Prevalence, determination, and control of histamine formation in food concerning food safety aspect

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REVIEW ARTICLE

Abstract

Histamine is a toxic metabolite produced in foods containing a high level of free histidine. This compound can be present in various food sources, especially seafood, dairy products, and fermented foods. Histamine poisoning is one of the most common health risks caused by consuming spoiled foods or improper processed and stored foods. This food poisoning usually causes mild symptoms with higher recovery rates, so people underestimate this hazard. Thus, understanding histamine formation food sources with a high risk for this poisonous agent is critical in improving the awareness of this hazard for food producers and consumers. To avoid histamine-associated food poisoning, the development of control solutions to minimize the formation of histamine and the sufficient detection methods to examine the content of this metabolite in food products are vital. In addition to quality control application and hazards management programs in food processing, the appropriate food regulations identifying the precise limit of histamine in foods are essential for preventing this poisoning from occurring in the food supply chain. This review discusses the prevalence, control strategies, detection techniques, and regulations related to histamine hazards in foods.

Keywords: control; detection; food safety; formation; histamine; poisoning

Introduction

Histamine (HA) is a biogenic amine, water-soluble, nitrogenous, and polar substance found in nature and the human body (Smith, 1981; Figure 1). This compound regulates specific functions related to the human immune, nervous, and intestinal systems. It is also defined as a toxic agent for human health if ingested (Colombo *et al.*, 2018). HA poisoning has been recognized as a foodborne hazard, mainly related to seafood and dairy product consumption (Comas-Basté *et al.*, 2019; Taylor, 1985). It is a metabolite product produced from histidine by the bacterial enzyme called histidine decarboxylase (Chin *et al.*, 1989). The produced HA eventually accumulates and diffuses into the internal parts of foods, and its excess concentration may result in poisoning for consumers (Tao *et al.*, 2009). Moreover, HAis also recognized as an indicator of food quality in quality assurance programs (Dasgupta, 2020; Kerr *et al.*, 2002).

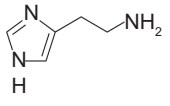

Figure 1. The structural formula of HA with an imidazole ring (Smith, 1981).

Many studies have reported the HA poisoning derived from spoiled foods, their relationship between food processing and storage practices, and HA formation (Dasgupta, 2020; Kerr *et al.*, 2002; Velut *et al.*, 2019; Visciano *et al.*, 2014). The first event of HA hazards was reported in 1799 in Britain (Taylor, 1985). However, the FDA recognized it as a foodborne disease in 1828 and was linked to seafood consumption (Pan and James, 1985). HA poisoning type is a mild disease and is misdiagnosed as an allergy occasionally, (Hajeb and Selamat, 2012). In clinical diagnosis, its symptoms are similar to Salmonella infection or food allergies, such as skin itching, rashes, swelling, and flushing (Taylor, 1985; Taylor *et al.*, 1989). However, recent research has well-documented their symptom characteristics (Chaidoutis *et al.*, 2019). Excessive HA production was primarily associated with the Scombridae fish family (Bartholomew *et al.*, 1987). To date, HA poisoning has also been reported to relate to the Clupeidae fish family and other food sources such as cheese (FAO/WHO, 2018; Møller *et al.*, 2020; Prabhakar *et al.*, 2020; Taylor, 1985).

Foodborne outbreaks are pivotal for both food authorities and producers if control measures and legislation are insufficient to minimize this hazard (EFSA, 2018; FAO/WHO, 2018; Feng *et al.*, 2016). Fully understanding and evaluating this hazard is necessary to improve food production practices. Many HA poisoning cases have not been recorded because of mild symptoms, and the higher recovery rate has made people underestimate this risk (FAO/WHO, 2018). Besides fish products, other food sources could also be potential sources of HA formation (Colombo *et al.*, 2018). Control and prevention strategies should be regulated and applied in the food supply chain. Precise data on regulatory limits of HA present in all food types apart from the existing seafood products needs to be identified and listed. This review article focuses on HA hazards present in foods. It primarily emphasizes on aspects of HA prevalence, detection, control measures, and regulations.

Although several review articles related to HA in seafood products have been published, only a few considered the mechanisms of HA formation in foods. Some others reported relevant outbreaks in recent years and the rapid methods for HA detection (Visciano, 2020). There has been limited information on the prevalence of HA in various food sources besides fish and fishery products. Thus, this review aims to discuss the HA formation associated with various types of food like meat, seafood, dairy, and vegetable products. The relevant food regulations applied in different regions will also be reviewed and confirmed with updated information. In addition, a summary of the conventional and newly developed HA detection approaches and control measures in research and food industry practices will be mentioned.

Histamine Poisoning Caused by Food Consumption

Formation and diffusion of HA in foods

The free histidine-rich foods contain the histidine decarboxylase enzyme. This enzyme in certain environmental conditions converts histidine into HA, which gradually accumulates in the food (Colombo *et al.*, 2018; Figure 2). Ladero *et al.* (2010) reported the enhancement of HA production because of other biogenic amines. This enhancement resulted from amines that stimulated bacterial activities, thereby increasing HA formation (Dasgupta, 2020; FAO/WHO, 2018).

The microorganism strains that stimulate the HA formation have been studied and well documented in previous studies (Dasgupta, 2020; Durak-Dados *et al.*, 2020; FAO/WHO, 2018; Tao *et al.*, 2009). Taylor *et al.* (1989) examined the HA production of 38 bacterial species including 112 strains in tuna fish infusion broth and trypticase-soy broth-histidine media. Superior HA production was observed in *Enterobacter aerogenes* and *Proteus morganii* with a concentration up to 200 nmol/mL of medium. Dominant bacteria species related to HA accumulation belonged to the *Enterobacteriaceae* family (Taylor *et al.*, 1989; Tsai *et al.*, 2005). The HA-forming strains such as *Raoultella planticola, Raoultella ornithinolytica*, and *Hafnia alvei* were also found in tuna sandwich samples (Kung *et al.*, 2010). The Gram-negative bacteria were linked to spoiled seafood. Gram-positive bacteria like *Lactobacillus* strains are commonly present in fermented products such as kimchi or cheese. Tsai *et al.* (2005) reported that HA-forming bacteria strains found in half of the kimchi products sold in Taiwan supermarkets were *Lactobacillus brevis* and *L. paracasei*. *L. buchneri* was

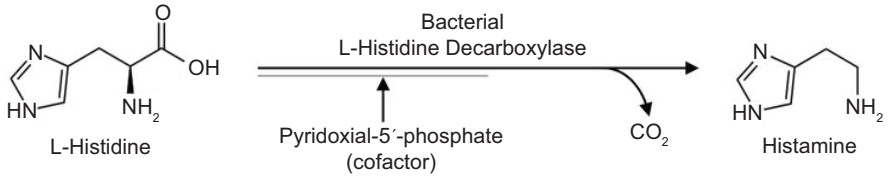

Figure 2. The formation of HA (Comas-Basté *et al.*, 2019).

isolated from Swiss cheese samples (Sumner *et al.,* 1985). In another study, yeasts including *Malaga*, *Burgundy*, and *Bordeaux* were found to be responsible for HA production in elderberry wine (Pogorzelski, 1992). Hence, these species represent different sources present in food and the surrounding environmental conditions.

Several main factors including environmental, processing, or storage conditions, caused the HA formation within the foodstuff. The primary causes were improper food processing or storing practices because of temperature and time abuses (FAO/WHO, 2018; Kerr *et al.*, 2002; Mercogliano and Santonicola, 2019). The role of the environmental conditions in the biogenic amine formation was first studied on *E. faecalis* strains. The production of biogenic amines, including HA, was affected by various factors, such as temperature, time, and pH (Gardini *et al.*, 2001). Temperature abuse during processing and storage was the most common reason leading to HA poisoning outbreaks in seafood consumption (Kerr *et al.*, 2002; Visciano *et al.*, 2014). Among investigated yellowfin tuna samples, the samples stored at 0°C accumulated lower HA content than those stored at 8°C or 12°C at the same storage intervals. Tuna stored at the highest temperature was rejected because of the spoilage and unacceptable sensory quality after only a day (Guizani *et al.*, 2005). Koral *et al.* (2013) found that low pH could enhance the HA formation based on the observation of higher HA contents in the brined samples with lower pH. Contamination is also considered a crucial factor, causing excessive HA levels in food products. Huss *et al.* (2000) indicated the importance of controlling the contamination as a significant contribution to HA prevention. In another investigation by Hwang *et al.* (2011), fish meat samples attained from the factory adhering to the hazard analysis and critical control points (HACCP) program for contamination control were compared with those factory samples without the HACCP program application. The findings revealed that the average HA level in the former group was significantly lower than that in the latter group.

Human health effects of histamine

HA poisoning associated with food consumption usually causes a mild disease in humans with a quick recovery (Comas-Basté *et al.*, 2020; Schirone *et al.*, 2016). It is previously defined as an allergy case (Ando *et al.*, 2017; Maintz and Novak, 2007). However, recent research clearly showed HA poisoning symptoms belong to food poisoning (Joenputri and Suryana, 2020; Velut *et al.*, 2019). HA could be naturally generated by erroneous and mast cells in the human body (Hungerford, 2010). This substance plays a vital role in controlling the nervous system, neurotransmission, and intestinal system (Kovacova-Hanuskova *et al.*, 2015). Juhlin and Shelley (1966) observed HA under fluorescence and found it in platelets, gastric mucosa, basophils, blood vessels, and mast cells in the human body. Zeng *et al.* (2014) evidenced the benefits of appropriate HA release levels to heart failure patients. Excessive HA concentration can cause stimulatory actions of the heart, which results in tachycardia and palpitations (Feng *et al.*, 2016). Symptoms caused by HA poisoning include gastrointestinal symptoms (diarrhea, vomiting, nausea, itching, hypotension, and abdominal cramps) and neurologic symptoms (flushing, tingling, palpitation, or headache). The most typical symptoms are neck, face, and upper trunk flushing (Colombo *et al.*, 2018; Hattori and Seifert, 2017; Taylor, 1985). The outset occurs about 20 minutes after the stale food digestion, and most nonsusceptible patients can recover within 6–8 hours (Feng *et al.*, 2016). Many cases related to this disease may not be sufficiently documented as people can recover after a short period. Thus this poisoning disease need not be considered a public health risk (Chaidoutis *et al.*, 2019). Incidence related to histamine intoxication in EU countries during 2010–2015 is presented in Figure 3 (EFSA, 2017).

HA's toxicology has been described and discussed in a variety of studies including clinical research by Durak-Dados *et al.* (2020). Morrow *et al.* (1991) investigated the characteristics of HA in patients suffering from HA poisoning symptoms. This study confirmed that HA was a toxic agent contributing to poisoning cases. The health effects of HA were linked toits binding to the receptors present on the cell wall membranes. Ijomah *et al.* (1991) doubted that HA alone was not entirely responsible for food poisoning since significant differences were observed in poisoning symptoms caused because of consuming pure HA compared with those who consumed an equal amount of HA in spoiled fish. A consistent severe result was also found among cases that consumed spoiled fish containing HA, which was in agreement with the study of Lehane and Olley (2000). Del Rio *et al.* (2017) revealed that HA and tyramine present spontaneously in some fermented foods could enhance the synergistic cytotoxicity towards intestinal cells. The different effects may be caused by other contributing factors along with HA components (Kovacova-Hanuskova *et al.*, 2015). Several biogenic amines such as putrescine or cadaverine are produced in spoiled foods mainly because of enzyme activities occurring in food. The availability of these amines enhanced the elevated HA formation (Chaidoutis *et al.*, 2019).

Histamine intolerance and dose response

The dose-response level in HA ingestion is inconsistent because of the variation in susceptibility and

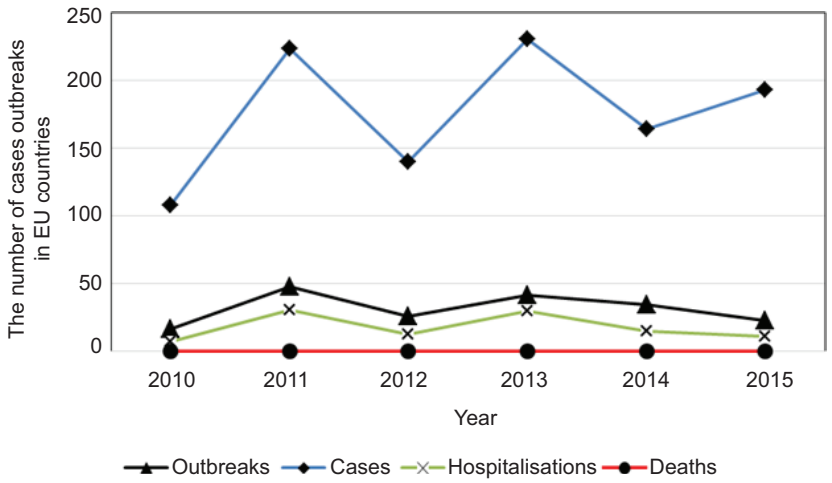

Figure 3. The incidence of histamine intoxication reported in EU countries during 2010–2015 (Adapted from EFSA, 2017).

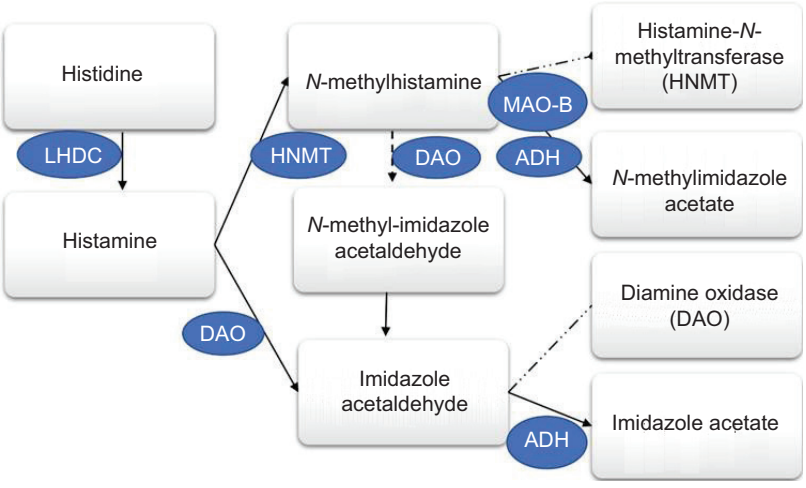

Figure 4. Histamine metabolism involving DAO and HNMT (adapted from Maintz and Novak, 2007). LHDC, L-histidine decarboxylase ($H^+ \rightarrow CO_2$); HNMT, histamine-*N*-methyltransferase (S-adenosyl-methionine → S-adenosyl homocysteine); MAO-B, monoamine oxidase; ADH, aldehyde dehydrogenase.

characteristics among individuals. Hungerford (2010) discussed the reasons for different HA intolerances. According to him, diamine oxidizes (DAO) is mainly responsible for such differences. Maintz and Novak (2007)reported the mechanism of HA ingesting. They recorded that the toxin could be metabolized by histamine-*N*-methyltransferase (HNMT) via the ring methylation pathway (Figure 4).

Therefore, the intolerance depends on its affinities with these enzymes. Factors impairing enzymatic activities may result in HA overproduction and cause poisoning symptoms to the human body (O'Mahony *et al.*, 2011). The produced HA explained by the pathways of HNMT and DAO in the intestine (Maintz and Novak, 2007) could be converted into an inactive form like acetyl-histamine in the intestinal tract by the enzymatic activities, which was later absorbed into the cell membrane. Accordingly, individual genetic and health status contribute to different HA ingestion responses (Hattori and Seifert, 2017; Lehane and Olley, 2000). The minimum level causing poisoning was reported at 50 mg HA per 100 g spoiled fish samples by Stommel (2007), while the corresponding levels were 75 mg as recorded in the study of Hungerford (2010).

Foods Associated with HA Formation and Accumulation

HA is present in different food sources including animals, plants, and microorganisms (EFSA, 2017; Durak-Dados *et al.*, 2020). The foods associated with this hazard are rich in free histidine (EFSA, 2017; Durak-Dados *et al.*, 2020). Many fish species contain high free histidine.

Their gills or gastrointestinal tracts naturally have bacteria with the histidine decarboxylase enzyme (EFSA, 2017; Bartholomew *et al.*, 1987; Mercogliano and Santonicola, 2019). Thisbacteria containing HA decarboxylase stimulates HA overproduction (Dasgupta, 2020; Morrow *et al.*, 1991). The decarboxylation bacteria may poison the foodstuff from the environment during harvesting, handling, and storage periods (WHO, 2018; Stommel, 2007; Visciano *et al.*, 2014).

Cheese, beverages, and other fermented foods could be potential sources of HA production (Leuschner *et al.*, 1998; Tsai *et al.*, 2005). Some studies have reported high HA content in fresh meats, fruits, and vegetables (Bodmer *et al.*, 1999). But the association between HA poisoning outbreaks with these sources was uncertain (Ekici and Omer, 2018; Lehane and Olley, 2000). Minimal research reporting this risk in fresh fruits and plants has been studied (Chin *et al.*, 1989; Durak-Dados *et al.*, 2020). In other words, natural HA contents in fresh fruits or vegetables are much lower than the action level causing adverse effects on human health (Comas-Basté *et al.*, 2019). In summary, free histidine content and available carboxylase significantly contribute to HA production in foods.

Fish and other seafood products

Fresh seafood is reported as the most common HA poisoning and accumulation-causing sources (Chung, 2019; Velut *et al.*, 2019). The fish containing high histidine is scombroid families that include tuna, mackerel, and bonito (Stommel, 2007). Other fish species with Higher HA levels include bluefish, mahi-mahi, marlin, herring, anchovies, pilchards, and sardines (Lehane and Olley, 2000). HA is one of the dominant biogenic amines in many fish species during storage (Hu *et al.*, 2012). Maximum-free histidine content was observed in fresh fish muscles and the decarboxylase bacteria was naturally present in their digestive systems (Mercogliano and Santonicola, 2019). Isolates were obtained from spoiled mackerel and tuna samples, and 31% of these species produced 0.1to 4 mg/mL HA in the cultural medium broth (Omura *et al.*, 1978). The reaction in which histidine is converted into HA by enzyme activity occurs rapidly at ambient temperature (Auerswald *et al.*, 2006). HA content in 10% of samples measured in 78 salted fish products purchased from Turkey and Europe was higher than 50ppm, the HA limit level in foods regulated by FDA (FDA, 2011; Koral *et al.*, 2013). Specifically, salted anchovy was detected at the highest level of HA level with 422 ppm by the high-performance liquid chromatography (HPLC) analysis method. Other processed foods, including fish hamburgers, sandwiches, adulteration containing fish, or canned tuna in different regions containing unsafe HA concentrations, were also reported (Durak-Dados *et al.*, 2020; Møller *et al.*, 2020).

Many investigations confirmed the prevalence of HA accumulation in varied seafood of different regions, and scombroid poisoning outbreaks occurred in many countries (Comas-Basté *et al.*, 2020; Chomchai and Chomchai, 2018; Durak-Dados *et al.*, 2020; Kang *et al.*, 2018). In England and Wales, 47 scombroid poisoning outbreaks were reviewed from 1970 to 1979 (WHO, 1982). The Centre for Disease Control (CDC) annual reports recorded 116 outbreaks linked to HA poisoning in America from 1978 to 1982 (Gellert *et al.*, 1992). In Australia, four patients have reported suffering HA poisoning linked to imported canned tuna consumption in Sydney,2015 (FAO/WHO, 2018). On the other hand, 17 samples, including fresh and processed seafood from South African countries, were quantified for HA contents. The finding showed that 6% of samples exceeding the limit level (50mg/100g; Auerswald *et al.*, 2006).

The study of three rich histidine-containing fish species showed that fresh and salted samples possess low concentrations of HA when compared with smoked and dried samples (more than 50mg/100g). Yellowtail samples were commonly related to the high HA level among fresh samples. In 2011, Tao *et al.* (2011) surveyed the HA level of samples collected from nine countries. The finding revealed that at least one sample from these countries, excluding Japan, contained HA, and 9% of samples tested had HA content higher than 50 mg/kg. However, these results are difficult to justify accurately since the statistical data and sample collection method were not analyzed in this study. Similarly, 60 canned tuna fish samples were analyzed for HA contents in Iran between 2012 and 2013 by the enzyme-linked immunosorbent assay (ELISA) method (Khezri *et al.*, 2014). All samples contained 3–383 mg/100 g HA, and 6.67% of samples had HA levels higher than the regulatory limit level.

An outbreak in San Francisco in 1977 related to sashimi consumption was observed by Lehane and Olley (2000). Suspected samples indicated the presence of spoiled tuna. Another severe outbreak related to tuna consumption containing high HA content was reported in Taiwan in 2008 (Chen *et al.*, 2008). In this outbreak, seven cases of poisoning illness by tuna dumpling consumption. The subsequent investigation showed a high HA concentration of 160.8 mg in 100 g samples in the suspected samples. Noticeably, even the *E. coli* count was higher than the regulatory level of food safety with a 50 CFU/g, which provided evidence for the correlation between the contamination level and the HA level of tested samples. Table 1 summarizes some HA poisoning outbreaks related to fish and seafood products in different countries in the last decade.

Table 1. Histamine poisoning outbreaks reported between 2016–2020.

Number	Associated foods	Number of cases	Location	Year	References
1	Fresh yellowfin tuna	40 cases	Reunion Island, France	April 2017	Velut *et al.* (2019)
2	Yellowfin/Ahi Tuna	50 cases	USA	November 2019	FDA (2020)
3	Tuna	3 cases	France	2017	Harmelin *et al.* (2018)
4	Butterfish	27 cases	Valladolid, Spain	July 2013	Fariñas Cabrero *et al.* (2015)
5	Tuna	2 clusters of people	Netherlands	2018	Morroy *et al.* (2018)
6	Yellowtail Fish steak	55 cases	Seoul, Korea	November 2016	Kang *et al.* (2018)
7	Canned sardines	28 cases	Vojvodina province, Northern Serbia	January 2014	Petrovic *et al.* (2016)
8	Fried Japanese Spanish mackerel fish meats	7 cases	Hualien County, eastern Taiwan	September 2014	Hwang *et al.* (2019)
9	Unproperly refrigerated fish	7 cases	Alaska, USA	May-August 2019	McLaughlin and Castrodale (2019)
10	Tuna salad	21 cases	Netherlands	2020	van Dijken *et al.* (2020)

Cheese and dairy products

Cheese and other dairy products also contain specific HA contents apart from high proteins ((Joosten, 1988; Joosten and Northolt, 1989; Møller *et al.*, 2020; Taylor, 1985). The prevalence of biogenic amines including HA in cheese is reported in the literature (Comas-Basté *et al.*, 2020; Møller *et al.*, 2020; Taylor, 1985). Because raw milk naturally contains high protein composition including histidine. HA could be produced by enzyme activity during the cheese fermentation process (Ekici and Omer, 2018), and its concentration depends on the type, age, and package of cheese products. The HA content increase with the age of cheese (Şanlı and Şenel, 2015). Fifty-four Chinese meal samples including cheese were analyzed for the HA level in the USA; 863.6 and 107 µg/g HA were detected in blue and parmesan cheese samples, respectively (Chin *et al.*, 1989). However, the detection method used may contain uncertainty factors in the calculation formula for quantification. In another study, the goat cheese was produced by fermenting raw goat milk with *Streptococcus faecalis* and *S. faecium* over 91 days ripen process. The later strain is HA decarboxylase strain, which caused the highest concentration of 8.2 µg HA/g in samples which was much lower than the HA limitation established by EU authorities (200 ppm),and did not perform any risk in consumption related to HA hazard (EU, 2013; Tham *et al.*, 1990).

Microorganism flora in dairy products may contribute to the HA formation. Linares *et al.* (2011) suggested that HA decarboxylase present in these products mainly belongs to gram-negative bacteria and eukaryotic organism classes. However, *Lactobacilli* was commonly associated with HA production (Kung *et al.*, 2007; Lehane and Olley, 2000). HA concentration was produced by *Lactobacilli* (*L. buchneri, Leuconostoc*, and *Lactococcus*) at 410 ppm after 3 months of cheese ripening (Joosten and Northolt, 1989). It is noticeable that this cheese was made from pasteurized milk and stater cells. The *E. coli* indicator of these samples was under an acceptable level of food safety regulation. *L. buchneri* was also isolated from Swiss cheese samples suspected of causing a small outbreak occurring in 1980 in New Hampshire, USA. This investigation implicated that this strain was strongly associated with the occurrence of HA production of up to 4.07 nmol/L of MRS broth (Sumner *et al.*, 1985). In miso products obtained from retails in the USA, eight isolate strains produced 10.4 to 39.4 mg/kg of this toxin in tryptic soy broth. These strains were identified by the polymerase chain reaction method, including *Bacillus megaterium*, *B. subtilis*, *B. amyloliquefaciens*, and *Staphylococcus pasteuri* (Kung *et al.*, 2007). An effort to detect the presence of histamine-producing species was conducted (Stratton *et al.*, 1992); however, this detection using the leu cocrystal violet method, which did not agree with isolation results in low-salt cheese. Several kinds of cheese, including Gruyere, Gouda, Cheshire, Cheddar, and Swiss, were associated with HA poisoning outbreaks. However, no limit of HA level was established for such food types (EFSA, 2011). There are a limited number of recent studies investigating HA production in dairy samples in the past decade.

Meat and poultry

Although HA poisoning outbreaks rarely occur with meat or poultry consumption, high HA levels have been detected in these foods too. Vidal-Carou *et al.* (1990) examined the relationship between HA content and quality of meat during storage. Their findings indicated higher HA levels in spoiled beef and pork meats during the storage period in both cooling and room temperature.

Besides, HA production in pork samples was faster than that in beef samples in similar storage conditions comparing initial contents (lower 2 ppm). In this research, HA levels in uncooked samples (0.25–249 ppm) were significantly higher than those in cooked meats (0.25–3.9 ppm).

Similarly, the investigation revealed a slight increase in the HA concentration in chicken meat during storage (Silva and Glória, 2002) between 3 and 5°C (less than 7.2 ppm). On the other hand, Masson *et al.* (1996) compared two species of HA-producing bacteria, mainly *Micrococcaceae* and *Lactobacillus* species isolated from meats. Here, HA was detected by HPLC and fluorometric methods. The finding indicated three strains among isolates (94 strains) with the ability of HA production (2.2 mg/mL) after 5 days of inoculation.

Fermented sausage samples were analyzed for HA content by Taylor *et al.* (1978). The level was quantified at low concentration with about 10 ppm on average sausage and salami samples sold in Spani (Dewaal *et al.*, 2006). Turkish fermented sausage was recently defined with HA concentrations ranging from 0 to 469.375 mg/kg (Ekici and Omer, 2018).

Fruits, vegetables, fermented foods, and other food products

HA was found in fruits, vegetables, cereal products, and fermented foods (EFSA, 2011; Durak-Dados *et al.*, 2020; Pogorzelski, 1992; Tsai *et al.*, 2005). Significant HA levels were detected in wine, kimchi, and soybean (Durak-Dados *et al.*, 2020; Mah *et al.*, 2019) by naturally present or added yeast activity during the preparation and fermentation process. According to Pogorzelski (1992), the highest HA production was recorded in Bordeaux yeast among investigated yeasts. However, the level was relatively low, and therefore, the likelihood of outbreak occurrence is not high. The HA determination conducted by the fluorescence method revealed that only 5 in 300 wine samples contained 5–10 mg/L of HA (Ough, 1971).

Canned sauerkraut was also reported to contain a high HA concentration with an average of 4.07 mg/100g in 10 tested samples (Taylor *et al.*, 1978). Kimchi samples purchased in Taiwan were found to possess 49.8 mg/100 g of HA on average (with the highest concentration recorded at 535 ppm; Tsai *et al.,* 2005) was the first high HA content reported in kimchi products.

Similarly, bacteria producing HA were also investigated in fermented soybean, and the finding revealed high concentrations produced at 500 ppm under 0.5–10% salt cultural conditions (Tsai *et al.*, 2007). A recent report showed that a 15-month-old baby was suffering HA intolerance because of eating strawberries containing HA (Ibranji *et al.*, 2015). However, research published until now may not fully cover the importance and significance of this emerging foodborne hazard in such fermented products (Durak-Dados *et al.*, 2020; Konakovsky *et al.*, 2011; Kovacova-Hanuskova *et al.*, 2015).

Legislation and Regulations

The commonly accepted HA level in food is lower than 50 ppm in healthy people. The evidence from some studies showed that consuming over 50 mg of this toxin could cause health effects for the human body. So this level can be examined as "no observed adverse effect level" (NOAEL; Visciano *et al.*, 2014). The maximum limits of this toxin in foods vary from region to region and for different food sources. According to European Commission Regulation (EC No 2073/2005/EC), The accepted HA level in raw fishes and processed fishery products, except fermented produced or fish sauce, is 100–200 ppm. However, amended European (EU) Commission Regulation No 1019/2013 accepts 200–400 ppm for the same food group and 400 ppm for fermented fish products(EU Commission Regulation, 2013). Hence food batches with higher than 400 ppm will be considered unsatisfactory for consumption in the EU(EFSA, 2011) when analyzed by the HPLC method.

In USA, the maximum legal HA level established by FDA is much lower than that in EU countries. Fishery products with HA levels higher than 50 ppm are not permitted for distribution and consumption in the US markets (FDA, 2020). The Canadian government in 2018 set 100 or 200 ppm in the foodstuff as HA limitations for pastes, fermented fish sauces, and anchovies or other fishery products, respectively. In Australia and New Zealand, a maximum level of 200 ppm of HA in fishery foods has been established by the Australian Food Standards Code (FSANZ, 2009; 2016). The HA limitations have also been reported in some Asian countries such as China and Korea (Table 2). Although the Food Safety Basic Act (Act No.48 of 2003) mentioned HA as a critical hazard in the imported food processing practice, the data for Japan is unavailable (Table 2).

Histamine Detection Methods

Chromatography techniques

Chromatography approaches for HA detection have been developed since the early stages. The fluorescence chromatography targeted the HA's imidazole ring characteristic to generate chromophores for visualization under

Table 2. HA limitations established by regulatory authorities or international agencies for food products of different regions.

Authorities/ agencies or regulations	Countries/ regions	Food associated	Limits (ppm)	Issued year	Reference
European Commission Regulation No 1019/2013	EU	Fishery products, except fermented products	200–400	2013	EU Commission Regulation (2013)
European Commission Regulation No 1019/2013	EU	Processed fish species associated with a high amount of histidine	400	2013	EU Commission Regulation (2013)
Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission 2013	Worldwide	Fish and fish products	200	2012	FAO/WHO (2018)
USFDA, FDA and EPA Safety Levels in Regulations	USA	Fishery products, decomposed fish	50		Visciano *et al.* (2020), FDA (2019)
Health Canada and the Canadian Food Inspection Agency	Canada	Anchovies, fermented fish sauces and pastes	200	2012	FAO/WHO (2018)
Health Canada and the Canadian Food Inspection Agency	Canada	Other fish and fish products	100	2012	FAO/WHO (2018)
Russian Federation, The Sanitary and Epidemiological Rules and Regulations, SanPin 2.3.2.1078-2001	Russia	Salmon, salmon, herring, tuna, and mackerel	100	2001	Verkhivker and Altman (2018)
Food Standards Australia New Zealand (FSANZ)	Australia New Zealand	Fish species without high histidine content and fish products	200	2016	FSANZ (2016)
Food Safety and Standards Authority of India	India	Dried/ salted fishery products	200	–	Surya *et al.* (2019)
China National Standards. GB 2733-2015; National Food Safety Standards for Fresh and Frozen Animal Aquatic Products	China	Fish species high histidine content and fish products	200	2015	Mah *et al.* (2019)
China National Standards. GB 2733-2015; National Food Safety Standards for Fresh and Frozen Animal Aquatic Products	China	Fish species with high histamine content	400	2015	Mah *et al.* (2019)
The Ministry of Food and Drug Safety (MFDS) of Korea; Food Code, Notification No. 2017-57	Korea	Fish species with high histamine content and fish products	200	2017	Mah *et al.* (2019)
The Food Safety Basic Act (Act No.48 of 2003) of Japan	Japan	Fish and fishery products	Not specified	2003	FAO/WHO (2018)

a UV detector (Juhlin and Shelley, 1966). The interaction between HA and *o*-phthalaldehyde attributes to the color. Ough (1971) applied this method for detecting HA levels in wine samples. However, the sample preparation was time-consuming and wasted because of frequent elution via ion exchange and could only be used as relative routine detection without accurate quantification. Thin-layer chromatography (TLC) was developed to attain higher accuracy (Ienisetea, 1973). Here, samples were mixed with methanol solution, heated, cooled, and filtered for extracting the targeted compounds. The detection's sensitivity was attained at a concentration of about 20 ppm (James and Pan, 1985). Although this method is inexpensive, it was only suitable for the semi-quantitative determination of HA.

Alternatively, gas chromatography (GC) was also used for HA quantitative detection in food products. A comparative study of GC and fluorescence methods was conducted to adjust the official detection technique (Rogers and Staruszkiewicz 1997). Careful consideration of the difference in the results highlighted the advantage of GC. The sensitivity of this analysis protocol was 5 ppm when applied to quantify the HA content of fish samples (Hwang *et al.*, 2003). Besides, the prepared megaspores capillary columns needed to be only a little monitoring, and the MS detector accompanying this equipment provided more efficiency. A previous study by Fernandes *et al.* (2001) also employed the GC-MS technique to determine amine content, including HA, in beer (. This approach had provided excellent sensitivity and accuracy with a sensitivity of less than 150 µg/L HA detected. But the major drawback of GC was its complicated operation, sample preparation, and relatively higher cost (McNair *et al.*, 2019).

The most potent feasible method in chromatography detection was the HPLC approach. This was also used to

analyze biogenic amine in foods (Önal, 2007). The HPLC equipment and an MS detector achieved relatively high sensitivity (Yoshida *et al.*, 2012). Since HA is a polar biological amine, the normal phase HPLC method was employed to determine HA content in red wine (Dang *et al.*, 2013) using a small organic compound contacting the silica surface as an aqueous phase. Analytes were detected with MS and UV detectors combining with the diamond hydride column filled with a normal aqueous phase. The wine samples were directly injected into the column of the HPLC machine. The advantages of this method are reproducible, cost-effective, and relatively simple. In a Turkey study, 63 fish samples from different cities were analyzed for biogenic amines concentration by the HPLC method. Total biogenic amines were determined, ranging from 26.6 to 406.6 mg/kg of HA, and this outcome agreed with the study of Bilgin and Gençcelep (2015). HPLC and capillary electrophoresis diode arrays detection showed excellent results with high precision, accuracy, and reproducibility (Cicero *et al.*, 2020). Recently, an ecofriendly and rapid detection method has been developed using the exiting ultra HPLC approach to analyze HA in fish products. This approach provides more accurate results with a total analysis operation time of only 6 minutes, with a detectable limit of 2.2 ppm (Cicero *et al.*, 2020).

Electrochemistry and electrophoresis techniques

The development of HA detection methods based on electrochemistry or electrophoresis was pivotal in research and industry practice. These methods are often portable, rapid, and inexpensive. Biosensor and microchip electrophoresis are good examples. The electrochemical biosensor could detect biogenic amines in salted anchovies (Draisci *et al.*, 1998). A platinum electrode was used in the cell. The electrode reaction was catalyzed by the enzyme DAO resulting in hydrogen peroxide formation. This method attained a detection limit at 5 x 10^{-7} moles/L of the sample. Compared with ion chromatography, the corresponding amine concentrations retained the same trend in the biosensor detection method, revealing that these biosensors could achieve similar results in measuring amines during the food storage period. This technique provides a measurement of the total content of amines present in samples, reducing the analysis cost, time, and ease of operation (Draisci *et al.*, 1998). An electrochemical biosensor based on gold nanoparticle/manganese dioxide electrode was used for detecting a single drop level at 0.08 μM. An automatic detection method based on magnetic separation combined with fluorescence was also developed, which can detect HA at a level much lower than 50 ppm, the limit established by the FDA (FDA, 2011; Gagic *et al.*, 2020). The combinations of fluorescence with other techniques have also been used as effective detection methods in HA analysis (Shi *et al.*, 2020; Zhang *et al.*, 2020).

ELISA and other rapid detection methods

Recently, more rapid methods such as ELISA, biosensors, enzymatic assays, or separation techniques are used in the analysis of HA content in foods (Gagic *et al.*, 2019) as they significantly reduce analyzing time and improve sensitivity. While chromatography methods are powerful in laboratory operation, the rapid method application has advantages in practical terms. Specifically, screening studies require a high capacity for analysis of a significant number of samples. Surya *et al.* (2019) compared the HPLC and a newly developed biomimetic immunoassay method that employed molecularly imprinted polymer and platinum nanozyme to determine HA content in soy sauce and dried shrimp samples. The results of this study showed the correlation between these measures. ELISA basing rapid method could gain sensitivity of 0–500 ppm detection range between 15 minutes and 2 hours (Surya *et al.*, 2019). In another study, 60 canned tuna samples were analyzed for HA content by the ELISA method (Khezri *et al.*, 2014), and the lowest level of HA was reported at 3.4 ppm. Moyano *et al.* (2019) has developed a histamine magnetic immune-chromatographic biosensor employing protein gold nanoparticle conjugates for labeling samples. This technique can detect a minimum level of 1.2 to 1.5 mg/L of HA in samples. Hungerford and Wu (2012) compared three rapid kits, namely Neogen Veratox ELISA, MaxSignal (Texas) based on enzymatic activity, and LFIC (lateral flow immune chromatography). There were no false-positive or negative samples that occurred. ELISA kit showed a negative logistic curve in the color response with increased analyte concentration, resulting in an increasing linear line in the response detected by enzymatic kits. Although ELISA provided good results, MaxSignal kits were more robust and quicker. On the other hand, the LFIC kit was not quantitative, but it could separate between high and low HA level groups. Collectively, while MaxSignal could be considered an appropriate alternative method for ELISA kit, especially in the screening plan, LFIC performed the quickest and simplest means for classification of fish samples into two groups higher or lower than 50 ppm HA (Verma *et al.*, 2020; Xu *et al.*, 2020).

Many enzymatic assays and rapid test kits termed performance- tested methods (PTM) have been validated and qualified by the Association of Official Analytical Collaboration International-Research Institute (AOAC-RI). These test kits include Biofish-300 HIS, BioSystems Y15 histamine dehydrogenase kit, Bioo Scientific MaxSignal histamine enzymatic assay kit, histamine test, HistaSure ELSIA fast track, Veratox

quantitative histamine test, and RIDASCREEN histamine (enzymatic) kit (AOAC-RI, 2021). These applications are commercially available and widely used in the food industry because of their rapidity, convenience, accuracy, and economic efficiency (Gone *et al.*, 2018; Lacorn *et al.*, 2019; Salleres *et al.*, 2019; Shimoji *et al.*, 2019; 2020; Tobeña et al., 2020). Table 3 summarizes the commonly used methods for the analysis of HA in foods.

Prevention of HA Formation and Control Strategies

Control of temperature and time

Time and temperature controls are considered the most effective prevention measure of HA production in food handling practices (Visciano *et al.*, 2014). Temperature control with a rapid chilling method can inactivate or slow enzyme activities; thereby, limiting HA production (Dalgaard and Emborg, 2009). It is indicated that the increase in temperature and time during food storage resulted in the corresponding increase of bacterial growth (Kerr *et al.*, 2002). Similarly, when the storage temperature increased from 5°C to 25°C, a considerable increase in HA formation was found in tuna samples (Nei, 2014). Another study indicated that storing food between 8°C to 20°C for 1–4 days is unsafe for consumption in terms of HA hazards (Guizani *et al.*, 2005). A temperature change was created during storage to investigate the difference in HA concentration in Indian mackerel, and the finding showed the correlation between factors examined (Zare *et al.*, 2013). HA can reach a high concentration before spoilage symptoms were observed because of post mortem proteolysis (Klausen and Huss, 1987). Freezing measures (below −18°C) could stop bacterial activity in HA production (Hu *et al.*, 2012). DeBeer *et al.* (2021) suggested a tempering process of the frozen tuna with a temperature from −3°C to −4°C to reduce the thawing time in water and meet the critical limits. Precooking could be a valid control measure in food processing to minimize HA formation. There was no increase in HA concentration found in Tuna samples within 12 hours to 18 hours after being precooked (Adams *et al.,* 2018).

The HACCP program was developed as an excellent food industry approach to assure quality and safety (Pierson, 2012). This approach is recommended to be applied by many food authorities in seafood processing and storage (WHO, 2018; Dalgaard and Emborg, 2009). However, HA-producing bacteria such as *Photobacterium phosphoreum* can survive at a low temperature below 5°C (Kanki *et al.*, 2004). Thus, additional factors, such as bacterial contamination and pH value, should also be considered in the control strategies.

Table 3. Commonly used detection methods for HA content analysis in foods

Detection method	Foods	Location	Reference
HPLC	Canned fish	7 European	Duflos *et al.*, 2019
TLC, ELISA, HPLC	Tuna	9 countries, Iran, USA	Tao *et al.* (2011)
TLC	Sardine, mackerel, herring, anchovies	9 countries	Tao *et al.* (2011)
HPLC, Microbial assay	Salted, dried fish	EU, Turkey	Koral *et al.* (2013)
Colorimetric histamine dehydrogenase (HDH) assay, enzyme immunoassay test kits, and HPLC	Raw and canned tuna (in oil and soup), fish meal	Japan	Sato *et al.* (2005)
ELISA kit	Molluscs Marine fish	South Africa Bulgaria	Auerswald *et al.* (2006) Bangieva *et al.* (2020)
Radioenzymatic HA assay, HPLC	Cheese	USA, Spain	Chin *et al.* (1989) Roig-Sagués *et al.* (2002)
Modified enzymatic histamine method based on colorimetric assay	Fermented foods (soy sauce, wine, sauerkraut, salami, and cheese)	Japan	Shimoji *et al.* (2020)
Microbial assay and HPLC	Yogurt,	Turkey	Gezginc *et al.* (2013)
HPLC	Soybean	Taiwan	Kung *et al.* (2007)
HPLC	Salami, Sausages,	Italia	Taylor *et al.* (1978)
Fluorometric method, HPLC, and HPLC-UV	Wine	USA	Pogorzelski (1992) Coton *et al.* (1998) Dang *et al.* (2013) Ough (1971)
HPLC	Kimchi	Taiwan	Tsai *et al.* (2005)

Control of bacterial contamination

Most of the bacteria producing HA are from the environment, so eliminating such bacterial contamination sources should be the key strategy in hazard prevention. It has also been recognized that the HACCP program brings considerable improvements to food quality (Pierson, 2012). In this case, good hygiene and processing practices contribute to a significant reduction in HA formed in food by minimizing temperature abuse and prevent bacterial contamination. Hwang *et al.* (2011) investigated the prevalence of these bacteria species in two groups of samples with and without applying HACCP in factories. The significantly lower average level of HA in the HACCP group indicated the significance of this application. The relationship between hygiene condition in processing or handling and HA production was also clearly shown with significant differences in HA contents in fish fillet investigated in Taiwan (Tsai *et al.*, 2005). On the other hand, rapid detection methods for HA-producing bacteria needs to be considered in practical operation of the food industry (Feng *et al.*, 2016). The application of these methods resulted in a significant reduction in the cost of food processing and storage procedures (Dalgaard and Emborg, 2009; Lehane and Olley, 2000; Prabhakar *et al.*, 2020).

pH adjustment

Degradation of HA can be another measure in controlling food hazards. Bjornsdottir-Butler *et al.* (2015) investigated the effect of trisodium phosphate (TSP) on the growth of some bacteria producing HA and suggested the probability of using TSP as a treatment to eliminate HA. Psychrotrophic HA-producing bacteria (HPB), including *C. freundii, H. alvei, P. damselae, E. aerogenes, R. planticola,* and *M. morganii* isolated from fish tissue, were selected for the investigation. Cocktails of these strains were inoculated in tuna fish infusion broth and incubated for 72 h at 30°C with pH 5.5 and 8.5. HPLC measured HA concentrations while a viable HPB count number was defined by the colony lift hybridization method. The study revealed significant findings as HA production at pH 5.5 medium was significantly greater ($P < 0.001$) than at pH 8.5 for all strains. However, no significant difference was observed ($P < 0.001$) in the tested bacterial strain growth. Treated samples were measured at significantly higher pH values than corresponding control sample figures over the storage period. More importantly, HA production in samples treated by phosphate was substantially lower than that in control samples. The findings of this study reveal that pH is also an option to prevent HA food hazards. Although this study first examined the phosphate treatment for fresh fishes, further investigation on the substance's food safety is necessary.

Other HA control and prevention measures

Conventional processing methods like salting, drying, smoking, canning, and freezing are not appropriate for HA reduction (Feng *et al.*, 2016; Hwang *et al.*, 2011; Taylor *et al.*, 1989). Although bacterial contamination can be minimized or eliminated by canning or salting, HA residue cannot be destroyed (Lehane and Olley, 2000). Salting treatment alone cannot be an effective measure to prevent HA production (Koral *et al.*, 2013). A vacuum-packed approach with *Rosmarinus officinalis* treatment was applied on swordfish steaks to evaluate sample shelf-life extension during a 16-day storage period. A significant difference in HA levels was recorded between the control and the treated samples at the end of the storage period with HA concentrations within the limit levels established by FDA (50 ppm) or EU regulations (200 ppm) (Anastasio *et al.*, 2014). Cleide *et al.* (2021) recently found that salt concentration and ripening temperature during cheese processing could reduce the HA formation ability of *Lentilactobacillus parabucheri* KUH8. Hence, these factors can be applied as control measures to prevent HA production. Kung *et al.* (2016) examined the capacity of *Bacillus polymyxa* to degrade HA formed in processed fish products. A significant reduction in HA content was observed in samples tested, and this bacteria could also be utilized as an additional measure to control HA content in processing fermented fish.

Conclusion

In recent years, the presence of HA in food and incidence related to HA poisoning are increasing. HA hazards are present in varying food sources throughout the world. Although HA poisoning is a mild disease, HA content can be considered a safety indicator for the food processing practice. Several regulatory agencies have actively revised and adjusted their relevant regulations for better food safety. It could be essential for other food regulators to consider existing technologies and available data to change or establish original rules accordingly. Effective and rapid detection methods with affordable operation costs should be applied in HA content assessment and regulation establishments. On the other hand, global warming because of climate change impacting the surrounding environment and the population increase leads to higher food contamination risks. It is necessary to introduce proper mitigation measures to good manufacturing practices, quality control programs, and advanced food processing technologies to apply in the food production system concerning this hazard. The development of novel approaches based on current scientific knowledge and available data in HA control and prevention measures will be vital and can significantly contribute to human health protection and prevention of HA content

occurring in the food supply chain. Furthermore, other foods rather than fishery products should also be checked for HA limitations in food legislation.

Conflict of interests

The authors declare no conflicts of interest.

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