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Manual on Assuring the Food Safety of Aquaculture Products



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Manual on Assuring the Food Safety of Aquaculture Products

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GLOSSARY OF TERMS

Approval	Official recognition that the health conditions in a vessel, or establishment meet regulatory requirements.
Aquaculture	The managed production in artificial enclosures of aquatic organisms used for human consumption, and includes the production of intermediate stages of the life cycle including eggs and larval stages of fish, crustacean and molluscs. It does not include the holding of live animals for short periods for the purpose of collecting for market or for purification.
Competent Authority	The central authority of a Member State (within the EU), or central national authority in any country, with authority to carry out sanitary checks and certify compliance.
Disinfection	The application of hygienically satisfactory chemical or physical agents and processes to clean surfaces with the intention of eliminating micro-organisms.
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.
Hygiene	General food safety conditions, including contaminants and other food safety hazards that may be found in fish and fishery products.
Inspection	The official examination of establishments, of animals and food, and the processing thereof, of food businesses, and their management and production systems, including documents, finished product testing and feeding practices, and of the origin and destination of production inputs and outputs, in order to verify compliance with the legal requirements in all cases.
Inspector	An official agent authorized by the Competent Authority to perform the duties of inspection in order to ensure food safety.
Risk	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
Traceability	The ability to trace and follow a fishery product, or other substance intended, or expected to be incorporated into a fishery product, through all stages of production, processing and distribution.
Withdrawal period	The minimum time before harvest during which treatment with a veterinary medicine must cease, to ensure that any residues of veterinary medicines in the edible parts of the aquaculture product are within the limits established for the safety of the consumer

LIST OF ABBREVIATIONS

CAC	Codex Alimentarius Commission
CARIFORUM	Grouping of 15 Caribbean Community states, along with the Dominican Republic
CRFM	Caribbean Regional Fisheries Mechanism
EDF	European Development Fund
EU	European Union
FAO	Food and Agriculture Organisation of the UN
FDA	Food and Drug Administration
HACCP	Hazard Analysis and Critical Control Point
MRL	Maximum Residue Limit
OIE	World Animal Health Organisation (Office International des Epizooties)
PCB	Polychlorinated Biphenyl
US	United States
UV	Ultra Violet
WHO	World Health Organisation
WTO	World Trade Organisation

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 operational manual 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 the national and regional levels for health and food safety requirements of fisheries and aquaculture (inland, marine) products, which 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 a structured approach to training in field, laboratory, market, and trade (import and export) activities related to the safety of fish and fish products for human consumption. The strengthening of sanitary conditions throughout the region is expected to lead to improved health and well-being of national populations, and increased international trade in fishery products.

1.2 About this manual

This document provides guidance for the production of safe aquaculture products produced within the Caribbean region. It concentrates exclusively on the hazards to human health which may arise in aquaculture production and harvesting, and the measures and systems which can be applied to minimise the probability of injury to consumer health.

The manual applies to aquaculture operations in freshwater, brackish water, or marine waters, and is applicable to finfish and crustacean production systems for human consumption. It applies equally to hatchery operations producing juveniles and to grow-out units. Whilst the general principles are applicable to aquaculture operations growing or relaying molluscan shellfish, it should be remembered that different requirements apply to the control of marine biotoxins, which are not addressed in this manual. These hazards are described in more detail in the Guide to Food Safety Hazards in Caribbean Fishery Products.

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 manual therefore provides up to date advice on the design and operation of aquaculture operations, with a view to minimizing the risks of hazards being present in the final product delivered to the consumer. It responds to a need to extend good practices within the region for a sustainable fishery sector, which can only be achieved with production that meets food safety requirements. In this respect, it recognises that the responsibility for food safety falls on the aquaculture business operator to apply a risk-based approach, and ensure safe products. The approach adopted focuses on monitoring of food safety conditions at all stages of the supply chain. In the case of aquaculture, this means a significant focus on inputs such as feeds and veterinary medicines, and these are explicitly addressed.

The manual reflects up to date approaches in aquaculture practices. The contents are coherent with the 2004 “food hygiene package” of EU legislation, which brings into full effect all of the food safety policies proposed in the 2000 White Paper on Food Safety. They are also in line with the

US Food Safety Modernisation Act of 2011. The manual also takes into account the Codex Code of Practice for Fish and Fishery Products (Codex Standard CAC/RCP 52-2003).

Aquaculture operations should implement aquatic animal health management programs set up in compliance with relevant national legislation and regulations, and with the OIE (World Organization for Animal Health) Codes of Practice (OIE Aquatic Animal Health Code, 15th Edition, 2012).

1.3 How to use the document

The manual is applicable on two levels. Firstly, it will aid aquaculture operators to design production facilities, and the management systems required to operate them. Operators adopting the recommendations set out in the manual can expect to meet international requirements for food safety. Secondly, on the level of inspectors from Competent Authorities, the manual provides a useful guide to be followed in setting up, undertaking, reporting and following up of inspections of aquaculture establishments.

The manual promotes a risk-based approach to food safety inspections, which addresses not only basic hygienic requirements, but also establishes that process variables which determine the characteristics of the final product are under effective control by the fishery business operators (i.e. based on the principles of Hazard Analysis and Critical Control Point). For this reason, the guide should be read in conjunction with the CRFM Guide to Food Safety Hazards in Caribbean Fishery Products, which sets out the specific scientific control measures for some of the major hazards encountered in the region's fishery products, and includes a specific section on the control of veterinary residue hazards in aquaculture.

It should be noted that the term fish, used in the context of this manual, includes fish, crustaceans and other aquaculture products, but does not include plants, such as marine algae.

2 POTENTIAL HAZARDS IN AQUACULTURE

2.1 Biological Hazards

Contamination of fish with pathogenic bacteria from the aquatic environment is a hazard in all fisheries. The level of contamination of fish at the time of capture will depend on the bacteriological quality of the water in which fish are harvested. Many factors will influence the microflora, the more important being water temperature, salt content, proximity of harvesting areas to human habitations, quantity and origin of food consumed by fish, and method of harvesting. The edible muscle tissue of finfish is normally sterile at the time of capture, but bacteria are usually present on the skin, gills and in the intestinal tract.

Examples of indigenous bacteria naturally present on fish which may pose a human health hazard are *Vibrio* species such as *V.parahaemolyticus*, *V.cholerae*, *V.vulnificus*, which are common in coastal and estuarine environments. Non-indigenous bacteria of public health significance (arising from contamination from a faecal origin) include members of the Enterobacteriaceae, such as *Salmonella* spp., *Shigella* spp., and *Escherichia coli*. Hazards from these pathogens can be controlled by harvesting fish from clean waters, holding fish at chilled temperatures, avoiding post-process cross-contamination, and by cooking fish sufficiently to kill the bacteria.

In some regions of the world, freshwater fish species are susceptible to helminth parasitic infections of public health significance. Cestodes and trematodes are particularly implicated. According to the WHO, at least 56 million people globally suffer from one or more food-borne trematodiasis, mostly caused by the consumption of raw fish or crustaceans which harbour the parasite larvae. These parasitic infections can result in severe liver and lung disease. They are most

prevalent in East Asia and South America, but cause substantial public health problems only in Asia, where there is a habit of raw fish consumption. However, freshwater aquaculture operations in some countries in the Caribbean region can present these risks, and it is appropriate to apply good practices to reduce the risk of occurrence (for example by restricting access of animals, and keeping ponds free of snails which provide intermediate hosts).

2.2 Chemical hazards

Aquaculture products may be harvested from coastal zones and inland habitats that are exposed to varying amounts of environmental contaminants. Of greatest concern are fish harvested from inland and estuarine areas. Agrochemicals and heavy metals may accumulate in products that can cause public health problems.

Aquaculture feeds are another source of potential chemical hazards. Feeds and feed ingredients such as grains are particularly susceptible to mould growth if not properly stored. There is a risk that carcinogenic mycotoxins, such as aflatoxins produced by the fungus of the genus *Aspergillus*, could be present in the fish if the feed storage is not properly managed.

Furthermore, intensive systems for aquaculture production may promote infectious diseases, which kill or reduce growth rates. In some cases, there may be a need to treat the fish with anti-fungal or antibiotic agents. Residues of these drugs in the product may harm the consumer, since they can be toxic, allergenic, or increase resistance to antibiotics. There is a need to control their application, and to observe a withdrawal period between application and harvesting. Good practices can ensure that, even if the aquaculture operation uses veterinary medicines during the production cycle, the resulting product is safe for consumption.

3 SITE LOCATION DESIGN AND CONSTRUCTION

3.1 Location

Aquaculture and freshwater fisheries activity should be located in areas where the risk of contamination with hazardous chemical effluents is minimal, and where sources of pollution can be controlled. This means that they should be sited at a safe distance from potential sources of water contamination in order to ensure protection of products. Sources could include:

- industry and mining
- intensive agriculture (especially animal husbandry)
- sewage outfalls
- densely populated areas or urban area
- hospitals
- major roads and railways

Before building a land-based aquaculture facility, a survey of the soil should be conducted in order to determine the concentration and extent of any contaminants of importance for the safety of end products, including heavy metals and pesticide residues. Such an analysis is often a legal condition of the licensing required for new aquaculture activity. Water quality should be monitored periodically thereafter, to check that water remains free of any of these potential hazards.

Cages, pens or any other form of aquaculture enclosures or water intakes should be sited away from routes of water-borne traffic, and upstream of any natural or man-made discharges of contamination.

3.2 Farm layout and design

3.2.1 Layout of aquaculture facilities

The farm should be laid in such a way that water intakes cannot be contaminated by outflow or any other activity on the farm or in the locality.

Areas such as engineering workshops, fish health laboratory, offices, sanitary facilities, and domestic accommodation, should be located separately from areas in which fish is produced and handled, and where feed is stored.

3.2.2 Materials used

Materials used in the construction of enclosures such as tanks, cages and raceways should be non-toxic and approved for use in contact with animals for human food. Particular care should be taken in selecting any anti-fouling materials applied to inhibit the growth of algae.

3.2.3 Provision of sanitary facilities

The aquaculture establishment should be provided with reasonably accessible sanitary facilities available for the use of people working in the enterprise. This should include toilets and hand washing facilities.

Sanitary facilities should not be located in the proximity of aquaculture production, tanks or ponds, feed storage, or where fish are harvested or handled.

Wherever feasible, toilets should be water flushing. However, earth closet facilities are acceptable, providing that they are properly managed.

Waste water from sanitary facilities should be piped away from aquaculture facilities, and should undergo at least primary treatment (sedimentation) and meet environmental standards before discharge. It should not discharge to a water course upstream of any intake which supplies water to the aquaculture facility.

The minimum of facilities depends on the number of staff of each sex at the site, according to the following table:

Number of employees	Minimum number of toilets
01 – 09	1
10 – 24	2
25 – 49	3
>50	for every 30 persons add 1 toilet

There should be at least one wash basin for every toilet, and an adequate supply of single use towels or appliances for drying the hands.

Cuts and abrasions to workers' hands can harbor bacteria. To minimize the risk of contamination of the product, the aquaculture facility should be provided with a first aid box, which should contain a sufficient quantity of impermeable dressings, antiseptic cream or disinfectant, cotton wool and adhesive tape.

3.2.4 Provision of secure facilities for chemicals

The facility should have separate lockable storage areas for a) cleaning and sanitizing materials; b) pest control materials; and c) aquaculture medicines.

4 FEEDS AND FEED MATERIALS

Many different materials of plant and animal origin, plus synthetic supplements, are used for feeding of fish in aquaculture production. Feed is one of the major cost elements in the aquaculture production. The choice of feed, its formulation, and feeding regime, are important to ensure efficient food conversion and healthy fish. However, for the purposes of this manual, the most important consideration is to ensure that feed does not include any substance or contaminant which could result in the aquaculture product becoming unsafe for human consumption. This section sets out some of the simple rules which should be observed

4.1 Sources of material for feed

Slaughterhouse waste and offal from other food animals, including fish processing waste, can be contaminated with pathogenic bacteria which should not be introduced to the farm environment. Such products should only be used as a food for fish if they are first cooked.

Similarly, so-called “trash fish” (bycatch from capture fishing) or fish offal from processing factories, which may be used as a fish feed in some locations, should be cooked before use.

Compound feeds should be purchased from reputable operators, who monitor their incoming ingredients for mycotoxin levels. The supplier should provide documentation describing the composition in terms of the nature of materials included, such as fishmeal, soybean meal, wheat bran etc. rather than just proximate analysis such as percentage of protein, fat etc. The compositional information should describe any supplements added by the manufacturer.

Compound feed treated with veterinary medical supplements (including hormones and antibiotics but excepting vitamin supplements), are considered to be veterinary medicines to which Section 6 of this manual applies. Labelling of medicated feeds should clearly identify them as such.

4.2 Feed storage facilities

Most aquaculture operations need to store feed onsite. The feed store should be in a properly constructed and well-ventilated facility, protected from the entry of insects, birds and rodents. It should have a concrete floor.

Feed should be stored in suitable sacks or bags or, if stored in bulk, in sealable containers or bins.

Sacks or bags containing feed should not be in contact with the floor or walls, and spaces should be left to allow for effective ventilation. This helps to prevent spoilage, mould growth and contamination.

Moist feed should be properly refrigerated according to manufacturer instructions.

Containers, sacks, bins etc. used to store feed, should be labelled in such a way as to identify the origin and batch of the feed they contain.

Stocks of feed should be rotated on a first-in, first out basis. They should be used prior to the expiry of any indicated shelf-life date.

4.3 Compositional regulatory requirements

Feed ingredients should not contain unsafe levels of pesticides, chemical contaminants, microbial toxins, or other adulterating substances. They should contain only permitted additives, such as preservatives, colours, and anti-oxidants. In some locations, feed suppliers must submit samples

of their products for official testing before they can be registered. This can be confirmed by checking with the official veterinary authority.

In general, the use of aquaculture feeds and their management should comply with the Codex Code of Practice on good animal feeding (Codex Standard CAC/RCP 54-2004).

For operators supplying aquaculture products for the EU, the precise requirements regarding contaminants are set out in Directive 2002/32/EC of the European Parliament, and of the Council of 7 May 2002, on undesirable substances in animal feed. The associated sampling and testing requirements are set out in Commission Regulation (EC) No 152/2009 of 27 January 2009 “laying down the methods of sampling and analysis for the official control of feed”. The Commission has also published guidance notes on sampling and testing of animal feeds to check compliance¹.

5 HYGIENIC AQUACULTURE OPERATIONS

5.1 Preparation for stocking

Where fish are cultured in earth ponds, weeds, rubbish and debris should be removed before preparing aquaculture ponds for filling with water. Ponds should be conditioned with lime and left for a period of at least two weeks before filling and stocking. At least once each year, after harvesting, the pond should be drained, allowed to dry out and re-conditioned with lime. Lime ensures that any eggs, larvae and cysts of parasites are killed, along with any snails, insects or other potential parasite hosts. As well as protecting human health, this treatment also helps to prevent the transmission of fish diseases within the farm.

Untreated animal manures should not be used for fertilizing of ponds (to encourage algal growth). Only chemical fertilizers or properly treated organic manure should be used.

5.2 Personal hygiene

To minimise the risk of contamination, workers should maintain a reasonable standard of personal hygiene, and should take all necessary precautions and actions to prevent the contamination of the aquaculture products. Any cuts or wounds on hands and forearms should immediately be covered by a suitable water-proof dressing or gloves.

Persons suffering from infectious diseases, or from a helminthic parasitic infection, who have infected wounds, boils or other skin infections, or who are suffering from diarrhoea, should not be permitted to work in an aquaculture operation. Workers should not suffer financial loss for reporting such conditions, otherwise they will have an incentive to conceal them.

Personnel who work in aquaculture operations should, on their appointment and at yearly intervals thereafter, undertake a health test to ensure that they do not suffer from any of the above conditions. These health documents should be kept at the facility and be available to the competent authority on request.

Workers (and any person entering an aquaculture establishment) should refrain from spitting, eating food, urinating or defecating, except in locations designated for these purposes, which must be away from production areas.

¹ See: http://ec.europa.eu/food/safety/docs/animal-feed-guidance_documents_691_2013_en.pdf

5.3 Harvesting operations

Harvesting of farmed fish, crustaceans and other aquaculture products (whether for transport alive or dead) should be undertaken in a manner that minimizes potential contamination with chemical or microbiological hazards.

Harvesting should be conducted quickly, and at such times of day as to reduce the exposure of fish to ambient temperatures.

Equipment used in harvesting (e.g. nets, traps, boxes, grading and sorting tables, conveyors) should be non-toxic, smooth, impervious, easy to clean, and kept in good condition. It should be regularly washed during use to reduce the accumulation of fish slime, blood, scales, and guts, and to reduce the risk of physical and microbial contamination. Run off from equipment washing should not be allowed to enter the aquaculture pond where fish are held.

If the harvesting results in aquaculture products contaminated with mud, detritus or vegetation, this should be removed and, if appropriate, the fish should be washed in clean water (freshwater or seawater).

Equipment used in harvesting should be washed and disinfected after use.

Containers for offal, waste material, dead fish, should be available and clearly identified. They should be constructed of impervious materials, be easy to clean, and have a lid which can be sealed to prevent the entry of vermin. They should be kept clean.

5.4 Post-harvest handling of fish

If any post-harvest treatment is applied (for example dipping of shrimp in a bath of sodium metabisulphite to prevent black spot) this should be permitted, and undertaken in accordance with relevant good practices.

The fish should be chilled as soon as possible, using an adequate quantity of ice. The temperature of the fish should reach 0°C as quickly as possible, and this temperature should thereafter be maintained throughout storage and distribution.

If harvested fish is stored at the facility before despatch to market or processing, the storage should be in a dedicated facility that meets minimum standards of hygienic design and construction for fish storage and processing facilities. These are set out in the CRFM Manual on Assuring Food Safety Conditions in Fish Landing and Processing.

Ice used for chilling of aquaculture products should be made from potable water. If water from a borehole or surface water supply is used on site, it should be subject to chlorination or other method of ensuring its microbiological safety (such as UV sterilization).

If ice is transported to the farm in vehicles, these should meet the requirements set for transport vehicles below. Typically, a vehicle will bring ice to the farm and return with fish on ice.

Any facilities for the storage of ice on the farm should meet the same requirements for minimum standards of hygienic design and construction as those for fish storage and processing facilities, as set out above.

After harvest, the fish must be packed, stored, and transported under conditions that minimize the potential for contamination and growth of microbial pathogens.

Fish should be stored and transported under temperature-controlled conditions.

If re-usable boxes are used to transport fish, the aquaculture operator should have access to facilities for washing and sanitizing them.

5.5 Cleaning, disinfection and pest control

5.5.1 Hygiene conditions

The aquaculture facility should be kept clean, and free from rubbish, waste, dead fish, packaging materials and other items not required.

All equipment, tanks, boxes etc. which come into contact with fish should be cleaned and disinfected regularly, at least after each use.

Domestic and farm animals, including guard dogs, should be excluded from access to areas adjacent to ponds where fish is grown or feed is stored.

The facility should have a sanitation management plan which sets out cleaning and disinfection schedules, monitoring and record-keeping procedures and corrective actions.

5.5.2 Cleaning and Disinfection Schedule

A permanent cleaning and disinfection schedule should be drawn up and displayed, to ensure that all parts of the fish farm facilities and equipment are cleaned appropriately and regularly.

The schedule should detail the cleaning procedures, and the use of appropriate detergents for the removal of dirt, grease and other materials which could harbour contamination. It should also describe the use of sanitising agents to kill or inactivate microorganisms.

As well as food safety considerations, the selection of appropriate cleaning and sanitizing chemicals should take into account their toxicity for fish which might come into contact with their residues.

The schedule should define the permitted cleaning and disinfecting materials and equipment and the methods of their use. Named person(s) should be responsible for implementation of the schedule.

The implementation of the schedule should be recorded on a checklist. The schedule and completed checklists should be available for inspection by the competent authority at all times.

Fish farm personnel should be trained in the use of cleaning equipment, methods of dismantling equipment for cleaning, and the procedures to be used in cleaning and sanitizing.

5.5.3 Pest Control Systems

A permanent pest control schedule should be drawn up and displayed, to ensure that all parts of the aquaculture facilities, including the feed store, remain free from infestations of insect and rodent pests.

The schedule should detail the pest monitoring and control procedures, and the use of appropriate pest control devices and materials.

Named person(s) should be responsible for implementation of the schedule, which should be recorded on a checklist. The schedule and completed checklists should be available for inspection by the competent authority at all times.

If the pest control is undertaken by fish farm personnel, they should be trained in the appropriate methods, including the safe disposal of used materials and dead pests. Otherwise a properly authorised contractor should be hired.

6 USE OF VETERINARY MEDICINES IN AQUACULTURE

6.1 Need for veterinary medicines

Fish and crustacea grown in aquaculture conditions can be susceptible to a range of bacterial, parasitic, viral and fungal infections. Examples are furunculosis, exoparasitic lice, kidney and gill diseases. Various veterinary interventions may be applied, either as a prophylactic or as therapeutic measures, to maintain good fish health. However, such compounds have the potential to leave residues in the product, which then enter the human food supply, and can impact on the health of consumers.

The use of veterinary medicines (including medicated feeds) in fish, as in other food animals, is therefore subject to regulatory controls to ensure the safety of the final products. Failure to comply with the requirements can result in unsafe products reaching the consumer, rejections, and prosecution for the operator.

6.2 Permitted and banned substances

A modern regulatory regime for drug use in food animals will typically contain two lists.

The first list will be banned substances, whose use in food animals including fish is prohibited, either due to the toxicity of their residues, or the risk of development of resistant strains of bacteria in the human population.

In particular, a number of common compounds are not generally permitted, although they have been, and continue to be used extensively in some countries. Chloramphenicol and nitrofurans antibiotics are banned for use in food production in all countries, due to the risk of resistance developing in bacterial populations, which would reduce the effectiveness of human medical applications. Malachite green and associated compounds are common dyes that have been used for a disinfectant bath in aquaculture. However, they leave carcinogenic residues in the fish and are also banned. Other banned substances (in the EU) include dimetridazole, metronidazole, and anabolic substances administered for growth promotion purposes².

Permitted veterinary medicines are given in the second list. This will also establish the safe limits (the maximum residue level) permitted in the final product sold for consumption, and any conditions of use (for example restricted to certain species or applications, such as immersion, injection or oral delivery).

The regulatory requirements are not the same for all markets, since animal health controls are established based on need, taking into account the national animal health status and disease risks, which should be managed in balance with the interests of consumers. The approach to ensuring an appropriate and WTO compliant regime for veterinary medicine controls is set out in the OIE Aquatic Animal Health Guide (see Annex I for the full reference).

Aquaculture operators serving export markets should be aware of the limits applicable in the market to which they are exporting. Some control regimes are stricter than others. Codex Alimentarius Standards only recognise one permitted veterinary medicine for general aquaculture use (oxytetracycline)³.

For aquaculture operators supplying the US market, the list of approved aquaculture drugs by the U.S. Food and Drug Administration is available at:

² Although other applications of anabolic substances, such as sex reversal, are permitted (for example use of methyl testosterone in tilapia hatchery operations)

³ See Codex Veterinary Drug Residue in Food Online Database; <http://www.fao.org/fao-who-codexalimentarius/standards/veterinary-drugs-mrls/en/>; emamectin and flumequin are permitted in trout.

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/Aquaculture/ucm132954.htm>

For the EU market, operators should refer to 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/mrl/mrl_20101212_consol.pdf.

Some examples of permitted compounds are provided in Annex 2.

6.3 Ensuring safe use of veterinary medicines

The safe use of veterinary medicines requires that operators follow recommended procedures for their prescription, storage, application, and monitoring. Some of the key controls are described here, but more details are provided in the OIE Aquatic Animal Health Guide.

6.3.1 Distribution of veterinary medicines

Specific veterinary products and preparations should be registered and approved by the appropriate national authority. Registration will usually require an analysis of the preparation, which ensures that only permitted active compounds are placed on the market.

The registration process should include a list of authorised applications. Veterinary therapeutic products, and medicinal pre-mixes for inclusion in fish feeds, should therefore be specifically approved by the national competent authority for use in aquaculture production.

Veterinary medicines should be obtained only from authorised veterinary pharmacies or suppliers. Under no circumstances should aquaculture operators procure drugs for human use and apply them to their animals.

6.3.2 Storage conditions

Storage and transportation conditions for therapeutic agents should follow the manufacturer's instructions.

Any storage of veterinary medicines on the farm should be in locked facilities, with a named key-holder. A written record of stock control should be maintained.

6.3.3 Prescription and application of veterinary medicines

Control of diseases with drugs should be carried out only on the basis of a professional diagnosis.

Veterinary medicines should be prescribed or distributed only by the persons permitted to do so under national legislation, such as a qualified veterinarian or fish health specialist.

In all circumstances, fish which are undergoing a veterinary drug treatment should be kept separate from those which are not (or which are subject to a different regime).

Veterinary drugs or medicated feeds should be used according to manufacturer's instructions. Note should be taken of all warning statements and contra-indications for use, particularly in relation to withdrawal periods.

The withdrawal period is the minimum time before harvest during which treatment with a veterinary medicine must cease, to ensure that any residues of veterinary medicines in the edible parts of the aquaculture product are within the limits established for the safety of the consumer,

A written record of veterinary applications should be made. This should record every application of drugs and other chemicals, and should include the treatment start date, treatment stop date, compound used, reason(s) for use, dose, identity of ponds or cages where the drug was applied, and harvest date for the treated ponds or cages.

The entries in the register should be signed by the veterinarian, or fish disease specialist responsible for administering the drug programme.

6.3.4 Harvesting and Withdrawal Period

Withdrawal periods under different conditions for each veterinary medicine used, and for each species to which it is applied, must be established by the operator of the aquaculture establishment and recorded in the register.

Aquaculture products must not be harvested before the end of the withdrawal period. At the end of the withdrawal period, and before harvest, consideration should be given to drawing a sample of treated fish for analysis of the residue level, to check that it does not exceed the permitted limit (the maximum residue level – MRL).

For those fish tested with drug residue concentrations above the MRL (or, in some countries, by an industry imposed lower level), harvest of the batch should be postponed until the batch complies with the appropriate MRL.

The amount of any veterinary drug residue in the harvested aquaculture product must not exceed any maximum residue limit specified. If MRLs are persistently exceeded after the withdrawal period, then consideration should be given to changing the treatment protocol or extending the withdrawal period.

If aquaculture products which are treated with a veterinary medicine are sold live for on-growing before the end of the withdrawal period, then the buyer must be informed in writing by the seller of the treatment applied, the last date of treatment and the date of termination of the withdrawal period.

6.3.5 Requirements for marketing

When aquaculture products are consigned to market for human consumption, the receiver may seek a written guarantee that either no veterinary medicines have been applied or, if they have been applied, that minimum withdrawal periods have been observed for the named medicines

It is good practice for the receiver, irrespective of any guarantees, to undertake his own checks on the raw material to ensure:

- a) that the consignment does not contain fish to which undeclared drug treatments have been administered
- b) where veterinary medicines have been applied, that minimum withdrawal periods have been observed and maximum residue limits are not exceeded
- c) that no prohibited substances are present

7 RESIDUE MONITORING PROGRAMMES

A residue monitoring programme is a series of sampling and testing activities, followed eventually by corrective actions, that provides information regarding the effectiveness of the controls applied.

The Competent Authority should implement a national annual residue monitoring programme, with the objective of assessing the extent of the compliance of aquaculture establishments with the regulatory provisions regarding veterinary medicines. In the case of exports to the EU market, this regime must follow the requirements set out in Council Directive 96/23/EC of 29 April 1996, on measures to monitor certain substances and residues thereof in live animals and animal products.

Residue monitoring can also be a series of routine checks undertaken by an aquaculture operator, to confirm that internal controls on the use of veterinary medicines are effective.

7.1 Sampling requirements

For aquaculture animals, the residue monitoring has two objectives. The first is to establish whether there has been any use of banned substances. Therefore, samples are drawn throughout the production cycle (fish feed, eggs, larvae, juveniles, grow-out, and market). Samples may include organs (liver and kidney), and tests are conducted with a view to detecting the presence of any banned substance at any level. In the EU these are termed Group A (anabolic and unauthorized substances).

The second objective is to check that permitted substances have been applied correctly (for example observance of withdrawal periods) and therefore samples are drawn from market-size and harvested fish, and tests conducted on edible portions (skin and muscle), to establish compliance with the MRL. In the EU regime, these are termed Group B (veterinary drugs and contaminants). The compounds falling within Groups A and B are shown in the box below.

For official sampling for a national residue monitoring programme by a Competent Authority, the sampling regime should be designed to take account of the pattern of usage of veterinary medicines in the sector. If there are known health issues, and a chemotherapeutic response is typically applied in one sector more than others, then the sampling rates should be skewed (i.e. biased) to that sector. In some cases, samples for both purposes can be drawn from the same farm.

For official sampling for a national Residue Monitoring Programme the requirements as required by the EU are set out in the box.

EU Requirements for sampling for residue monitoring programme

I. Finfish farming products

A sample is one or more fish, according to the size of the fish in question, and of the requirements of the analytical method.

Member States must respect the minimum sampling levels and frequencies given below, depending on the production of farmed fish (expressed in tonnes).

The minimum number of samples to be collected each year must be at least 1 per 100 tonnes of annual production.

The compounds sought, and the samples for analysis, should be selected according to the likely use of these substances.

The following breakdown must be respected:

Group A: one third of the total samples: all the samples must be taken at farm level, on fish at all stages of farming including fish ready to be placed on the market for consumption.

Group B: two thirds of the total samples, the sampling should be carried out:

- (a) preferably at the farm, on fish ready to be placed on the market for consumption;
- (b) either at the processing plant, or at wholesale level, on fresh fish, on condition that, in the event of positive results, the fish can be traced back to the farm of origin.

In all cases, samples taken at farm level should be taken from a minimum of 10 % of registered sites of production.

2. Other aquaculture products

When Member States have reason to believe that veterinary medicine or chemicals are being applied to other aquaculture products, or when environmental contamination is suspected, then these species must be included in the sampling plan, (in proportion to their production) as additional samples to those taken for finfish farming products.

- (1) For sea-farming, in which sampling conditions may be especially difficult, samples may be taken from feed in place of samples from fish.

Source: Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products

Additional detailed sampling procedures required by the EU are set out in Commission Decision 98/179/CE of 23 February 1998, laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products

7.2 Monitoring Parameters

The monitoring should identify and quantify the relevant parameters. The Box below sets out the standard monitoring parameters required to meet EU requirements, in terms of the implementation of an official residue monitoring plan. For own checks, an aquaculture operator can adapt this to meet specific requirements.

GROUP A — Substances having anabolic effect and unauthorized substances

- (1) Stilbenes, stilbene derivatives, and their salts and esters
- (2) Antithyroid agents
- (3) Steroids
- (4) Resorcylic acid lactones including zeranol
- (5) Beta-agonists
- (6) Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990

GROUP B — Veterinary drugs and contaminants

- (1) Antibacterial substances, including sulphonamides, quinolones
- (2) Other veterinary drugs
 - (a) Anthelmintics
 - (b) Anticoccidials, including nitroimidazoles
 - (c) Carbamates and pyrethroids
 - (d) Sedatives
 - (e) Non-steroidal anti-inflammatory drugs (NSAIDs)

- (f) Other pharmacologically active substances
- (3) Other substances and environmental contaminants
 - (a) Organochlorine compounds including PCBs
 - (b) Organophosphorus compounds
 - (d) Chemical elements
 - (d) Mycotoxins
 - (e) Dyes
 - (f) Others

Source: Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products

For the EU market, a few of the MRLs applicable to typical Caribbean aquaculture products are shown in Annex 2. For more details and up to date MRLs, the reader should refer to Commission Regulation (EU) No 37/2010 of 22 December 2009 and subsequent amendments.

It should be noted that, for the detection of Group A substances in the frame of an official residue monitoring programme in compliance with EU requirements, there are minimum performance criteria specified for the laboratory tests conducted⁴. More details are provided in the CRFM Guide to Food Safety Hazards in Caribbean Fishery Products.

7.3 Follow up and reporting on residue monitoring

Results from residue monitoring that indicate the presence of a banned substance, or that permitted substances are present in excess of predetermined MRLs, indicate a failure in the control system. In all cases they should be followed up to determine the cause, and the conditions giving rise to the non-compliance should be corrected.

If non-compliant products are detected and have not been released to the market, then appropriate control measures should be applied. In the case of detection of banned substances, the affected batch(es) should be destroyed. They cannot be used for animal feed since they contain banned substances.

In the case of residues in excess of the MRL, if the fish are alive, the withdrawal period can be extended to allow the residues to be metabolised, and harvested at a later date after the level falls below the MRL. If the fish have already been harvested then they should not be used for human consumption, but may be used for animal feed (e.g. fishmeal).

If non-compliant aquaculture products have been released to the market, they should be the subject of a recall or a withdrawal process.

⁴ See: Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results

8 TRACEABILITY REQUIREMENTS FOR AQUACULTURE

8.1 Need for traceability systems

Traceability is defined by the Codex Alimentarius Commission⁵ as “the ability to follow the movement of a food through specified stage(s) of production, processing and distribution”.

Traceability is an important tool that allows food safety to be maintained, by providing the means to remove unsafe food from the market, and following-up food safety problems, to identify their source and cause. Therefore, the traceability of aquaculture products, feeds used in aquaculture systems, and any other substance intended to be, or expected to be, incorporated into an aquaculture product or aquaculture feed should be established at all stages of production, processing and distribution.

To operate a traceability system, aquaculture operators should be able to identify any person from whom they have been supplied with an aquaculture product, aquaculture feed, or any other substance incorporated into an aquaculture product or aquaculture feed (such as a veterinary medicine). They should also be able to identify anyone to whom they have sold their products.

To this end, such operators should have systems and procedures to generate and keep written records of inputs, batches and outputs. The key elements of traceability systems applied in aquaculture operations are described here. However, the CRFM Manual on Traceability Systems for Fish and Fishery Products deals with this subject in more detail.

8.2 Traceability of raw material inputs

All inputs received (feed, seed, fertilizers, juveniles, supplements and medicines) should be recorded, along with details of the supplier (name, address etc.). Any identification of the input batch (such as date and supplier codes) should also be recorded. An internal batch code may be applied.

During storage of feed, the operator should ensure that products are labelled or otherwise identified through relevant documentation or labels. Different batches should be kept separately; this also helps with stock rotation.

8.3 Traceability during production

As far as possible the operator should ensure separation during the production process of batches of fish which are treated differently. Where batches are mixed (e.g. after size grading to ensure an appropriate feeding regime for their size) the mixing should be recorded.

Effective records should be kept of each batch of fish grown in each enclosure, to include veterinary drug regimes, feeding methods and quantities, pond fertilisers added, and any results of water quality parameters.

8.4 Traceability of outputs

Each batch of fish leaving the farm should be allocated a batch number that relates it to the information records above.

⁵ The Procedural Manual of the Codex Alimentarius Commission, 17th Edition, Joint FAO/ WHO Food Standards Programme

Each batch of fish leaving the farm for market or for processing should be marked to include the following information:

- Approval number of the aquaculture enterprise
- Name of the enterprise
- Date of harvesting
- Species
- Batch Number

8.5 Record keeping and withdrawal plans

The records should be kept for a period of one year after harvest.

The operator should also prepare a written withdrawal and recall plan, detailing the procedures to be followed in case a batch of aquaculture products which has left the possession of the operator needs to be withdrawn or recalled from distribution.

Annex 1: References

Codex Alimentarius Commission. 2010. Code of Practice for Fish and Fishery Products. CAC/RCP 52-

2003, Rev. 2010. <http://www.codexalimentarius.org/>

FAO. 2007. Aquaculture development. 2. Health management for responsible movement of live aquatic animals. FAO Technical Guidelines for Responsible Fisheries. No. 5, Suppl. 2. Rome, FAO. 2007. <http://www.fao.org/docrep/010/a1108e/a1108e00.htm>

United States Food and Drug Administration. Approved Drugs for Aquaculture.

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/Aquaculture/ucm132954.htm>

World Health Organization. 2006. Guidelines for the Safe Use of Wastewater, Excreta and Greywater. Volume 2: Wastewater and Excreta Use in Aquaculture.

www.fao.org/nr/water/docs/volume2_eng.pdf

World Organization for Animal Health. 2012. OIE Aquatic Animal Health Code, 15th Edition.

<http://www.oie.int/international-standard-setting/aquatic-code/access-online/>

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	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 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	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.	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 200 µg/kg	Muscle Liver Kidney 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