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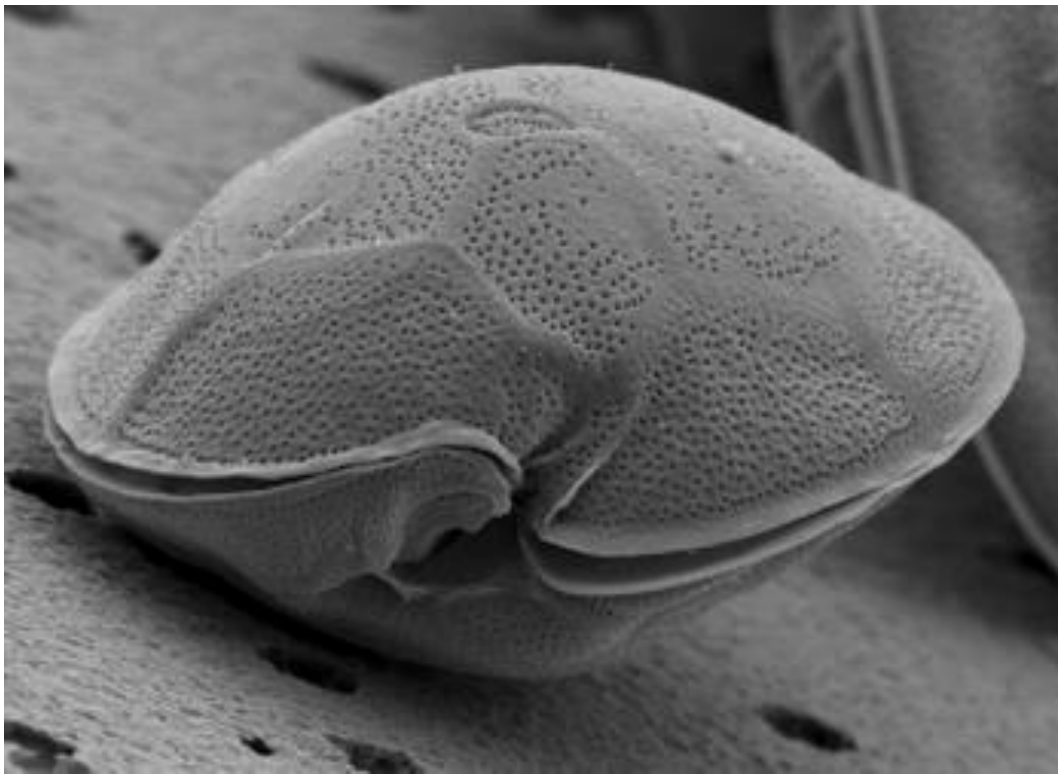
Guide to Food Safety Hazards in Caribbean Fishery Products



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Guide to Food Safety Hazards in Caribbean Fishery Products

Prepared by: Ian Goulding, Megapesca Lda., November 2016, under contract to the Inter-American Institute for Cooperation on Agriculture (IICA), through the 10th EDF funded Sanitary and Phytosanitary Project

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Cover Photo: The marine algae *Gambierdiscus toxicus*, responsible for producing ciguatera toxins (Image taken by Dr. Maria A. Faust, Department of Botany, National Museum of Natural History, Smithsonian Institution, Washington D.C., U.S.A.)

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GLOSSARY OF TERMS

Dose-response assessment	The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated health effects (response)
Exposure assessment	The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food, as well as exposures from other source\s if relevant.
Hazard	A biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse effect on human or animal health.
Hazard characterization	The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physicals agents which may be present in food.
Hazard identification	The identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food, or group of foods.
Risk	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
Risk analysis	A process consisting of three components: risk assessment, risk management and risk communication.
Risk assessment	A scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation
Risk characterization	The qualitative and/or quantitative estimation, including attendant uncertainties of the probability of occurrence and severity of known or potential adverse effects in a given population based on hazard identification, hazard characterization and exposure assessment.
Risk communication	The interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.
Risk management	The process of weighing policy alternatives in the light of results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

LIST OF ABBREVIATIONS

µg	Microgram
3-MCPD	3-monochloropropane-1,2-diol or 3-chloro-1,2-propanediol
AAS	Atomic Absorption Spectroscopy
AOAC	Association of Analytical Chemists
ASP	Amnesic shellfish poisoning
Cd	Cadmium
CFP	Ciguatera fish poisoning
DSP	Diarrheic shellfish poisoning
EDF	European Development Fund
EU	European Union
FDA	Food and Drug Administration
HABs	Harmful algal blooms
HACCP	Hazard Analysis and Critical Control Point
Hg	Mercury
HPLC	High performance liquid chromatography
ICMSF	International Commission on Microbiological Specifications for Foods
IQ	Intelligence Quotient
kg	Kilogram
LC-MS	Liquid chromatography-mass spectrometry
MRL	Maximum Residue Limit
MRPL	Minimum required performance limit
NaCl	Sodium Chloride
NACMCF	National Advisory Committee for Microbiological Criteria for Foods
NSP	Neurotoxic shellfish poisoning
Pb	Lead
ppm	parts per million
PSP	Paralytic Shellfish Poisoning
SO_2	Sulphur dioxide
USA	United States of America
WHO	World Health Organization

FOREWORD

The fishery sector is of great importance for CARIFORUM States, as it provides employment for an estimated 121,000 persons, and contributes significantly to food security and export earnings. The marine capture sector is mostly characterized by a small-scale multi-gear fishery, but several countries have also developed distant water fleets of industrial vessels. Aquaculture is also becoming more important, with some large-scale investments in shrimp and tilapia production as well as numerous experimental and small-scale operations. The fishery sector of CARICOM countries also engages in significant international trade with combined exports worth US$390 million in 2015, with imports over US$180 million (which supply not only domestic markets, but also help to sustain our tourism sector). All this business, and the resulting benefits to the people of our region, depend wholly on the fishery products we produce and market being safe for human consumption. However, ensuring such safety against the background of a diversified and globally integrated fishery sector presents significant challenges, requiring not only considerable resources, but also a high level of expertise and knowledge.

The Caribbean Regional Fisheries Mechanism was formed in 2002 with the objective to promote and facilitate the responsible utilization of the Region's fisheries and other aquatic resources for the economic and social benefits of the current and future population of the region. In line with this aim, we are therefore pleased to present this Manual, which is one of a series, which provides valuable, up-to-date, regionally relevant and practical advice on ensuring the food safety of Caribbean fishery products. The Manuals are intended for use by both fishery sector operators, as well as those involved in protecting our consumers, through the implementation and enforcement of sanitary regulations. We are sure that these documents will help to provide a solid technical basis for the ensuring the continued and sustainable growth of our seafood sector.

1 INTRODUCTION

1.1 Background

This guide was developed within the framework of the EU funded 10th EDF Sanitary and Phytosanitary (SPS) Project, under the terms of a contract "Capacity Building of regulatory and industry stakeholders in Aquaculture and Fisheries Health and Food Safety, to meet the SPS requirements of international trade", implemented by Megapesca Lda., Portugal.

The primary objective of the project is to:

> *Build capacities of CARIFORUM States in health and food safety requirements of fisheries and aquaculture (inland, marine) products. and as such ensure safe food standards for fisheries products in the region, while meeting the requirements of the region's trading partners worldwide.*

The expected result is that capacities will be built at national and regional levels for health and food safety requirements of fisheries and aquaculture (inland, marine) products. This will also ensure safe food standards for fisheries products in the region, while meeting the requirements of the region's trading partners worldwide.

This operational manual is one of eight manuals aimed at providing structured guidelines to ensuring the safety of fish and fishery products for human consumption, in terms of best practices and official controls. The strengthening of sanitary conditions throughout the region is expected to lead to improved health and well-being of national populations, and to increased trade in international trade in fishery products.

1.2 About these guidelines

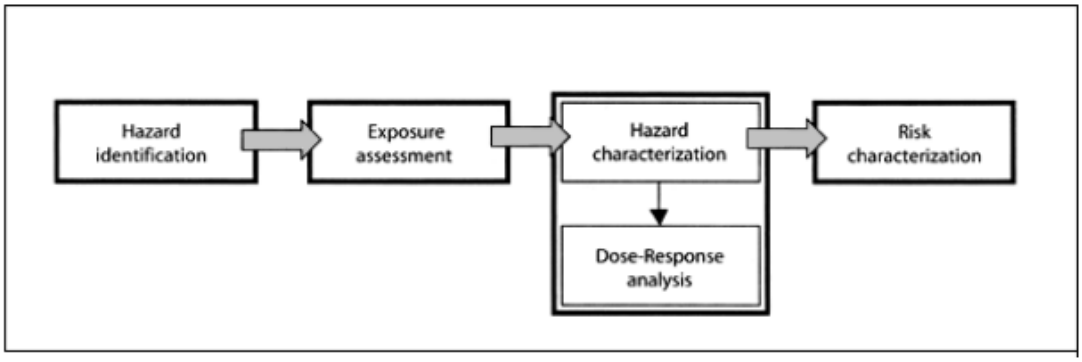
The guide is aimed at technical staff working in the fishery sector. In this respect, it will be useful for quality control managers and inspectors of relevant Competent Authorities.

This document sets out the food safety risks associated with fishery products produced within the CARIFORUM region, and responds to an initial assessment that the implementation of HACCP-based controls is hampered by a lack of scientific knowledge about the specific hazards encountered in the region and the methods for their control.

It will be of particular value in the design and implementation of HACCP (Hazard Analysis and Critical Control Point) plans, and in their assessment for the purposes of official control. It will thus support the implementation of the CRFM Guidelines on Developing and Implementing HACCP Plans for Fish and Fishery Products, September 2015.

At present, there is insufficient data regarding the frequency of hazards in Caribbean fishery products to allow for the implementation of a formal risk assessment approach as shown in Figure 1. The guide therefore seeks to combine elements of risk assessment with practical advice regarding the control of food known safety hazards present in the region's fishery sector.

FIGURE 1: FORMAL APPROACH TO FOOD SAFETY RISK ASSESSMENT



Source: FAO FISHERIES TECHNICAL PAPER 462 "A primer on risk assessment modelling: focus on seafood products"

1.3 How to use this Guide

The guide commences with an introductory summary of the main hazards found in Caribbean fishery products, and the types of products affected. Operators should use this summary table to identify whether their particular products present a significant risk of a particular hazard.

The advantage of such a risk-based approach is that valuable resources can be targeted at recognized weak points, so that the more robust elements in the supply chain can be inspected less frequently.

Where hazards are identified as presenting a significant risk, they must be addressed by the HACCP plan, which frequently requires the sanitary approval awarded by the relevant Competent Authority. This may also be demanded as a condition of supply by the customers of Caribbean fishery enterprises (for example, if exporting to the USA).

The following sections of the guide provide a more detailed presentation describing each of nine significant hazards encountered in the region's fishery products. In each case the section describes the hazard and how it arises in fishery products (hazard identification), the health impacts on consumers (hazard characterisation), and the risks associated with the hazard in the Caribbean situation.

Each section of the guide then describes how to address the hazard within the frame of a HACCP plan. It sets out the requirements in terms of the critical control points to be identified within the process, the monitoring variables and procedures to be specified, and the critical limits for the variables identified. Where there are regulatory requirements, for example in relation to EU or FDA limits to the levels of a particular contaminant, these are specified, along with any other requirements applicable to the design of monitoring and control systems. Finally, corrective actions are specified for occasions where the critical limits are exceeded. A list of further reading is provided in Annex 1.

With a view to supporting operators to develop, and inspectors to inspect, HACCP plans, this guide sets out the different categories of hazard, the species or type of product in which the hazard may be encountered, and the type of presentation, where this may impact on the hazard. It should be noted that the species or types of product described apply only to current product presentations. Should any operator develop new products or presentations, then the hazard profile will need to be assessed independently.

2 FOOD SAFETY HAZARDS IN FISHERY PRODUCTS

2.1 Classification of food safety hazards

2.1.1 Biological hazards

Food-borne biological hazards include microbiological organisms such as bacteria, viruses, fungi and parasites. These organisms are commonly associated with humans and with raw products entering the food establishment, and many occur naturally in the environment where foods are grown. Most are killed or inactivated by cooking, and numbers can be minimized by adequate control of handling and storage practices (hygiene, temperature and time).

TABLE 1: SOME EXAMPLES OF BIOLOGICAL HAZARDS IN FISHERY PRODUCTS [1]

Bacteria (spore-forming)
Clostridium botulinum
Bacteria (non-spore-forming)
Pathogenic *Escherichia coli* (e.g. E. coli 0157) *Listeria monocytogenes* *Salmonella* spp. *(S. typhimurium, S. enteriditis)* *Shigella* spp. *Staphylococcus aureus* *Streptococcus pyogenes* *Vibrio cholerae* *Vibrio parahaemolyitcus* *Vibrio vulnificus* *Yersinia enterocolitica*
Viruses
Hepatitis A and E Norwalk virus group Rotavirus
Protozoa and parasites
Diphyllobothrium latum *Entamoeba histolytica* *Giardia lamblia* *Clonorchis sinensis*

The majority of reported food-borne disease outbreaks and cases are caused by pathogenic bacteria. A certain level of these microorganisms can be expected with some raw foods. Improper storage or handling of these foods can contribute to a significant increase in the level of these microorganisms.

[1] The source of the information in Tables 1 and 2 is "Food Quality and Safety Systems - A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System", Food Quality and Standards Service Food and Nutrition Division, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, Rome, 1998, ISBN 92-5-104115-6

http://www.fao.org/docrep/W8088E/w8088e00.htm#Contents

Cooked foods often provide fertile media for rapid growth of microorganisms if they are not properly handled and stored. They are regarded as high risk since there is no further heat treatment before consumption which would otherwise kill the microorganism.

Viruses can be food-borne, water-borne or transmitted to food by human, animal or other contact. Unlike bacteria, viruses are unable to reproduce outside a living cell. They cannot therefore replicate in food, and can only be carried by it. They are a particular risk in filter- feeding bivalve molluscs.

Parasites are most often animal host-specific and can include humans in their life cycles. Parasitic infections are commonly associated with undercooked fishery products or contaminated ready-to-eat food. Some parasites in products that are intended to be eaten raw, marinated, or partially cooked, can be killed by effective freezing techniques.

Fungi include moulds and yeasts. Fungi can be beneficial, as they can be used in the production of certain foods (e.g. cheese). However, some fungi produce toxic substances (mycotoxins), which are toxic for humans and animals, and can enter the food chain via animal feeds.

2.1.2 Chemical hazards

Chemical contaminants in food may be naturally occurring or may be added during the processing of food. Harmful chemicals at high levels have been associated with acute cases of food-borne illnesses and can be responsible for chronic illness at lower levels.

TABLE 2: EXAMPLES OF CHEMICAL HAZARDS

Naturally occurring chemicals Allergens Mycotoxins (e.g. aflatoxin) Scombrotoxin (histamine) Ciguatoxin Shellfish toxins: - Paralytic shellfish poisoning (PSP) - Diarrhoeic shellfish poisoning (DSP) - Neurotoxic shellfish poisoning (NSP) - Amnesic shellfish poisoning (ASP) **Contaminants, additives and residues** Environmental contaminants: Polychlorinated biphenyls (PCBs) Agricultural chemicals - Pesticides - Fertilizers - Antibiotics - Growth hormones Toxic heavy metals: - Lead - Cadmium - Mercury Food additives - Polycyclic aromatic hydrocarbons - Carbon Dioxide - Sulphur

Contaminants

- Lubricants
- Cleaners
- Sanitizers
- Paints
- Refrigerants
- Water or steam treatment chemicals
- Pest control chemicals

From packaging materials

Plasticizers
Vinyl chloride
Printing/coding inks
Adhesives
Lead
Tin

2.1.3 Physical hazards

Illness and injury can result from hard foreign objects in food. These physical hazards can result from contamination and/or poor practices at many points in the food chain from harvest to consumer, including those within the food establishment. Examples are metal and glass inclusions.

2.2 Significant hazards in Caribbean Fishery products

Some of the main food safety hazards likely to be encountered in Caribbean fishery products are shown in Table 3.

It should be noted that this guide does not cover all possible food safety hazards linked to fishery products. It excludes food safety hazards related to poor hygienic practices, since these are addressed through pre-requisite programmes (good hygiene practices, water treatment etc.), rather than HACCP programmes. Thus, issues such as post-process contamination with Salmonella, Listeria, enteric pathogens, are not specifically addressed. It also excludes environmental contaminants such as PCBs, dioxin like PCBs and polycyclic aromatic hydrocarbons in smoked fish (PAHs), and certain process-related hazards such as botulism, which are not considered to be major hazards in this region. Treatment of tuna with carbon monoxide (to maintain colour) is not permitted in the EU. It is not prohibited in the USA, nor in Caribbean countries which import significant quantities of tuna from the USA and is therefore not considered in this Guide. If required, information on these hazards can be obtained from the list of further reading in Annex 1, or by detailed reference to the scientific literature on specific hazards.

TABLE 3: FOOD SAFETY HAZARDS IDENTIFIED IN DIFFERENT SPECIES OF CARIBBEAN FISHERY PRODUCTS

Hazard category	Hazard	Typical species implicated	Main control method(s)
BIOLOGICAL HAZARDS			
Biogenic amines	Histamine	Scads (*Decapterus* spp.) Four winged flyingfish (*Hirundichthys affinis*) Blackfin tuna (*Thunnus altlanticus*) Cero mackerel (*Scomberomorus regalis*) Dolphinfish (*Coryphaena hippurus*) Wahoo (*Acanthocybium solandri*) Frigate tuna (*Auxis thazard thazard*) Bullet tunas (*Auxis rochei*) King mackerel (*Scomberomorus cavalla*) Little tunny (*Euthynnus alletteratus*) Serra Spanish mackerel (*Scomberomorus brasiliensis*) Albacore (*Thunnus alalunga*) Atlantic bonito (*Sarda sarda*) Bigeye tuna (*Thunnus obesus*) Black marlin (*Makaira indica*) Northern bluefin tuna (*Thunnus thynnus*) Skipjack tuna (*Katsuwonus pelamis*) Yellowfin tuna (*Thunnus albacares*)	Lowering temperature post-mortem < 4.4°C
Marine biotoxins	Ciguatera	Greater amberjack (*Seriola dumerili*) Parrotfishes (Scaridae) Squirrelfishes (Holocentridae) Grunts (Pamadosydae), Surgeonfishes (Acanthuridae), Triggerfish (Balistidae) Hinds, sea-basses, groupers (Serranidae) Snappers (Lutjanidae) Dog snapper, (*Lutjanus jocu)* Jacks (Carangidae) Barracuda (Sphyraenidae) Spanish/King mackerel *(Scomberomorus spp)* West Indian top shell (*Cittarium pica)*	Monitoring and closure of fishery when hazard is present
	Shellfish poisons (PSP, ASP, DSP)	Queen Conch (*Lobatus gigas)* West Indian top shell (*Cittarium pica)*	Monitoring and closure of fishery when hazard is present
CHEMICAL HAZARDS			
Heavy metals	Mercury Cadmium Lead	*Thunnus* species Sharks Groupers Spiny Lobster (Cd) Swordfish (*Xiphias gladius)*	Cease harvest of affected species in affected zones. Larger predatory fish are at greater risk
Additives	Sodium/ Potassium meta-bisulphite	Shrimp Lobsters	Apply GMPs to use of additives
Residues	Residues of veterinary drugs	Aquaculture species (currently shrimp and some fish species)	Farm level checks (banned substances not used); observe GAPs and withdrawal periods

Source: Fish and Fisheries Products Hazards and Controls Guide, U.S. Food & Drug Administration

3 CIGUATERA

3.1 Hazard Identification

Ciguatera is a food-borne illness poisoning in humans caused by eating marine species whose flesh is contaminated with a toxin known as ciguatoxin, present in many marine algae (and particularly the micro-alga *Gambierdiscus toxicus*) living in tropical waters. This micro-alga is a marine benthic dinoflagellate, growing on the surface of dead coral and on macro algae associated with coral reefs. Like many naturally and artificially occurring toxins, ciguatoxin bio-accumulates in lower-level organisms, resulting in higher concentration of the toxin at higher levels of the food chain, a phenomenon known as biomagnification. Ciguatoxin is very heat-resistant, so ciguatoxin-laden fish cannot be detoxified by conventional cooking.

The two most common toxins associated with ciguatera are ciguatoxin and maitotoxin, and they are some of the most lethal natural substances known. In mice, ciguatoxin is lethal at 0.45 µg/kg, and maitotoxin at a dose of 0.15 µg/kg. Oral intake of as little as 0.1µg ciguatoxin can cause illness in the human adult.

Ciguatoxin, a lipid-soluble substance, induces membrane depolarization. The respiratory arrest induced by a lethal dose results mainly from depression of the central respiratory centre. It also causes prolonged symptoms, indicated by nerve blockage or damage. Recovery is slow, requiring regeneration of nervous tissue. Maitotoxin is water-soluble, and also increases the calcium ion influx through cell membranes.

3.2 Hazard characterization

Typical symptoms of ciguatera include gastrointestinal and neurological effects. Gastrointestinal symptoms include nausea, vomiting, and diarrhoea, usually followed by neurological symptoms such as headaches, muscle aches, paresthesia, numbness, ataxia, and hallucinations. Severe cases of ciguatera can also result in a reversal of hot/cold temperature sensation. Doctors are often at a loss to explain these symptoms, and ciguatera poisoning is frequently misdiagnosed as Multiple Sclerosis. As diarrhoea and facial rashes have been reported in breastfed infants of mothers with ciguatera poisoning, it is likely that ciguatera toxins are also transferred into the breast milk.

The symptoms can last from weeks to years, and in extreme cases as long as 20 years, often leading to long term disability. Most people do recover slowly over time. Often patients recover but redevelop symptoms in the future. Such relapses can be triggered by consumption of nuts, alcohol, fish or fish-containing products, chicken or eggs, or by exposure to fumes such as those of bleach and other chemicals. Exercise is also a possible trigger.

Previously, mannitol was used as a treatment for poisoning, after one study reported the reversal of symptoms following its use. Follow-up studies in animals and case reports in humans also found benefit from mannitol. However, a randomized, controlled, double-blind clinical trial of mannitol for ciguatera poisoning did not find any difference between mannitol and normal saline, and based on this result mannitol is no longer recommended. There is no effective treatment or antidote for ciguatera poisoning. The mainstay of treatment is supportive care. Also used are steroids and vitamin supplements, but these merely support the body's recovery rather than directly reducing the toxic effects.

3.3 Frequency in the Caribbean Region

Predator species near the top of the food chain in tropical waters, such as barracudas, moray eels, parrotfishes, groupers, triggerfishes and amberjacks, are most likely to cause ciguatera poisoning,

although many other species have been found to cause occasional outbreaks of toxicity. Ciguatoxin has been reported in over 400 species of reef fish from tropical regions around the world. Due to the localized nature of the ciguatoxin-producing micro-organisms, ciguatera illness is only common in tropical waters, particularly the Pacific and Caribbean, and is often, but not exclusively, associated with fish caught over coral reefs.

There is some evidence that growth of the toxic algae is stimulated during periods when the reef is disturbed, such as during storms or other conditions that lead to environmental reef damage. The existence of fish kills provides evidence of the development of toxic algae and should be considered as a risk factor, with suspension of harvesting until adequate testing has determined the safety of the locality.

Ideal conditions for the production of ciguatera are widespread in the Caribbean. Outbreaks of ciguatera have been reported from the Florida coast (northern limit) to Martinique Island (southern limit) and ciguatera should be considered as a significant risk in reef fishes caught in this region. Top predator species feeding over coral reefs such as barracuda, jacks and groupers are the most likely to be implicated, with large specimens being the most likely to have higher levels of the toxin. The distribution of the hazard is highly location specific and dependent on oceanographic conditions. The risk is considered to be higher in the waters to the north of Martinique (see Figure 2), although this map does not indicate relative frequencies of outbreak.

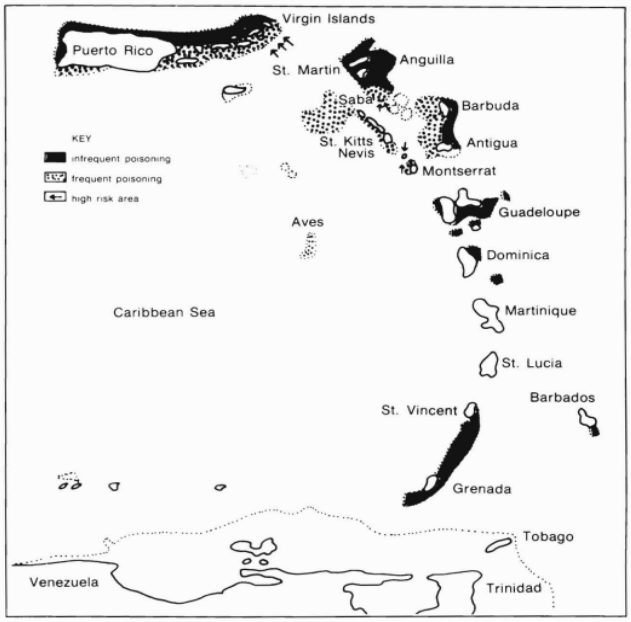


FIGURE 2: DISTRIBUTION OF CIGUATERA IN THE CARIBBEAN

Source: Ciguatera in the Eastern Caribbean David A. Olsen, David W. Nellis, And Richard S. Wood, Marine Fisheries Review, 46(1), 1984

3.4 HACCP Requirements

3.4.1 Critical control points

Toxicity is innate, and dependent on the feeding habits of specific populations of fish. Toxicity therefore depends on species, location, season and, since the toxin bio-accumulates, the size/age of the fish.

The only control method available is to develop awareness of the spatial and time distribution of the levels of the toxin in the product, to cease harvest and supply of species which are susceptible

to ciguatera, and to monitor ciguatera levels in all susceptible species and locations. Producers should aim to develop this information through monitoring programmes.

3.4.2 Monitoring procedures

Detection for ciguatera requires specialized analytical methods and/or particular bioassays. The most common assay is the live mouse assays.

Several laboratory methods are available to detect ciguatoxins, including liquid chromatography-mass spectrometry (LCMS). In recent years, several rapid tests have been developed, both qualitative and quantitative. However, emerging epidemiological data regarding the level of toxin which can cause development of acute symptoms suggests that such test methods can have detection limits above the toxic dose.

It is worth noting that the toxins isolated in the Pacific, the Caribbean and in the Indian Ocean all differ slightly, and therefore caution should be taken in using reference material or tests developed from another region.

3.4.3 Critical limits

The pathogenic dose for humans is 23-230 µg depending *inter alia* on body weight. The usual regulatory requirement is that ciguatera must not be detected in a product. There are no maximum limits specified.

3.4.4 Corrective actions

The corrective action is to avoid harvest of fish which has a known risk of ciguatera. Origins of fish of species which may be susceptible should therefore be monitored. Fish caught in areas, or at times, which present a known risk of ciguatera, should be regarded as unfit and destroyed unless proven to be safe.

4 HISTAMINE

4.1 Hazard Identification

Certain bacteria produce the enzyme histidine decarboxylase during growth. This enzyme reacts with free histidine, a naturally occurring amino acid that is present in higher proportions in certain species of fish, particularly those of the Scombridae family. This is the family of the mackerels, tunas, and bonitos, and thus includes many of the most important and familiar food fishes. The result is the formation of histamine. Histamine poisoning is often referred to as scombrotoxin poisoning because of the frequent association of the illness with the consumption of spoiled scombroid fish.

Histamine-forming bacteria are capable of growing and producing histamine over a wide temperature range. Growth is more rapid at high temperatures e.g. above 30°C. Histamine is more commonly the result of high temperature spoilage than of long term, relatively low temperature spoilage. Nonetheless, there are a number of opportunities for histamine to form under more moderate temperature conditions.

Once the enzyme histidine decarboxylase has been formed, it can continue to produce histamine from histidine in the fish even if the bacteria are not active. The enzyme can be active at or near

refrigeration temperatures, is likely to remain stable while in the frozen state and may be reactivated very rapidly after thawing.

Histamine development is more likely in raw, unfrozen fish. Once histamine is formed, it cannot be eliminated by heat (including retorting) or by freezing. Freezing inactivates the enzyme-forming bacteria but they can re-commence multiplication on thawing. Both the enzyme and the bacteria can be inactivated by heating. After cooking, recontamination of the fish with the enzyme-forming bacteria may give rise histamine development.

The kinds of bacteria that are associated with histamine development are commonly present in the salt water environment. They naturally exist on the gills and in the gut of live, salt water fish, with no harm to the fish. Upon death, the defence mechanisms of the fish no longer inhibit bacterial growth, and histamine-forming bacteria start to grow and produce histamine. Evisceration and removal of the gills in a sanitary manner may reduce, but not eliminate, the number of histamine-forming bacteria. However, when done under insanitary conditions, these steps may accelerate the process of histamine development in the edible portions of the fish by spreading the bacteria to the flesh of the fish.

At least some of the histamine-forming bacteria are halo-tolerant (salt-tolerant) or halophilic (salt-loving). This causes some salted and smoked fish products produced from scombrotoxin-forming species to continue to be suspect for histamine development. Further, a number of the histamine-forming bacteria are facultative anaerobes that can grow in reduced oxygen environments.

4.2 Hazard characterization

Histamine poisoning of humans is a chemical intoxication occurring a few minutes to several hours after ingestion of foods that contain unusually high levels of histamine. It is usually a mild disorder with a variety of symptoms. The primary symptoms are cutaneous (rash, urticaria, oedema, localized inflammation), gastrointestinal (nausea, vomiting, diarrhoea), haemodynamic (hypotension) and neurological (headache, tingling, oral burning and blistering sensation, flushing and perspiration, itching). More serious complications such as cardiac palpitations are rare. The toxicity of histamine is probably potentiated by other biogenic amines. Putrescine, cadaverine, trimethylamine and trimethylamine oxide have been suggested as potentiators.

Histamine poisoning occurs throughout the world and is perhaps the most common form of toxicity caused by the ingestion of fish. Japan, the USA and the UK are the countries with the highest number of reported incidents, although this possibly implies better reporting on their part. Despite its toxicity, histamine is not a substance foreign to the human body. It is stored in specialized cells, where its release is involved in the regulation of such critical functions as the release of stomach acid. But in large doses, histamine becomes toxic and can precipitate poisoning symptoms.

4.3 Frequency in the Caribbean Region

A wide range of scombroid fish are typically harvested in Caribbean waters, they include:

- tuna (*Thunnus* spp. and *Euthynnus* spp)
- skipjack (*Katsuwonus pelamis*)
- Mackerel (*Scomber* spp.)
- Spanish and King mackerel (*Scomberomorus* spp)
- Wahoo (*Acanthocybium solandri*)

Some species of non-scombroid fish have also caused outbreaks of this illness, and these should also be considered to present a risk. These species include:

- jacks and trevallies (*Caranx* spp)
- mahi-mahi (*Coryphaena* spp.)
- horse mackerel/scads (*Decapterus* spp)

Other species which could be implicated include:

- marlin (*Makaira* spp.)
- anchovies (*Engraulis* spp)
- flying fish *(Hirundichthys affinis)*

It should be noted that these species lists are not exclusive and other species within these genera may be implicated. It should be noted that risks are increased with some harvesting practices. In long lining, death can occur before the fish is removed from the water. Under the worst conditions, histamine formation can already be underway before the fish is landed on the vessel. This condition can be aggravated when the fish is allowed to remain on the line for a period of time after death. Note that in certain tuna species, *post mortem* glycolysis may cause an increase in internal temperature to a more favourable growth range for the enzyme-forming bacteria.

4.4 HACCP Requirements

4.4.1 Critical control points

Rapid chilling of fish immediately after death is the most important element in any strategy for preventing the formation of scombrotoxin, especially for fish that are exposed to warmer waters or air, and for large tuna that generate heat in the tissues of the fish following death. This will prevent the formation of the enzyme histidine decarboxylase. Once this enzyme is formed, control of the hazard is unlikely.

The recommended conditions are:

- Fish should be placed in ice or in refrigerated seawater or brine at 4.4°C or less within 12 hours of death, or placed in refrigerated seawater or brine at 10°C or less within 9 hours of death;
- Fish exposed to air or water temperatures above 28°C should be placed in ice (including packing the eviscerated belly cavity of large fish with ice) or in refrigerated seawater or brine below 4.4°C or less within 6 hours of death;
- Large tuna (i.e., above 10kg) that are not eviscerated before on-board chilling should be chilled to an internal temperature of 10°C or less within 6 hours of death.

Further chilling towards the freezing point is also desirable to safe-guard against longer-term, low-temperature development of histamine. The time required to lower the internal temperature of fish after capture will be dependent upon a number of factors, including:

- the harvest method: delays in removing fish from a long line may significantly limit the amount of time left for chilling and may allow some fish to heat up after death; the quantity of fish landed in a purse seine or on a long line may exceed a vessel's ability to rapidly chill the product;
- the size of the fish
- the chilling method: ice alone takes longer to chill fish than does an ice slurry or recirculated refrigerated sea water or brine, a consequence of reduced contact area and heat transfer; the quantity of ice or ice slurry and the capacity of refrigerated sea water or brine systems must be suitable for the quantity of catch.

Specific handling procedures should be determined which reflect the fishing and chilling methods adopted. Once chilled, the fish should be maintained chilled (at the temperature of melting ice) (or alternatively be kept frozen) until it is consumed. Exposure to ambient temperature should be minimized. The allowable exposure time is dependent primarily upon the speed with which the fish were chilled on-board the harvest vessel, and whether the fish has been previously frozen (e.g. on-board the harvest vessel).

Preventive measures for histamine formation can therefore include:

- Making sure through harvest vessel records that incoming fish were properly handled on-board the harvest vessel:
- Rapidly chilling the fish immediately after death e.g. by proper icing
- Controlling temperatures in storage and distribution thereafter
- Controlling the amount of time that the product is exposed to temperatures that would permit histamine formation during processing.

Given the prevalence of the affected species and the high temperatures encountered in the Caribbean region, development of histamine in fishery products remains a high risk. Icing at sea of affected species is strongly recommended. Changes in fishing methods, resulting in a longer delay between catch and application of ice (for example, the introduction of longlining), should be approached with caution and accompanied by applied research to fully understand the risks.

4.4.2 Monitoring procedures

Temperature monitoring

Monitoring requirements for control of the histamine hazard therefore focus on measuring the time and temperature history, not only at the point of reception, but from the point of capture. Where this is not known from the point of harvest, the exporter should check incoming raw materials for histamine levels.

Reception checks include:

- Checking temperature records after capture
- Checking incoming fish to ensure that they are not at an elevated temperature at time of receipt;
- Checking incoming fish to ensure that they are properly iced or refrigerated at time of receipt;
- Performing sensory examination on incoming fish to ensure that they do not show signs of decomposition;
- Sampling and testing incoming fish for levels of histamine

Sensory evaluation is generally used to screen fish for spoilage odours that develop when the fish is exposed to time/temperature abuse. It is an effective means of detecting fish that have been subjected to a variety of abusive conditions. However, odours of decomposition that are typical of relatively low temperature spoilage may not be present if the fish has undergone high temperature spoilage. This condition makes sensory examination alone an ineffective control for scombrotoxin.

Observations for the presence of honeycombing in pre-cooked tuna loins (a condition in which the flesh exhibits irregular holes) intended for canning is also a valuable means of screening for fish that have been exposed to the kinds of temperature abuse that can lead to histamine development. Any fish that demonstrate the trait should be destroyed.

During processing, the monitoring procedures should aim to monitor time and temperature throughout the process, until the product is stabilised (cooked/frozen). Time and temperature

records should be traceable to the batch of products to which they apply. Where a processor receives fish which has not been under his control, steps should be taken to ensure that temperatures and histamine levels at reception are properly monitored.

Histamine analysis

Examinations for official control should be carried out in accordance with the high-performance liquid chromatography (HPLC) method. This is described in the following publications:

a) Malle P., Valle M., Bouquelet S. Assay of biogenic amines involved in fish decomposition. J. AOAC Internat. 1996, 79, 43-49 and

b) Duflos G., Dervin C., Malle P., Bouquelet S. Relevance of matrix effect in determination of biogenic amines in plaice (Pleuronectes platessa) and whiting (Merlangus merlangus). J. AOAC Internat. 1999, 82, 1097-1101.

More details are provided in the CRFM Manual on Laboratory Testing of Fishery Products.

However, for routine monitoring for the purpose of HACCP plans, it is acceptable to undertake rapid testing using ELISA based methods. Histamine test kits may be qualitative, semi-quantitative, or fully quantitative. Table 4 shows a selection of some the commercial testing systems available for rapid testing of histamine in fishery products. All providers advertise their products via the internet.

TABLE 4: SOME COMMON COMMERCIAL TEST PRODUCTS FOR HISTAMINE

Test	Analytical Technique	Approx. Total Test Time	Supplier
ALERT® for Histamine [Sensitivity: 2.5 ppm] Veratox® for Histamine [Sensitivity: < 2.5 ppm, quantitative from 0 to 50 ppm]	ELISA	35 min	Neogen Corporation Contact: Jennifer Baker 620 Lesher Pl. Lansing, MI 48912 Phone: 800/234-5333; 517/372-9004 E-mail: neogen-info@neogen.com Web: www.neogen.com
BIOLAN BIOFISH 300-003[1]	ELISA	1 hour	BIOLAN Laida Bidea Edificio 409 · Parque Tecnológico de Bizkaia 48170 Zamudio Bizkaia SPAIN http://www.biolanmb.com/
RIDASCREEN® Histamin R1602 [Sensitivity: 2.5 ppm; quantitative]	ELISA	2-5/6h	R-Biopharm, Inc. Contact: Sean Tinkey 7950 US 27 South Marshall, MI 49068 Phone: 877/789-3033 E-mail: sales@r-biopharm.com Web: www.r-biopharm.com/food/other/hista.html
RidaQuick Histamin (R1603-96 Wells) [Sensitivity 20 ppm; quantitative]	ELISA	12 min	R-Biopharm, Inc. Contact: Sean Tinkey 7950 US 27 South Marshall, MI 49068 Phone: 877/789-3033 E-mail: sales@r-biopharm.com Web: www.r-biopharm.com/quickhistamin.pdf

[1]AOAC Approved

Source: Internet search, 2016

4.4.3 Critical limits

Temperature limits

In histamine producing species, any exposure time above 4.4°C reduces the expected safe shelf-life. For this reason, it is recommended that have not been previously frozen should not be exposed to temperatures above 4.4°C for more than 4 hours in total if any portion of that time is at a temperature above 21°C. If the temperature of exposure is less than 21°C, the maximum total period of exposure to temperatures above 4.4°C is 8 hours. The safety of the product therefore depends substantially on ambient temperatures and proper handling at sea. In the Caribbean region, with ambient temperatures mostly above 21°C, the maximum exposure above 4.4°C should be less than 4 hours.

Chemical testing is an effective means of detecting the presence of histamine in fish flesh. However, given that histamine levels vary considerably within a batch, the validity of such testing is dependent upon the design of the sampling plan.

Histamine limits

For products marketed to the EU, the requirements for histamine are set out in Commission Regulation (EC) No 1441/2007 of 5 December 2007 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs. This measure requires that:

1. A consignment of fishery products comprising a fish species which is susceptible to the production of histamine, shall not be placed on the market if the level of histamine in nine samples, selected at random from the consignment, exceeds the minimum levels specified below.
2. The results of the analysis shall fulfil the following requirements-
    a) the mean value shall not exceed 100 ppm;
    b) no more than two samples may each have a value of more than 100 ppm but less than 200 ppm;
    c) no sample may have a value exceeding 200 ppm.
3. Fish which have undergone enzyme-ripening treatment in brine are permitted to have higher histamine levels, but not more than twice the above values.

4.4.4 Corrective actions

Exporters should be aware of which species they are dealing with that may be histamine producers. In cases of doubt, or where there is no data, there is a strong case for undertaking trials to assess the potential of a species for development of histamine.

In the HACCP plan, the time and temperature limits should be established that ensure that histamine development does not approach the maximum limits. Where time and temperature limits exceed those specified in the HACCP plan, additional temperature controls and accelerated processing may be specified as the corrective actions. Where time and temperature limits indicate a high risk, it may be necessary to submit the batch to additional testing, and to reject it if the maximum limit is exceeded. Batches rejected for export on the basis of confirmed histamine toxicity should be destroyed.

5 VIBRIO PARAHAEMOLYTICUS

5.1 Hazard Identification

V.*parahaemolyticus* is a halophilic bacterium found naturally in estuarine and marine waters and in marine animals. It was first described as the cause of gastroenteritis in Japan. It has a worldwide distribution, and has been isolated from many species of fish, shellfish, and crustaceans.

V. parahaemolyticus has been implicated in numerous outbreaks of seafood-borne gastroenteritis around the world, especially in relation to shellfish such as crab, oyster and shrimp. The consumption of raw or insufficiently heated seafood, or properly cooked seafood contaminated after cooking, is the main cause of the illness.

Hazards from *Vibrio* can be prevented by cooking seafood thoroughly, and by preventing cross-contamination once the seafood is cooked. Cooking to an internal temperature of 65°C effectively inactivates this organism. Freezing is ineffective in killing all the bacteria but does reduce numbers. It is very sensitive to drying but can grow in NaCl concentrations up to10%.

Seafood which is habitually consumed in raw or lightly cooked state is therefore regarded as being high risk. The highest risk products are filter-feeding bivalve molluscs, since these can concentrate the bacteria by their feeding mechanism. This applies to oysters and other bivalves. Note that depuration is not effective at removing *Vibrio* spp from filter-feeding shellfish. However, other seafood may be implicated when consumed raw, or when subject to cross contamination of cooked product with raw. This includes squid, mackerel, tuna, and sardines. An outbreak in the Bahamas in 1991 was associated with the consumption of conch.

5.2 Hazard characterization

Outbreaks tend to be concentrated along coastal regions during the summer, when higher water temperatures favour higher levels of bacteria. Infection occurs via the oral route through ingestion of bacteria in raw or undercooked seafood, usually oysters. The infective dose of *Vibrio* spp is suspected to be in the order of 1,000,000 total cells. The bacteria infects the gut lining causing acute gastroenteritis. The incubation period of about 24 hours is followed by explosive, watery diarrhoea accompanied by nausea, vomiting, abdominal cramps, and sometimes fever. Symptoms of *Vibrio parahaemolyticus* typically resolve within 72 hours, but can persist for up to 10 days in immuno-compromised individuals. Since the majority of cases of *V. parahaemolyticus* food infections are self-limiting, treatment is not normally necessary. In severe cases, fluid and electrolyte replacement is indicated.

5.3 Frequency in the Caribbean Region

There are no data on the frequency of the *Vibrio parahaemolyticus* bacteria in Caribbean waters. However, it should be assumed to be present. The main products at risk are those which are not likely to be cooked prior to consumption. In the Caribbean, the main risk appears to be presented by cooked lobster tails and conch, through cross contamination from raw product. There is also a risk with tunas and other fishery products which may be consumed raw.

5.4 HACCP requirements

5.4.1 Critical control points

It is not possible to avoid entry to the supply chain of products which may be contaminated with these bacteria. Control strategies depend on the product, but will typically include one or more of the following steps.

In relation to cooked lobster tails and cooked conch there is a need to ensure that:

- cooking is adequate (cooking to an internal temperature of 65°C at the coolest part of the product)
- product is chilled to below 5°C rapidly and held at that temperature
- there is no potential for cross contamination from raw to cooked product, including clear separation of raw and cooked products, and including the areas, equipment and staff involved in their handling.

In the case of tunas, it is necessary to maintain the product under refrigeration and to control refrigeration temperatures e.g. chilling throughout the production process to ensure that temperatures are kept below 5°C. The amount of time the product is exposed to temperatures that would permit pathogen growth should be strictly limited.

Note that compliance with HACCP conditions for control of histamine hazard should ensure an adequate level of protection against *Vibrio.*

5.4.2 Monitoring procedures

Time and temperature are therefore the most important variables to be monitored under the HACCP plan. The precise requirements will depend on the nature of the product (cooked or raw). A microbiological laboratory is required to perform the culture and isolation of *Vibrio* species.

5.4.3 Critical limits

Table 5 shows the ICSMF recommended limits for this hazard in fishery products. It should be noted that the specification for this hazard is not expressed in EC Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

TABLE 5: ICMSF RECOMMENDED MICROBIAL LIMITS FOR *V. PARAHAEMOLYTICUS* IN FISH

Product	n[1]	c[2]	Bacteria/gram or/cm[2]	
			m[3]	M[4]
Fresh and frozen fish and cold-smoked fish	5	2	10^2	10^3
Frozen raw crustaceans	5	1	10^2	10^3
Frozen cooked crustaceans	5	1	10^2	10^3
Cooked, chilled, and frozen crabmeat	10	1	10^2	10^3
Fresh and frozen bivalve molluscs	10	1	10^2	10^3

[1]Number of representative sample units.
[2]Maximum number of acceptable sample units with bacterial counts between m and M.
[3]Maximum recommended bacterial counts for good quality products.
[4]Maximum recommended bacterial counts for marginally acceptable quality products.

Source: ICMSF, 1986

Plate counts below "m" are considered good quality. Plate counts between "m" and "M" are considered marginally acceptable quality, but can be accepted if the number of samples does not exceed "c." Plate counts at or above "M" are considered unacceptable quality (ICMSF, 1986).

5.4.4 Corrective actions

In the case of cooked product, where heat processing is not adequate to ensure death of *Vibrio* spp, the corrective action may involve re-processing, for example repeating the cooking process.

6 SHELLFISH POISONS (PSP, ASP, DSP)

6.1 Hazard Identification

Shellfish poisoning is caused by a group of toxins produced by planktonic algae (dinoflagellates, in most cases) upon which some molluscs (amongst other organisms) feed, either by browsing or by filter feeding. The toxins are accumulated and sometimes metabolized by the shellfish.

The 20 toxins responsible for paralytic shellfish poisonings (PSP) are all derivatives of saxitoxin. The saxitoxins act by blocking sodium ion movement through voltage-dependent sodium channels in nerve and muscle cell membranes. Conduction block occurs principally in motor neurons and muscle. The toxin is made by dinoflagellates of the *Gonyaulax* species (also known as red tide).

Diarrhetic shellfish poisoning (DSP) is caused by a group of high molecular weight polyethers, including okadaic acid, the dinophysis toxins, the pectenotoxins, and yessotoxin. This group of toxins is made by dinoflagellates of the species *Dinophysis* and *Prorocentrum*.

Neurotoxic shellfish poisoning (NSP) is the result of exposure to a group of polyethers called brevetoxins. Brevetoxins are polycyclic ethers that, like ciguatoxin, bind to and stimulate sodium flux through voltage-gated sodium channels in nerve and muscle. Brevetoxins are made by the dinoflagellate *Ptychodiscus brevis*.

Amnesic shellfish poisoning (ASP) is caused by the unusual amino acid, domoic acid, a contaminant of shellfish. Domoic acid is structurally similar to the excitatory neurotransmitter glutamate and is produced by the diatom *Nitzschia pungens*.

6.2 Hazard characterization

Ingestion of contaminated shellfish results in a wide variety of symptoms, depending upon the toxins(s) present, their concentrations in the shellfish, and the amount of contaminated shellfish consumed. In the case of PSP, the effects are predominantly neurological and include tingling, burning, numbness, drowsiness, incoherent speech, and respiratory paralysis leading to death.

Less well characterized are the symptoms associated with DSP, NSP, and ASP. DSP is primarily observed as a generally mild gastrointestinal disorder, i.e., nausea, vomiting, diarrhoea, and abdominal pain, accompanied by chills, headache, and fever. However, it can be fatal in elderly patients. Both gastrointestinal and neurological symptoms characterize NSP, including tingling and numbness of lips, tongue, and throat, muscular aches, dizziness, reversal of the sensations of hot and cold, diarrhoea, and vomiting. ASP is characterized by gastrointestinal disorders (vomiting, diarrhoea, abdominal pain) and neurological problems (confusion, memory loss, disorientation, seizure, coma and possible death).

Of these toxicoses, the most serious from a public health perspective appears to be PSP. The extreme potency of the PSP toxins has, in the past, resulted in an unusually high mortality rate. Fatality rates from PSP ranges from 1-12% in isolated outbreaks. Its high mortality rate in some

areas is caused by poor access to advanced life support capabilities. The mortality rate in the only known outbreak of ASP was 3%. To date, no deaths have been reported for NSP or DSP. Based on mortality figures from recent outbreaks, children appear to be more sensitive to the saxitoxins of PSP than adults.

The existence of regional fish kills (events in which large numbers of fish of different species are found dead in the water) provides evidence of the development of toxic algae, and should be considered as a risk factor, with suspension of harvesting until adequate testing has determined the safety of the locality.

6.3 Frequency in the Caribbean Region

All filter-feeding bivalve molluscs are potentially toxic. In addition, there is a potential risk in relation to gastropod molluscs and other edible marine animals which browse on benthic algal growth. This includes gastropods such as conch and potentially echinoderms such as sea urchins and tunicates (sea cucumbers).

In the Caribbean, there is only a limited harvest of marine clams but there is a substantial consumption and export of marine gastropods. There is no statistical data on the occurrence and severity of shellfish poisoning. However, a precautionary approach requires that controls be put in place.

6.4 HACCP Requirements

6.4.1 Critical control points

The toxins responsible for most shellfish poisonings are water-soluble, heat and acid-stable, and are not inactivated by ordinary cooking methods. However, severe heating processes, such as retorting, may be effective at reducing the levels of some natural toxins.

Significant elements of the control of the harvesting of molluscan shellfish (as well as other organisms potentially affected, such as gastropod molluscs and tunicates) include the following requirements:

1) Harvest areas should be defined, monitored and classified, based on the presence of natural toxins. As a result of these classifications, harvesting is allowed from specified areas, and only at certain times, or under certain conditions. During periods of higher risk, the harvest area is closed.

2) Mechanisms for enforcement of fishery closure

3) All harvesters to be licensed;

4) Containers of shellfish consigned to market to bear a label with the processor's name, address, and certification number.

5) Only registered and certified processors allowed to process or ship, reship, or repack the harvested product

6.4.2 Monitoring procedures

Monitoring of water quality

Water quality monitoring is based on sampling of water from defined sampling points within the nominated harvesting areas, and identification and counting of the species of marine algae involved

in development of harmful algal blooms (HABs). This requires specialised staff trained in the taxonomy of marine algae.

Blooms can be caused by several factors. An increase in nutrients can cause algae growth and reproduction to increase dramatically into a bloom. In other instances, something may change in the environment so that certain algae can surpass the other algae for food, which can result in a bloom of the algae with the advantage. This environmental change can be related to the water quality, temperature, nutrients, sunlight, or other factors. Remote sensing is being increasingly employed to monitor environmental variables to help identify the times and locations where HABs become more likely, thus allowing focused sampling. Typically, sampling every 2 weeks is a minimum requirement. However, since HABs can develop rapidly, more frequent monitoring is required during high risk periods.

Monitoring of toxicity of shellfish

Shellfish samples should also be collected by the operator, as part of their HACCP system, and by the Competent Authority with a view to monitoring the levels of the toxins, since these may accumulate over a season. Note that toxic specimens cannot be purified by the normal depuration processes applied for bacterial contamination of filter-feeding shellfish.

The mouse bioassay has historically been the most universally applied technique for examining shellfish (especially for PSP). Unfortunately, the dose-survival times for the DSP toxins in the mouse assay fluctuate considerably, and fatty acids interfere with the assay, giving false-positive results. In recent years, considerable effort has been applied to development of chemical assays to replace these bioassays.

A High Performance Liquid Chromatography (HPLC) procedure has been developed to identify individual PSP toxins. This is the Lawrence method[2] and is recognised by the EU as a reference method (see Commission Regulation (EC) No 1664/2006 of 6 November 2006). There are no validated, rapid test methods suitable for any of these toxins.

6.4.3 Critical limits

European limits regarding content of the toxins are set by Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004, laying down specific hygiene rules for food of animal origin. Such products must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:

> (a) For paralytic shellfish poison (PSP), 800 micrograms of saxitoxin equivalent per kilogram;
>
> (b) For amnesic shellfish poison (ASP), 20 milligrams of domoic acid per kilogram;
>
> (c) For okadaic acid, dinophysistoxins and pectenotoxins together, 160 micrograms of okadaic acid equivalents per kilogram;
>
> (d) For yessotoxins, 1 milligram of yessotoxin equivalent per kilogram;
>
> (e) For azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.

FDA has also established action levels for all of the above toxins.

- PSP - 0.8 ppm (80µg/100g) saxitoxin equivalent;
- NSP- 0.8 ppm (20 mouse units/100g) brevetoxin-2 equivalent;

[2] *Journal of AOAC INTERNATIONAL* (Vol. 88, No. 6), "Quantitative Determination of Paralytic Shellfish Poisoning Toxins in Shellfish Using Pre-chromatographic Oxidation and Liquid Chromatography with Fluorescence Detection"

- DSP- 0.2 ppm okadaic acid plus 35-methyl okadaic acid (DXT 1);
- ASP - 20 ppm domoic acid, except in the viscera of Dungeness crab, where 30 ppm is permitted.

6.4.4 Corrective actions

Once a rise in algal species which present a toxin risk is identified, or rising levels of the toxins are detected in the product, the control action is to prohibit fishing or gathering until such time as re-testing indicates that the hazard is no longer present.

It should be noted that there are no means of re-processing the products. The toxins are stable to heat treatment, and levels in live animals decline only slowly.

7 HEAVY METALS

7.1 Mercury

7.1.1 Hazard Identification

Methylmercury is an organo-metallic cation with the formula [CH3Hg]+. It is a bio-accumulative environmental toxicant. Mercury in other forms (non-organic) is tightly bound and is not generally toxic.

In the past, methylmercury was produced directly and indirectly as part of several industrial processes. Current methylmercury sources are from the release of inorganic mercury from both anthropogenic and natural sources.

1. Burning of wastes containing inorganic mercury and burning of fossil fuels, particularly coal.

2. Natural sources such as volcanoes, forest fires and weathering of mercury-bearing rocks, including underwater sources.

Methylmercury is formed from inorganic mercury by the action of anaerobic organisms that live in aquatic systems including lakes, rivers, wetlands, sediments, soils and the open ocean. About three times as much additional inorganic mercury is contributed by natural sources compared to manmade sources.

Because methylmercury is formed in aquatic systems and is not readily eliminated from organisms, it is bio-accumulated in aquatic food chains from bacteria, to plankton, through macroinvertebrates, to herbivorous fish and predatory marine animals. At each step in the food chain, the concentration of methylmercury in the organism increases. The concentration of methylmercury in the top level aquatic predators can reach a level a million times higher than the level in the water. This is because methylmercury has a half-life of about 72 days in aquatic organisms. Organisms, including humans, fish-eating birds, and fish-eating mammals such as otters and whales that consume fish from the top of the aquatic food chain, receive the methylmercury that has accumulated through this process. Fish and other aquatic species are the only significant source of human methylmercury exposure.

The concentration of mercury in any given fish depends on the species of fish, the age and size of the fish and the type of water body in which it is found. In general, fish-eating fish such as shark, swordfish, marlin, and larger species of tuna, have higher levels of methylmercury than herbivorous fish or smaller fish such as sardine and mackerel. Long-lived fish such as groupers, which may also

inhabit volcanic seamounts, may also be implicated. Within a given species of fish, older and larger fish have higher levels of methylmercury than smaller fish.

7.1.2 Hazard characterization

Ingested methylmercury is readily and completely absorbed by the gastrointestinal tract. It is transported freely throughout the body including across the blood-brain barrier and across the placenta, where it is absorbed by the developing foetus. Because of this characteristic and its strong binding to proteins, methylmercury is not readily eliminated. Methylmercury has a half-life in human blood of about 50 days.

Several studies indicate that methylmercury is linked to developmental defects in children exposed in-utero, such as loss of IQ points, and decreased performance in tests of language skills, memory function and attention deficits. Methylmercury exposure in adults has also been linked to increased risk of cardiovascular disease including heart attack. Some evidence also suggests that methylmercury can cause autoimmune effects in sensitive individuals. However, to date, methylmercury has not been linked to any specific neurologic or autoimmune disease.

There have been several episodes in which large numbers of people were severely poisoned by food contaminated with high levels of methylmercury, notably the dumping of industrial waste that resulted in the pollution and subsequent mass poisoning in Minamata and Niigata, Japan. This episode resulted in neurologic symptoms including paresthesias, loss of physical coordination, difficulty with speech, narrowing of the visual field, hearing impairment, blindness, and death. Children who had been exposed in-utero through their mothers' ingestion were also affected with a range of symptoms including motor difficulties, sensory problems and mental retardation. Exposures of this magnitude are rarely seen and are confined to isolated incidents.

Accordingly, concern over methylmercury pollution is currently focused on more subtle effects that may be linked to levels of exposure presently seen in populations with high to moderate levels of dietary fish consumption. These effects are not necessarily identifiable on an individual level, or may not be uniquely recognizable as due to methylmercury. However, such effects may be detected by comparing populations with different levels of exposure.

US FDA has published an advice for pregnant women, women who might become pregnant, nursing mothers and those feeding young children. This is shown in the following box (for illustrative purposes):

1. Don’t eat shark, swordfish or kingfish because they contain high levels of mercury
2. Levels of mercury in other fish can vary. You can safely eat up to 12 ounces (2 to 3 meals) of other purchased fish and shellfish a week. Mix up the types of fish and shellfish you eat and do not eat the same type of fish and shellfish more than once a week.
3. Check local advisories about the safety of fish caught by family and friends in your area. If no advice is available, you can safely eat up to 6 ounces (one meal per week) of fish you catch from local waters, but don’t consume any other fish during that week.
4. Follow these rules when feeding fish and shellfish to your young child, but the serving sizes should be smaller.

7.2 Cadmium

7.2.1 Hazard Identification

Cadmium is a soft, malleable, ductile, toxic, bluish-white bivalent metal. It is similar in many respects to zinc but reacts to form more complex compounds. Cadmium is produced mainly as a by-product from mining, smelting, and refining sulfide ores of zinc and, to a lesser degree, lead and copper.

Cadmium is released to the atmosphere from both natural and anthropogenic sources. It is widely distributed in the earth's crust and consequently, may be released to the air from entrainment of dust particles, volcanic eruptions, or other natural phenomena. However, industrial activities are the main sources of cadmium release to air, and emissions from anthropogenic sources have been found to exceed those of natural origin by an order of magnitude. About three-quarters of cadmium is used in batteries (especially Ni-Cd batteries), and most of the remaining quarter is used mainly for pigments, coatings and plating, and as stabilizers for plastics. Other uses include solder and as a photoconductive surface coating for photocopier drums.

Industrial development led to high levels of industrial exposure to cadmium and emissions to the environment. But as the toxic effects of cadmium became apparent, limits on cadmium emissions, waste disposal and industrial exposure of workers have been introduced in most industrialized nations.

In fishery products, the source of cadmium is soluble salts in water, from both natural and anthropogenic sources. A cadmium-dependent enzyme has been found in some marine diatoms, in which cadmium does the same job as zinc in other similar enzymes. This may be one source of the initial concentration of cadmium in the marine environment. The compound is concentrated at each trophic level of the food chain. Thus top predators and carnivores are likely to have higher levels.

Typically, higher levels of cadmium are found in the flesh and viscera of crustacean, cephalopod molluscs, and in the flesh of certain large pelagic fishes such as tunas, sharks and swordfishes. Cadmium is accumulated mainly in the hepato-pancreas (digestive gland) of the crab, and cadmium levels as high as 30-50 ppm have been detected in this edible part of the animal. However, a feeding study in mice to determine the bioavailability of cadmium from crab hepato-pancreas concluded that cadmium from boiled crab has a lower bioavailability for absorption in the gastrointestinal tract of mice than inorganic cadmium. Typically, therefore the brown meat of crabs and head meat of lobsters, and the viscera of cephalopods are excluded from the compositional regulations.

7.2.2 Hazard characterization

Cadmium has no constructive purpose in the human body. It, and its compounds, are extremely toxic even in low concentrations, and will bio-accumulate in animals and plants. In the general population, diet is the most common source of exposure. Plants may contain significant amounts if grown in polluted areas. Cadmium typically bio-accumulates in the liver and kidneys of adult animals. Livers and kidneys of food animals and certain fishery products are the most important dietary sources. However, for smokers, cigarettes are also a significant source of cadmium exposure (accounting for up to 50%).

Toxicity of cadmium depends on the method of ingestion. Acute inhalation exposure to cadmium fumes may cause severe influenza-like symptoms including impaired lung function, chills, fever, and muscle aches and can lead rapidly to death.

Longer term dietary exposure of lower doses may result in the bones becoming soft (osteomalacia), and loss of bone mineral density (osteoporosis), with increased risk of fractures. The kidney is the main target organ of cadmium toxicity following extended oral exposure. Kidney damage inflicted by cadmium poisoning is irreversible and does not heal over time. The kidneys lose their function to remove acids from the blood, causing muscle weakness and sometimes coma, and accumulation of uric acid crystals in the joints. Compounds containing cadmium are also carcinogenic. Cadmium induced neurotoxicity has not been clearly demonstrated in human studies, but it has been observed in animal studies.

7.3 Lead

7.3.1 Hazard Identification

Lead is a naturally occurring bluish-grey metal found in small amounts in the earth's crust. Lead can be found in all parts of our environment. Much of it comes from human activities including burning fossil fuels, mining, and manufacturing. Lead has many different uses. It is used in the production of batteries, ammunition, metal products (solder and pipes), and devices to shield X-rays. Tetra-alkyl lead compounds were previously added to gasoline to increase combustibility. However, because of health concerns, its use for this, as well as in paints and ceramic products, caulking, and pipe solder has been dramatically reduced in recent years.

Lead chloride and lead carbonate are the primary complexes formed in seawater. Lead is known to form strong complexes with organic matter and with Fe-Mn oxides. In water, tetra-alkyl lead compounds, such as tetraethyl lead and tetra-methyl lead, are subject to photolysis and volatilization, but some of the degradation products including tri-alkyl lead carbonates, hydroxides, and halides are persistent.

Uptake of lead in animals may occur as a result of inhalation of contaminated ambient air, or ingestion of contaminated foods. Organo-lead compounds, such as tri-alkyl and tetra-alkyl lead compounds, are more toxic than inorganic forms and have been shown to bio-concentrate in aquatic organisms. However, they are also excreted relatively rapidly, with for example half-life values of 30–45 hours for rainbow trout exposed to tetra-methyl lead. Whilst older organisms tend to contain the greatest body burdens (bio-concentration), lead is not biomagnified in aquatic or terrestrial food chains. In aquatic organisms lead concentrations are usually highest in benthic organisms and algae, and lowest in upper trophic level predators (e.g. carnivorous fish).

In fishery products, high levels of lead tend to be associated with point sources of pollution, and fish caught in industrial and urban areas. Fish from polluted lakes, rivers, and inland seas therefore present the greatest risks. In addition, higher levels may be found in molluscs and crustacean.

7.3.2 Hazard characterization

Lead is absorbed by eating food or drinking water that contains lead. Water pipes in some older homes may contain lead solder, and lead can leach out into the water. Some human toxicity is caused by dust from the use of lead-based paints.

The effects of lead are the same whether it enters the body through breathing or swallowing. Lead can affect almost every organ and system in the body. The main target for lead toxicity is the nervous system, both in adults and children. Long-term exposure of adults can result in decreased performance in some tests that measure functions of the nervous system. It may also cause weakness in fingers, wrists, or ankles. Exposure to high lead levels can severely damage the brain and kidneys and ultimately cause death. High level exposure in men can damage the organs responsible for sperm production.

Children are more vulnerable to lead poisoning than adults. A child who ingests large amounts of lead may develop blood anaemia, severe stomach ache, muscle weakness, and brain damage. Even at much lower levels of exposure, lead can affect a child’s mental and physical growth. Therefore, exposure to lead is more dangerous for young and unborn children. Unborn children can be exposed to lead through their mothers. Harmful effects include premature births, smaller babies, decreased mental ability in the infant, learning difficulties, and reduced growth in young children. Controls are therefore aimed at limiting exposure of lead to pregnant and lactating women, and children.

7.4 Frequency in the Caribbean Region

Several species of fish associated with heavy metal contamination are caught in the marine fisheries of the region. Tuna, shark, swordfish and large demersal fish (groupers and snappers) may be implicated, but there is no data available.

7.5 HACCP Requirements

7.5.1 Critical control points

With sufficient information, fishing operations may be directed to ensure that specimens with a high risk of excessive heavy metal content (based on variables such as species, location, size, season) are not targeted, or that if they are caught they are subject to a sampling and testing regime. Monitoring of raw material inputs therefore provide the typical critical control points.

7.5.2 Monitoring procedures

Sampling of products should be risk based, with a higher proportion of samples taken from species most susceptible to contamination. Heavy metal content should be recorded with information regarding species, size/age of fish, catch location, and season, to allow the operator to build up a picture of the distribution.

Sampling procedures and performance criteria for methods of analysis required by the EC are laid down in COMMISSION REGULATION (EC) No 333/2007 of 28 March 2007, laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons in foodstuffs.

The typical analytical method for all heavy metals uses Atomic Absorption Spectroscopy (AAS). More details are provided in the **Fishery products laboratory testing manual** published separately. Due to the requirement for qualified chemists to prepare samples and operate the equipment, AAS analyses are usually undertaken in specialised laboratories.

7.5.3 Critical limits

Critical limits applied should be the legal maximum limits. The EU has set limits for mercury, cadmium and lead content of different fish species in the Commission Regulation (EC) No 1881/2006 of 19 December 2006, setting maximum levels for certain contaminants in foodstuffs (as amended). Batches of fishery products in which the levels of heavy metal contaminants exceed the maximum limits indicated in the following tables shall be regarded as unfit for human consumption.

TABLE 6: EU MAXIMUM LIMITS OF MERCURY ALLOWED IN FISH FOR HUMAN CONSUMPTION

Substrate	Maximum Limit (ppm) Mercury
Muscle meat of all fish except where indicated below:	0.5
Little tuna (*Euthynnus* spp.) Marlin (*Makaira* spp.) Sail fish (*Istiophorus platypterus*) Rays (*Raja* species) Shark and dogfish (all species) Tunas (*Thunnus* spp, and *Katsuwonus pelamis*) Bullet tuna *(Auxis species)* Swordfish (*Xiphias gladius*)	1.0
Crustaceans (excluding brown meat of crabs and thorax meat of lobsters of the genus *Palinuridae*)	0.5
Bivalve Molluscs	0.5
Cephalopods (without viscera)	0.5

Source: Commission Regulation (EC) No 1881/2006 of 19 December 2006

TABLE 7: MAXIMUM LIMITS OF CADMIUM ALLOWED IN FISH FOR HUMAN CONSUMPTION

Substrate	Maximum Limit (ppm) Cadmium
Muscle meat of all fish except where indicated below:	0.05
Mackerels (Scomber spp) (*Thunnus species,* *Katsuwonus pelamis*, *Euthynnus species)*,	0.1
Bullet tuna *(Auxis species)*	0.15
Swordfish (*Xiphias gladius*)	0.25
Crustaceans (excluding brown meat of crabs and thorax meat of lobsters of the genus *Palinuridae*)	0.5
Bivalve Molluscs	1.0
Cephalopods (without viscera)	1.0

Source: Commission Regulation (EC) No 1881/2006 of 19 December 2006

TABLE 8: MAXIMUM LIMITS OF LEAD ALLOWED IN FISH FOR HUMAN CONSUMPTION

Substrate	Maximum Limit (ppm) Lead
Muscle meat of all fish except where indicated below:	0.3
Crustaceans (excluding brown meat of crabs and thorax meat of lobsters of the genus *Palinuridae*)	0.5
Bivalve Molluscs	1.5
Cephalopods (without viscera)	1.0

Source: Commission Regulation (EC) No 1881/2006 of 19 December 2006

7.5.4 Corrective actions

It is not possible to reduce the heavy metal content of fish. The only control method for this hazard is to cease capture or discard affected species. This requires a detailed knowledge of the variables which affect the distribution of mercury in the catch. Typically, this will involve species, size/age of fish, catch location, and season.

An alternative approach is to direct affected specimens of fish to markets which have higher maximum limits, or less rigorous monitoring requirements. In this case, the exporter should take steps to ensure that consumers who may be at risk (pregnant or lactating women, children) should be informed of the risk of mercury and advised to restrict consumption.

8 RESIDUES OF VETERINARY DRUGS

8.1 Hazard Identification

Most fish is hunted from the wild. Wild populations of fish are generally in good health, since weak or sick specimens die. Production of animals in farming situations requires that animal health be actively managed by the farmer. In the case of fish (and crustacea), as with other animals, this frequently requires the intervention of chemicals to reduce or eliminate infections or parasites, or to achieve specific production objectives, for example in terms of growth rates, or tranquilization (e.g. during transit).

Residues of these chemicals may be present in the final food product prepared from the animal, and in some cases this may present a hazard to the consumer. The specific hazards depend on the biological activity of the compound.

8.2 Hazard characterization

Broadly speaking there are two kind of hazard involved in residues of veterinary compounds:

- toxicity to humans of compounds used in a veterinary context (e.g. carcinogenic properties)
- since human and veterinary medicine share many active compounds (especially antibiotics), exposure of pathogenic bacteria to environmental residues of the medicine may give rise to resistance, thus reducing the scope for the use of compound in human medicine

Specific substances whose use is generally regarded as a food safety hazard for one or both of these reasons when used in food animals, are the following classes of chemotherapeutic treatments.

a) chloramphenicol and derivatives e.g. thiamphenicol (TAF)

b) dimetridazole

c) metronidazole

d) compounds which produce a nitrofuran metabolite

e) anabolic substances for growth promotion purposes

f) malachite green and leucomalachite green

The use of these medicines for animal production is often banned. This is the case for example with the US and EU markets.

8.3 Frequency in the Caribbean Region

These risks are only found in aquaculture production. In the Caribbean, almost all fishery products are harvested from the wild, and aquaculture production is limited to a few locations, and mostly small scale operations. Several countries, such as Belize, Guyana, Bahamas, Jamaica and Suriname have substantive intensive aquaculture production systems, but other countries also have development plans in place.

The general risks within the region are considered to be low, but should be considered and addressed by aquaculture operators. Should there be further investment in aquaculture in future, then the hazards will need to be addressed in a more systematic way.

8.4 HACCP Requirements

8.4.1 Critical control points

The HACCP system should be applied to the production of aquaculture animals, and should be designed to ensure that:

- Unauthorised or prohibited substances are not applied to food animals
- Authorised substances are used in such a way to ensure that their residue levels in foods of animal origin do not exceed the permitted maxima. This means that there should be provision for:
    - Adequate monitoring of storage and stock controls on farm
    - Record keeping of medicinal applications on farm
    - Separation of treated and non-treated animals
    - Holding of treated animals for withdrawal period prior to slaughter
    - Information and communication requirements in respect of animals sold before the end of the withdrawal period.

Critical control points are therefore applied at the level of the farm. Although generally, HACCP plans are not required for primary production, processors and exporters will need to monitor production of farmed fishery products using HACCP principles. Where this is not possible, they

should seek the relevant batch by batch written guarantees of compliance. More details regarding the practical implementation of control requirements for veterinary medicines in aquaculture are set out in the CRFM Manual on Assuring the Food Safety of Aquaculture Products.

8.4.2 Monitoring procedures

Note that the above steps constitute an outline of a residue control system for veterinary medicines, and should be applied at the level of the enterprise, as well as by the Competent Authority, to assess whether the control system is working to prevent contaminated products from the market.

Under Council Directive 96/23/EC of 29 April 1996 "on measures to monitor certain substances and residues thereof in live animals and animal products", there is a requirement for preparation of a Residue Monitoring Programme for products of animal origin. This should include monitoring of the substances set out above. The requirement applies to "aquaculture animals" but not to other fishery products.

Specific guidance on the development of monitoring plans for aquaculture products is provided by the European Commission at:

http://ec.europa.eu/food/safety/chemical_safety/vet_med_residues/index_en.htm

Confirmatory testing should be undertaken by sampling and testing of the consignment. For several substances, which have been expressly prohibited from use in food producing animals in the EU (e.g. chloramphenicol, nitrofurans), or not authorised (e.g. malachite green), the concept of the minimum required performance limit (MRPL) for the testing method has been established in Commission Decision 2002/657/EC implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results. MRPLs are defined as "*minimum content of an analyte in a sample, which at least has to be detected and confirmed*" and are the reference point for action in relation to the evaluation of consignments of food. To date MRPLs have been established for a number of important substances such as chloramphenicol, nitrofuran metabolites and malachite green.

Typically, the analytical method used to obtain these levels of analytical performance is liquid chromatography-mass spectrometry (LC-MS). This is an analytical technique that combines the physical separation capabilities of liquid chromatography (HPLC) with the mass analysis capabilities of mass spectrometry. LC-MS is a powerful technique used for many applications that has very high sensitivity and specificity. Generally, its application is oriented towards the specific detection and potential identification of chemicals in the presence of other chemicals (in a complex mixture).

8.4.3 Critical limits

In relation to substances which are not authorised for use on a farm, the presence of any above the detection limits should be considered to render the product unfit, and such consignments should be destroyed.

In relation to permitted substances, excess levels in the final product render the product unfit.

Typical maximum residue limits of permitted substances are shown in Annex 2 (based on the EU requirements, correct at the time of going to press in 2016). It is important to note that these MRLs are based on the levels which may be expected to be present when the drugs are administered in accordance with good veterinary practices (including withdrawal periods), and may be therefore be varied depending on circumstances.

8.4.4 Corrective actions

Corrective actions will depend on the specific compound, and the stage of production at which the non-compliance is detected. Use of non-authorised compounds at any stage will render the batch unfit for human consumption. It will also be unfit for animal consumption, and should be destroyed. Presence of authorised compounds in excess of the MRL detected in the live animals prior to harvest may be addressed by an extension of the withdrawal period, delaying slaughter. If the fishery product has been harvested, then it should be regarded as unfit for human consumption, but may be used for animal consumption.

9 SODIUM/POTASSIUM METABISULPHITE

9.1 Hazard Identification

A range of sulphite salts are used as a means of controlling melanosis in raw crustacea such as shrimp and lobster. Melanosis is an enzymic deterioration of the shell pigments, which produces a black or grey discolouration of the shell. The reaction is initiated by a naturally occurring enzyme polyphenol oxidase. In the presence of oxygen, this converts monophenols (colourless) to diphenols, which are then converted to highly coloured quinones. Quinones react with amino acids to form complex black/brown pigmented polymers. In severe cases the discolouration can enter the flesh. Being an enzymic process, the development of the pigment is temperature dependent, and it can continue during frozen storage, albeit at a slower rate. The pigment is not harmful to human health, but is commercially unacceptable and affected product is often rejected by the buyer.

Various treatments are applied to prevent this process from occurring. Typically, the raw product is dipped in a solution of sodium or potassium sulphites or bisulphites. Other ways of addressing the problem are through permitted antioxidants such as 4-hexylresorcinol (available in the commercial product EverFresh). Treatment with bisulphites may take place at more than one stage of the process e.g. on the vessel, and before packing. Sulphur dioxide reverses the formation of quinones. As sulphites are consumed in the reaction, repeated treatment is needed. Sulphite is also washed away upon thawing and washing, and therefore re-treatment is required. Peeled shrimp is less susceptible. Sulphites are also a permitted additive for use in bleaching of cephalopod molluscs and dried/salted fish.

The permitted levels of sulphite in the final product are therefore limited by law in many countries. In the EC the levels are set by Directive 2006/52/EC of the European Parliament and of the Council of 5 July 2006 amending Directive 95/2/EC on food additives other than colours and sweeteners, and Directive 94/35/EC on sweeteners for use in foodstuffs. The permitted forms of the additive and limits are shown in Table 9.

TABLE 9: PERMITTED ADDITIVES IN FISHERY PRODUCTS

Permitted additives	Products	Maximum concentration
Sulphur dioxide Sodium sulphite Sodium hydrogen sulphite Sodium metabisulphite Potassium metabisulphite Calcium sulphite Calcium hydrogen sulphite Potassium hydrogen sulphite	Fresh, frozen crustacean and cephalopods	150 mg/kg (as SO_2)
	Cooked crustacean	50 mg/kg (a SO_2)
Triphosphates of sodium and potassium Polyphosphates of sodium, potassium and calcium	Frozen fishery products	5 g/kg

Source: EU Directive 2006/52/EC of 5 July 2006 amending Directive 95/2/EC on food additives other than colours and sweeteners

9.2 Hazard characterization

Inhalation of sulphur dioxide produces sulphuric acid in the lungs and the use of the additive is a hazard to workers.

Those who have asthma are most at risk to sulphite sensitivity and other forms of sulphite reactions. Sulphites are known to increase asthma symptoms in approximately 5% of asthmatics, particularly in adults with severe disease.

Sulphites have also been implicated in an allergic-type reaction. The symptoms of a reaction usually develop quickly (within minutes) and can rapidly progress from mild to severe. The most severe form of an allergic reaction is anaphylactic shock, which can be fatal.

9.3 Frequency in the Caribbean Region

In the Caribbean, sulphites are used in the shrimp and spiny lobster sector, and these products are therefore at risk of showing excessive levels of sulphites. All species which are treated are at risk from excessive levels of this additive. Note that cooked lobster tails may also have a residue of sulphites, but much of the material is volatilised during cooking. Since these products may not be cooked again before consumption the permitted limits shown in Table 10 are correspondingly lower.

9.4 HACCP Requirements

9.4.1 Critical control points

The critical control point in the process is the dipping of the product in the treatment bath. This is where the process conditions should be controlled to ensure that the final product does not contain excessive concentrations of the additive.

Finished product labels for product processed from sulphite-containing raw materials must contain a sulphiting agent declaration.

9.4.2 Monitoring procedures

Monitoring of critical variables should include:

- Strength of solution, bearing in mind that the concentration of the active ions reduces over time and with successive uses. The concentration of the sulphites in the solution should therefore be monitored during use.
- Duration of the dipping in the solution; increased residence time in the solution will result in increased uptake of the additive
- Size of the product; larger specimens will have lower rate of uptake (in terms of ultimate concentration of additive in the final product) than smaller specimens.
- Temperature of the solution; higher temperatures result in more rapid uptake of the sulphite by the product

Periodic monitoring of the effectiveness of the treatment and its controls should be required. Testing for sulphites is by the Optimized Monier William Method (AOAC Official Method 990.28). In this method, a homogenised sample (edible portion only i.e. minus shell) is distilled with hydrochloric acid and heat to release the sulphur dioxide. The distillate is collected for analysis of SO_2 by titration (with standardised NaOH).

Rapid test kits are available as shown in Table 10, which are acceptable for regular monitoring in plant.

TABLE 10: COMMERCIAL TEST PRODUCTS FOR SULPHITES.

Test	Analytical Technique	Approx. Total Test Time	Supplier
Alert for Sulfites [identifies sulfite level in ppm]	chemical reaction with colour change indicator	< 2 min	Neogen Corporation Contact: Jennifer Baker 620 Lesher Pl. Lansing, MI 48912 Phone: +1 800/234-5333; 517/372-9004 E-mail: neogen-info@neogen.com Web: www.neogen.com
Sulfite (E0725854)	Enzymatic	85 min	R-Biopharm, Inc. Contact: Sean Tinkey 7950 US 27 South Marshall, MI 49068 Phone: +1 877/789-3033 E-mail: sales@r-biopharm.com Web: www.r-biopharm.com/

Source: Internet search, 2016

9.4.3 Critical limits

Critical limits should be determined to ensure that the final product complies with the regulatory limits for the type of product specified.

9.4.4 Corrective actions

Where process conditions result in excessive levels of sulphite in the product, then there is a need to modify the process, so as to reduce the concentration, either by reduced concentration of solution or reduced residence time.

10 PRELIMINARY RISK ASSESSMENT

Within the Caribbean region there is only limited epidemiological data on food safety illnesses caused by fishery products. However, a brief qualitative assessment of severity of hazard and the associated level of risk (in relation to an estimated probability of occurrence), can be undertaken and is shown below. The degree of risks is indicated by the colour (red-high, yellow – medium and green-low), and anecdotal evidence suggests that ciguatera and histamine are probably the most serious of the food safety hazards to be addressed in both official and HACCP-based controls.

TABLE 11: RISK AND SEVERITY OF HAZARDS IN CARIBBEAN FISHERY PRODUCTS.

		Severity of hazard		
		High	Medium	Low
Probability of occurrence	High	**1,2**	**4,5**	
	Medium	**3**	**6**	**7**
	Low			**8**

1	**Histamine in *Scomber, Decapterus* spp., Spanish mackerel *Scomberomorus* spp. *Coryphaena* spp., Carangids, Tunas: *Auxis spp. Thunnus* spp & *Euthynnus* spp**
2	**Ciguatera in reef fishes**
3	**Marine biotoxins in shellfish (conch)**
4	**Mercury in grouper/tunas/sharks**
5	**Cadmium in demersal fish/lobsters/swordfish**
6	**Bisulphites in shrimp and lobster**
7	**Residues of veterinary medicines in farmed shrimp/tilapia**
8	**Lead in tuna**

The approach is crude, but the table allows operators and inspectors to focus, and allocate greater resources, on those risk/hazard combinations which have potential to cause greater damage, i.e. towards the top left of the table. These hazards are the most serious and most likely to occur in the region.

The hazard and risk combinations towards the bottom right of the table can be considered to be lower priority, and therefore not as demanding in terms of the technical resources required for their control.

However, this approach should not be applied to risk profiling of fishery products to the region. The food safety risks (in terms of severity and frequency of hazard) are highly specific to the origin, and each country should be subject to an independent assessment of the food safety risks.

ANNEX 1: FURTHER READING

This guide is based on a number of different sources of information. These are listed below, and may be consulted for additional information regarding the nature and characterisation of the different hazards identified.

Seafood inspection and control

Fish and Fisheries Products Hazards and Controls Guide
U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition
Third Edition June 2001

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm

Manual/Handbook for the Execution of Sanitary Inspection of Fish as Raw Material and Fish-Products as Food for Human Consumption, Strengthening Fishery Products

Health Conditions In ACP/OCT countries, Secretariat of the ACP Group of States

SFP-ACP/OCT Management Unit, REG/70021/000

http://www.megapesca.com/files/manual.rar

Source: FAO FISHERIES TECHNICAL PAPER 462 "A primer on risk assessment modelling: focus on seafood products" by Aamir M. Fazil, Food and Agriculture Organization Of The United Nations, Rome, FAO 2005

http://www.fao.org/docrep/009/a0238e/A0238E01.htm

EU Legislation:

COMMISSION REGULATION (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:338:0001:0026:EN:PDF

COMMISSION REGULATION (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1881&from=en

Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.

http://ec.europa.eu/health/files/eudralex/vol-5/reg_2010_37/reg_2010_37_en.pdf

ANNEX 2: SOME TYPICAL MRLS OF VETERINARY MEDICINES USED IN AQUACULTURE

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target tissues	Other provisions	Therapeutic Classification
Cloxacillin	Cloxacillin	All food producing species	300 µg/kg 300 µg/kg 300 µg/kg 300 µg/kg 30 µg/kg	Muscle Fat Liver Kidney Milk	For fin fish the muscle MRL relates to 'muscle and skin in natural proportions'. MRLs for fat, liver and kidney do not apply to fin fish. Not for use in animals from which eggs are produced for human consumption.	Anti-infectious agents/Antibiotics
Emamectin	Emamectin B1a	Fin fish	100 µg/kg	Muscle and skin in natural proportions		Antiparasitic agents/ Agents acting against endo- and ectoparasites
Deltamethrin	Deltamethrin	Fin fish	10 µg/kg	Muscle and skin in natural proportions.		Antiparasitic agents/ Agents against ecto parasites
Erythromycin	Erythromycin A	All food producing species	200 µg/kg 200 µg/kg 200 µg/kg 200 µg/kg 40 µg/kg	Muscle Fat Liver Kidney Milk	For fin fish the muscle MRL relates to 'muscle and skin in natural proportions'. MRLs for fat, liver and kidney do not apply to fin fish.	Anti-infectious agents/Antibiotics

			150 µg/kg	Eggs		
Flumequine	Flumequine	Fin Fish	600 µg/kg	Muscle and skin in natural proportion.		Anti-infectious agents/Antibiotics
Oxolinic acid	Oxolinic acid	All food producing species	100 µg kg 50 µg/kg 150 µg/kg 150 µg/kg	Muscle Fat Liver Kidney	For fin fish the muscle MRL relates to 'muscle and skin in natural proportions'. MRLs for fat, liver and kidney do not apply to fin fish. Not for use in animals from which milk or eggs are produced for human consumption.	Anti-infectious agents/Antibiotics
Oxytetracycline	Sum of parent drug and its 4- epimer	All food-producing species	100 µg/kg 300 µg/kg 600 µg/kg 100 µg/ kg 200 µg/kg	Muscle Liver Kidney Milk Eggs	For fin fish the muscle MRL relates to 'muscle and skin in natural proportions'.	Anti-infectious agents/Antibiotics

Source: Commission Regulation (EU) No 37/2010 of 22 December 2009