



SECTION 10

LEGISLATION AFFECTING FISH & SHELLFISH PRODUCTS

Traceability: Standards and legal requirements

There has always been a degree of traceability within the food industry, with individual companies able to identify both their suppliers and customers. In recent years however the role of traceability in the control and safety of food has been identified as requiring greater transparency and regulation. This has been achieved by the development of international standards, industry guidelines and legislation. ([see case study on FF of Denmark](#))

10.1. Codex Alimentarius Commission

The Codex Alimentarius Commission (CAC) was formed under the joint sponsorship of the United Nations World Health Organisation (WHO) and the Food and Agriculture Organisation (FAO) in 1962, to develop international standards for food safety. The main purpose of CAC is to protect the health of the consumer and ensure fair trading practises based on sound scientific evidence. The World Trade Organisation (WTO) has designated the CAC as the organisation with responsibility for settling trade disputes relating to food, specifically as they relate to Codex standards of Application of Sanitary and Phyto-sanitary measures (SPS) and the Agreement on Technical Barriers to Trade (TBT).

As such, the CAC produced guidelines to be incorporated into regulations of individual countries, rather than specific legislative requirements. In terms of traceability the issue has been discussed in various committees and the following standards that relate to product traceability have been developed:

- **General Standard for Pre-packaged Food (GSPPF)**
 - **Sec. 4.5.1:** the country of origin of the food shall be declared if its omission would mislead or deceive the consumer
 - **Sec 4.5.2:** when food undergoes processing in a second country which changes its nature, the country in which the processing is performed shall be considered the country of origin for the purpose of labelling.
- **Guidelines for Generic Official Certificates Formats and Production and Issuance of Certificates. CAC/GL 38-2001**
 - 16. The details of the product being certified should be clearly documented on the certificate which should at least contain the following information:
 - nature of food
 - name of product



- quantity in appropriate units
- lot identifier or dating code
- identity and as appropriate the location of production establishment
- name and contact details of exporter or consignor
- country of dispatch
- country of destination

These details are not specific to food but constitute the normal fields of information contained on any Bill of Lading for trade between two countries.

10.2. Tracefish & SeaFoodPlus

The EU established a program to further these ideas with respect to seafood in 2000, under a project known as Tracefish (see: www.tracefish.org). This project has been continued under the SeaFoodPlus (www.seafoodplus.org) program which is currently designing further scientific standards for traceability of seafood products. This initiative has three main elements:

- required information for capture fishery distribution chains
- required information for farmed fish distribution chains
- technical specification for the electronic encoding of data, based on EAN.ICC numbering system

Each piece of information (data element) that was collected was provided with a unique identity code and categorised as either:

- **Shall:** the information is necessary to ensure the product traceability
- **Should:** it is recommended that this information is included
- **May:** this information may be useful to be included and beneficial to business

At the current time this is still in development, but will eventually be incorporated in existing EU legislation.

10.3. EU Legislation

EU food legislation can be categorized as the following:

- **Horizontal Legislation:** applies to all foodstuffs
- **Vertical Legislation:** applies to specific foods e.g. fish products

The current EU legislation for traceability is horizontal legislation and not specific to fish products, though this will change with the SeaFoodPlus projects' findings:

Council for European Parliament Regulation (EC) No 178/2002 - laying down the general principles and requirements of food law, establishing the



European Food Safety Authority and laying down the procedures in matters of food safety. (O.J, L31 1Feb 2002)

The central component of this regulation is that in order to ensure food safety, the food production chain should be treated as a continuum from primary production to the consumer and that includes the production of animal feed. Key points of this regulation are:

- **Article 18 - Traceability:** This makes it compulsory for all substances intended or expected to be incorporated into food to be traced back to the supplier and customers; and that systems are operated in order to provide this information to the competent authority on request. It is also necessary that all food or animal feed placed on the market be adequately labelled to facilitate its identification and traceability
- **Article 19:** outlining the responsibilities of food business operators
- **Article 20:** outlining the responsibilities of feed manufacturers

Articles 19 & 20 make it the individual responsibility of companies to:

- Withdraw product suspected of being unfit for human consumption
- Inform the competent authority of such incidents and cooperate with them to reduce or eliminate risk

Article 11 requires that all food and feed imported to the EU from third countries meet the regulatory standards of the EU.

Directive 2001/95/EC is also related to traceability and requires companies to;

- Have traceability back to the point of production
- Have systems to recall unsafe products
- Notify competent authorities of unsafe products

This legislation comes in to force on the 1st January, 2005 and incorporates all of the existing EU legislation which refers to hygiene and HACCP requirements. This legislation includes:

- **Directive 93/43/EEC** – on the hygiene of foodstuffs and the obligations of food businesses to exercise due diligence in their operations
- **Directive 91/493/EEC** – laying down the health conditions for the production and the placing on the market of fishery products and providing regulations on hygiene specific for the fish industry



- **Directive 89/396/EEC** – requirement that all food products are identified by “lot or batch” number: i.e. foods manufactured under same conditions/day/etc.
- **Directive 2003/89/EC** – amending Directive 2000/13/EC with regards to ingredients present in foodstuffs
- **Council Regulation (EC) No 104/2000** – laying down of specific information to be contain on a fishery product label
- **Commission Regulation (EC) No 2065/2001** – requiring on labels under 104/2000 that production method was identified e.g. capture fishery or aquaculture
- **Council Regulation (EEC) No 2092/91** – on the organic production of agricultural products – this gives the possibility to trace organic production

EU legislation is constantly being updated and added to and this can be reviewed on www.europa.eu.int/eur-lex/en/index.html

10.3. Non-EU legislation for production & traceability

USA seafood legislation is controlled by the Food and Drug Administration (FDA). The cornerstone legislations is **FDA rule 21 CFR 123 “The procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products”**. Implicit in this legislation is the Hazard Analysis and Critical Control Point (HACCP) system which sets standards and controls for the production and processing standards, with an emphasis on hygiene.

HACCP Systems require that the producer/processor constructs, maintains and reports to agreed certified standards, and that the facilities are regularly inspected by the local competent authority to ensure compliance to the prescribed standards. To a large degree, the standards set by the EU and those within HACCP are the same. The major difference is that there is no enforced traceability (trace-back) from the USA, but within the HACCP system there must be a linkage between batches of product and processing records that can only be achieved by recording batch identification codes onto processing records.

As of October 2004, the USA has introduced new labelling legislation which mirrors that which is in place in the EU. Additional legislation covers the production and export of fish products to the USA under **Public Health Security and Bio-terrorism Preparedness and Response Act of 2002 (PL107-188)**

The act is divided into five sections of which **Title III: Protecting Safety and Security of Food and Drug Supply** has the most relevance to traceability and seafood imports. In this section the following should be noted:



- **Section 305 – Registration of Food Facilities:** requires the owner, operator or agent in charge of a domestic or foreign food processing facility to register with the FDA
- **Section 306 Establishment and Maintenance of Records –** requires the creation and maintenance of records needed to determine the immediate previous sources and the immediate subsequent receivers of food (trace- back). Such records allow the FDA to address credible threats of serious health consequences or death in humans or animals. This section is important to all companies wishing to export foods to the USA and it ensures that they enact their own internal traceability systems
- **Section 307 Prior Notice of Imported food Shipments –** requires that prior notice of food shipments be given to the FDA, and must include;
 - description of article/product
 - the manufacturer and shipper
 - the grower (if known)
 - the country of origin
 - the country from where the article is shipped
 - the anticipated port of entry

The amount of notice required depends on the method of shipment, but this should not exceed five days or be less than eight hours.

In addition the FDA has issued guidelines that include the company ensuring;

- an effective product recall strategy is in operation
- incoming materials correspond to the orders sent to specific suppliers
- suppliers of all materials including; packaging, ingredients, labels etc. are known, preferably by means of independent audit
- the coding and packaging of incoming products should be known in advance and authenticated on receipt
- the location, storage and use of all materials should be tracked throughout their time in the processing plant
- final product tracking to be conducted

All of the above will rely on the producer and processor being able to set-up and operate a system of traceability or “trace-back” in the USA. The FDA has a contact address under www.cfsan.gov/...../html which gives detailed instructions and overviews for regulations affecting the importation of seafood in to the USA.

Japan has similar controls and requirements which include;

- **Product liability law –** the product has to be fit for its purpose



- **JAS Law legally required to display specific ingredients –**
hormones, antibiotics, etc
- **Container and Packaging Recycling Law**
- **HACCP Certification Guidance**

It is often considered better to actively search for a Japanese partner for the importation of seafood into Japan than to try and negotiate access unaided. Support is often forthcoming if the importer/exporter is seen as a joint venture rather than an individual. The local partner can also advise on markets, Japanese customs, etc. A useful contact point is Japan External Trade Organization which can be found under; www.jetro.org