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Review

Histamine Limits by Country: A Survey and Review

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ABSTRACT

Histamine is a biogenic amine and a food safety hazard, and it is the only biogenic amine regulated by statute or hazard analysis and critical control point guidance. This article reviews the regulations for histamine levels in fish in countries around the world, including maximum limits or levels and sampling procedures in different fish preparations. The maximum histamine levels, sampling plans, and fish products are listed. The country-by-country regulations for maximum histamine acceptance levels in some food products vary by a factor of 8, from 50 ppm in some countries to a maximum of 400 ppm in other countries. For similar food products, the maximum histamine levels vary by a factor of 4 (from 50 ppm to 200 ppm) in, for example, fresh tuna. The country-by-country sampling plans vary widely as well, and these, too, are covered in detail.

Key words: Codex Alimentarius; European Union; Hazard analysis and critical control point; Histamine regulations; Histamine sampling; U.S. Food and Drug Administration

Molecules of histamine are formed from molecules of L-histidine, an amino acid, by a decarboxylation reaction caused by a bacterial enzyme, histidine decarboxylase. Histamine can form in many different species of saltwater fish that have elevated levels of free L-histidine. Histamine formation is completely preventable, and these methods are described as well. Although there are multiple maximum histamine acceptance levels, rapidly chilling the fish immediately after harvest by any means available is the only method to stop the formation of histamine. Fishermen should chill the fish rapidly using ice, chilled seawater, dense cold brine, or air blast freezers as soon as possible.

Regulations of the maximum allowable limit or levels of histamine in fish and fishery products vary by trading blocs and individual countries, so this report attempts to collect and list all of these limits, regulations, and sampling plans in one place. This article should be useful for exporters of tuna products who need to know the regulations of the importing country. Since portion size along with the portion consumed is important to causing the physiological intensity of the reaction to histamine poisoning *(91),* each sovereign nation or group of nations must determine that a certain maximum level of histamine is safe to eat per eating occasion. This determination must also be balanced with the risk of having insufficient protein in the diets of the people in their countries. The difficulties any country might encounter in determining and controlling the histamine hazard in its own food supply include the ability to provide enough refrigeration or ice to control the hazard by chilling and keeping the fish properly cold on the harvest vessels, during onshore processing, and during transportation, as well as the ability to measure the level of that hazard rapidly and inexpensively.

Histamine levels are reported in many units, for example, 10 mg percent, which is the same as 10 mg% or 10 mg/100 g or 100 mg/kg or 100 μg/g or 100 μg/mL or 0.45 μmoles/mL or 100 ppm *(1)*. Throughout recent history, there have been several units of reporting, but most reporting by 2021 uses the standard of mg/kg or ppm.

Histamine is formed by bacterial activity in certain fishes and other foods. The presence of excess levels of histamine is an indicator of decomposition and bacterial spoilage *(93)*. Histamine is the only biogenic amine that is regulated by statute, compliance polices, or hazard analysis and critical control point (HACCP) guidance *(132, 146, 158)*. Histamine can be formed and is found in many different foods, including wine, cheese, fermented foods, and fish *(93, 117)*; however, this review will focus on the presence of histamine in fish and fish-based products.

In humans, the ingestion of excessive amounts of histamine from fish-based products produces an allergic-like reaction that can be reversed with an antihistamine drug. It is rarely fatal, but if untreated, it can produce hours of discomfort *(102)*. Histamine is not considered to be an

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allergen, but "It is frequently misdiagnosed as a food allergy because the symptoms are so similar" *(137)*. Histamine poisoning is termed a "food-borne intoxication" as opposed to an allergy, which is an immune system response to a foreign substance. "Histamine poisoning can be easily distinguished from food allergy on the basis of (a) the lack of a previous history of allergic reactions to the incriminated food, (b) the high attack rate in group outbreaks, and (c) the detection of high levels of histamine in the incriminated food" *(135)*.

Many countries have limited the maximum levels of histamine in foods allowed in commerce because of the impact of this reaction. The Food and Agriculture Organization/World Health Organization (FAO/WHO) expert committee on the public health risk of histamine determined that the no observed adverse effect level (NOAEL) was a total consumption of 50 mg of histamine, so based on a maximum serving size of seafood of 250 g, they determined the maximum safe level of histamine to be 200 mg/kg, which equals 200 ppm *(63)*.

The International Commission on Microbiological Specifications for Foods (ICMSF) ranks the presence of histamine as a moderate hazard, as it is not usually life threatening, has no sequelae, is normally of short duration, and has self-limiting symptoms but can cause severe discomfort *(76)*. Risk Rangers counts histamine as a mild toxin *(46)*. Data from Bartholomew et al. *(10)* led to recommendations that a level of up to 50 ppm of histamine is normal and safe for consumption, a level of 50 to 200 ppm is considered mishandled and possibly toxic, a level of 200 to 1,000 ppm is considered unsatisfactory and probably toxic, and a level of >1,000 ppm is toxic and unsafe for human consumption.

The U.S. Food and Drug Administration (FDA) considers the presence of elevated levels of histamine in fish or fishery products to be a decomposition issue and that histamine levels are a measure of decomposition *(58)*. The opening sentences of the FDA compliance guide at CPG 540.535 state, "Decomposition in fish, such as tuna and mahi-mahi, is detected by organoleptic evaluation. It is also indicated by elevated histamine levels in the muscle tissue" *(146)*. The FDA considers that fishery products with histamine levels over 50 ppm are decomposed and with histamine levels over 500 ppm are a health hazard *(57)*.

The histamine molecule is heat stable, but cooking the fishery product can mask the sensory evidence of decomposition, or cause it to be "cooked off." Thus, testing for histamine must be used to detect and measure decomposition in raw or cooked fish. Per Title 21 U.S. Code chapter 9/subchapter IV, §342 (a)(3) "if it consists in whole or in part of any filthy, putrid, or *decomposed* substance" *(142)* it will be deemed *adulterated,* and per 21 USC chapter 9, Subchapter III, §331 (a) (Prohibited acts), "The introduction or delivery for introduction into interstate commerce of any food . . . that is adulterated or misbranded" *(141),* thus the decomposed product cannot be shipped and sold between states.

The scarcity of dietary protein in the world throughout history and the lack of ice have forced people to make use of many different methods to preserve protein-rich food stuffs by fermentation using either natural bacteria or designated bacterial starters. About 30% of the world's food of all kinds is derived from fermented products, including wine, beer, bread, and fish pastes *(16)*. There are many versions of fermented fish paste produced globally, depending on the fish available, historical usage, and taste preferred *(56, 134, 168)*. In many developing countries, the best quality fish is sold for export, foreign exchange earnings, or other reasons, while the damaged, bruised, or otherwise nonexportable fish are processed into fish paste, fish sauces, or other fermented fish products *(97, 98)*. The production of fish sauces or pastes provides for a large employment base in many countries: for example, 6 million people are employed in Indonesia in the fish paste–fish sauce industry *(114)*.

The food usage of fish-based products varies by country, culture, and product form. These fish-based items can serve as a meal entrée, sandwich filling, salad topping, a mixture with vegetables and condiments, a base for a stir fry dish, a pizza or flat bread topping, an appetizer, a finger food snack, a fish sauce flavor enhancer, or a fish paste. Small volumes of fish pastes that are processed for personal or neighborhood usage are often not considered to be as great an allergenic hazard as a large batch of canned tuna or sardines with high levels of histamine that are packed using several packing lines into multiple products to be sold in many regions *(39, 68, 110)*.

Several large-scale outbreaks of histamine poisoning have been reported in the past 50 years involving canned and fresh tuna and other species. In 1973, 232 people were reported to have become ill from canned tuna packed by a West Coast canner in the United States *(95)*. In 2003, there was a large outbreak of histamine poisoning from fresh escolar (*Lepidocybium flavobrunneum*) in the United States; more than 40 people became ill at a retreat center in California *(60)*. In 2010, 71 members of the French military were reported to have become ill from fresh tuna served at a military mess hall in Dakar, Senegal *(45)*. In 2017, 40 cases of histamine poisoning from fresh yellowfin (*Thunnus albacares*) imported from Reunion Island were reported in a French military unit near Paris *(165)*. In 2019, 50 people were reported to have gotten ill from fresh yellowfin imported from Vietnam and distributed to multiple seafood brokers and retailers in the United States *(156)*.

Causes of histamine formation. Histamine is formed during bacterial decomposition because of the growth of histamine-forming bacteria (HFB) in unchilled dead fish. As the HFB grow, they make the enzyme histidine decarboxylase. This enzyme converts the L-histidine molecules to histamine molecules by a simple enzymatic decarboxylation reaction that removes a carbon dioxide (CO_2) molecule and a proton (H^+) from the L-histidine molecule to form the histamine molecule *(140)*. There are numerous species of bacteria that can make the enzyme histidine decarboxylase *(120, 134, 167),* and many are common to the human environment but less common in the marine environment *(136)*. The rate of histamine formation varies for different bacterial species: *Morganella morganii* has been determined

to be the most heat resistant *(48)*. A list of possible or probable HFB is listed in these reviews *(120, 134, 167)*.

The detection of the presence of high levels of free L-histidine in the fish induces the production of the enzyme histidine decarboxylase by the HFB, which then cause the L-histidine→histamine reaction *(82)*. An antiporter mechanism transports the L-histidine molecule into the bacterial cell, the decarboxylation reaction occurs, and the histamine molecule is moved out of the cell *(88, 96, 140)*. This decarboxylation reaction is energetically favorable for the HFB because the bacteria gain a proton of energy to use for pH control or metabolic energy *(61, 83, 96)*. Thus, this reaction maintains a localized acid balance, provides a proton of energy, and helps control the pH in the local area *(88)*. A clear explanation and schematic of the proton motive force generation by the decarboxylation and electrogenic antiporter is provided by the European Food Safety Authority (EFSA) *(56)* and Landete et al. *(88)*.

Histamine is formed in multiple saltwater fish families with high free L-histidine levels, and the rate of histamine formation can be increased or decreased depending on the capture and preservation methods. Tuna and other members of the Scombridae family contain high levels of free L-histidine in their muscle tissues *(2, 13, 17, 137)*. The free L-histidine acts as an effective pH buffer when the fish are swimming fast, either feeding or fleeing, as excess lactic acid forms in the muscle cells. The muscle cells need to be buffered so that the pH balances are maintained. Without this pH balance, the cells can shut down, and the predator becomes easy prey *(3, 17)*.

Living and immediately postmortem tuna or any other fish contains no histamine *(64, 74)*. According to European Commission Regulation EC No 2073/2005 *(50),* the limits for levels of histamine were established for fish species with high levels of L-histidine. These include species in the families of Scombridae (tunas, mackerels, ~54 species), Scomberesocidae (sauries, 5 species), Clupeidae (sardines, herring, ~198 species), Engraulidae (anchovies, ~150 species), Coryphaenidae (mahi-mahi, 2 species), and Pomatomidae (bluefish, 1 species) *(65, 103)*. Other families of potential histamine formers are Istiophoriformes (marlins), Carangidae (amberjacks), and other Scombriformes including the family Gempylidae (escolar) *(146)*. The Gazette from India also gives a very extensive list of fish species in which histamine could potentially form *(144)*. A Joint FAO/WHO Expert Meeting on histamine and other biogenic amines presented a list of the world's fish species associated with scombroid poisoning *(63)*. Kose has a list of fish with a health risk of histamine poisoning *(85)*. The FDA indicates the species of fish that have the potential for histamine formation in Table 3-2 of its HACCP guidance *(158)*. Thus, there are many fish that have a potential hazard because of histamine formation based on their history and elevated levels of free L-histidine.

Regulatory limits on histamine levels. The maximum regulatory limits for histamine levels are associated with sampling plans. The maximum limits will be discussed first, followed by the different sampling plans by country or trading bloc. Maximum limits for histamine in food items exist around the world depending on the types of foods that are customarily eaten in those countries. The variety of seafood-based products, their processing recipes and parameters, handling history, and intended uses provide for setting a range of histamine values that depend on the portion size consumed *(63)*. For example, the United States has one set of limits for all seafoods, fresh, frozen, and processed (canned), but the Codex Alimentarius (Codex) has two sets of limits and the European Union has three sets of limits depending on the species and types of finished products processed.

The maximum limits and sampling plans, if any, are listed in Tables 1 through 8. Table 9 has the regulation references listed by country. In a supplemental Excel spreadsheet, there is a list of histamine limits by country by type by sampling plan, and the source for each reference is hyperlinked.

The regulations can be split into two groups: limits that are applied to modern or to traditional foods. Modern foods include commercially sterile canned seafood, canned foods that are treated with salt but not heat treated, vacuum-packed fresh seafoods, and fresh fish that is chilled and delivered to customers hundreds or thousands of miles from the capture area or landing port. Modern foods can be considered foods protected by packaging developed in the last 150 years, such as cans with double seams, pouches, and plastic cups (hermetically sealed and retorted items) or fish in trays or bags that may or may not have been retorted.

Traditional foods are those foods that are salted, salted and dried, dried with no additives, or fermented for making pastes or thin or thick fish sauces. Many of these recipes are handed down through families and communities for generations. The raw materials and finished products of traditional foods are generally not tested for the histamine content, as opposed to the raw materials or the finished products for canned fish or fresh fish destined for distribution in international commerce (modern foods).

Original regulations have been cited as often as possible for this article, but second-hand citations, such as published articles, have also been used if the original documents were unavailable. Additionally, there are many countries for which maximum histamine levels do not exist. There are 188 countries that are members of Codex *(37)*. The Codex limits can be used in trade for these or other countries that do not have their own guidelines but agree with Codex guidance.

The regulations are cited based on these 5 parameters: N = lot size, n = sample size, and c = number of defects allowed in the sample, and the acceptance limits are denoted as m and M with context definitions. These will be further described in the sampling section.

The *maximum limits* for histamine levels in foodstuffs are determined for the protection of *human safety,* but all of these limits have legally enforceable ramifications in the seafood trade. Raw or processed seafood that is unsaleable because of unacceptable histamine levels constitutes an economic loss to buyers. Well documented, well accepted limits, well defined sampling plans, and accurate laboratory

TABLE 1. *Histamine limits for canned products*

Histamine limit(s)[a]	Sampling plan	Country(ies) or organization; comment
Max = 200 ppm		Australia, China, Egypt, Mexico, New Zealand, South Korea, Taiwan, Turkey
Max = 100 ppm		Armenia, Belarus, Benin, Canada, Indonesia, Iran, Kazakhstan, Kyrgyzstan, Libya, Mercosur countries (Argentina, Brazil, Paraguay, Uruguay, Venezuela), Russia, South Africa, Sri Lanka, Switzerland, Trinidad, Vietnam
Max = 50 ppm		Columbia, Costa Rica, Ecuador
Avg $\leq$ 100 ppm, max = 200 ppm	AQL 6.5 sampling plan, thus *n,* sample size, is based on *N,* lot size	Codex Alimentarius, Gulf States countries (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates), Yemen, Solomons, Ghana, Codex agreements
Avg $\leq$ 100 ppm, max = 200 ppm	$n = 9$, $c = 2$, no more than 2 over 100 ppm, and less than 200 ppm	EU countries (Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden.) and India, Ukraine, Morocco, Norway, Peru, Serbia, Seychelles, UK
1 sample < 100 ppm, max < 200 ppm (2 samples combined)		Mauritius
Max = 50 ppm, 2 samples in 24	$n = 24$, $c = 1$, $m = 50$ ppm, $M =$ 500 ppm	U.S.; one can of over 50 ppm is evidence of decomposition, more than 2 cans in a production date code over 50 ppm and a seizure can be ordered, any can over 500 ppm, the lot is considered adulterated.
Max = 50 ppm	$n = 18$, $c = 0$, $m = 50$ ppm	U.S.; receipt in tuna cannery
Max = 50 ppm	$n = 60$, $c = 2$, $m = 50$ ppm	U.S.; rectification of an organoleptic sample
Max = 30 ppm	$n = 18$, $c = 0$, $m = 30$ ppm	NFI; recommendation for receipt in a tuna cannery
>100 ppm, decomposition; >200 ppm, unsafe for humans		South Africa
Avg $\leq$ 100 ppm		Fiji, Samoa, Thailand

[a] Max, maximum.

TABLE 2. *Histamine limits for fresh or fresh-frozen fish*

Histamine limit(s)[a]	Sampling plan	Country(ies) or organization; comment
400 ppm		People's Republic of China
200 ppm		Australia, Chile, Israel, New Zealand, Philippines, Taiwan (ROC), South Korea
$m = 100$ ppm, $M = 200$ ppm	$n = 9$, $c = 2$, no more than 2 over 100 ppm, and less than 200 ppm	India, Morocco, Peru, Vietnam
$m = 50$ ppm, $M = 500$ ppm	$n = 18$, $c = 2$, $m = 50$, $M = 500$, recheck if over 35 ppm	U.S.; imported raw fish incoming sampling, after organoleptic sampling
Avg = 100 ppm		Fiji, Samoa
Max = 100 ppm		Mercosur (Argentina, Brazil, Paraguay, Uruguay, Venezuela), Eurasian Customs Union (Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia), Canada, Sri Lanka, Singapore, Indonesia
Max = 50 ppm	$n = 18$, $c = 0$, $m = 50$	U.S.; tuna canneries receiving fish, HACCP
Max = 50 ppm	$n = 60$, $c = 0$, $m = 50$	U.S.; canneries, rectification sampling
Avg $\leq$ 100 ppm, max = 200 ppm	AQL 6.5 sampling plan, thus $n =$ sample size is based on lot size of N	Codex, Solomons
Max = 30 ppm	$n = 18$, $c = 0$, $m = 30$	U.S.; tuna canneries, NFI guidance

[a] Max, maximum.

TABLE 3. *Histamine limits for enzyme-treated products (fermented)*

Histamine limit(s)	Sampling plan	Country(ies) or organization
400 ppm		People's Republic of China, Taiwan (ROC)
200 ppm		Canada
100 ppm		Indonesia
$m = 100$ ppm, $M = 200$ ppm	$n = 9$, $c = 2$, $m = 100$ ppm, $M = 200$ ppm	Morocco
$m = 200$ ppm, $M = 400$ ppm	$n = 9$, $c = 2$, $m = 200$ ppm, $M = 400$ ppm	EFSA (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Peru, Poland, Portugal, Romania, Serbia, Seychelles, Slovakia, Slovenia, Spain, Sweden, Switzerland, Ukraine, United Kingdom)

analyses for histamine levels must be vetted, robust, and, therefore, enforceable. The U.S. regulations clearly spell out that fishery products with histamine values over a certain limit and that have been tested by the government and vetted by trained and certified sensory experts are subject to seizure if they are not voluntarily withdrawn from the commercial market *(146)*.

These maximum limits can include limits on product groups like canned fish, fresh fish, frozen fish, enzyme-treated or fermented fish, dried fish, or fish sauces. Examples of maximum histamine levels in whole fresh or frozen fish and canned tuna range from 50 ppm in the United States to 200 ppm for Codex and European Union (EU) countries and in fish sauces are up to 400 ppm for Sri Lanka. For the United States, a maximum histamine level of 500 ppm also defines adulteration, and thus, possible enforcement action can be taken, such as a seizure. There are also countries with single general limits that do not include sample size. Some countries or groups of trading countries have simple regulations, while others include more elaborate sampling plans. The acceptable histamine levels for raw tuna to be processed in hermetically sealed products destined for the U.S. market are the lowest and most strict in the world.

There are two histamine limits cited in the United States, $m = 50$ ppm and $M = 500$ ppm. Three sampling plans are also cited, depending on the situation, and include organoleptic or sensory evaluations. The defect action level (DAL) is 50 ppm, and the action level (AL) is 500 ppm *(58)*. The DAL of 50 ppm according to the FDA means there "is evidence that raw, frozen, or canned tuna, and raw or frozen mahi-mahi, are in a state of decomposition," and the AL of 500 ppm means "the agency considers histamine to present a hazard to public health" *(58)*.

The EFSA consists of 27 EU member nations and 5 EU candidate countries, as well as Iceland, Norway, and Switzerland, that agree to use the EU regulations for histamine levels *(55)*. The histamine regulation uses $n = 9$ (sample size) with $c = 2$ for an average m of 100 ppm with an M of 200 ppm for fishery products, meaning that 2 of the 9 samples can exceed 100 ppm, but no samples can exceed 200 ppm. The same $n = 9$ and $c = 2$ for $m = 200$ ppm and $M = 400$ ppm is used for fishery products that have undergone enzyme maturation treatment in brine. There is an $M = 400$ ppm with no sample size for fish sauce produced by fermentation. Applying the FAO/WHO finding that 50 mg of histamine is the NOAEL *(63)*, $M = 400$ ppm is safe if the serving size is no bigger than 125 g.

Codex represents the largest number of countries from around the world *(37)*. There are Codex standards that include maximum histamine limits on a variety of fishery products *(36)*. In some of these standards. the histamine limits apply only to the finfish families of Scombridae, Clupeidae, Engraulidae, Coryphaenidae, Pomatomidae, and Scomberesocidae (SCECPS).

Codex designates two sets of maximum histamine limits. The first set has a sample average of 100 ppm, with no value over 200 ppm. This includes canned finfish (SCECPS) *(21),* in particular, canned tuna and bonito (Scombridae) *(23),* canned sardines (Clupeidae) *(24),* quick-frozen fish fillet blocks (SCECPS) *(25),* quick-frozen fish sticks or fingers (SCECPS) *(26),* quick-frozen fish fillets (SCECPS) *(27),* boiled and dried anchovies (Engraulidae) *(31),* salted Atlantic herring (Clupeidae) *(33),* smoked fish

TABLE 4. *Histamine limits for dried fish or boiled and dried*

Histamine limit(s)[a]	Sampling plan	Country(ies) or organization
Avg $\leq$ 100 ppm, max = 200 ppm	AQL 6.5 sampling plan	Codex
Max = 100 ppm		Eurasian Customs Union (Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia), Sri Lanka
Max = 200 ppm		Philippines, Republic of China (Taiwan), South Korea
$m = 200$ ppm, $M = 400$ ppm	$n = 9$, $c = 2$, $m = 200$, $M = 400$	India, Peru

[a] Max, maximum.

TABLE 5. *Histamine limits for smoked fish*

Histamine limit(s)[a]	Sampling plan	Country(ies) or organization
Avg $\leq$ 100, max = 200 ppm	AQL 6.5 sampling plan	Codex
200 ppm		Sri Lanka
m = 100 ppm, M = 200 ppm	n = 9, c = 2, m = 100 ppm, M = 200 ppm	India, Peru

[a] Max, maximum.

and dried fish (SCECPS) *(35),* and quick-frozen finfish (SCECPS) *(22)*. The $M = 200$ ppm with a $c = 0$ or no value over 200 ppm is based on NOAEL *(36)*. The second set of maximum histamine levels is for fish sauce and has a maximum of 400 ppm of histamine *(34)* (no species restrictions). Fish sauces–pastes are used as a condiment, so the amount of usage per serving is not as much as an entrée would be, so the total histamine ingested is less.

Recalls—United States. If there are regulations, then when the limits are exceeded, the regulating bodies need procedures to withdraw the product from the market. In the United States, the FDA was given mandatory recall authority with the passage of the 2011 Food Modernization and Safety Act (FSMA) *(153)*. Prior to that, all recalls were voluntary; however, the FDA still prefers to have the recalls be voluntary, so much so that there has been only one mandatory recall for any food product since the 2011 passage of FSMA through 2020 *(154)*.

The FDA has had a long-term policy of encouraging voluntary recalls because they think it affords better protection of the consumer than a seizure of the product *(155)*. During a 2019 high-histamine incident with fresh yellowfin tuna from Vietnam, the FDA encouraged the vendor to execute a voluntary recall and discard the remaining product. When the vendor did not comply, but instead requested that the implicated product be sent back to Vietnam, the FDA wrote to the Vietnamese government and requested that the Vietnamese government ban any re-export of this product. The Vietnamese government issued an official letter to monitor and detain shipment of the tuna upon arrival at ports in Vietnam.

This incident resulted in 50 total illnesses and 1 hospitalization but still was essentially classified as a decomposed fish problem and qualified as a voluntary rather than mandatory recall. Information from a Freedom of Information Act (FOIA) request showed that the maximum level of histamine analyzed by an FDA laboratory for this violative product from Vietnam was 1,900 ppm, and the average level was over 500 ppm *(159)*. Three of four lots tested failed the sensory evaluations, and the same three of four failed the histamine testing. However, the FDA did not think that histamine values in the product could be used to demand a mandatory recall: "Because scombrotoxin fish poisoning causes temporary or medically reversible adverse health consequences this incident did not meet the threshold for the use of the FDA's mandatory recall authority" *(156)*.

TABLE 6. *Histamine limit for fish with vegetables*

Histamine limit	Sampling plan	Organization (countries)
40 ppm		Eurasian Customs Union (Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia)

TABLE 7. *Histamine limits for salted herring and sprats*

Histamine limits	Sampling plan	Organization
Avg $\leq$ 100 ppm, M = 200 ppm	AQL 6.5 sampling plan	Codex

Hermetically sealed (canned) products. The FDA maintains a searchable electronic database on the Internet for all recalls in recent years *(163)*. This plus additional earlier data is available through FOIA requests for information back to 1 October 2002 *(160),* and we requested and received a listing of all the histamine recalls from 1 October 2002 through 31 December 2020 by such a request.

There were two recalls for histamine in canned tuna in the FDA FOIA database, and both were for imported retorted flaked tuna product: a lot packed in the Philippines plus a lot packed in Spain *(160)*. Newspaper and published accounts not in the database also indicate recalls of canned tuna packed by a U.S. West Coast packer in 1973 and canned tuna packed for the U.S. Department of Defense by a cannery in American Samoa in 2004 *(115)*. To our knowledge, these four recalls are the only recalls in the United States of canned tuna for high histamine since 1973 (48 years) *(18, 115)*. These findings show that the U.S. safety procedures, protocols, and practices of tuna processing for retorted products are very robust and that the system works. Since these procedures work and work well, any failures are the result of not implementing them properly.

Colombo et al. *(39)* noted that they found only two canned tuna recalls after 1985 (non–United States). However, they did not include a recall by Hagoromo Foods in Japan in 2013 for 6.72 million cans of tuna *(69)*.

According to the newspaper accounts, the Hagoromo recall was not due to a vessel problem, since the histamine levels would have been picked up in the incoming sampling testing. Newspaper reports suggest that a packer lost control of refrigeration *(68)*. Histamine does not form in fish when the temperature is below 0°C, as shown by the fact that freezing or keeping fish on ice always prevents histamine formation *(44, 74, 148)*. This recall spanned almost 2 months of production for three different items, suggesting a loss of control of the production process after precooking by perhaps letting it stand around for too long after precooking. This is only an educated guess from the authors, because the authors have experienced such histamine formation in precooked tuna when it was not handled properly, especially because of delays after thawing and precooking and prior to retorting. Properly precooking tuna following HACCP critical control points (CCPs) and critical limits (CLs)

TABLE 8. *Histamine limits for fish sauces*

Histamine limit(s)	Sampling plan	Organization and countries
400 ppm		EFSA (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia. Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom), Sri Lanka, Republic of China (Taiwan), Serbia
400 ppm	Single well-mixed sample	Codex
200 ppm		Canada, Thailand
$m = 200$ ppm, $M = 400$ ppm	$n = 9$, $c = 2$, $m = 200$ ppm, $M = 400$ ppm	India, Peru

delays histamine formation, but the tuna needs to be precooked to a proper backbone temperature (60°C) and can only be kept at ambient temperatures (unchilled) after precooking, for cleaning and filling, for 12 hours before canning and retorting *(4)*.

The FDA FOIA database for retorted fish shows three histamine recalls for canned anchovies, one for canned sardines, and then one for tuna as an ingredient when the temperature was not recorded during preparation.

Fresh (uncooked) tuna. In contrast to the paucity of recalls of canned products for elevated histamine levels, there have been multiple recalls or market withdrawals in the United States and elsewhere for products using fresh fish. This suggests several basic types of problems: failure to use enough ice on the fishing grounds, failure in the incoming sampling on the dock at the source of the raw fish, or failure to chill properly during transportation to the market.

TABLE 9. *Histamine regulation references by country*

Country	Reference(s)	Country	Reference(s)	Country	Reference(s)
Armenia	*49*	Iceland	*50, 51*	Qatar	*67*
Argentina	*14*	India	*144*	Taiwan (ROC)	*133*
Australia	*8*	Indonesia	*128–131*	Romania	*50, 51*
Austria	*50, 51*	Iran	*108*	Russia	*49*
Bahrain	*67*	Ireland	*50, 51*	Samoa	*119*
Belarus	*49*	Israel	*100*	Saudi Arabia	*67*
Belgium	*50, 51*	Italy	*50, 51*	Serbia	*107, 122*
Benin	*5, 78*	Kazakhstan	*49*	Seychelles	*89*
Brazil	*14*	Kuwait	*67*	Singapore	*124*
Bulgaria	*50, 51*	Kyrgyzstan	*49*	Slovakia	*50, 51*
Canada	*72*	Latvia	*50, 51*	Slovenia	*50, 51*
Chile	*19*	Libya	*70*	Solomons	*125*
Codex	*36*	Liechtenstein	*50, 51*	South Africa	*126*
Colombia	*38*	Lithuania	*50, 51*	South Korea	*84*
Costa Rica	*40*	Luxembourg	*50, 51*	Spain	*50, 51*
Cot d'Ivoire	*6*	Malaysia	*77*	Sri Lanka	*127*
Croatia	*50, 51*	Malta	*50, 51*	Sweden	*50, 51*
Cyprus	*50, 51*	Mauritius	*94*	Switzerland	*50, 51*
Czech Republic	*50, 51*	Morocco	*46*	Thailand	*138, 139*
Denmark	*50, 51*	Netherlands	*50, 51*	Togo	NA[a]
Ecuador	*75*	New Zealand	*101*	Trinidad and Tobago	*90*
Estonia	*50, 51*	Norway	*50, 51*	Tunisia	NA
Egypt	*47, 123*	Oman	*67*	Turkey	*108*
Fiji	*62*	Panama	*104*	Ukraine	*145*
Finland	*50, 51*	Paraguay	*14*	United Arab Emirates	*67*
France	*50, 51*	People's Republic of China	*143*	United Kingdom	*50, 51*
Germany	*50, 51*	Peru	*109*	United States	*147*
Ghana	*12, 66*	Philippines	*111–113*	Uruguay	*14*
Greece	*50, 51*	Poland	*50, 51*	Venezuela	*14*
Hong Kong	NA	Portugal	*50, 51*	Vietnam	*166*
Hungary	*50, 51*			Yemen	*67*

[a] NA, not available.

In the FDA FOIA database of histamine-related recalls *(160),* there were 53 recalls for histamine in uncooked fish, over 80% being fresh tuna, primarily yellowfin tuna (family Scombridae). The tuna loins were raw and not precooked; thus, they did not pass through the strict HACCP receiving system for canned (hermetically sealed) tuna processing. For the other species of uncooked fish, there were additional recalls as well: three for escolar, one for mackerel, three for mahi-mahi, and two for anchovy sauce.

Recalls—Europe. The Rapid Alert System for Food and Feed (RASFF) was developed by the 31 European countries in the European Commission. It was organized to provide the food and feed authorities of the member countries with a tool for the exchange of information regarding serious hazards and risks found in food or feed. This allows their member states to act quickly and in a coordinated fashion to respond to a health threat. When a RASFF member state has information about a serious health risk from food or feed, it must immediately notify the European Commission using RASFF. The exact workings of the RASFF are well documented at its Web site *(54)*.

The RASFF logs all the various food and feed safety incidents in a searchable database available to the public *(53)*. A search of the RASFF database for histamine poisoning for the period of 1981 to 2020 yielded 737 entries: of these, most (725) entries were for fish or fish-based products. The data were sorted by species and style, and the maximum histamine was recorded by reportable incident. Out of 21 fish species or categories, there were 6 fish species or categories that each had nine or more reportable histamine incidents in the 39-year period. Those histamine incidents consisted of 9 for herring, 10 for fish sauce, 54 for mackerel, 75 for anchovies, 95 for sardines, and 444 for tuna or other Scombroid fish. There were 13 categories of style recorded, and of these, tuna was recorded in 10 of the style categories. The style categories included canned, dried, fresh, frozen, and others. There were 98 reportable histamine incidents for canned tuna recorded (about 22%) of that of the total tuna, which means 14% of all the incidents. The maximum histamine levels reported were 10,000 ppm for a canned product and 7,270 ppm for some fresh tuna. Thus, this RASFF database gives us a sampling of the species of fish and style of preparation that contribute the most histamine problems. We do not know exactly how the recall system works for the individual countries in the European Commission so will not comment further, but many of these incidents must have resulted in recalls or market withdrawals.

Sampling plans for decomposition and histamine. A formal sampling plan is required to support the legal standing and potential court challenges to the limits on histamine in fish. The determination of whether to accept individual items with limits such as weight or histamine level involves a field of study called "acceptance sampling." These sampling plans depend on the risk of the hazard, lot size, number of samples collected (sample size), number of rejects allowed, and maximum limits. The parameters used in acceptance sampling are as follows: (i) *N,* the lot size from which to draw the sample (such as tons of fish or numbers of fillets or cans); (ii) *n,* the sample size or the number of items to evaluate; (iii) *c,* the number of defects to accept in the lot; and (iv) *m* and *M,* the limits defined in the context provided *(32)*. For example, *m* may be a starting limit or an average and *M* is an absolute minimum or maximum. The term AQL is used and means acceptable quality level.

A lot is the group of items containing fish, cans, pouches, or frozen loins that are to be sampled and should be from a similar source and have had the same treatment. Sampling plans are always built on the assumption that a lot is of a uniform quality with any defects randomly distributed so that sampling is completely random. Since, in fact, defects can and do occur in clusters, it is doubly important to devise sampling procedures which randomly represent an entire lot.

For the U.S. market, the maximum lot size (*N*) for round frozen fish to be processed at any canning factory is 25 metric tons (mt) *(151)*. The maximum lot size (*N*) for imported raw fish products entering the United States depends on the shipment lot size. The maximum lot size for imported canned products is the number of cases in a single production date code *(164)*.

Because histamine molecules are formed by HFB naturally occurring on the gills, in the gut, and on external surfaces of the fish *(148),* there may be different levels of histamine formed from different bacterial species or levels colonizing different parts of the fish. That is, a lot with individual whole fish or raw fish loins may have many different histamine levels in samples taken from different fish or different portions of a single fish. This variation of histamine levels in the fish and the lot must be reflected in the sampling scheme and the number of samples: the sampling scheme must consider if the fish is fresh or frozen, canned, salt treated and canned, dried in an oven or ambient air, or formed into a well-mixed paste or fish sauce.

Individual countries may have differing regulations regarding sampling schemes. The range of regulations includes some histamine level limits with no sampling plans cited, while others state that if more than one sample is collected, the results are averaged but there is no individual maximum limit. There are national regulations with simple maximum limits regardless of product type and others with simple maximum limits that vary by product type. There are also national regulations that have histamine level limits that vary by product type and include a sampling plan that contains more than one sample.

AQL sampling uses the lot size (*N*) to determine the sample size (*n*) for large batches (lots) of items such as whole fish, cans, fish fillets, etc. The sample size required for testing can quickly increase as the lot size increases. Generally, the number of items in these lots (*N*) is so large compared with the sample size (*n*) and sampling is conducted without replacement that the lot sizes can be treated as infinitely large *(121)*. Because histamine testing is a destructive test, the sampling costs can quickly escalate, as it includes the cost of laboratory supplies and the cans and

pouches, as well as the fish products themselves. The number of samples required for analysis can quickly overwhelm an unprepared laboratory.

Sample size calculations for attribute sampling where $c = 0$ depend on the binomial distribution, or "accept or reject" *(116)*. The decision to accept or reject generally uses two factors: the 95% confidence limit and the reliability of screening. The simple formula derived from the binomial distribution is sample size (n) = ln(confidence limit)/ln (reliability), so for the AQL (6.5), the sample size = ln (0.05)/ln(0.935) $\cong$ 45 *(7, 79)*. The latest draft for Codex sampling is for a 95% confidence level and 5% reliability, so sample size = ln(0.05)/ln(0.95) $\cong$ 59. The Codex sampling plan *(36)* does allow for compositing the five items so that only 12 chemical analyses have to be made.

Although histamine formation and its presence are clearly noted by Codex to be a product of the decomposition process, sensory evaluations are not included as part of the Codex sampling plan. In the 2018 Codex revisions (CX/FH 18/50/6) for finished product sampling plan guidance, decomposition is excluded *(36)*.

The Codex sampling plans include "General guidelines on sampling" in CAD/GL50-2004 *(32),* "for sensory evaluations" in CAC-GL 31-1999 *(29),* and microbiological criteria *(28)*. Ten of 11 of the Codex fish standards refer to sampling plans with an AQL of 6.5. The draft Codex histamine sampling plan is based on risk and lot size and depends on an AQL of 6.5 *(36)*. The specific guidelines suggested for histamine sampling for many years were based on the 1969 Codex sampling plans for prepackaged foods (AQL 6.5), Codex standard 233-1969 *(20)*. In the past decade, a revision of the code of practice for fish and fishery products (CAC/RCP 52-2003) *(30)* and a review of document CX/FH 18/50/6 have been completed *(36)*. However, a current Codex sampling plan has not yet been codified.

The European Union has a three-component sampling plan for (i) general fishery products, (ii) fishery products that have had an enzyme maturation process such as canned but unretorted anchovies, and (iii) fish sauce.

In the United States, compliance sampling guidelines are written for testing canned or raw fish products at customs and/or in the commercial marketplace, including public warehouses *(146)*. There are import inspection testing *(147, 152)* and acceptance sampling for processing at tuna canneries *(158)*. Tuna canneries sample and test fish from incoming lots for decomposition with organoleptic (sensory) and histamine analyses. For every 25-mt lot accepted at the cannery for processing, 136 fish are sampled and inspected regardless of fish size. This inspection includes 118 tuna evaluated organoleptically for decomposition and 18 tuna tested for histamine levels.

The FDA considers the presence of elevated levels of histamine as decomposition. Decomposition can be identified by organoleptic (sensory) attributes, elevated histamine levels, or both. Histamine molecules are not degraded by cooking or freezing, so once they have been formed, they remain in the flesh *(148)*. Histamine is only formed in seafood that is already dead, so histamine levels determined in tuna that are over the regulatory limit are evidence of decomposition and/or adulteration.

The organoleptic evaluation of decomposition is a qualitative result, while histamine testing is quantitative. The sensory evaluation of raw or cooked seafood must confirm that there are persistent odors of decomposition and must be by a recognized seafood expert for lot seizure or destruction *(58, 146)*. Organoleptic sampling can occur on frozen fish by thawing them or by using a drill to remove flesh and evaluate the flesh *(147)*.

The sampling plan for decomposition generally starts with or includes an organoleptic evaluation component and would also include a histamine sampling component for the fish species that have the potential for histamine formation. For raw fish, the organoleptic sampling and evaluation is nondestructive testing. For tuna canning, histamine sampling only removes a portion of the fish, so the remainder can be processed. Since the recommended sample weight for histamine testing is 250 g, for smaller fish, such as sardines and anchovies, several fish may be required to make up the histamine sample *(158)*. For cans, cups, and pouches that are greater than 170 g (6 oz) net weight, the sample unit is the individual item or product. For cans, cups, or pouches that are less than 170 g (6 oz) net weight, multiple units are required to be collected and composited to make the single sample of the right sample weight *(152)*.

U.S.-based sampling plan for compliance and enforcement (CPG 540.525). A consumer complaint of an allergy-like reaction or illness can begin the formal compliance investigation and sampling process by the FDA. The FDA would then notify the retail establishment that sold the product, as well as the importer of record or the manufacturer of the product can or date code. An appropriate sample would then be drawn from the identified lot of cans or raw product for organoleptic evaluation and histamine analysis. The sampling scheme for the histamine analysis is $n = 24$, $c = 1$, $m = 50$, $M = 500$, and the overall investigation includes organoleptic evaluation of the product for decomposition *(146)*. The lot is presumed to be decomposed and subject to seizure and destruction if one can has a histamine level over 50 ppm and another can is determined to be decomposed by a trained seafood organoleptic evaluator. The lot is considered decomposed and subject to seizure and destruction if two cans are over 50 ppm of histamine. When two results over 50 ppm of histamine are determined before the 24 cans are completely analyzed, no further analysis is needed. Similarly, the lot is considered adulterated and can be seized if one individual can or sample is over 500 ppm. When a documented illness is associated with the product lot, irrespective of the histamine content, the lot is considered adulterated *(146)*. The FDA has set the maximum allowable histamine level per sample (m) at 50 ppm because organoleptic experts have associated this level with decomposition *(58)*.

Testing products imported into the United States. The standard protocol for selecting imported fresh fish or canned products for testing considers the species risk,

TABLE 10. *A summary of the U.S., EU, and Codex decomposition and histamine sampling plans*

Trade bloc, country, or organization; comment	*N*	Sample size	Acceptable defects	*m, M,* ppm limit, other parameter	Comment(s)	Reference
U.S., NFI; tuna receiving	25 mt	$n = 18$ $n = 118$	$c = 0$ histamine $c = 2$ sensory	$m = 30$ ppm $M = 500$ ppm Sensory failure		*99*
U.S., NFI; tuna receiving	25 mt	$n = 60$ $N =$ total lot	$c = 0$ histamine, sensory	$m = 30$ ppm $M = 500$ ppm >10% sensory failure	Rectification	*99*
FDA; tuna receiving	25 mt	$n = 18$ $n = 118$	$c = 0$ histamine $c = 2$ sensory	$m = 50$ ppm $M = 500$ ppm Sensory failure		*158*
FDA; tuna receiving	25 mt	$n = 60$ $N =$ total lot	$c = 0$, histamine sensory	$m = 50$ ppm $M = 500$ ppm Sensory failure	Rectification	*158*
U.S.; compliance		$n = 24$	$c = 2$ either histamine or sensory or a combo	$m = 50$ $M = 500$ Or sensory failure	CPG 540.525	*146*
U.S.; import sampling		$n = 18$ or 24	$c = 2$ either histamine or sensory or a combo	$m = 50$ $M = 500$ Or sensory failure	18 fresh-frozen 24 processed CMPG 7303.844	*147*
EU		$n = 9$	$c = 2$	$m =$ avg 100 ppm $M = 200$ ppm	Ordinary fish	*50*
EU		$n = 9$	$c = 2$	$m =$ avg 200 ppm $M = 400$ ppm	Enzyme treated in brine	*51*
EU		$n = 9$	$c = 2$	$M = 400$ ppm	Fish sauce	*51*
Codex		$n = 59$		Avg $m \leq 100$ ppm $M = 200$ ppm	10 types of fish products	*36*
Codex		$n = 1$		$M = 400$ ppm	Fish sauce	*36*

importer risk, knowledge of past audits, etc. *(147)*. Batches or lots of products are sampled and organoleptically evaluated for odors of decomposition. These first organoleptic (sensory) sample sizes are $n = 18$ for raw fresh or fresh-frozen fish and $n = 24$ for processed (canned, cup, or pouch) products. If odors of decomposition are detected during the sensory evaluations, six subsamples are analyzed for histamine content, including the samples with decomposition. If any subsample contains over 35 ppm of histamine, all the remaining individual samples are analyzed for levels of histamine. If two or more individual samples contain over 50 ppm of histamine or one sample is over 500 ppm of histamine, that lot of product is considered decomposed and, thus, adulterated and cannot be imported *(146)*. The FDA recommends organoleptic evaluations in addition to histamine analysis on all samples tested. If an organoleptic analysis is not conducted by a recognized sensory expert, then 24 samples need to be collected and tested for histamine *(147)*.

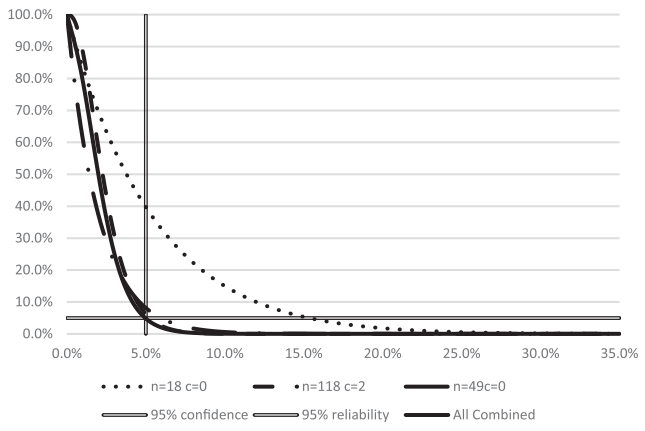

FIGURE 1. *Operating characteristic curves for U.S. sampling plans for tuna-receiving factories.*

All of the incoming raw fish used for producing hermetically sealed (canned) tuna products for the United States is tested on a lot-by-lot basis at the cannery receiving the fish, using a formal histamine sampling plan which is based on the HACCP guidance *(148, 158)*. This FDA requirement is the most extensive formal histamine and sensory sampling scheme for any fish product in the world *(158)*. As a reminder, products over the 50-ppm level (DAL) for histamine are considered decomposed and adulterated in the United States, and products over the 500-ppm level (AL) for histamine are considered adulterated and the lot is subject to seizure.

A summary of the major sampling plans for decomposition and histamine levels for Codex, the European Union, and the United States is shown in Table 10. Operating characteristic curves (OCCs) can be used to compare the effectiveness (AQL) of sampling plans. Figures 1 and 2 show the OCCs for multiple sampling plans. Figure 1 shows the OCCs for the U.S. sampling plans, and Figure 2 shows the OCCs for the EU, Codex, and U.S. import plans. These curves were calculated using an infinite lot size, and the samples were collected without replacement. The parame-

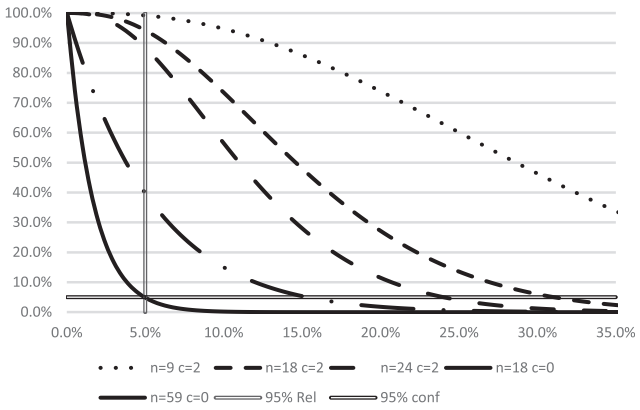

FIGURE 2. *Operating characteristic curves for U.S. imports, EU, and Codex. EU,* n = *9,* c = *2. U.S. imports,* n = *18,* c = *2;* n = *24,* c = *2;* n = *18,* c = *0. Codex,* n = *59,* c = *0.*

ters of the OCC are n (sample size or number of items inspected), c (the number of accepted defects), a desired confidence level of 95%, and the reliability level or acceptable defect levels (5 or 6.5%). An OCC line that is closer to the y axis, i.e., has a steeper slope, reflects a sampling plan with greater reliability and a smaller defect rate. When three of the four parameters are known, the fourth can be calculated. The sample size that is needed for the histamine testing and sensory evaluation can be calculated for the confidence and reliability limits chosen.

The OCCs in Figure 1 for the United States have been calculated based on a 95% confidence level, n values of 18 and 49, $c = 0$; $n = 118$, $c = 2$; and $n = 185$ (all combined). With the U.S. OCC, the 60-fish rectification sample for histamine was adjusted because a maximum of 11 fish (10%) from the 118-fish sensory sample could be rejected for decomposition so, although they are analyzed for histamine, they were rejected prior to this as part of the 118-fish sensory sample; thus, the 60-fish histamine sample becomes 49 to 57 fish for the calculation because 3 to 11 were rejected without replacement.

The OCCs in Figure 2 were calculated based on a 95% confidence level, $n = 9$, $c = 2$ for the European Union; $n = 59$, $c = 0$ for the Codex regulation; and $n = 18$, $c = 0$ and $n = 24$, $c = 2$ for the U.S. imports.

A product safety sampling curve differs from a product quality sampling curve. The AQL for a product safety sampling plan should be lower than an AQL for a product quality curve, as the former should allow for fewer defects for product safety sampling than for product quality sampling. A sampling plan for seafood processing or fresh fish trading will also enhance a good customer-vendor relationship if one is established and provides for immediate feedback and response.

Laboratory tests for histamine. Numerous analytical laboratory methods and semiquantitative or quick tests are available for evaluating histamine levels in fish products. The different methods are reviewed in EFSA *(56)* and Kose *(86, 87)*. Some are primarily screening methods to determine if the amount if histamine in the fish is above or below a certain level, such as 50 ppm. While various screening methods use simplified kits or test strips and require different preparation methods, there are also laboratory methods which require very sophisticated equipment to determine histamine levels very precisely. For example, there is a new test that uses enzymatic biosensors (the Biofish-300 HIS method) *(118)*.

Many tuna canneries have very well equipped quality assurance laboratories and can conduct the official U.S. standard method for testing for histamine, the AOAC International method 977.13, section 35.1.32, Fluorometric method *(147),* for all samples. Other factory laboratories use screening methods to determine lots with elevated histamine levels and then use the standard AOAC fluorometric test to verify the positive screening results. All the histamine test kits used in the United States need to be validated against the AOAC 977.13 standard in order to be used for HACCP screening *(149, 161)*.

The Codex and EU have differing official analytical methods. Codex uses AOAC 977.13, a fluorometric method, and the EU mandated method is a high-performance liquid chromatography separation of histamine, with the histamine subsequently detected by a UV detector; however, this method has not been validated by a collaborative study *(52)*.

U.S. HACCP guidelines for tuna processing. All seafood processed for consumption in the United States must be processed in compliance with the FDA's seafood HACCP regulations, Title 21 Code of Federal Regulations Part 123 (21 CFR 123) *(59),* which took effect in 1997. Periodically the FDA has issued a "Fish and Fishery Products Guidance" to provide guidance for compliance with the HACCP regulations, most recently in 2020 with the revision of the 4th edition *(158)* first published in 2011 *(148)*. This guidance provides CCPs and CLs as recommendations regarding histamine and other potential hazards for receiving and processing tuna fish for canning or raw fish used for sushi or fish sold wholesale, at retail, or restaurants.

A HACCP plan is designed to prevent food safety hazards from occurring by controlling potential hazards by using CCPs with CLs of time-and-temperature parameters that keep potential hazards from developing during processing, transport, or storage *(158)*. There are also strict time-and-temperature controls for processing foods to prevent the potential for *Staphylococcus aureus* growth. Tuna canners control potential food safety hazards using HACCP protocols and procedures as opposed to unreliable final canned product testing for *S. aureus* enterotoxin, the botulinum toxin, and histamine.

The failure of a processor of fish or fishery products to develop and implement a HACCP plan that complies with the requirements of 21 CFR 123 results in the fish or fishery products being considered *adulterated* within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 USC 342(a)(4) *(157)*.

Another part of the HACCP process control action is the low acid canned foods (LACF) process, documented in 21 CFR 113. The LACF regulations "were the first to utilize

aspects of the HACCP approach to process control" *(150)*. The LACF regulations require that a safe process for producing a commercially sterile container of food that is free of botulism spores be developed and approved by a process authority.

In particular, the HACCP guidelines offer guidance to control histamine formation by providing strict time-and-temperature controls for the cannery process *(4, 44, 158)*. These controls include testing the incoming tuna fish and conducting cannery processes that prevent bacterial growth and subsequent histamine formation by controlling the elapsed time during canned tuna processing from the start of thawing to precooking.

HACCP guidance requires plans for sampling and testing raw tuna for decomposition at receiving in any tuna factory that produces either frozen precooked and cleaned tuna loins or canned product destined for the U.S. market. This sampling plan must include the two components of organoleptic (sensory) evaluation and histamine analysis on every single lot of fish *(158)*. These receiving lots are categorized by species and generally by size. During unloading of the harvest vessel or carrier vessel, the fish are separated into lots of up to a maximum of 25 mt *(151)*. On the refrigerated carriers, the unloading lots must keep the harvest vessels separated as well until the fish is canned. A minimum sample of 136 fish is randomly collected from each lot: 18 for histamine testing and 118 for sensory evaluation. A histamine value of >50 ppm found in any of the 18 fish tested will result in rejection of the entire lot for decomposition. When all of the histamine results of the tested fish are all under 50 ppm of histamine, the remaining 118 sample fish are thawed and evaluated organoleptically, and if two or fewer of them are determined to be decomposed, the entire lot can be released for processing. Individual fish from all accepted lots are also evaluated for decomposition subsequently, during cannery processing.

When more than 2 of the 118 sample fish are determined to be decomposed, the lot is rejected or rectified. Rectifying the lot includes random sampling and collection of 60 additional fish for histamine testing. This additional 60-fish sample must include the decomposed fish found during the organoleptic evaluation of the 118-fish sample. The rectification includes inspecting every fish (100%) in the fish lot by organoleptic evaluation using specially trained inspectors *(158)*. The National Fisheries Institute (NFI) Tuna Council has suggested more stringent restrictions or limits for canned tuna, including an acceptable limit (*m*) for histamine levels of 30 ppm and the rejection of the receiving lot if it is found to have over 10% decomposition during rectification *(99)*. The more stringent limit for sensory evaluation during rectification is based on the concerns that the inspectors' noses will "burn out" if too many bad fish need to be evaluated and that the organoleptic evaluation process does not completely detect all potentially decomposed fish for removal from the processing line and the canned product.

During processing, if the ambient air temperature exceeds 70°F (21.1°C) *(4),* the time allowed between when thawing is started and when the center of the fish reaches the inhibitory temperature for HFB growth and histamine formation (60°C) is 4 h for never-frozen fish or 12 h for previously frozen fish. Adams et al. *(4)* validated an additional 12-h processing time for after precooking until the fish in the can in the retort reached inhibitory temperatures (60°C). This means 12 h more to cool, deskin, and clean the fish, pack and seal the cans, load the retorts, vent the retorts, and heat the can until the meat in the center is at 60°C.

Minimizing the risks of histamine formation. All the histamine found in fish muscle is formed because of bacterial action after death *(64)*. The formation of histamine is prevented by rapid chilling of the fish using ice, chilled seawater, cold dense brine of –4°C, or air blast freezers. When chilling is delayed, histamine formation can occur, and it happens rapidly at higher temperatures *(11)*.

Captured tuna can easily be chilled properly on a super seiner vessel, modern bait boat, or troller vessel, which all have plenty of fully functional refrigeration equipment and capacity for the number of fish that can be captured in a day. The fish harvested by and off-loaded from these vessels rarely have elevated histamine problems. Individual fish caught on modern longliners with air blast freezers also rarely have histamine problems (albacore, yellowfin, bigeye) *(42)*.

The conditions for histamine to form are found on smaller local fishing boats which use insufficient ice to chill the fish, or no ice. If fish are poorly treated or unchilled on boats, processed on the beach, dried in the sun, or fermented without boiling them first, these conditions will allow the HFB to grow and form histamine. Fresh fish that arrives in port in excellent condition can experience further high-temperature abuse during processing and produce high histamine levels if the temperatures are not kept below 4°C at all times during transport, receiving, and processing *(158)*. The cold chain during capture, processing, and transportation must be maintained at all times.

Each type of market may have to develop its own methods for its needs to maintain the cold chain. For example, there is a fresh finfish auction in Hawaii, supported by a long-line fleet. All the fish is caught in the Pacific Ocean, chilled on ice, and sold in the U.S. mainland, Japan, Canada, Europe, and elsewhere. The fish is excellent and inspected organoleptically for every auction, 6 days a week *(71)*. That group has worked very hard at developing techniques for chilling the fish quickly and keeping it cold. They have found that removing the gills and viscera from larger fish will help them cool faster *(80, 81)*.

Baranowski et al. *(9)* indicated that freezing the fish delayed histamine formation after thawing, and Hongpattarakere et al. *(73)* suggested that freezing and thawing the fish before processing delayed histamine formation. These studies suggest that chilled, never-frozen fish develops histamine faster than thawed, previously frozen fish. In addition, the fourth edition of the FDA HACCP guidance allows longer temperature exposure times for previously frozen histamine-forming fish than for never-frozen fish *(148)*.

Proper management of the cold chain for fresh fish from start to finish is important: ice is critical, and robust sampling systems are needed. We also suggest organoleptic training about the potential for histamine formation for all fish handlers. The FDA offers guidelines for sensory analysis of seafood and requirements for sensory analysts *(162)*. In the long run, organoleptic sampling is far less expensive than laboratory sampling. No chemicals or glassware are needed. Better sensory evaluations may at least eliminate some of the problems but will not eliminate all of the problems.

CONCLUSIONS

The U.S. HACCP program for canned tuna has proven to be very successful in preventing histamine formation in the canned tuna industry. In 1973, prior to HACCP and an understanding of the causes of histamine formation, there was a large recall in the United States for canned tuna having elevated levels of histamine. Although no hospitalizations were reported, over 230 people were sickened in eight states *(95)*. This was the first reported case of histamine poisoning in canned tuna reported by the then Centers for Disease Control (CDC) *(18)* and was from one canner but only two day codes. In 2004, after HACCP implementation, a lot of canned tuna was recalled by the Department of Defense. Packed in American Samoa *(115),* after an extensive series of testing *(105),* this recall was isolated to one defined lot of canned product, and the product did not make it into public distribution. Histamine was not detected in canned tuna that was collected from California markets by Li et al. *(92),* and the maximum histamine level found in the tuna in pouches was 8 ppm. This study found two more recalls of canned tuna for histamine in the United States *(160)*. Considering the large amount of canned tuna consumed in the United States, this limited amount of recalled product for histamine contamination indicates an excellent control of this food safety hazard. The implementation of the HACCP system of food safety control is fundamental to this achievement by the canned tuna industry.

In 1995, the FDA reduced the DAL for histamine content *(58)* from 200 ppm set in 1982 *(57)* to 50 ppm, based on the judgment of organoleptic experts. The AQL of the U.S.-based sampling system for the potential food safety hazard of decomposition, including elevated levels of histamine, was discussed earlier in this article. The FDA has acknowledged that the histamine levels found in canned tuna in the United States were low *(57, 58)*. Prior to the implementation of the formal U.S. HACCP system, the U.S. tuna canneries collaborated with tuna fishing vessels (purse seiners) on histamine prevention and control *(15, 106)*. This collaborative quality improvement program focused on chilling and freezing the fish rapidly, both to reduce salt penetration into the fish and to minimize histamine formation *(43)*. Three research trips on purse seiner vessels were conducted in the mid-1980s for this collaborative study, which culminated in a refrigeration manual for tuna purse seiners that is a good reference for preventing histamine formation and salt penetration into the tuna *(15)*.

Odors of decomposition and elevated histamine levels correlate well in fresh tuna. In the early 1990s during albacore harvesting in Samoa with double-hulled canoes, or alias, powered by an outboard motor, there was very limited cargo space and ice storage capacity. Odors of decomposition were tied very closely with elevated histamine levels in the fish. The histamine levels were low when no odors were detected, while elevated histamine levels were found with any detection of odors of decomposition *(42)*. Such a correlation does not seem to exist for frozen or frozen-and-thawed fish.

Because elevated histamine levels and odors of decomposition both are the result of the growth of spoilage bacteria, including HFB, the only way to prevent histamine formation and the decomposition process is to provide good refrigeration processes for rapid chilling of newly caught fish. Because modern tuna harvesting vessels are equipped with the necessary refrigeration capability, the only reasons that fish might be delivered with elevated levels of histamine are because of an equipment breakdown or because too many fish are brought on board, causing the refrigeration equipment to be overwhelmed. At U.S. canneries, the received fish are very closely screened, and very strict HACCP controls are implemented for the fish being processed through the cannery.

The primary concern for histamine formation at tuna canneries is deliveries of nonfrozen fresh fish from small boats without adequate supplies of ice. This inadequate amount of ice occurs when ice is unavailable, is too expensive, or is misappropriated or because the fishermen do not understand the importance of using ice. Histamine formation is easily controlled with rapid chilling and temperature control during transit and processing. Once histamine levels get high, nothing can be done to lower them.

According to DeBeer *(41),* it is all about the process: if you have a grade A process and a grade C team, the product will still be okay, but if you have a grade C process and a grade A team, the product will not be satisfactory all of the time. Fish properly iced will not produce histamine, and this constitutes a grade A process: the fish may get sour or produce other odors of decomposition on long multiday trips, but histamine will not form if the fish have been iced properly and rapidly chilled. Fishing and storing fish on the boats or on shore, without ice or with insufficient ice, will produce decomposed fish with high histamine levels (grade C process), for example, when fishing trips last all day in tropical waters, even if the fishing teams are grade A fishermen.

Histamine formation is entirely preventable. Even though the regulations for actionable levels for histamine levels and sampling methods differ around the world, the goals are the same, very low histamine levels, so the fishermen, brokers, and processors should chill the fish quickly, no matter the size.

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SUPPLEMENTAL MATERIAL

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REFERENCES

1. Ababouch, L., M. E. Afilal, S. Rhafiri, and F. F. Busta. 1991. Identification of histamine-producing bacteria isolated from sardine (*Sardina pilchardus*) stored in ice and at ambient temperature (25°C). *Food Microbiol*. 8:127–136. https://doi.org/10.1016/0740-0020(91)90005-M
2. Abe, H. 1983. Distribution of free L-histidine and related compounds in marine fishes. *Bull. Jpn. Soc. Sci. Fish*. 49:1683–1687. https://doi.org/10.2331/suisan.49.1683
3. Abe, H., R. W. Brill, and P. W. Hochachka. 1986. Metabolism of L-histidine, carnosine, and anserine in skipjack tuna. *Physiol. Zool*. 59:439–450. https://doi.org/10.1086/physzool.59.4.30158597
4. Adams, F., F. Nolte, J. Colton, J. DeBeer, and L. Weddig. 2018. Precooking as a control for histamine formation during the processing of tuna: an industrial process validation. *J. Food Prot*. 81:444–455. https://doi.org/10.4315/0362-028X.JFP-17-276
5. Anihouvi, V., G. S. Ayernor, J. D. Hounhouigan, and E. Sakyi-Dawson. 2006. Quality characteristics of lanhouin: a traditional processed fermented fish product in the Republic of Benin. *Afr. J. Food Agric. Nutr. Dev.* 6:1–15. https://doi.org/10.4314/ajfand.v6i1.19173
6. Anoman, A. T., K. M. Koffi, K. N. Aboua, and M. Koussemon. 2018. Determination of ETM, histamine and mycotoxins in garba, a traditional Ivoirian meal. *Am. J. Analyt. Chem*. 9:245–256. https://doi.org/10.4236/ajac.2018.94019
7. Anonymous. 12 July 2017. How many samples do you need to be confident your product is good? The Minitab Blog. Available at: https://blog.minitab.com/blog/the-statistical-mentor/how-many-samples-do-you-need-to-be-confident-your-product-is-good. Accessed 23 December 2020.
8. Australia New Zealand Food Standards. 2016. Imported food risk statement. Fish and fish products from the families specified and histamine. Available at: https://www.foodstandards.gov.au/consumer/importedfoods/Documents/Fish%20and%20fish%20products%20and%20histamine.docx. Accessed 27 November 2020.
9. Baranowski, J. D., H. A. Frank, P. A. Brust, M. Chongsiriwatana, and R. J. Premaratne. 1990. Decomposition and histamine content in mahi-mahi (*Coryphaena hippurus*). *J. Food. Prot*. 53:217–222. https://doi.org/10.4315/0362-028X-53.3.217
10. Bartholomew, B. A., P. R. Berry, J. C. Rodhouse, R. J. Gilbert, and C. K. Murray. 1987. Scombrotoxic fish poisoning in Britain: features of over 250 suspected incidents from 1976 to 1986. *Epidemiol. Infect*. 99:775–782. https://doi.org/10.1017/S0950268800066632
11. Behling, A. R., and S. L. Taylor. 1982. Bacterial histamine production as a function of temperature and time of incubation. *J. Food Sci*. 47:1311–1314. https://doi.org/10.1111/j.1365-2621.1982.tb07675.x
12. Beyens, Y., P. Failler, and B. Asiedu. 2018. Institutional challenges and constraints for Ghana in exporting fishery products to the European Union. *Food Rev. Int*. 34:265–289. https://doi.org/10.1080/87559129.2017.1289386
13. Biji, K. B., C. N. Ravishankar, R. Venkateswarlu, C. O. Mohan, and T. S. Gopal. 2016. Biogenic amines in seafood: a review. *J. Food Sci. Technol*. 53:2210–2218. https://doi.org/10.1007/s13197-016-2224-x
14. Brazil, Ministério da Agricultura e do Abastecimento. 1997. Portaria no.185 de 13 de maio de 1997. Aprova o Regulamento Técnico de Identidade e Qualidade de Peixe Fresco (inteiro e eviscerado). Diário Oficial daUnião, 19 de maio, seção 1. Brasília, DF. Available at: http://www.cidasc.sc.gov.br/inspecao/files/2012/08/portaria-185-1997.pdf. Accessed 26 October 2020.
15. Burns, F. D. 1985. Tuna handling and refrigeration on purse seiners. NOAA technical memorandum NMFS. Available at: https://repository.library.noaa.gov/view/noaa/5685. Accessed 2 February 2021.
16. Campbell-Platt, G. 1994. Fermented foods: a world perspective. *Food Res. Int*. 27:253–257. https://doi.org/10.1016/0963-9969(94)90093-0
17. Castellini, M. A., and G. N. Somero. 1981. Buffering capacity of vertebrate muscle: correlations with potentials for anaerobic function. *J. Comp. Physiol*. 143:191–198.
18. Center for Disease Control. 1973. Scombroid fish poisoning in canned tuna fish—United States. *Morb. Mortal*. 22:69–70.
19. Chile, Diario Oficial. 2018. Reglamento sanitario de los alimentos, DTO. No. 977/96, p. 119. Available at: http://extwprlegs1.fao.org/docs/pdf/chi9315.pdf. Accessed 17 October 2020.
20. Codex Alimentarius Commission. 1969. Codex sampling plans for prepackaged foods (AQL 6.5). Available at: https://www.academia.edu/34797815/CODEX_SAMPLING_PLANS_FOR_PREPACKAGED_FOODS_AQL_6_5_CODEX_STAN_233_1969. Accessed 11 December 2020.
21. Codex Alimentarius Commission. 1981. CXS 119-1981 (revised 2018). Standard for canned finfish. Available at: http://www.fao.org/fao-who-codexalimentarius/codex-texts/all-standards/en/. Accessed 18 November 2020.
22. Codex Alimentarius Commission. 1981. CXS 36-1981 (revised 2013). Standard for quick frozen finfish, uneviscerated and eviscerated. Available at: http://www.fao.org/fao-who-codexalimentarius/codex-texts/all-standards/en/. Accessed 18 November 2020.
23. Codex Alimentarius Commission. 1981. CXS 70-1981 (revised 2018). Standard for canned tuna and bonito. Available at: http://www.fao.org/fao-who-codexalimentarius/codex-texts/all-standards/en/. Accessed 19 November 2020.
24. Codex Alimentarius Commission. 1981. CXS 94-1981 (revised 2018). Standard for canned sardines and sardine-type products. Available at: http://www.fao.org/fao-who-codexalimentarius/codex-texts/all-standards/en/. Accessed 18 November 2020.
25. Codex Alimentarius Commission. 1989. CXS 165-1989 (revised 2014). Standard for quick frozen blocks of fish fillet, minced fish flesh and mixtures of fillets and minced fish flesh. Available at: http://www.fao.org/fao-who-codexalimentarius/codex-texts/all-standards/en/. Accessed 18 November 2020.
26. Codex Alimentarius Commission. 1989. CXS 166-1989 (revised 2016). Standard for quick frozen fish sticks (fish fingers), fish portions and fish fillets—breaded or in batter. Available at: http://www.fao.org/fao-who-codexalimentarius/codex-texts/all-standards/en/. Accessed 18 November 2020.
27. Codex Alimentarius Commission. 1995. CXS 190-1995 (revised 2014). Standard for quick frozen fish fillets. Available at: http://www.fao.org/fao-who-codexalimentarius/codex-texts/all-standards/en/. Accessed 18 November 2020.
28. Codex Alimentarius Commission. 1997. CAC/GL 21-1997 (CXG 21-197). Principles and guidelines for the establishment and application of microbiological criteria related to foods. Available at: http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/. Accessed 21 November 2020.
29. Codex Alimentarius Commission. 1999. CAC-GL 31-1999. Guidelines for the sensory evaluation of fish and shellfish in laboratories. Available at: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B31-1999%252FCXG_031e.pdf. Accessed 19 November 2020.
30. Codex Alimentarius Commission. 2003. CAC/RCP 52-2003. Code of practice for fish and fishery products. Available at: http://www.fao.org/input/download/standards/10273/CXP_052e.pdf. Accessed 11 December 2020.
31. Codex Alimentarius Commission. 2003. CXS 236-2003 (revised 2013). Standard for boiled dried salted anchovies. Available at: http://www.fao.org/fao-who-codexalimentarius/codex-texts/all-standards/en/. Accessed 18 November 2020.
32. Codex Alimentarius Commission. 2004. CAC/GL 50-2004. General guidelines on sampling. Available at: http://www.fao.org/uploads/

media/Codex_2004_sampling_CAC_GL_50.pdf. Accessed 19 November 2020.
33. Codex Alimentarius Commission. 2004. CXS 244-2004 (revised 2018). Standard for salted Atlantic herring and salted sprat. Available at: http://www.fao.org/fao-who-codexalimentarius/codex-texts/all-standards/en/. Accessed 18 November 2020.
34. Codex Alimentarius Commission. 2011. CXS 302-2011 (revised 2013). Standard for fish sauce. Available at: http://www.fao.org/fao-who-codexalimentarius/codex-texts/all-standards/en/. Accessed 18 November 2020.
35. Codex Alimentarius Commission. 2013. CXS 311-2013 (revised 2018). Standard for smoked fish, smoke-flavoured fish and smoke-dried fish. Available at: http://www.fao.org/fao-who-codex alimentarius/codex-texts/all-standards/en/. Accessed 18 November 2020.
36. Codex Alimentarius Commission. 2018. CX/FH 18/50/6. Revision of the code of practice for fish and fishery products (CXC 52-3002) and revisions of the section on sampling, examination and analyses related to histamine food safety. Available at: https://www.foodstandards.gov.scot/downloads/Revision_of_the_code_of_practice_for_fish_and_fishery_products_%28cxc_52_3002%29_and_revision_of_section_on_histamine.pdf. Accessed 26 October 2020.
37. Codex Alimentarius Commission. 2019. The year of food safety. Available at: http://www.fao.org/3/ca5180en/ca5180en.pdf. Accessed 13 November 2020.
38. Colombia, Ministerio de la Protección Social. 2007. Diario Oficial 46528. Available at: http://www.suin-juriscol.gov.co/viewDocument.asp?ruta=Resolucion/30033908. Accessed 24 November 2020.
39. Colombo, F. M., P. Cattaneo, E. Confalonieri, and C. Bernardi. 2018. Histamine food poisonings: a systematic review and meta-analysis. *Crit. Rev. Food Sci. Nutr*. 58:1131–1151. https://doi.org/10.1080/10408398.2016.1242476
40. Costa Rica, El Ministro de Economía, Industria y Comercio. 2004. Reglamento RTCR 385:2004. Atun y Bonito en conserva. Especificaciones. Available at: http://extwprlegs1.fao.org/docs/pdf/cos78204.pdf. Accessed 17 October 2020.
41. DeBeer, C. 2021. Personal communication.
42. DeBeer, J. 2021. Personal communication.
43. DeBeer, J., F. Nolte, C. W. Lord, and J. Colley. 2019. Salt penetration in whole raw tuna frozen onboard vessel by brine immersion: an industrial study. *Mar. Fish. Rev.* 81:40–52. https://doi.org/10.7755/MFR.81.1.2
44. DeBeer, J., F. Nolte, C. W. Lord, J. Colton, and J. Colley. 2021. Tempering large tuna prior to thawing to minimize histamine formation. *Food Prot. Trends*. 41:36–45.
45. Demoncheaux, J. P., R. Michel, C. Mazenot, G. Duflos, C. Iacini, F. Delaval, E. M. Saware, and J. C. Renard. 2012. A large outbreak of scombroid fish poisoning associated with eating yellowfin tuna (*Thunnus albacares*) at a military mass catering in Dakar, Senegal. *Epidemiol. Infect*.140:1008–1012. https://doi.org/10.1017/S0950268811001701
46. El Hariri, O., N. Bouchriti, and R. Benguedour. 2018. Risk assessment of histamine in chilled, frozen, canned and semi-preserved fish in Morocco: implementation of risk ranger and recommendations to risk managers. *Foods* 7:157. https://doi.org/10.3390/foods7100157
47. Elshafey, W. S., H. M. Ibrahim, M. A. Hassan, and A. A. Maarouf. 2018. Assessment of histamine and putrescine residues in fish and shellfish. *Benha Vet. Med. J*. 34:178–187. https://doi.org/10.21608/bvmj.2018.44744
48. Enache, E., A. Kataoka, D. G. Black, M. Hayman, L. Weddig, and K. Bjornsdottir-Butler. 2013. Heat resistance of histamine producing bacteria in irradiated tuna loins. *J. Food Prot*. 76:1608–1614. https://doi.org/10.4315/0362-028X.JFP-12-467
49. Eurasian Customs Union. 2016. Technical regulations of the Customs Union. TR EEU 040/2016. On safety of fish and fish products. Available at: https://globexpert.ru/upload/tcu/10.pdf. Accessed 24 November 2020.
50. European Commission. 2005. Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. *Off. J. Eur. Union* L 338:1–26. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005R2073&from=EN. Accessed 20 October 2020.
51. European Commission. 2013. Commission Regulation (EC) No 1019/2013, Annex 1 No. 2073/2005 of 23 October 2013 amending Annex I to Regulation (EC) No 2073/2005 as regards histamine in fishery products (text with EEA relevance). *Off. J. Eur. Union* L 282:46–47. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32013R1019. Accessed 15 December 2020.
52. European Commission. 2014. Equivalence testing of histamine methods. Final report. Available at: https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/equivalence-testing-histamine-methods-final-report#:~:text=The%20EU%20mandated%20method%20is,detection%20by%20a%20UV%20detector.&text=The%20Codex%20method%20is%20AOAC,been%20validated%20by%20collaborative%20trial. Accessed 7 March 2021.
53. European Commission. 2020. RASFF (Rapid Alert System for Food and Feed) window. Available at: https://webgate.ec.europa.eu/rasff-window/portal/?event=SearchForm&cleanSearch=1. Accessed 9 January 2021.
54. European Commission. 2020. RASFF (Rapid Alert System for Food and Feed) portal. Available at: https://ec.europa.eu/food/safety/rasff/portal_en. Accessed 9 January 2021.
55. European Food Safety Authority. 2005. Commission Regulation (EC) No 2073/2005 of the European Parliament and of the Council of 15 November 2005 on microbiological criteria for foodstuffs (text with EEA relevance). *Off. J. Eur. Union* L 338:1–26.
56. European Food Safety Authority. 2011. Scientific opinion on risk-based control of biogenic amine formation in fermented foods. *EFSA J.* 9:2393. https://doi.org/10.2903/j.efsa.2011.2393
57. Federal Register. 1982. Docket no. 81D-0175. Defect action levels for histamine in tuna; availability of guide. *Fed. Regist*. 47:40487–40488. Available at: https://tile.loc.gov/storage-services/service/ll/fedreg/fr047/fr047178/fr047178.pdf. Accessed 26 November 2020.
58. Federal Register. 1995. Docket no. 95D-0157. Decomposition and histamine—raw, frozen tuna and mahi-mahi; canned tuna; and related species; revised compliance policy guide; availability. *Fed. Regist*. 60:39754–39756. Available at: https://www.govinfo.gov/content/pkg/FR-1995-08-03/pdf/95-19059.pdf. Accessed 25 November 2020.
59. Federal Register. 1995. Docket no. 93N-0195. RIN 0910-AA10. Procedures for the safe and sanitary processing and importing of fish and fishery products. 60:65096–65202. http://www.gpo.gov/fdsys/pkg/FR-1995-12-18/pdf/95-30332.pdf. Accessed 24 December 2016.
60. Feldman, K. A., S. B. Werner, S. Cronan, M. Hernandez, A. R. Horvath, C. S. Lea, A. M. Au, and D. J. Vugia. 2005. A large outbreak of scombroid fish poisoning associated with eating escolar fish (*Lepidocybium flavobrunneum*). *Epidemiol. Infect*. 133:29–33. https://doi.org/10.1017/S095026880400322X
61. Ferrario, C. 2013. *Lactococcus garvieae* and *Morganella morganii*: two bacterial models to study quality and safety of fish products. Ph.D. thesis. Universita Degli Studi Di Milano. https://doi.org/10.13130/ferrario-chiara_phd2013-01-30
62. Fiji Islands. 2009. Food Safety Regulations 2009. Sixteenth Schedule, Standards on fish and fisheries products. Available at: http://www.health.gov.fj/wp-content/uploads/2014/09/33_The-Food-Safety-Regulations-2009.pdf. Accessed 9 November 2020.
63. Food and Agriculture Organization of the United Nations and World Health Organization. 2012. Joint FAO/WHO expert meeting on the public health risks of histamine and other biogenic amines from fish and fishery products, meeting report, FAO, Rome, 23 to 27 July 2012. Available at: https://apps.who.int/iris/handle/10665/89216. Accessed 21 November 2020.
64. Frank, H. A., D. H. Yoshinaga, and W. K Nip. 1981. Histamine formation and honeycombing during decomposition of skipjack

tuna, *Katsuwonus pelamis,* at elevated temperatures. *Mar. Fish. Rev.* 43:9–14.
65. Froese, R., and D. Pauly (ed.). 2019. FishBase. Available at: www.fishbase.org. Accessed 23 December 2020.
66. Ghana Standards Authority. 2011. GS 207:2011. ICS no. 67.120.30. Fish and fishery products: specification for canned tuna and tuna products. Ghana Standards Authority, Accra, Ghana. [A personal copy was received from a factory in Ghana.] Available from the first author at: jdebeer2005@gmail.com.
67. Gulf Technical Committee for Standards of Food and Agriculture Products. 2016. GSO 1817:2016 (update from GSO 1817:2007). ICS no. 67.120.30. Canned tuna. Available at: https://members.wto.org/crnattachments/2015/SPS/SAU/15_4786_00_e.pdf. Accessed 19 October 2020.
68. Hagoromo Food Corp. 2013. Canned tuna recall. Available at: http://www.atuna.com/archive.php?article=13533. Accessed 16 December 2020.
69. Hagoromo Food Corp. 2013. Japanese company recalling tuna. Available at: https://www.upi.com/Top_News/World-News/2013/10/12/Japanese-company-recalling-tuna/94181381599217/?spt=su&ur3=1. Accessed 15 December 2020.
70. Hassan, T. M., T. A. Abuhlega, A. F. Lawila, and S. R. Alkekli. 2017. Histamine in tuna sandwiches and hygienic status of some school food vendor premises in Tripoli city, Libya. *J. Med. Pharm. Sci*. 1:33–41.
71. HawaiiSeafood. 2015. Honolulu fish auction. Available at: https://www.hawaii-seafood.org/honolulu-fish-auction/. Accessed 23 February 2021.
72. Health Canada. 2020. Maximum levels for chemical contaminants in foods. Available at: https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/chemical-contaminants/maximum-levels-chemical-contaminants-foods.html. Accessed 7 November 2020.
73. Hongpattarakere, T., N. Buntin, and A. Nuylert. 2016. Histamine development and bacterial diversity in microbially-challenged tonggol (*Thunnus tonggol*) under temperature abuse during canning manufacture. *J. Food Sci. Technol*. 53: 245–256. https://doi.org/10.1007/s13197-015-2042-6
74. Hungerford, J. M. 2010. Scombroid poisoning: a review. *Toxicon* 56:231–243. https://doi.org/10.1016/j.toxicon.2010.02.006
75. Instituto Ecuatoriano de Normalización. 2013. NTE INEN 184:2013, segunda revisión. Atún y bonito en conserva. Requisitos. Primera edición. Available at: http://www.acuaculturaypesca.gob.ec/wp-content/uploads/2018/09/nte_inen_184-2013-ATUN-Y-BONITO-EN-CONSEERVA.REQUISITOS.pdf. Accessed 24 November 2020.
76. International Commission on Microbiological Specifications for Foods. 2018. Microorganisms in Foods 7. Microbiological testing in food safety management, 2nd ed. Springer International Publishing, Cham, Switzerland. https://doi.org/10.1007/978-3-319-68460-4
77. Ishak, N. B. 2008. Regional survey of histamine in fish and fish products (2004–2008): Malaysia. Available at: http://aquaticcommons.org/26308/1/IshakNB2008.pdf. Accessed 17 October 2020.
78. Journal Officiel De La Republique du Benin. 15 Octobre 2003. Arrêté no. 419 MAEIP/D-CAB/SGM/DA/CSRH/SA 17 Avril 2003. Fixant les valeurs limites en azote basique volatile total, en triméthylamine et en histamine dans les produits de la péche. Le Ministre de l'Agriculture, de l'Elevage et de la Péche. Available at: http://extwprlegs1.fao.org/docs/pdf/ben42836.pdf. Accessed 30 October 2020.
79. Kalegaonkar, S. 2017. Reliability confidence and sample size, part 1. Available at: https://shrikale.wordpress.com/2017/07/29/reliability-confidence-and-sample-size/. Accessed 23 December 2020.
80. Kaneko, J., J. W. Bell, and D. R. Hawn. 2004. Verification of a HACCP-based strategy for the control of histamine for the fresh tuna industry. A report by PacMar, Inc. pursuant to National Oceanographic and Atmospheric Administration award no. NA16FD2472. PacMar, Inc., Honolulu, Hawaii.
81. Kaneko, J., B. Takenaka, and P. Bartram. 2005. Keeping Hawaii seafood safe to eat. PacMar, Inc., Hololulu, Hawaii. Available at: https://hawaii-seafood.org/uploads/Keeping%20Hawaii%20Seafood%20Safe%20to%20Eat.pdf. Accessed 23 February 2021.
82. Kimura, B., H. Takahashi, S. Hokimoto, Y. Tanaka, and T. Fujii. 2009. Induction of the histidine decarboxylase genes of *Photobacterium damselae* subsp. *damselae* (formally *P. histaminum*) at low pH. *J. Appl. Microbiol*. 107:485–497. https://doi.org/10.1111/j.1365-2672.2009.04223.x
83. Konings, W. N., J. S. Lolkema, and B. Poolman. 1995. The generation of metabolic energy by solute transport. *Arch. Microbiol*. 164:235–242. https://doi.org/10.1007/BF02529957
84. Korea, Ministry of Food and Drug Safety. 2019. Ministry of Food and Drug Safety notification (no. 2019-57, July 3 2019). Food Code 2019. Chap. 1, General provisions. Available at: https://www.mfds.go.kr/eng/brd/m_15/view.do?seq=69982. Accessed 24 November 2020.
85. Köse, S. 2010. Evaluation of seafood safety health hazards for traditional fish products: preventive measures and monitoring issues. *Turk. J. Fish. Aquat. Sci*. 10:139–160. https://doi.org/10.4194/trjfas.2010.0120
86. Köse, S. 2017. Biogenic amines, p. 85–152. *In* A. Witczak and Z. Sikorski (ed.), Toxins and other harmful compounds in foods. CRC Press, Boca Raton, FL.
87. Köse, S., N. Kaklıkkaya, S. Koral, B. Tufan, S. Genç, K. Buruk, and F. Aydın. 2006. Comparison of seven commercial histamine test kits and HPLC analytical methods for application to salted and fermented fish product. Poster presentation. TrueFood contract number FOOD-CT-2006-016264. 3rd International Symposium on Recent Advances in Food Analysis, Prague, Czech Republic, 7 to 9 November 2007.
88. Landete, J. M., B. De Las Rivas, A. Marcobal, and R. Munoz. 2008. Updated molecular knowledge about histamine biosynthesis by bacteria. *Crit. Rev. Food Sci. Nutr*. 48:697–714. https://doi.org/10.1080/10408390701639041
89. Laws of Seychelles. 2012. Export of fishery products acts. Chap. 77A. Export of fishery products act. Subsidiary legislation. Export of fishery products (sanitary) regulations. Available at: https://seylii.org/sc/legislation/consolidated-act/77a. Accessed 18 October 2020.
90. Laws of Trinidad and Tobago. 2007. Food and drugs act, chap. 30:0. Available at: https://tradeind.gov.tt/wp-content/uploads/2016/02/Food-and-Drugs-Act-30.01.pdf. Accessed 26 October 2020.
91. Lehane, L., and J. Olley. 2000. Histamine fish poisoning revisited. *Int. J. Food Microbiol*. 58:1–37. https://doi.org/10.1016/S0168-1605(00)00296-8
92. Li, C., G. Vrdoljak, and B. Moezzi. 2018. Sampling and analysis of histamine in fish products from local northern California markets. *Food Nutr. J.* 3:189. https://doi.org/10.29011/2575-7091.100089
93. Mahmoudi, R., and K. Mardani. 2015. Histamines and foods: a review on importance, detection and controlling in foods. *Malays. J. Sci*. 34:103–107. https://doi.org/10.22452/mjs.vol34no1.11
94. Mauritius. 1999. GN 173/1999. Food regulations 1999. Available at: https://www.mcci.org/media/165439/food-regulations-1999-updated.pdf. Accessed 23 November 2020.
95. Merson, M. H., W. B. Baine, E. J. Gangarosa, and R. C. Swanson. 1974. Scombroid fish poisoning: outbreak traced to commercially canned tuna fish. *JAMA (J. Am. Med. Assoc.)* 228:1268–1269. https://doi.org/10.1001/jama.228.10.1268
96. Molenaar, D., J. S. Bosscher, B. Ten Brink, A. J. Driessen, and W. N. Konings. 1993. Generation of a proton motive force by histidine decarboxylation and electrogenic histidine/histamine antiport in *Lactobacillus buchneri*. *J. Bacteriol*. 175:2864–2870. https://doi.org/10.1128/jb.175.10.2864-2870.1993
97. Naila, A., S. Flint, G. Fletcher, P. Bremer, and P. Meerdink. 2010. Control of biogenic amines in food—existing and emerging approaches. *J. Food Sci*. 75:R139–R150. https://doi.org/10.1111/j.1750-3841.2010.01774.x
98. Naila, A., S. Flint, G. C. Fletcher, P. J. Bremer, and G. Meerdink. 2011. Biogenic amines and potential histamine–forming bacteria in

rihaakuru (a cooked fish paste). *Food Chem*. 128:479–484. https://doi.org/10.1016/j.foodchem.2011.03.057
99. National Fisheries Institute. 2014. Tuna Council HACCP guidance for canned tuna. Available at: https://www.aboutseafood.com/wp-content/uploads/2008/04/Canned-Tuna-HACCP-Handbook-4-16-2014.pdf. Accessed 7 February 2020.
100. National Oceanic and Atmospheric Administration. 2021. Export requirements by country and jurisdiction (G-M). Israel. NOAA Fisheries, Silver Spring, MD. Available at: https://www.fisheries.noaa.gov/export-requirements-country-and-jurisdiction-g-m-2. Accessed 2 May 2021.
101. New Zealand Seafood Standards Council. 2013. A guideline for the seafood industry. Available at: https://www.nzssc.co.nz/resource-single/20. Accessed 7 November 2020.
102. Osgood, A. 2020. Phone call.
103. Özogul, Y., and F. Özogul. 2020. Biogenic amines formation, toxicity, regulations in food, chap. 1. *In* B. Saad and R. Tofalo (ed.), Biogenic amines in food: analysis, occurrence and toxicity. Royal Society of Chemistry, Cambridge, UK. https://doi.org/10.1039/9781788015813-00001
104. Panama, Ministerio De Comercio E Industrias. 2001. Aprobar la norma tecnica panameña dgnti-copanit 493-00 productos de la pesca-atun, barrilete y bonito en conserva – requisites. Available at: http://200.46.254.138/legispan/PDF_NORMAS/2000/2001/2001_301_2752.pdf. Accessed 3 December 2020.
105. Parks, M. Personal communication.
106. Patterson, P., and F. D. Burns. 1984. Salt uptake, and histamine and honeycomb formation in brine frozen tuna. U.S. Tuna Foundation Technical Report. Available from the first author at: jdebeer2005@gmail.com.
107. Pavlović, M. S., S. D. Ivanović, I. N. Pavlović, N. I. Roković, V. I. Radosavljević, and D. D. Vasilev. 2019. Histamine levels in fish samples collected from Serbian market in 2018. *Food Feed Res*. 46:37–43. https://doi.org/10.5937/FFR1901037P
108. Peivasteh-Roudsari, L., A. Rahmani, N. Shariatifar, B. Tajdar-Oranj, M. Mazaheri, P. Sadighara, and A. M. Khaneghah. 2020. Occurrence of histamine in canned fish samples (tuna, sardine, kilka, and mackerel) from markets in Tehran. *J. Food Prot*. 83:136–141. https://doi.org/10.4315/0362-028X.JFP-19-288
109. Peru, Organismo Nacional de Sanidad Pesquera. 2016. Resolucíon de Direccíon Ejecutiva no 57-2016-SANIPES/DE. Indicadores o criterios de seguridad alimentaria e higiene para alimentos y piensos de origen pesquero y acuícola. Available at: http://www.sanipes.gob.pe/procedimientos/13_ManualIndicadoresocriteriosdeseguridadalimantaria-rev02-2010.compressed.pdf. Accessed 17 October 2020.
110. Petrovic, J., J. Babić, S. Jaksic, B. Kartalovic, D. Ljubojevic, and M. Cirkovic. 2016. Fish product–borne histamine intoxication outbreak and survey of imported fish and fish products in Serbia. *J. Food Prot*. 79:90–94. https://doi.org/10.4315/0362-028X.JFP-15-190
111. Philippine National Standard. 2006. PNS/BFAD 04:2006. Ethnic food products. Dried, salted fish. Specification. Available at: https://archive.org/details/pns.04.2006/page/n9/mode/2up. Accessed 1 July 2021.
112. Philippine National Standard. 2006. PNS/BFAD 06:2006. Thermally processed fish products. Specification. Available at: https://archive.org/details/pns.06.2006/page/n3/mode/2up. Accessed 1 July 2021.
113. Philippine National Standard. 2014. PNS BAFPS 138:2014. Fresh-chilled, fresh-frozen, and treated tuna. Available at: http://www.spsthailand.net/admin/admin_stdata/FileSPS/Text%20SPS%20PHL%20257.pdf. Accessed 1 July 2021.
114. Rachmawati, N. 2019. Assessing the risk of histamine from the Indonesian salted-boiled fish (pindang). Ph.D. dissertation. University of Tasmania. https://doi.org/10.25959/100.00031478
115. Radio New Zealand. 2004. Tuna recall in American Samoa because of high levels of histamine. Available at: https://www.rnz.co.nz/international/pacific-news/148974/tuna-recall-in-american-samoa-because-of-high-levels-of-histamine. Accessed 21 November 2020.
116. Reliability Analytics. 2020. Reliability Analytics toolkit. Available at: https://reliabilityanalyticstoolkit.appspot.com/sample size. Accessed 12 December 2020.
117. Ruiz-Capillas, C., and A. M. Herrero. 2019. Impact of biogenic amines on food quality and safety. *Foods* 8:62. https://doi.org/10.3390/foods8020062
118. Salleres, S., I. González, A. Arantzamendi, R. González, S. Maza, A. Jaureguibeitia, J. Hungerford, C. A. DeWitt, and R. A. Benner. 2016. Validation of the biofish-300 HIS enzymatic biosensor for the detection of histamine in fishery products. *J. AOAC Int*. 99:1338–1355. https://doi.org/10.5740/jaoacint.16-0180
119. Samoa. 2017. S.R. 2017/9. Food (safety and quality) regulations 2017. Available at: https://samoa.tradeportal.org/media/S.R.-2017-9-Food-Safety-and-Quality-Regulations-2017-Eng.pdf. Accessed 9 November 2020.
120. Satomi, M. 2016. Effect of histamine-producing bacteria on fermented fishery products. *Food Sci. Technol. Res*. 22:1–21. https://doi.org/10.3136/fstr.22.1
121. Schilling, E. 1982. Acceptance sampling in quality control, 2nd ed. Marcel Dekker, Inc., New York.
122. Serbia. 2018. Official Gazette of RS. Rulebook on general and special conditions of food hygiene at any stage of production, processing, and trade. 72/2010, 62/2018. Available at: https://www.tehnologijahrane.com/pravilnik/pravilnik-o-opstim-i-posebnim-uslovima-higijene-hrane. Accessed 7 November 2020.
123. Shalaby, A. R. 1996. Significance of biogenic amines to food safety and human health. *Food Res. Int*. 29:675–690. https://doi.org/10.1016/S0963-9969(96)00066-X
124. Singapore Food Agency. 2020. Maximum limits for marine biotoxins, inorganic arsenic, and methanol in food. Available at: https://www.sfa.gov.sg/docs/default-source/default-document-library/circular—maximum-limits-marine-biotoxins-inorganic-arsenic-methanol.pdf. Accessed 30 November 2020.
125. Solomon Islands Gazette. 2010. Pure food (food control) regulations. Legal notice 154. Available at: http://extwprlegs1.fao.org/docs/pdf/sol136439.pdf. Accessed 13 December 2020.
126. South Africa, Department of Health. 1997. GNR.692 of 16 May 1997. Regulations governing microbiological standards for foodstuffs and related matters. Available at: https://www.foodfocus.co.za/assets/documents/Regulations%20-%20Governing%20Microbiological%20standards%20R692%20of%201997%20updated.pdf. Accessed 7 November 2020.
127. Sri Lanka, Ministr of Health. 2020. Food (fish & fish product) regulation—2020. Available at: http://eohfs.health.gov.lk/food/images/pdf/Draftregulations/FoodFish–Fish-ProductsRegulations-2020.pdf. Accessed 7 November 2020.
128. Standar Nasional Indonesia. 2009. Ikan pindang—Bagian 3: Penanganan dan pengolahan [Fish sauce]. SNI 2717.3:2009. Available at: https://drive.google.com/file/d/1NUC3raqjY8R7q21ZEGyTZ8tbQtbF57u0/view?usp=sharing. Accessed 14 November 2020.
129. Standar Nasional Indonesia. 2013. Ikan segar [Fresh fish]. SNI 2729:2013. Available at: https://docplayer.info/32151388-Ikan-segar-sni-2729-2013.html. Accessed 13 November 2020.
130. Standar Nasional Indonesia. 2016. Sarden dan makerel dalam kemasan kaleng [Sardines and mackerel in cans]. SNI 8222:2016. Available at: https://kupdf.net/queue/sni-8222-2016pdf_59fb228ce2b6f5c607125bf6_pdf?queue_id=-1&x=1606271011&z=NzIuMjIwLjU3LjIyMw. Accessed 24 November 2020.
131. Standar Nasional Indonesia. 2016. Tuna dalam kemasan kaleng [Tuna in cans]. SNI 8223:2016. Available at: https://kupdf.net/download/sni-8223-2016_5a1981f0e2b6f55d1b599f5a_pdf. Accessed 13 November 13 2020.
132. Tabanelli, G. 2020. Biogenic amines and food quality: emerging challenges and public health concerns. *Foods* 9:859. https://doi.org/10.3390/foods9070859
133. Taiwan, Ministry of Health and Welfare. 2020. Sanitation standard for contaminants and toxins in food, app. 3. Available at: https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0040138. Accessed 16 October 2020.

134. Tamang, J. P., P. D. Cotter, A. Endo, N. S. Han, R. Kort, S. Q. Liu, B. Mayo, N. Westerik, and R. Hutkins. 2020. Fermented foods in a global age: East meets West. *Compr. Rev. Food Sci. Food Saf.* 19:184–217 https://doi.org/10.1111/1541-4337.12520
135. Taylor, S. L. 1986. Histamine food poisoning: toxicology and clinical aspects. *Crit. Rev. Toxicol*. 17:91–128. https://doi.org/10.3109/10408448609023767
136. Taylor, S. L., and M. W. Speckhard. 1983. Isolation of histamine-producing bacteria from frozen tuna. *Mar. Fish. Rev.* 45:35–39.
137. Taylor, S. L., J. E. Stratton, and J. A. Nordlee. 1989. Histamine poisoning (scombroid fish poisoning): an allergy-like intoxication. *J. Toxicol. Clin. Toxicol*. 27:225–240. https://doi.org/10.3109/15563658908994420
138. Thailand. 2006. Canned tuna and bonito standard. Thai agricultural commodity and food standard 7015-2006. Available at: http://www.acfs.go.th/standard/download/canned_tuna_and_bonito.pdf. Accessed 30 November 2020. (In Thai.)
139. Thailand, Department of Fisheries, Fish Inspection and Quality Control Division. 2014. Chemical aquaculture products standards, chilled, chilled and canned products (lot by lot). Available at: https://www.fisheries.go.th/quality/Std%20chem%20FZ.php. Accessed 27 November 2020.
140. Trip, H., N. L. Mulder, and J. S. Lolkema. 2012. Improved acid stress survival of *Lactococcus lactis* expressing the histidine decarboxylation pathway of *Streptococcus thermophilus* CHCC1524. *J. Biol. Chem*. 287:11195–11204. https://doi.org/10.1074/jbc.M111.330704
141. United States Code. 2021. Title 21—Food and drugs, chap. 9—Federal Food, Drug, and Cosmetic Act, subchap. III—Prohibited acts and penalties. §331. Prohibited acts. Available at: https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section331&num=0&edition=prelim. Accessed 1 July 2021.
142. United States Code. 2021. Title 21—Food and drugs, chap. 9—Federal Food, Drug, and Cosmetic Act, subchap. IV—Food. §342. Adulterated food. Available at: https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section342&num=0&edition=prelim. Accessed 1 July 2021.
143. U.S. Department of Agriculture. 2016. GAIN report. China published final standard for fresh and frozen aquatic animal products. Available at: https://apps.fas.usda.gov/newgainapi/api/report/downloadreportbyfilename?filename=Fresh%20and%20Frozen%20Aquatic%20Animal%20Product_Beijing_China%20-%20Peoples%20Republic%20of_2-29-2016.pdf. Accessed 26 October 2020.
144. U.S. Department of Agriculture. 2017. GAIN Report. India. GOI notifies standards for histamine level in fish and fish products. Available at: https://apps.fas.usda.gov/newgainapi/api/report/downloadreportbyfilename?filename=GOI%20Notifies%20Standards%20for%20Histamine%20Level%20in%20Fish%20and%20Fish%20Products_New%20Delhi_India_2-7-2017.pdf. Accessed 19 December 2020.
145. U.S. Department of Agriculture. 2020. GAIN Report. Ukraine. Ukraines MRLs for microbiological contaminants. Available at: https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Ukraine%27s%20MRLs%20for%20Microbiological%20Contaminants_Kyiv_Ukraine_04-27-2020. Accessed 27 November 2020.
146. U.S. Food and Drug Administration. 2005. CPG sec. 540.525. Decomposition and histamine raw, frozen tuna and mahi-mahi; canned tuna; and related species. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-540525-decomposition-and-histamine-raw-frozen-tuna-and-mahi-mahi-canned-tuna-and-related. Accessed 15 December 2020.
147. U.S. Food and Drug Administration. 2010. Compliance program guidance manual—7303.844—Chap. 3, Foodborne biological hazards—import seafood products compliance program. Available at: https://www.fda.gov/media/78911/download. Accessed 4 November 2020.
148. U.S. Food and Drug Administration. 2011. Fish and fishery products: hazards and controls guidance, 4th ed. Available at: https://seafood.oregonstate.edu/sites/agscid7/files/snic/fish-and-fishery-products-hazards-and-controls-guidance-4th-ed-2011.pdf. Accessed 1 July 2021.
149. U.S. Food and Drug Administration. 2011. Warning letter to P. T. Intimas Surya 12 September 2011. Available at: https://www.fdalabelcompliance.com/letters/ucm274600. Accessed 12 December 2020.
150. U.S. Food and Drug Administration. 2014. Low acid canned food manufacturers part 1—Administrative procedures/scheduled processes. Available at: https://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074992.htm. Accessed: 12 December 2020.
151. U.S. Food and Drug Administration. 2016. Warning letter to Unicord Public Company. Available at: https://wayback.archive-it.org/7993/20191214151214/https://www.fda.gov/node/369538. Accessed 1 July 2021.
152. U.S. Food and Drug Administration. 2018. Compliance program guidance manual—7303.842—Chap. 3, Seafood processor inspection program—Domestic and foreign facilities. Available at: https://www.fda.gov/media/71302/download. Accessed 11 November 2020.
153. U.S. Food and Drug Administration. 2018. FDA finalizes guidance on mandatory recall authority. Available at: https://www.fda.gov/food/cfsan-constituent-updates/fda-finalizes-guidance-mandatory-recall-authority#:~:text=FDA%20has%20issued%20a%20mandatory,were%20found%20to%20contain%20Salmonella. Accessed 26 December 2020.
154. U.S. Food and Drug Administration. 2018. FDA orders mandatory recall for Kratom products due to risk of Salmonella. Available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fda-orders-mandatory-recall-kratom-products-due-risk-salmonella. Accessed 26 December 2020.
155. U.S. Food and Drug Administration. 2019. 21 CFR 7.40. Title 21—Food and drugs, part 7—Enforcement policy, sec. 7.40—Recall policy. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=7.40. Accessed 5 November 2020.
156. U.S. Food and Drug Administration. 2019. Outbreak investigation of scombrotoxin fish poisoning: yellowfin/ahi tuna (November 2019). Available at: https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-scombrotoxin-fish-poisoning-yellowfinahi-tuna-november-2019. Accessed 3 November 2020.
157. U.S. Food and Drug Administration. 2019. Warning letter to PT. SIG ASIA. MARCS-CMS 592584—October 28, 2019. Available at: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/pt-sig-asia-592584-10282019. Accessed 17 November 2020.
158. U.S. Food and Drug Administration. 2020. Fish and fishery products hazards and controls guidance, 4th ed.. Available at: https://www.fda.gov/media/80637/download. Accessed 24 December 2020.
159. U.S. Food and Drug Administration. 2020. Freedom of Information Act request regarding Truong Phu Xanh Ltd high-histamine incident in 2019. [FOIA data received 23 December 2020 and indexed in J. DeBeer's personal library.] Available from the first author at: jdebeer2005@gmail.com.
160. U.S. Food and Drug Administration. 2020. Freedom of Information Act request regarding histamine recalls for the period 2002 thru 2020. [FOIA data received 14 January 2021 and indexed in J. DeBeer's personal library.] Available from the first author at: jdebeer2005@gmail.com.
161. U.S. Food and Drug Administration. 2020. ORA laboratory manual, vol. IV, sec. 9—Seafood chemistry, subsec. 7.2—Histamine. Available at: https://www.fda.gov/media/73579/download. Accessed 7 March 2021.
162. U.S. Food and Drug Administration. 2020. ORA laboratory manual, vol. IV, sec. 8—Sensory analysis. Available at: https://www.fda.gov/media/73572/download. Accessed 22 February 2021.

163. U.S. Food and Drug Administration. 2021. Data dashboards: recalls. Available at: https://datadashboard.fda.gov/ora/cd/recalls.htm. Accessed 15 January 2021.
164. U.S. Food and Drug Administration. 2021. Investigations operations manual 2021, chap. 4—Sampling. Available at: https://www.fda.gov/media/75243/download. Accessed 22 February 2021.
165. Velut, G., F. Delon, J. P. Mérigaud, C. Tong, G. Duflos, F. Boissan, S. Watier-Grillot, M. Boni, C. Derkenne, A. Dia, G. Texier, P. Vest, J. B. Meynard, P. E. Fournier, A. Chesna, and V. P. de Santi. 2019. Histamine food poisoning: a sudden, large outbreak linked to fresh yellowfin tuna from Reunion Island, France, April 2017. *Euro Surveill*. 24:1800405. https://doi.org/10.2807/1560-7917.ES.2019.24.22.1800405
166. Vietnamese Standard. 2006. TCVN 6388:2006 (Codex Stan 70-1981, Rev.1-1995) Cá Ngủ đóng Hộp [Canned tuna and bonito]. Available at: https://luatvietnam.vn/thuc-pham/tieu-chuan-viet-nam-tcvn-6388-2006-bo-khoa-hoc-va-cong-nghe-184028-d3.html. Accessed 20 December 2020.
167. Visciano, P., M. Schirone, R. Tofalo, and G. Suzzi. 2012. Biogenic amines in raw and processed seafood. *Front. Microbiol.* 3:188. https://doi.org/10.3389/fmicb.2012.00188
168. Xiang, H., D. Sun-Waterhouse, G. I. Waterhouse, C. Cui, and Z. Ruan. 2019. Fermentation-enabled wellness foods: a fresh perspective. *Food Sci. Hum. Well*. 8:203–243. https://doi.org/10.1016/j.fshw.2019.08.003