

MINISTERIAL CONFERENCE ON FISHERIES
COOPERATION AMONG AFRICAN STATES
BORDERING THE ATLANTIC OCEAN



CONFERENCE MINISTERIELLE SUR LA COOPERATION
HALIEUTIQUE ENTRE LES ETATS AFRICAINS
RIVERAINS DE L'OCEAN ATLANTIQUE

US FDA Regulations and private Standards

Regulatory websites

- **USA:**
 - Code of Federal Regulation
- **Canada**
 - <http://www.cfia.acia.agr.ca> Canadian Food Inspection Agency
- **Japon:**
 - Food Sanitation Law In Japan - March 2003 - Standard Information Service

Code of Federal Regulations

- Title 21--Food and Drugs Chapter I-FDA, Department of health and human services - Part 123--Fish and fishery products
http://www.access.gpo.gov/nara/cfr/waisidx_03/21cfr123_03.html
- Subpart A--General Provisions
 - 123.3 Definitions.
 - 123.5 Current good manufacturing practice.
 - 123.6 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.

Code of Federal Regulations

- Title 21 - Chapter I - Part 123
 - Subpart B--Smoked and Smoke-Flavored Fishery Products
 - 123.15 General.
 - 123.16 Process controls.
 - Subpart C--Raw Molluscan Shellfish
 - 123.20 General.
 - 123.28 Source controls

Special requirements for imported products

- (a) Importer verification
 1. MOU- equivalency or compliance of the inspection system of the foreign country with the U.S. system,
 2. Written verification procedures for ensuring that fishery products were processed in accordance with the requirements of this part:
 - i. Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act
 - ii. Affirmative steps
 - A. HACCP and sanitation monitoring records required
 - B. Continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party
 - C. Regularly inspecting the foreign processor's facilities
 - D. Maintaining on file a copy, in English, of the foreign processor's HACCP plan
 - E. Periodically testing the imported fish or fishery product, and maintaining on file a copy,
 - F. Other such verification measures as appropriate that provide an equivalent level of assurance of compliance

Special requirements for imported products

- (b) Competent third party.
 - An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2)
- (c) Records.
 - The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in (a)(2)(ii)
- (d) Determination of compliance
 - There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If such assurances do not exist, the product will appear to be adulterated and will be denied entry

The Food and Drug Administration's Seafood Regulatory Program

<http://www.cfsan.fda.gov/~lrd/sea-ovr.html>

- ▣ The FDA operates an oversight compliance program for fishery products. Responsibility for the product's safety, wholesomeness, identity and economic integrity rests with the processor or importer? Who must comply with regulations promulgated under the Federal Food, Drug and Cosmetic (FD&C) Act, as amended, and the Fair Packaging and Labeling Act (FPLA).
- ▣ Most FDA in-plant inspections consider product safety, plant/food hygiene and economic fraud issues
- ▣ Samples may be taken during FDA inspections

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, and 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 also has the authority to promulgate regulations for food plant sanitation (i.e., Good Manufacturing Practices (GMP) regulations), standards of identity, and common or usual names for food products
- 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 World Health Organization (FAO), both United Nations organizations.
- The FDA also operates two other specific regulatory programs directed at seafood -- the Salmon Control Plan and the National Shellfish Sanitation Program (NSSP), recently augmented by the Interstate Shellfish Sanitation Conference (ISSC).

The Bioterrorism Act of 2002

<http://www.fda.gov/oc/bioterrorism/bioact.html>

The screenshot shows a web browser window displaying the FDA's page for the Bioterrorism Act of 2002. The browser's address bar shows the URL <http://www.fda.gov/oc/bioterrorism/bioact.html>. The page header features the FDA logo and the text "U.S. Food and Drug Administration" and "U.S. Department of Health and Human Services". Navigation links include "FDA Home Page", "Search FDA Site", "FDA A-Z Index", and "Contact FDA".

The Bioterrorism Act of 2002

[Sign up for Bioterrorism Act email updates.](#)

The Act

The events of Sept. 11, 2001, reinforced the need to enhance the security of the United States. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which President Bush signed into law June 12, 2002.

Complete Text: [HTML](#); [PDF](#)

The Bioterrorism Act is divided into five titles:

- [Introduction](#)

Plans for Implementing the Act

Title I (National Preparedness)

- [Section 123](#) (Animal Trials)
[Federal Register Notice](#)
[View Comments](#)

Title III (Safety of Food and Drug Supply):

- **Subtitle A (Food Supply Protection)**
 - [Section 301](#) (Security Strategy)
 - [Section 302](#) (Food Adulteration)
[Report to Congress: Testing for Food Adulteration](#) (February 2005)
 - [Section 303](#) (Detention)
[Final Rule](#) (June 4, 2004)
[Press Release](#) (May 27, 2004)
[Fact Sheet](#)

Register Your Food Facility

This is the Official U.S. FDA Site for Free Food Facility Registration

- [Important Notice About Firms Offering Registration Services](#)
- [Register Online](#)
- [Register via Mail/Fax](#)
- [Registration Help Desk](#)
- [Verification of Registration](#)

Prior Notice-Food Imports

- [Information/Log in](#)
- [Plan for Uniform System and Coordinated Timelines](#)

The browser's taskbar at the bottom shows several open applications, including "Club Inter...", "US FDA R...", "Micros...", "Harrap's...", and "The Bioter...". The system tray on the right shows the time as 18:58.

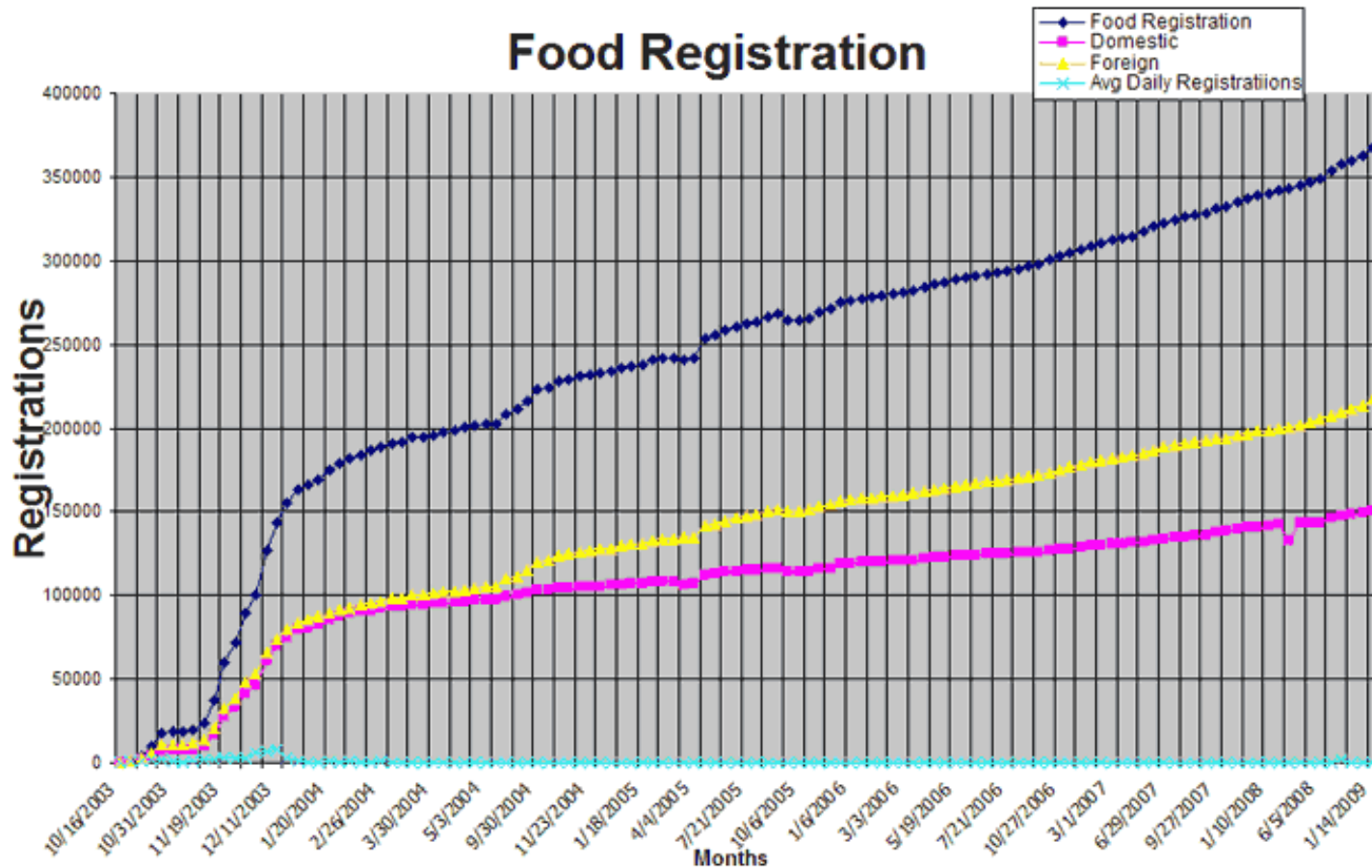
Compliance Information: Registration

- Overview of Registration Interim Final Rule Implementing the Bioterrorism Act (68 FR 58894, Oct. 10, 2003)
<http://www.cfsan.fda.gov/~dms/fsbtac16.html>

Registration of Food Facilities

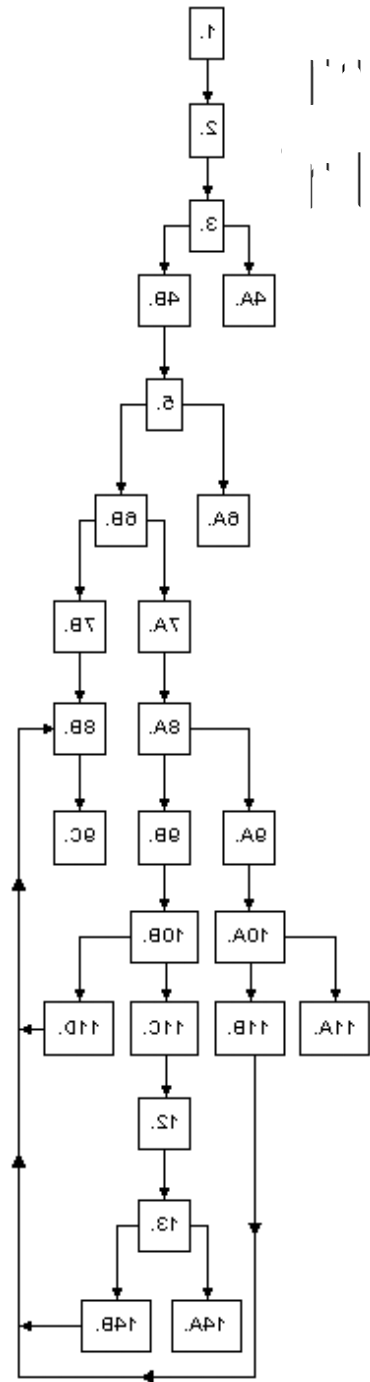
January 14, 2009

- As of January 14, 2009, food facilities registered with FDA are 367,600, of which 216,825 are foreign facilities and 150,775 are domestic facilities



Importing Food and Cosmetics to the United States

- FDA Import procedures
<http://www.cfsan.fda.gov/~lrd/imports.html>



Labels customer oriented

- ◆ “**CPA**” (conformity product Assessment) - guaranty of a regular quality distinct from basic product, some qualities or processed following particular conditions strictly controlled,
- ◆ “**Label rouge**” - superior quality - severe and controlled requirement at each step of the production, processing and commercialisation of the product,
- ◆ “**AOC**” (Appellation d’origine contrôlée) - typical and specific product linked to origin (**terroir**), expression of a strong link between a production and an area and the local know-how.
- ◆ “**AB**” (biologic agriculture),
- ◆ “**NF agro-alimentaire**” - the product follows an AFNOR standard and respects CCP conditions,
- ◆ **Collective marks** - controlled by independent organisations

Labels customer oriented

- **Nature:** voluntary
- **Regulation**
 - ◆ **official national quality signs:**
 - ❖ **CCP, Label rouge and AB** regulated by national body CNLC
 - ✓ **agreed specifications**, eventually ask for a PGI or specificity attestation,
 - ✓ **agreed certification bodies** (verification of agreement **NF 45011** + efficiency of their control scheme)
 - ❖ **AOC** regulated by INAO (recognition, control and protection of AOC) each AOC noted in French official journal
 - u **collective marks**
 - ✓ **own specifications**
 - ✓ controlled by **independent organisations**

NB: the collective marks not controlled by an independent organisation are not considered here



CCP (certification de conformité produit)

3 wild products - 1 farmed product

■ scallops from Côtes d'Armor

- alive shell on classified area - Size > 102 mm
- fresh shelled Fishing date – species :*Pecten maximus*
- frozen shelled 2 days max between fishing & packaging

■ salmon from Norway

Farmed in fjords

Feed (mini 70% from fish)

3 in progress - not yet obtained

- ✓ *oysters refined in fattening pond at Marennes Oléron*
- ✓ *oysters from Etang de Thau*
- ✓ *fresh salmon*



Label rouge – 4 aquaculture products

- **Oysters (*C. gigas*) green, “fines de claire” from Marennes Oléron – 1989**
- **Oysters (*C. gigas*) “Pousse en claire” from Marennes Oléron – 1998**
- **Scottish salmon – 1990**
- **Mediterranean farmed sea bass - 2000**

AFNOR standard

- ▣ **Fish farming trout** production, processing, specification - 2000
- ▣ **Processed fish** – frozen fillet portions – specifications - 1999
- ▣ **Oysters** – Denominations & Classification - 1985
- ▣ **Cephalopods** - Size Classification

AB (biologic agriculture) **specification about fish farming production in progress**

Collective marks

- **Bretagne Qualité Mer**
 - Many species of fish & shellfish – sale limit date
 - Fishery GMP + Specifications wholesalers/retailers
- **Golfe du Lion – Qualité producteurs**
 - Many species – 1st sale limit
- **Poitou Charentes – troll sea bass**
- **Normandie Fraîcheur Mer (NFM) - scallops**
- **Fraîcheur Littoral de Haute Normandie - scallops**