

US FDA Regulations Applied to fishery Products



International Regulatory Framework -Seafood Safety And Quality-

The **increasing demand for fish and fishery products** and the development in international fish trade have raised major concerns about:

- ❑ **The overexploitation** of aquatic resources
- ❑ **The quality and safety of the products** internationally traded.
- ❑ **Globalization of the economy and the development of regional economic groupings** have highlighted the need for harmonizing fish safety and quality assurance approaches, with the view to ensure fish safety and fair trade practices

The World Trade Organization (WTO) agreement

- ❑ **The Final Act of the Uruguay Round** of multilateral trade negotiations, which began in Punta del Este, Uruguay in September 1986 and concluded in **Marrakesh**, Morocco in April 1994, established the **World Trade Organization (WTO)** to succeed the **General Agreement on Tariffs and Trade (GATT)**.
- ❑ **Significant implications for food safety and quality arise** from the Final Act of the Uruguay Round, especially from two binding agreements:

The Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures

The Agreement on Technical Barriers to Trade (TBT Agreement).

Rules and regulations governing fish and seafood safety and quality

INTERNATIONAL CONTEXT

As early as 1980, there was an international drive towards reforming **fish inspection systems** to move away from **end-product sampling and inspection** into **preventative Hazard Analysis Critical Control Point (HACCP)-based safety and quality systems**.

This **preventative approach** requires that:

- ❑ **The fish products are prepared/processed** in certified plants and establishments.
- ❑ The certification process requires that the **plant meets minimal requirements** in terms of layout, design and construction, hygiene and sanitation;
- ❑ The industry takes responsibility in **fish safety control and implements HACCP-based in-plant quality control programs**;
- ❑ **A regulatory competent authority** is in charge of certifying fish plants and establishments, approving and monitoring HACCP-based in-plant quality control programs and certifying fish and fishery products before distribution;
- ❑ where necessary, **national surveillance programs** of the harvesting areas should be in place to control the threats of biotoxins and other biological and chemical pollutants;
- ❑ **For export, an additional control can be exercised** by the importing party and involves an audit of the national control system of the exporting country to ensure that it meets the requirements of the importing country.

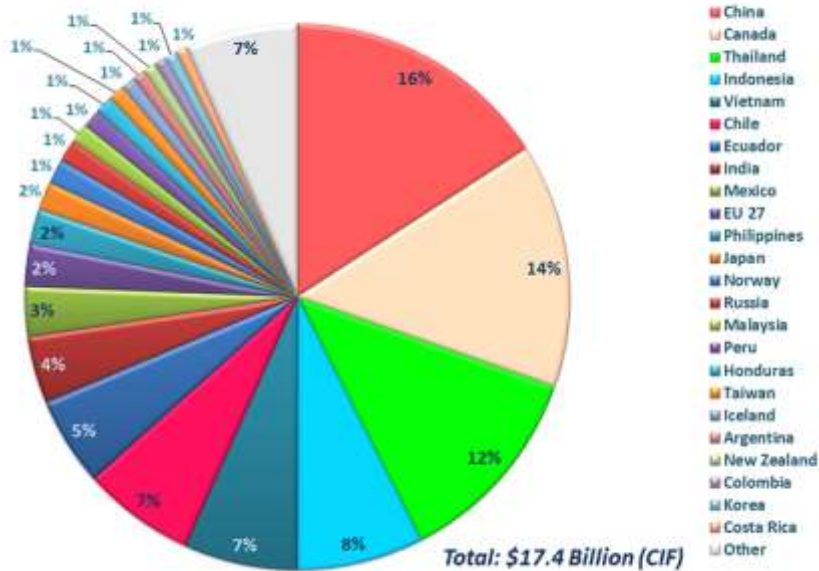
This should lead to the signing of mutual recognition agreements between trading countries.

Fisheries food chain approach to food safety Requirements

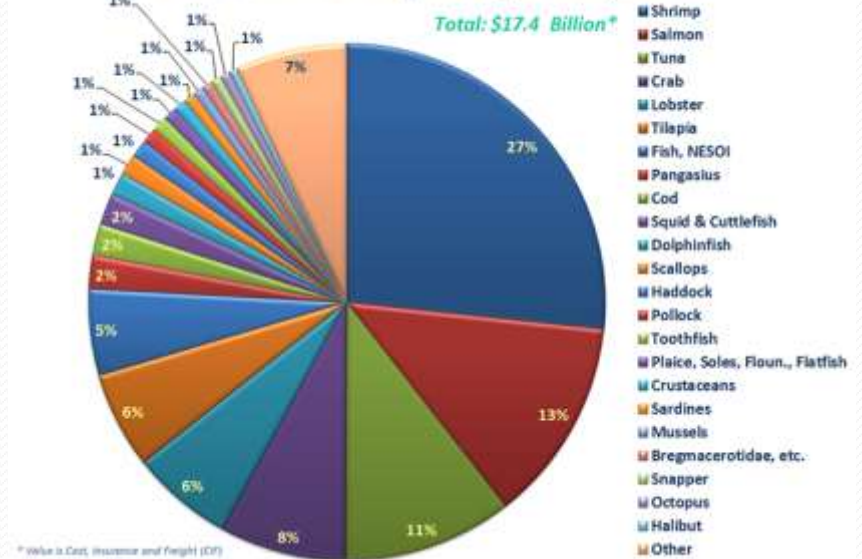
- ❑ In fisheries, stakeholders include **farmers, fishers, food processors, transport operators, distributors - and consumers, as well as governments obliged to protect public health**
- ❑ In fisheries, there are **five broadly-defined needs** on which a strategy in support of a food chain approach to food safety should be based:
 - **Fish safety and quality** from a food chain perspective should incorporate the three fundamental components of risk analysis - *assessment, management and communication* - and, within this analysis process, there should be an institutional separation of science-based risk assessment from risk management, the latter being the regulation and control of risk.
 - **Tracing techniques (*traceability*)** from the primary producer (including animal feed and therapeutants used in aquaculture), through post-harvest treatment, processing and distribution to the consumer must be improved.
 - **Harmonization of fish quality and safety standards** is necessary, implying increased development and wider use of internationally agreed, scientifically-based standards.
 - **Equivalence in food safety systems** - achieving similar levels of protection against fishborne hazards and quality defects whatever means of control are used - must be further developed.
 - **An increased emphasis is needed on "risk avoidance or prevention at source"** within the whole food chain - *from farm or sea to table*. In the farmed sector, this includes development and dissemination of good aquaculture practices and safety and quality assurance systems (i.e. HACCP) to complement the traditional approach to fish safety and quality management based on regulation and control.

United States Seafood Market

U.S. Seafood Import Sources, 2012



U.S. Seafood Import Species, 2012



The U.S. Food and Drug Administration

- ❑ The U.S. Food and Drug Administration is responsible for **regulating seafood guidelines**
- ❑ The Federal Food, Drug and Cosmetic Act, the Public Health Act, and similar regulations aim **to prevent the occurrence** of marine toxic poisoning through the publication of the Fish and Fisheries Products Hazards and Controls Guidance manual
- ❑ This serves **to provide up-to-date** science and policies regarding potential hazards of seafood.



21 CFR Part 123 - FISH AND FISHERY PRODUCTS

- ❑ On December 18, 1995, the FDA published as a final rule 21 CFR 123, "*Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products*" that requires processors of fish and fishery products to develop and implement *Hazard Analysis Critical Control Point (HACCP)* systems for their operations.
- ❑ The regulation became effective December 18, 1997



Fish and Fishery Products Hazards and Controls Guide

The agency also published the "*Fish and Fishery Products Hazards and Controls Guide*" ("the Guide") in September, 1996:

- ❑ **Assist processors** in the development of their HACCP plans
- ❑ **Provide information** to help them identify hazards that may be associated with their products
- ❑ **Formulate control strategies** for those hazards. The guide was developed to coincide with the issuance of the final regulation



Regulations

The **guidelines** presented by the FDA serve as reference to fish and fishery product regulatory programs globally with **regulations** addressing:

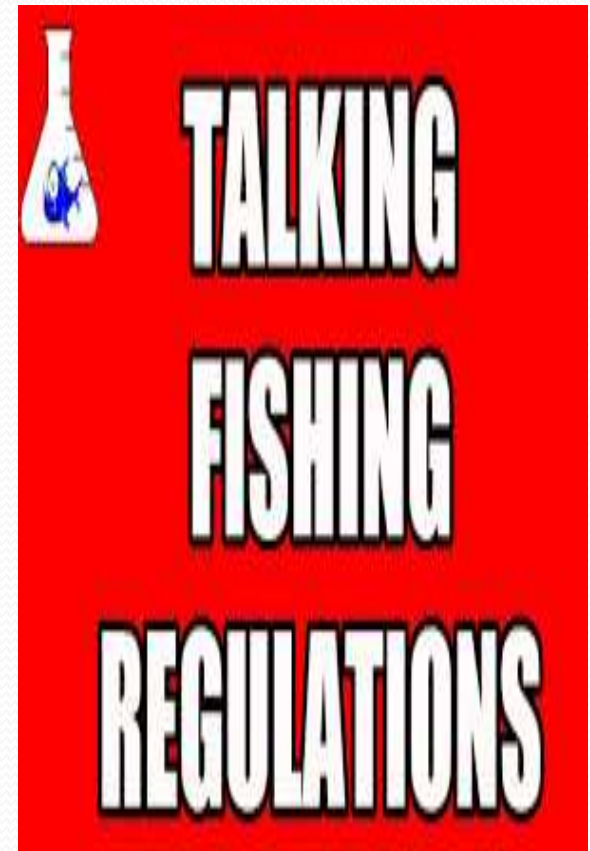
- ❑ Procedures for the **safe and sanitary processing** and importing of fish and fishery products
- ❑ Enhanced aquaculture and seafood **inspection**



Regulations (Cont)

In addition to providing strict regulations, the FDA provides **extensive guidance** by which fish industries may follow to prevent **seafood poisoning**, including:

- ❑ Guidance for purchasing reef fish species
- ❑ Guidance for interstate commerce
- ❑ Processes for **inspection and certification of seafood export**
- ❑ Guidance for implementing a HACCP (Hazard Analysis and Critical Control Points) prevention system)



General Provisions of Part 123 Code of Federal Regulations

- ❑ § 123.3 Definitions
- ❑ § 123.5 Current good manufacturing practice
- ❑ § 123.6 Hazard analysis and Hazard Analysis Critical Control Point (HACCP) plan
- ❑ § 123.7 Corrective actions
- ❑ § 123.8 Verification
- ❑ § 123.9 Records
- ❑ § 123.10 Training
- ❑ § 123.11 Sanitation control procedures
- ❑ § 123.12 Special requirements for imported products

Current good manufacturing practice

□ 123.5

(a) Except as provided by [§ 117.5\(b\)](#), parts 110 and 117 of this chapter **apply in determining whether the facilities, methods, practices, and controls used to process [fish](#) and [fishery products](#) are [safe](#)**, and whether these products have been processed under sanitary conditions.

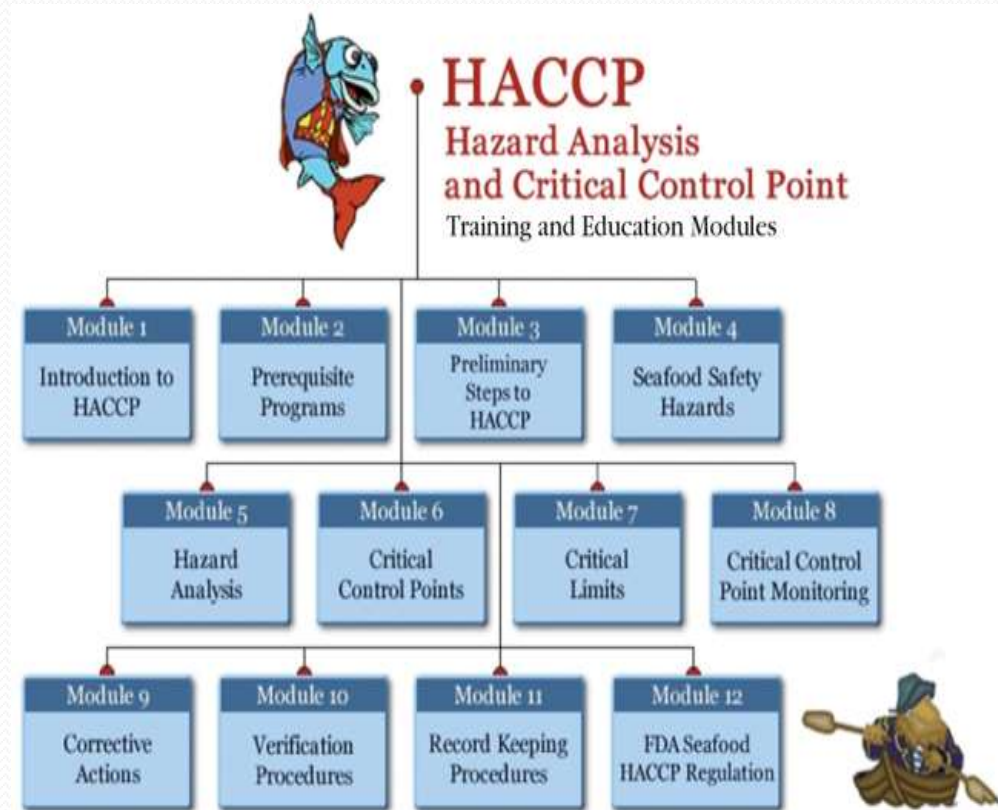
(b) The purpose of this part is to set forth requirements specific to the processing of [fish](#) and fishery products.



Hazard analysis and Hazard Analysis Critical Control Point (HACCP) plan

□ 123.6

- (a) *Hazard analysis*
- (b) *The HACCP plan*
- (c) *The contents of the HACCP plan*
- (d) *Signing and dating the HACCP plan*
- (e) *Products subject to other regulations*
- (f) *Sanitation*
- (g) *Legal basis*



Special requirements for imported products

□ **123.12 section** sets forth specific requirements for imported **fish** and fishery products:

- (a) *Importer verification*
- (b) *Competent third party*
- (c) *Records*
- (d) *Determination of compliance*



FDA Seafood Regulatory Program Importations

- ❑ FDA has the authority to **detain or temporarily hold food being imported into the U.S.** while it determines if the product is misbranded or adulterated

- ❑ The FDA **receives notice of every seafood entry**, and at its option:
 - ✓ conducts wharf examinations
 - ✓ collects and analyzes samples
 - ✓ where appropriate, **detains individual shipments** or invokes "**Automatic Detention**," requiring private or source country analysis of every shipment of product when recurring problems are found, before the product is allowed entry



FDA Seafood Regulatory Program

Legal actions and Technical assistance

- ❑ FDA has the authority to take legal action against adulterated and misbranded seafood and to recommend criminal prosecution or injunction of responsible firms and individuals
- ❑ FDA provides extensive technical assistance in the area of seafood safety and sanitation to foreign governments through direct contacts and through the WHO, FAO, both United Nations organizations.
- ❑ FDA also operates two other specific regulatory programs directed at seafood
 - ✓ the Salmon Control Plan
 - ✓ the National Shellfish Sanitation Program (NSSP)

Conclusion and recommendations

FDA operates a mandatory safety program **for all fish and fishery products** under the provisions of the Federal Food, Drug and Cosmetic (FD&C) Act, the Public Health Service Act, and related regulations.

The FDA program includes **research, inspection, compliance, enforcement, outreach, and the development of regulations and guidance**

The principles of achieving harmonization of standards and equivalency in food control systems and the use of scientifically-based standards **are embodied in two binding agreements of WTO - the SPS and TBT Agreements.**

The SPS agreement confirms the right of WTO member countries to **apply measures necessary to protect human, animal and plant life and health**

As the main objective of our seminar is **to improve market access chances and opportunities for fisheries and aquaculture products of ATLAFCO countries**, recommendations that we can draw from my presentation are:

- ❑ **MS should take the example of US among other to improve the use of fish products (handling, packaging, processing ...)**
- ❑ **To set up control procedures based on HACCP as the key instrument in an integrated approach to seafood safety and quality in order to facilitate the marketing of fish marketing for better and larger market access**
- ❑ **To master WTO SPS and TBT agreement to allow more chance for the African products to enter the International Market**
- ❑ **To share best practices and experiences between ATLAFCO MS(reasearch, training enforcement.....)**

Thank you for your Attention

