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Executive Summary

Text will be added later

# Introduction

The **Caribbean Forum** (**CARIFORUM**) is a subgroup of the African, Caribbean and Pacific Group of states and serves as a base for economic dialogue with the European Union, mainly within the framework of the Cotonou Agreement between the ACP and the European Union, and also the CARIFORUM-European Community Economic Partnership Agreement (EPA). The EPA aims at sustainable development through trade partnership between EU and the CARIFORUM states. The CARIFORUM-EU EPA addresses how the EU and CARIFORUM co-operate on a wide range of trade-related issues, including duties charged on imports of goods, achievement of certain agreed market standards, trade in services, etc. The EPA can offer benefits, but benefits come with costs and obligations.

In regards to food trade in the EPA agreement, both parties have affirmed their commitment to the rights and obligation provided for in the World Trade Organisation Agreement on Sanitary and Phytosanitary Measures (WTO SPS Agreement). Furthermore the Agreement notes that the parties should cooperate in establishing the appropriate level of SPS measures. Such cooperation calls for negotiation but as SPS measures deal with the level of food safety the EC requirements are non-negotiable. Consequently, the dialog between the parties relate to measures needed and assistance that may be available to comply with the EU standards.

Many of the CARIFORUM states are currently not authorised to export fish and fisheries products to the European market as they have not fulfilled the EC SPS requirements. Those countries are currently emphasising on exportingexporting their fish and fishery products to the United States (US). With the new Food Safety Modernisation Act in the US that emphasises on preventive measures, the access requirement to that market may change in the near future and especially if the CARIFORUM countries intend to increase their value of the catch through further processing.

The provisions of the WTO SPS agreement relate to the following:

* The protection of animal or plant life or health within a territory from risks arising from the entry, establishment, or spread of pest, disease, disease-carrying organisms, or disease-causing organisms.
* The protection of human or animal life or health within a territory from risks arising from additives, contaminants, toxins, or disease-causing organisms in foods, beverages, or feedstuffs.
* The protection of human life or health within a territory from risks arising from diseases carried by animals, plants, or products thereof, or from entry, establishment, or spread of pests.
* The prevention or reduction of the risks of other damages within a territory from the entry, establishment, or spread of pests.

All WTO member states have agreed to the rights and obligations provided for in the WTO Agreement on Sanitary and Phytosanitary Measures but countries are allowed to set their own appropriate level of protection. The measures must though, be based on scientific principles, must not be maintained without sufficient scientific evidence and may be applied only to the extent necessary to protect human, animal or plant life or health. Furthermore such appropriate level of protection must be based on risk assessment, as appropriate to the circumstances. The risk that a particular substance or product, including a process or production method, poses to human, animal, or plant life or health.

The scope of the SPS measures is complex and covers the whole food chain. With increased scientific knowledge and consumer awareness various hazards chemicals and trace elements have been identified as food safety hazards and maximum limits set that need to be monitored at regular basis. In some instances such testing need access to high-tech laboratory facilities and well trained and skilled technicians. This may put a strain on small and under developed countries that do not possess the capacity and capital to invest in human resources and expensive equipment’s.

The SPS status of the CARIFORUM States varies and in some cases considerable effort is needed to get a country up to standard. Currently there is a project being implemented, titled “Support to the Caribbean Forum of ACP States in the implementation of commitments undertaken under the Economic Partnership Agreement (EPA): Sanitary and Phytosanitary measures”. This project is funded under the 10th European Development Fund (EDF) programme. The project is implemented by IICA, and the Caribbean Regional Fisheries Mechanism (CRFM) is responsible for the fisheries component of the project. The project is divided into three sub-components, that is: the establishment of a sound and comprehensive national and regional legislative framework; the development and organization of the national and regional institutional frameworks and coordinating mechanisms; and capacity building, and in particular, the capacity needs of environmental monitoring programmes for achieving good SPS standards for the fisheries and aquaculture situation in CARIFORUM States. This report covers the assessment of the capacity needed for environmental monitoring, but in some instances covers partly the two other components also, as they are closely related.

# Scope of the work

## Project description

The assignment intends to provide support to CARIFORUM States and CRFM in establishing/strengthening monitoring programmes for food safety requirements of fisheries and aquaculture products. The scope of assessment includes harvesting, handling, production, storage, transport and marketing of fish and fisheries products intended for human consumption.

## Project approach

The main activities of the project involves:

1. Eight country missions to undertake national consultations, consult with key informants and make direct observations in the field (landing sites, processing plants, aquaculture sites), in order to assess the current strengths and weaknesses of the environmental monitoring programmes relevant for supporting a SPS regime in fisheries and aquaculture
2. Prepare country and regional assessment reports, as well as proposal for improving such programmes.
3. Review, approval and finalization of the report and proposals through available consultation networks.

## Project output

At the end of the assignment the following will be achieved

* A Regional Assessment report of existing fisheries and aquaculture sectors' environmental monitoring programmes related to Sanitary Standards in CARIFORUM States;
* Completed and documented national consultations/technical seminars on environmental monitoring in 8 CARIFORUM countries (country assessment reports);
* A Proposal on establishing/strengthening national and regional monitoring programmes formulated.

## Project method

The approach used included gathering material on SPS measures (e.g. regulations, technical & scientific information) of the main marketing areas of Caribbean countries, with emphasis on the EU market. Reports from former EU missions were also reviewed to gain an understanding of the strengths and weaknesses of the countries to be visited.

Assessment of the SPS status of the region was approached by visiting eight countries. The aim was to meet with the Competent Authority of each of the countries to gather information on what SPS measures were in place and how they were being enforced. Following those meetings, the implementation and enforcement of the regulations was evaluated by visiting landing sites, processing facilities, aquaculture sites and by consulting with other stakeholders to gather information and input. Furthermore, the approach included visits to laboratories to evaluate their capability to conduct necessary analytical testing. It should be noted that the actual numbers and types of meetings and consultations varied with country, as arrangements for such were dependent on the local organiser, as well as the availability and cooperation of the local stakeholders.

# Sanitary and Phytosanitary requirements for fish and aquaculture

In order to secure food safety and animal and plant health the World Trade Organization (WTO) member states have agreed to that governments can apply Sanitary and Phytosanitary measures in food trade, but they must be based on:

* Recognized international standards, preferably FAO/WHO Codex Alimentarius Commission, the World Organization for Animal Health (OIE), the International Plant Protection Convention (IPPC)
* Science, including scientific assessment of risk
* A temporary precautionary principle in the absence on international standards or scientific evidence

## Policy and procedures

According to the WTO-SPS agreement, Member States can therefore either follow international standards or base their appropriate level of protection on science and scientific assessment of risk.

Fish is the biggest food entity traded internationally and fish exports to valuable markets have been difficult for many developing countries due to strict SPS requirements. It is understandable though that governments set strict levels of protection in order to protect their consumers if scientific evidence indicates that certain chemicals or biological substances could cause short or long term problems.

SPS measures should be applied throughout the entire food chain and they include the same basic requirements for all fish and fishery products (from wild and aquaculture):

* Environmental contamination of the aquatic/marine environment that could affect the aquatic/marine catch. SPS measures for the possible environmental contamination include setting up monitoring programs for contaminants, marine toxins, heavy metals, persistent organic pollutants and for aquaculture additional programs involve pesticides and drug residues.
* For harvesting the main SPS measures include the design and cleanliness of the boats/vessels that catch, store and transport the catch ashore and the handling and preservation of the catch. Official requirements therefore address the material of food contact surfaces and cleaning and sanitation programs. Furthermore emphasis is placed on icing the catch, and requirements can include minimum temperature at landing. If processing is applied at sea, further SPS requirements are set.
* In fish processing, the SPS measures become more complicated as once the fish is opened the edible part is more prone to contamination. The HACCP system (Hazard Analysis and Critical Control Points) is now mandatory in most countries. This system is based on the *Codex Alimentarius* guidelines and requires that before the process is analysed for hazards, the processor needs to set up a so called prerequisite program (PRP). The PRP is defined as basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption.

Most of the items identified in the PRP are set in regulations and they include:

* **Location** of the processing facility, meaning that it should be located away from polluted areas and areas that are prone to infestations. Furthermore that it should be in an area where waste can be removed effectively.
* The **design and layout** of the facility should permit good food hygiene practices and protect the product against cross-contamination.
* **Internal structure and fittings** such as walls, floors, windows, doors and food contact surfaces should be of impermeable material that is easy to clean and sanitize.
* **Equipment and containers** should be clean, well maintained and made from material intended for food production.
* **Water supply**. Sufficient quantity of potable water.
* **Drains and waste disposal**. There should be adequate drainage for the process and a waste disposal system and facility.
* **Personnel facilities and toilets**. There should be adequate means of washing and drying hands, including wash basins and a supply of hot and cold water and adequate and clean changing facilities for personnel.
* There should be adequate **ventilation** to minimize air-borne contamination of food and to control odour that may affect the suitability of food. Furthermore the ventilation should minimize or limit condensation.
* Adequate natural or artificial **lighting** to enable the undertaking operation in a hygienic manner.
* In order to **prevent food contamination** clean and unclean areas should be separated, external access controlled, avoid accumulation of food waste during processing and establish monitoring procedures for glass, oil and metal.
* **Water and ice** in processing must fulfil set criteria of potable water/clean seawater.
* **The management** must have sufficient knowledge in food safety to secure correct actions if needed.
* **Documentation and records**. Food safety issues must be confirmed with records. Work procedures increase the system reliability and effectiveness.
* **The cold chain** must be maintained i.e. raw material in reception, material in storage and during processing. Temperatures in freezers and cool storage must be monitored and recorded.
* **Calibration** of measuring equipment to ensure correct control (thermometers, pH equipment).
* Clear work procedures on **product recall and traceability**.
* **Cleaning plan** should be in place and include cleaning procedures, confirmation of cleaning, monitoring of cleaning and cleaning records.
* **Pest control plan** that includes facility resistance to pest, harbourage and infestation, monitoring, eradication and records.
* **Maintenance plan** for the facility and equipment.
* **Medical certification** for all staff members that enter the processing facilities and health monitoring of personnel.
* Rules on **personnel hygiene** including hand washing, use of protective clothing and handling of wound/cuts.
* **Accessibility and circulation of guests**. Same rules should apply to guests as staff.
* During **transport** the product should be sufficiently protected and kept at right temperature.
* **Labelling**. All food products should be accompanied by or bear adequate information to enable the next person in the food chain to handle, display, store and prepare and use the product safely and correctly. Furthermore the product bear a lot identification mark in case of product recall.
* **Staff training**. The training need is based on the nature of the food being processed and in particular its ability to sustain growth of pathogens or spoilage microorganism. The minimum requirement is that staff receive training on hygiene requirement in food production.

Once the PRP is established, the process can be analysed for hazards that are associated with the product (product related hazards) and hazards that are linked to the processing (process related hazards). If hazards are identified in the process, control procedures are set to secure production of safe food.

At distribution and retail level the main SPS measures for fish and fishery product are temperature control and temperature records should be retained for official verification. Once the product reaches the consumer he/she is responsible for handling and maintaining the product in accordance to the labelling instruction. The only SPS measures at this stage is consumer education.

## Main regulatory framework for SPS measures

### SPS regulations in the European Union

The main European food safety and hygiene requirements are covered in regulations EC 178/2002 (so-called Food Law), EC 852/2004 and EC 853/2004 (often referred to as the Hygiene package). These regulations set the stage for the SPS measures of the European market.

The Food Law provides the basis for the assurance of the level of protection of human health. It establishes common principles and responsibilities. With the Food law the European Food Safety Authority was established (EFSA), which is the keystone of the EU risk assessment regarding food and feed and is the basis of the EC SPS requirements. EFSA is an independent agency funded by the EU budget and provides scientific advice on existing and emerging risks. EFSA operates separately from the European Commission, European Parliament and EU Member States.

Regulation EC 852/2004 sets down general rules for food business operators on the hygiene of foodstuffs.

Regulation EC 853/2004 lays down the specific hygiene rules for food of animal origin. The requirements are set for food businesses handling food of animal origin at all stages of the food chain.

Both EC 852/2004 and EC 853/2004 apply to production and handling of fish and fisheries products. Additionally there are number of supportive Regulations and Directives that deal with detailed issues, and these follow.

Regulation EC 885/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare.

Regulation EC 854/2004 on laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

Regulation EC 2073/2005 on microbiological criteria for foodstuffs.

Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

Commission Regulation (EC) No. 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs.

### Main regulatory framework in the Unites States of America

The main SPS regulations in United States (US) are the

* 21 CFR 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food and
* 21 CFR 123 Fish and Fishery Products HACCP
	+ 21 CFR 123.12 on specific requirement for imported fish and fishery products.

Furthermore there are regulations on bioterrorism and on country of origin labelling that affect import of fish and fishery products. There are also regulations on maximum limits of pesticides, contaminants, toxins, heavy metals and other chemicals risks related to foodstuff.

Of interest is also the FDA Food Safety Modernization Act (FSMA) from January 4. 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. This is in line to European approach and is not proposed to introduce new requirements but to increase the enforcement of the current laws and regulations.

## Chemical risks

### Pollutants and toxic ingredients

Various chemical risks are documented food safety hazards in fishery products and the terminologies used for these risks have not been harmonised, therefore the terms and definitions used in this report are listed in table 1 below.

Table 1: Terms and definitions used to identify and verify chemical risks in food and feed

|  |  |  |
| --- | --- | --- |
| **Terms** | **Definitions** | **Examples** |
| **Pollutant\**** **Residue**
* **Contaminants/undesirable substances**
 | All s**ubstances** that can be harmful to plants, animals, humans, the environment |  |
| **Substances** to exert **an intended effect** on the production and storage of feed / food and primary products, while partly remaining in the final product | Pesticides, feed and food additives, pharmacologically active substances |
| **Substances** that **unintentionally** come in contact with feed / food and primary products and thereby are carried over to consumers | Heavy metals, toxic elements, chlorinated organic substances, PCB's and dioxins, marine biotoxins, radionuclides |
| **Toxic Ingredients** | **Substances** which are **formed** on or in feed / food during production and storage, and remain in the final product | Alkaloids, glycosides, PAHs, mycotoxins, phenols, nitrate nitrite, biogenic amines, nitrosamines |

\*Pollutant is the overarching term used, while residue and contaminants refer to specific type of substances as explained in the table

The most important regulation regarding contaminants in foodstuff in Europe is EC regulation No 1881/2006 with additional later amendments to this regulation.

Regulations (EC) No 1881/2006 covers the following aspects:

a) Environmental contaminants in foodstuff

- Mycotoxins (Aflatoxins, Ochatoxin A, Patulin, Dioxynivalenol, Zearalenone, Fumonosins, T 2/HT 2 Toxin)

- Metals (Lead, Cadmium, Mercury, Tin (inorganic))

- Dioxins and PCBs (Polychlorinated biphenyls)

b) Processing contaminants in foodstuff

- Nitrate

- Melamine

- PAHs (Polycyclic aromatic hydrocarbons)

- 3-MCPD (3-Monochloropropane-1,2-diol)

Regulations (EC) No 1881/2006 describes the following:

a) Regulation of maximum residues level (MRL) for several foodstuffs and comprehensive list with MRL for e.g. metals & Dioxins and PCBs in foodstuff are included in Annex to this regulation;

b) Sets the ALARA principle (*as low as reasonably achievable*) for genotoxic substances;

c) Regulations of sampling and analytical methods for official control, these are specified in Article 8 for the various chemical contaminants;

Biogenic amines (BAs) are non-volatile, heat stabile, organic bases formed in food by microorganisms through enzymatic decarboxylation of amino acid. BAs are a food safety hazard because they can trigger an allergic response in humans, they can be found in various foods such as inappropriately handled and/or stored scombroid fish (e.g. tuna, mackerel, herring). Since these amines cannot be destroyed by cooking or detected with organoleptic evaluation, the European Council requires the determination of histamine in fish and fish products with High Pressure Liquid Analysis (HPLC) and regulates the maximum levels of histamine according to EC regulation No 2073/2005.

Polycyclic aromatic hydrocarbons (PAHs) is the name of a compound class which includes a large variety of different substances, which have in common an organic molecular structure of at least two fused aromatic rings. PAHs are generated during incomplete pyrolysis or combustion of organic matter and humans are exposed to them through many ways e.g. smoked and thermally processed food products. Because of their harmful effects on health, the EC regulates the maximum levels of PAH concentration in food according to EC Regulation No. 835/2011.

### Drugs and residues

It is often inevitable to apply certain veterinary drugs in Aquaculture. Therefore, it is necessary to be able to monitor certain drug substances and residues thereof in aquaculture products. According to Council Directive 96/23/EC the EC requires that each country adopts and implements a national residue control plan (NRCP). The aim of the NRCP is to: i) Monitor that veterinary drugs are applied in accordance with legal provisions, ii) Monitor compliance with provisions on the prohibition of certain substances iii) Collect data on contamination originating in the environment. The substances of interest according to ANNEX I to Directive 96/23/EC are listed in table 2 below. The purpose of this plan is to safeguard consumers from illegal drug residues in aquaculture products.

The NRCP shall include the following:

* National legislation on the use of the substances listed in Annex I to Council Directive 96/23/EC, in particular provisions on their prohibition or authorization, distribution and placing on the market.
* The infrastructure of the relevant departments e.g. a list of approved laboratories with details of their capacities for processing samples.
* National tolerances for authorized substances where no maximum residue levels have been set under Regulation (EC) No 37/2010 and Regulation (EC) No 396/2005.
* A list of the substances to be detected, methods of analysis, standards for interpreting the findings.
* The number of official samples to be taken in relation to the number of animals of the species concerned slaughtered in preceding years.
* Details of the rules governing the collection of official samples.
* The type of measures laid down with regard to animals or products in which residues have been detected.

|  |
| --- |
| Table 2: Substances of interest according to ANNEX I to Directive 96/23/EC |
| **GROUP A** – Substances having anabolic effect and unauthorized substances |
| A.1.  | Stilbenes, stilbene derivatives, and their salts and esters |
| A.2.  | Antithyroid agents |
| A.3. | Steroids |
| A.4. | Resorcylic acid lactones, including zeranol |
| A.5.  | Beta-agonists |
| A.6.  | Compounds included in Annex IV to Council Regulation (EEC) N° 2377/90 of 26 June 1990 |
| **GROUP B** – Veterinary drugs and contaminants  |
| B.1.  | Antibacterial substances e.g. sulphonamides, tetracycline, quinolones |
| B.2.  | Other veterinary drugsa) Anthelminticsb) Anticoccidialsc) Carbamates and pyrethroidsd) Sedativese) Non-steroidal anti-inflammatory drugs (NSAIDs)f) Other pharmacologically active substances |

## Responsibility of private sector

According to the EU food law the food companies i.e. primary producers, food processors and retailers are responsible for ensuring food safety and these parties are expected to exercise due diligence and self-controls.

## Official control

### Role and responsibility

According to the EU food law the official food control shall be carried out by the relevant competent authorities (CA) and this control should be based on risk-oriented manufacturing control and risk-oriented sampling in order to minimize food risks. The CA should provide guarantees that an official inspection service is responsible for carrying out official controls throughout the production chain of fishery products to be exported to the EU i.e. from the fishing vessels or aquaculture farm to the exporting establishment. These official controls should cover all the relevant community requirements on hygiene, public health and, in the case of aquaculture products, also aquaculture health aspects.

The main EU related to official controls are Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food and Regulation (EC) No 854/2004 on specific rules for the organisation of official controls on products of animal origin intended for human consumption.

The main requirements regarding official food controls according to Regulation No 882/2004 are:

* Documented procedures
* Quality management through surveillance and monitoring
* Appropriate competence & training of staff performing controls
* Contingency plans for feed and food
* National control plans
* Annual reports
* Audits

### Working procedures

The CA shall ensure that documented procedures are applied for their inspection service. The CA should also guarantee that official controls for fishery products intended for export to the EU include at least the following: organoleptic examinations, freshness indicators (in case of doubt of freshness of fishery products), histamine, residues and contaminants (including heavy metals, dioxins and PCBs, PAH) microbiological checks, parasites and poisonous/toxic fishery products, in line Regulation (EC) No 854/2004 and with the relevant Community requirements (Regulations (EC) Nos 2073/2005, 2074/2005, 1881/2006 and 333/2007).

The methods of sampling and laboratory analysis of official food/feed samples are crucial in order to obtain reliable analytical result and therefore the appropriate procedures for these important tasks are specified in Article 11 and 12 in regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law. According to this regulation (Article 11)

 “Sampling and analysis methods used in the context of official controls shall comply with relevant Community rules”, further “The competent authorities shall establish adequate procedures in order to guarantee the right of feed and food business operators whose products are subject to sampling and analysis to apply for a supplementary expert opinion” and “Samples must be handled and labelled in such a way as to guarantee both their legal and analytical validity.” According to regulation (EC) No 882/2004, “The competent authority shall designate laboratories that may carry out the analysis of samples taken during official controls. However, competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with the following European standards:

(a) EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’

(b) EN ISO/IEC 17011 on ‘General requirements for accreditation bodies accrediting conformity assessment bodies’.

taking into account criteria for different testing methods laid down in Community feed and food law.”

### Monitoring and surveillance

Various official monitoring and surveillance are required for foodstuff according to EC regulations and the type and objectives of these programmes are listed in table 3 below. When the objective is to monitor to assess consumer exposure the sampling of the food/feed items should be planned so that it represents the exposure of the average population and the average levels in food and feed. When the objective on the other hand is surveillance for compliance with the legislation the sampling of the food/feed items should be risk based official control. The sampling and the analysis for the official control of the maximum levels specified in the Annex of Regulation (EC) No 1881/2006 shall be performed in accordance with Article 8 in this regulation.

Table 3. Official monitoring and surveillance is required in foodstuff according to EC regulations

|  |  |
| --- | --- |
| **Type of monitoring and surveillance** | **Objectives of Program** |
| Official food control according Reg. (EC) No 882/2004 from production, over processing, to distribution inspections for sample tests | Surveillance for compliance with the legislation |
| Nationwide monitoring plan and food-monitoring according Reg. (EC) No 882/2004 (annual program) | Monitoring to assess consumer exposure |
| Dioxin-monitoring according Reg. (EC) No 1883/2006 | Monitoring to assess consumer exposure |
| Control programs for Residues of Pesticides according Reg. (EC) No 396/2005 (multi-annual national control program 2013 – 2015) | Surveillance for compliance with the legislation |
| National Residue Control Plan according to Directive No 96/23/EC (pharmacologically active substances) | Surveillance for compliance with the legislation |
| Zoonoses-Monitoring according Dir. No 2003/99/EC in the food chain | Monitoring to assess consumer exposure |
| Integrated measurement program in radiation protection for food according Reg. (Euratom) No 3954/87 | Surveillance for compliance with the legislation |

### Training

The CA should ensure that all staff performing official controls have an adequate knowledge of Community export requirements for fishery products.

# Assessment of current state in seven Caribbean countries

## Assessment report for Guyana

Please refer to a separate document/file with the assessment report for this country

## Assessment report for St. Vincent

Please refer to a separate document/file with the assessment report for this country

## Assessment report for Grenada

Please refer to a separate document/file with the assessment report for this country

## Assessment report for Suriname

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## Assessment report for the Bahamas

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## Assessment report for Dominic Republic

Please refer to a separate document/file with the assessment report for this country

## Assessment report for Belize

Please refer to a separate document/file with the assessment report for this country

# Regional assessment report

This text will be added later