve understanding for harvesters and processors around the risk of histamine poisoning including:

- The specific types and fish size with naturally high levels of the amino acid histidine. In general, dark fish muscle contains higher levels of histidine in comparison to white fish muscle. There is also inter- and intra- species variability in the histidine level in fish, which is not uniformly distributed throughout the fish flesh (Lehane and Olley 2000; Osako et al. 2004; Prester 2011)
- Impact of harvesting techniques and duration, season of capture and water temperature on histamine levels in fish (Osako et al. 2004; McLauchlin et al. 2006)
- The impact of the presence of histidine decarboxylase producing bacteria in adequate numbers on the fish
- Unhygienic handling techniques, storage conditions and temperature control during and after capture that supports bacterial growth. The length of time and the temperature in which fish are stored, are extremely influential on the level of bacterial growth and subsequent histamine level in the fish (Lehane and Olley 2000; Baixas-Nogueras et al. 2009; Torido et al. 2012; Visciano et al. 2012; Cheong et al. 2014)
- Correct identification of fish, and the appropriate handling and storage measures to reduce the risks.

Compliance history:

In 2011-2012, Australia imported over 140,000 tonnes of edible fish in a variety of forms (e.g. live, fresh or chilled, frozen, prepared or preserved, smoked, dried and salted). The imported fish types in this period included: tuna, salmonids, swordfish, shark, hake, toothfish, herrings, sardines, anchovies, mackerels, cod and others (Skirtun et al. 2013).

The imported food compliance data sourced from the Imported Food Inspection Scheme of the Australian Department of Agriculture and Water Resources for October 2005 – August 2013 showed that of the 11,897 samples tested for histamine in fish and fish products, there were 173 fails, a 1.5 % failure rate. The fish types that failed to comply with the ML for histamine in the Code included: mackerel, tuna, bonito, anchovy, maldive, seer fish, thalpath, sprats, katta, salmon, sardines, pilchards, loitta, gourami fish and kaporan.

There were approximately 343 notifications on the European Commission's Rapid Alert System for Food and Feed (RASFF) for histamine in fish and fish products from October 2005 – September 2014. The fish implicated were: tuna, mackerel, sardines, anchovy, queenfish, scad, wahoo, dolphinfish, herring and cobia (EC 2014).

There have been six food recalls in Australia of fish and fish products with high histamine concentrations from 2005 to September 2014, with the majority of recalls from imported products. The types of fish products recalled were anchovy, herring, tuna and fish sauce product (fish type not specified). Mackerel and sardines have also been recalled for excess histamine levels prior to this (ACCC 1999; ACCC 2005; ACCC 2008; FSANZ 2009; FSANZ 2010; ACCC 2014).

Surveillance information:

Illness associated with consumption of fish and fish products contaminated with histamine

Histamine poisoning from fish and fish products is not a notifiable disease in Australia. However cases of foodborne illness in two or more related cases is notifiable, which therefore may capture some cases of histamine poisoning when linked to the consumption of fish and fish products.

The OzFoodNet Outbreak register for the period of 2009 to 2013 has recorded 16 outbreaks involving a total of 57 people with gastrointestinal illness as a result of histamine poisoning linked to the consumption of fish. The main food vehicle in descending order was: tuna; mahi-mahi; fresh mullet fillets; seafood (unknown); seafood extender; seafood marinara; anchovies; and yellow-tail kingfish. Given histamine poisoning can be mild and medical treatment is not always sought, it is highly probable that cases of histamine poisoning from

fish are under-reported (OzFoodNet 2014). A number of cases of histamine poisoning in Australia are reported in the literature (Smart 1992; Hall 2003; Saunders 2003; Leask et al. 2004; Adams and Langley 2004; Ward 2011; Anon 2013). Outbreaks in other countries have also been reported (Chen and Malison 1987; Gellert et al. 1992; Stell 1997; Lehane and Olley 2000; Becker et al. 2001; Attaran and Probst 2002; Wu and Chen 2003; Predy et al. 2003; Feldman et al. 2005; Guly and Grant 2006; Davis et al. 2007; Chen et al. 2010; Hwi-Chang et al. 2010; Chen et al. 2011; Wilson et al. 2012; Visciano et al. 2012; CDC 2014).

Data on the prevalence of histamine in fish and fish products

There have been a number of monitoring and surveillance activities conducted in Australia and New Zealand in recent years in relation to histamine levels in fish and fish products (MAF 2011). Compliance with the ML in the Code from these studies was 85% or greater, with some fish sauce samples containing histamine at levels 2-3 fold higher than the ML (SA Health 2010). In addition to fish sauce, older analytical surveys have shown non-compliance with the ML for histamine in the Code (at the time of the study) in catfish, dried fish, snake fish, tench fish and pickled fish, (DHS Vic 2002). Additional research and reviews of outbreaks in Australia have demonstrated that histamine poisoning was generally linked to failures in the cold chain processes (NSW FA 2012; DHS Vic 2000; DHS Vic 2002c).

Other relevant standards or guidelines

Codex has set maximum levels for a range of fish types and products. A summary of these are outlined below. This risk advice is in accordance with Codex, with the exception of the *Carangidae* family. This family has been included as members can contain high levels of histamine together with the reports of histamine poisoning from the consumption of these fish (Korashy and Farag 2005; Sasikala et al. 2005; Auerswald et al. 2006; Yu-Ru et al. 2010; EFSA 2011; MAF 2011). The identification of the *Carangidae* family as an 'at risk' group for histamine poisoning is also recognized by a number of international food regulatory counterparts (ANSES 2009; FDA 2011; CFIA 2012; FAO/WHO 2013; James et al. 2013).

Codex Maximum Level for fish/fish products from specific fish families/species

Decomposition indicator level: 10 mg/100g; Hygiene & handling indicator in final product: 20mg/100g

- Quick frozen fish fillets (Codex 1995)
- Quick frozen fish sticks (fish fingers), fish portions and fish fillets – breaded or in batter (Codex 1989a)
- Quick frozen blocks and fish fillet, minced fish flesh & mixtures of fillets and minced fish flesh (Codex 1989b)
- Canned finfish (Codex 1981a)

For the families: *Scombridae; Scombresocidae; Clupeidae; Coryphaenidae; Pomatomidae.*

- Canned tuna and bonito (Codex 1981b)

For the species: *Thunnus alalunga; Thunnus albacares; Thunnus atlanticus; Thunnus obesus; Thunnus maccoyii; Thunnus Thynnus; Thunnus tongue; Euthymmus affinis; Euthynnus alleteratus; Euthynnus lineatus; Katsuwonus pelamis (syn Euthynnus pelamis); Sarda chilensis; Sarda orientalis; Sarda sardi.*

- Canned sardines and sardine-type products (Codex 1981c)

For the species: *Sardina pilchardus; Sardinops melanostictus; S. neopilchardus; S. ocellatus; S. sagax; S. caeruleus; Sardinella aurita; S. brasiliensis; S. maderensis; S. longiceps; S. gibbosa; Clupea harengus; Clupea bentincki; Sprattus sprattus; Hyperlophus vittatus; Nematalosa vlaminghi; Etrumeus teres; Ethmidium maculatum; Engraulis anchoita; E. mordax; E. ringens; Opisthonema oglinum.*

- Smoked fish, smoke-flavoured fish and smoke-dried fish (Codex 2013)

For the families: *Scombridae; Scombresocidae; Clupeidae; Coryphaenidae; Pomatomidae; Engraulidae*

- Boiled dried salted anchovies (Codex 2003a)

For all commercial species belonging to the family *Engraulidae* that have been salted, boiled and dried.

- Salted atlantic herring (*Clupea harengus*) and salted sprat (*Sprattus sprattus*) (Codex 2004)

Codex Maximum Level for fish sauce

Hygiene & handling indicator in final product: 40mg/100g

- Fish sauce (Codex 2011)

Other relevant guidelines and standards include:

- Codex general principles of food hygiene CAC/RCP 1 – 1969 (Codex 2003b)
- Codex Code of practice for fish and fishery products implemented in 2003 (Codex 2003c).

Approach by overseas countries

HACCP-based regulatory measures for fish are in place in a number of countries including those represented by the European Union (EU), Canada, U.S.A. and New Zealand (FDA 1995; EC 2004; CFIA 2013; MPI 2013a). Additional fish regulations by some of these countries are listed below:

- EU regulates fish species associated with high levels of histidine such as: *Scombridae* (mackerel, tuna and bonito), *Clupeidae* (herring, sardine), *Engraulidae* (anchovy), *Coryphaenidae* (mahi mahi), *Pomatomidae* (bluefish), *Scombrosidae* (saury)(EC 2005; EC 2013).
- Canada has established a maximum contaminant concentration of 200 mg/kg level of histamine in enzyme ripened products (e.g. anchovies, anchovy paste, fish sauce). For all other fish and fish products (e.g. canned or fresh or frozen fish), the maximum contaminant concentration is 100 mg/kg (Health Canada 2012; CFIA 2012; CFIA 2013).
- The USFDA have a 50 ppm defect action level for histamine in tuna, mahi-mahi and related fish. A list of histamine susceptible fish is available (FDA 2011).
- New Zealand has a maximum level of 200 mg/kg for histamine in fish. NZ specifies a number of species in the imported food requirements that are susceptible to histamine formation. These include: all tuna species; mackerel (*Scomber scombrus*, *Scomber australasicus*, *Scomber japonicus*); jack and horse mackerel (*Trachurus spp*); amberjack (yellowtail kingfish) (*Seriola lalandei*); mahi mahi (*Coryphaena hippurus*); bluefish (*Pomatomus saltatrix*); sardine including pilchard (*Sardinia pilchardus*, *Sardinops spp*, *Sardinella spp*); and herring (*Clupea harengus*, *Clupea pallasii*) (MPI 2013b).
- Consumer advice and media statements released by regulatory agencies in Australia, New Zealand and other countries (NSW FA 2011).

Other considerations

Regulatory requirements apply to products under this commodity classification including compliance with the Code. Requirements vary depending on the exporting country and intended end use. Refer to the [BICON database](#).

This risk statement was completed by FSANZ in: June 2016

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