European Union: *Exporting Seafood to the European Union – August 2014 Update*

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Fish Abstract by Heidi – www.paintingsIlove.com

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I. Introduction

A) Scope of the Report:

Given the complexity of the EU legislation, this report provides an overview of key EU legislation governing trade in edible seafood products. It does not intend to answer all questions; additional comments or concerns should be addressed to specific competent authorities (see Points of Contacts at the end of the report).

B) Background:

Twenty-eight countries compose the European Union (EU). The current Member States (MS) are: Austria, Belgium, Bulgaria, Croatia, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Romania, Spain, Sweden, the United Kingdom, Latvia, Lithuania, Estonia, Poland, Malta, Cyprus, Hungary, Slovenia, Slovakia and the Czech Republic. The EU population is approximately 505 million people since the accession of Croatia on July 1, 2013.

C) The Institutions:

The EU has seven different institutions that function in many ways as the different branches of the US government:

The **European Commission** is the EU executive body. It has three main tasks: to initiate EU policies, to act as the guardian of EU treaties and to supervise implementation of EU law. The Commission is divided in 32 directorates general (DG), of which ***DG Mare*** and ***DG Sanco*** share responsibility for food safety consumer policy and public health protection. A college of 28 Commissioners who are named by their national governments but should make decisions independently, head the Commission.

The **Council of the EU** consists of Ministers from the National Governments from EU Member States. Each Member State holds the rotating presidency of the Council for six months. The Council and the European Parliament share the responsibility for passing laws and making policy decisions. It also bears the responsibility for what the EU does in the fields of Common Foreign and Security Policy and EU action on several justice and freedom issues. The Council has working parties and permanent or special committees consisting of representatives from Member States. The best known is the Committee of Permanent Representatives of the Member States, or COREPER.

The **European Council** is made up of the heads of state from each Member State. They hold regularly scheduled meetings. This Council is responsible for defining the general political direction and priorities of the EU.

In addition to the Heads of State, there is a semi-permanent President who serves a two and half year term and the rotating President of the Council. While the European Council has no formal legislative power, it is an institution that deals with major issues and any decisions made by it are "a major impetus in defining the general political guidelines of the European Union." The Council meets at least twice every six months

The **European Parliament** (EP) is elected every five years by the people of Europe to represent their interests. The core mission of the European Parliament is to pass European laws. It shares this responsibility with the Council of the EU. Proposals for new laws are generated by the European Commission. The EP has the power to dismiss the entire European Commission. The European Parliament has gained authority over time, reaching its peak with the Lisbon Treaty's "co-decision" authority as well as budget oversight of the European Commission. Co-decision means that no law can be adopted without both European Parliament's and Council's consent.

The **European Court of Justice** rules on disputes involving interpretation and application of the EU treaties and legislation. It makes sure that EU law is interpreted and applied in the same way in all MS. The Court is located in Luxemburg and has one judge from each MS.

The **European Central Bank** has gained greater prominence during the Euro Zone crisis and the **Court of Auditors** audits EU finances; its role is to improve EU financial management and report on the use of public funds**.**

D) What are the different measures?

Regulations:

A Regulation is a law that is binding and directly applicable in all Member States without implementing any new national legislation. Both the Council and the Commission can adopt Regulations.

Example: Council Regulation (EC) No 1093/94 of 6 May 1994 setting the terms under which fishing vessels of a third country may land directly and market their catches at Community ports.

Directives:

A Directive is a law, with specific results to be achieved, that is binding on all Member States. However, each MS has the ability to choose how it is to be implemented. In practice, the Commission will issue approved implementing legislation after a Directive is adopted, known as Implementing Measures. Usually, the Commission works with the Member States regarding the details of the implementing measures in order to ensure correct implementation of the referred Directive. This is an important point, as businesses affected by a Directive have to take into account the national implementing legislation as well as the Directive. All Directives include a date by which Member States must transpose the Directive into their national legislation. In case of Member State non-implementation, the Directive remains the legal framework for adjudication. The Commission can act against Member States that have not implemented a Directive on time.

Example: Council Directive 91/493 laying down the health conditions for the production and marketing of fishery products.

Decisions:

A Decision is binding entirely on those to whom it is addressed. No national implementing legislation is required. Both the Council and the Commission can adopt decisions.

Example: Commission Decision 95/328 laying down certain transitional measures concerning the certification of fishery products from third countries in order to facilitate the switch over to the arrangements laid down in Council Directive 91/493/EEC.

Recommendations:

A Recommendation has no binding effect -it is not a law. Both the Council and the Commission can adopt recommendations.

Example: Commission Recommendation 92/540 concerning a coordinated program for the official control of foodstuffs for 1993.

II. How Fishery Policies are handled at the EU Level

DG Mare is responsible for negotiating international fishing agreements, resources management, aquaculture, fleet management, and the Common Fisheries Policy (CFP). It also proposes tariff reductions import quotas. It supports DG Trade, part of which is the EU equivalent to the Office of the US Trade Representative for WTO matters. Some fish species are subject to trade restrictions under the Convention on International Trade of Endangered Species, which is the responsibility of DG Environment. DG Mare and DG Environment work together closely due to the current status of worldwide fish resources. Fishery products are also subject to measures introduced by DG Agriculture and DG Internal Market, and are supervised by DG Sanco. DG Agriculture is responsible for the Common Agricultural Policy (CAP) and all “vertical” measures on raw materials.

These DGs initiate proposals on all EU measures concerning sanitary legislation and inspection, by type of products (beef, pork, poultry, vegetables, seafood, etc.).

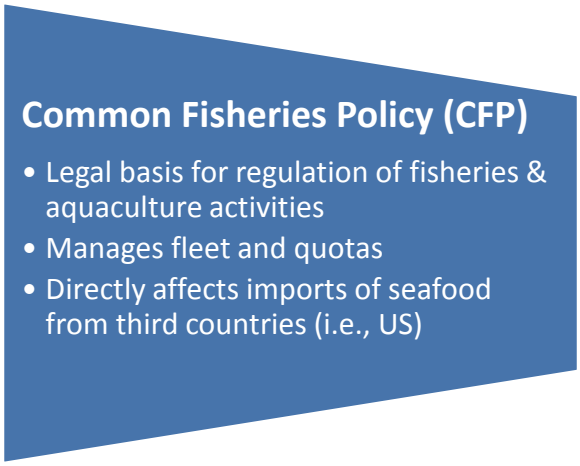
DG Mare	DG Environment	DG Agriculture	DG Internal Market	DG Sanco
•Negotiates international fishing agreements, resources management, aquaculture, fleet management & Common Fisheries Policy (CFP) •Proposes tariff reductions, and import quotas •Supports DG Trade in fisheries related matters •Works with DG Environment to manage worldwide fish resources	•Monitors trade restrictions on species that fall under the Covention on International Trade of Endangered Species •Works with DG Mare to manage worldwide fish resources	•Responsible for Common Agriculture Policy (CAP) •Responsible for all "vertical" measures on raw materials	•Responsbile for "horizontal" measures for processed products •Proposes legislation on additives, microbiological criteria, colorings, antibotics, and labeling in conjunction with DG Sanco	•Proposes legislation on additives, microbiological criteria, colorings, antibiotics, and labeling •Is in charge of EU food and feed legislation •Handles import controls for food and feed •Includes the Food & Veterinary Office (FVO)

DG Internal Market deals with “horizontal” measures for processed products. Together with DG Sanco, they propose legislation on additives, microbiological criteria, colorings, antibiotics, and labeling. All those texts refer to “foodstuffs.” DG Sanco oversees all scientific committees that advise DG Internal Market and DG Agriculture on matters concerning consumer health. DG Sanco also includes the Food and Veterinary Office (FVO), which is based in Ireland.

The main responsibilities of the FVO are to monitor the observance of food hygiene, veterinary, and plant health legislation within the European Union, and to help promote confidence in Europe’s food safety to consumers. The FVO is responsible for auditing Member States’ competent authorities and for inspecting third countries’ compliance and/or equivalency to EU legislation.

The European Food Safety Authority (EFSA) was created on January 28, 2002. EFSA covers risk assessment as well as risk communications. The relevant EU institutions maintain risk management responsibility for the EU. Part of EU legislation is defined according to EFSA’s scientific opinions and recommendations.

The primary EU laws that impact US seafood exports are: the Common Fisheries Policy (CFP) and the Food Hygiene Legislation. The CFP establishes a legal framework for the regulation of fisheries and aquaculture activities. It has a direct impact on the EU's production capacity through fleet and quotas management. Therefore, it can directly affect imports of seafood from third countries such as the US. The Food Hygiene Legislation is the EU's instrument that guarantees safe food to European consumers. It makes sure that "domestically made" as well as imported food complies with the EU's minimum hygiene standards.



III. The Common Organization of the Market in Fishery and Aquaculture Products

The Common Organization of the Market in Fishery and Aquaculture Products was first introduced in 1970, reviewed in 1993 and 2000 and last amended in 2013 (Council Regulation 1379/2013). Its purpose is to stabilize the market, to guarantee a steady supply of quality products, to ensure reasonable prices for consumers and support fishermen's incomes.

The five components of the Common Organization of the Markets are:

- Marketing standards and consumer information for fresh products for quality, grades, packaging and labeling for domestic production as well as imports.
- Producers' organizations (voluntary fishermen associations) are officially recognized and are set up to help stabilize markets fluctuations. Their role is to protect fishermen from sudden changes by adjusting supply to demand. They also help to improve product quality and ensure that fishing quotas are respected.
- Interbranch Organizations and Agreements are aimed at facilitating a total integration of the sector from producer to consumer.

- Prices and Intervention by which certain species cannot be sold below a given price. Financial support is available to producers' organizations to withdraw fish from the market when products reach the floor price. They can be stored and sold when market improves or processed.
- Trade with third countries in order to ensure an adequate supply of fishery and aquaculture products to the EU intended for the processing industry, the EU adopts regulations providing reduced duty rates, quotas, and autonomous suspensions for specified products.

IV. Exporting Seafood to the EU

A) General Provisions:

As a general principle, seafood is imported into the EU from only approved countries and from approved establishments, e.g., processing plants, factory or freezing vessels, cold storages or brokers. Aquaculture products, including live bivalve mollusks, may be exported from only approved establishments located within approved production zones or areas.

U.S. "EU approved" exporters must also source their raw materials from EU approved establishments in third country of origin.

Since 2006, the U.S. Seafood Inspection System has been recognized by the EU as an equivalent of the European Seafood Inspection System. **This status does not apply yet to the export of live bivalve mollusks, in whatever form.**

This mutual recognition facilitates seafood trade between the U.S. and the EU. Furthermore, it creates a framework under which Member States cannot impose national requirements on U.S. seafood exporters on top of EU harmonized legislation. However, differences of interpretation among Member States can lead to delays at border inspection posts.

B) List of Countries:

Commission Decision 2006/766/EC is the list of countries and territories from which imports of fishery products and bivalve mollusks, echinoderms, tunicates and marine gastropods are permitted. One may note that the U.S. does not appear on the list of countries authorized to export bivalve mollusks, echinoderms, tunicates and marine gastropods. This means that, unlike fishery products, the U.S. inspection system for shellfish has not been recognized as equivalent to the EU's inspection system.

The U.S. and the EU are currently negotiating a veterinary equivalency agreement but lack of progress from both sides has led the EU to adopt a ban of all U.S. shellfish per Commission Decision 2009/951.

However, article 1, paragraph 2 of the Decision 2006/766/EC, mentioned above, indicates that any third country, not listed in the Decision can export adductor muscles of wild *Pectinidae* completely separated from the viscera and gonads. In other words, the EU accepts "roe-off" scallops from the U.S., provided that they are wild caught. In this case, a regular health certificate for fishery products is required.

C) Approved Establishments

U.S. operators that wish to export seafood to the EU must be approved by and registered with their National competent authority. The Food & Drug Administration (FDA) is the U.S. agency responsible for the approval of seafood establishments. Once they are approved, U.S. exporters are included on the FDA list, which is updated every quarter. This FDA list is then sent to the EU for validation. The process can take up to three months. The list of FDA District Offices in charge of the approval process can be found at:
http://www.fda.gov/ForIndustry/SmallBusinessAssistance/SmallBusinessGuidetoFDA/default.htm

U.S. exporters MUST NOT send shipments to the EU before the EU list is in force within the EU.

D) Certification

Each shipment of seafood products must be accompanied by **a Sanitary** AND a **Catch Certificate**, effective January 1, 2010. You will find a separate chapter on the catch certificate later in this report.

U.S. exporters should pay specific attention to the fact that health certificates must be issued and signed by USDOC-NOAA **before** the shipment leaves the U.S.
Bills of lading should always be dated the day of or after issuance of the health certificate.
See Certification Checklist in Annex

Important Notice:
Effective June 2009, the U.S. Department of Commerce, NOAA/National Marine Fisheries Service, is the U.S. agency responsible for the certification of fishery and aquaculture products intended for the EU. A health certificate may be issued for goods produced by different establishments, but can only be made to one consignee.

A health certificate may be issued for several containers of the same product considered to be a single lot. The health certificate must define the lot. Therefore, a rejection at the point of entry will include all goods covered by the same health certificate, even if only a part of it presents a sanitary or documentary problem. It is acceptable to list fresh and/or live products on the same health certificate. However, frozen products must be listed on a separate health certificate. Instructions regarding the language of health certificates can be found at the end of Regulation 1663/2006, noted in chapter III. In summary, health certificates must be issued in one of the official languages of the country of entry into the EU territory, and if necessary, in the language of the country of destination. However, a Member State may consent to the use of one of the 23 official EU languages other than its own.

In practice, the Border Inspection Post (BIP) at the first point of entry into the EU conducts the documentary check and issues a Common Veterinary Entry Document (CVED) in conformity with Commission Decision 2003/279/EC, last amended by Commission Regulation 136/2004.

This CVED must be:

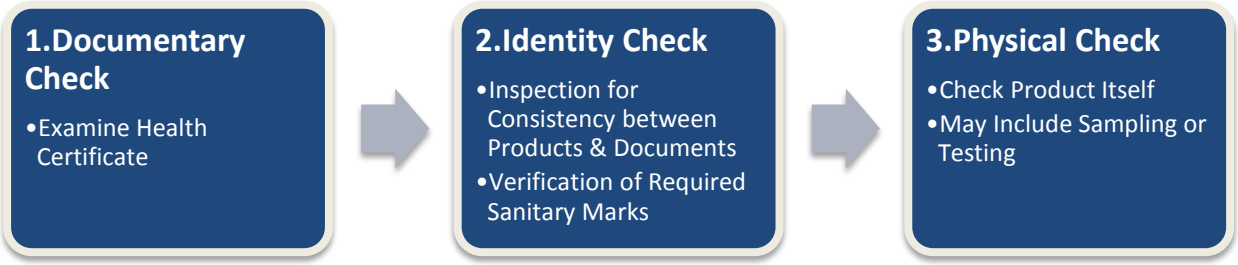
1. Either in the language or one of the languages of the border inspection post where the products are entering into the EU, and
2. Either in the language or one of the languages of the destination country.

Important Notice:
Effective April 1, 2007, Switzerland adopted EU sanitary legislation regarding import requirements for fishery products. Therefore, U.S. seafood shipments must be accompanied by the same health certificate as required by any EU Member State. A health certificate intended for Switzerland may be in French or English.

E) Import Controls:

Principles for veterinary checks are laid down in Council Directive 97/78/EC, Council Directive 2002/99/EC, Regulations 882/2004 and 854/2004. Inspections of consignments originating from third countries must be carried out on all consignments, at the first point of entry into the EU territory and at approved border inspection posts.

Import controls are done in three consecutive steps:



1. **Documentary check:** examination of the health certificate;
2. **Identity check:** visual inspection to confirm consistency between documents and products, verification for the presence of required sanitary marks - country of origin, approval number; and,
3. **Physical check:** check of the product itself, organoleptic control, packaging, temperature. This may include sampling and laboratory testing.

Products imported from "harmonized" countries, such as the U.S., are subject to the documentary, identity and physical checks at the approved border inspection post at the first point of entry into the EU territory. When a consignment satisfies EU requirements, it can be marketed freely in all EU Member States.

While the documentary and the identity checks must be performed on all consignments, the frequency of physical checks is reduced for products from "harmonized" countries. Approximately 20 percent of fish products in hermetically sealed containers, fresh and frozen fish, and dry or/and salted products undergo physical checks. For other fishery products and bivalve mollusks, about 50 percent are subject to actual physical checks. Each import control - one certificate = one control - is subject to inspection fees. In the case of processed food containing animal products, surimi, for example, the European importer must have an "import license" from their customs authorities before the import process begins.

European border inspection posts may randomly conduct specific analysis on shipments presented to them for clearance. The analyses can target residues, heavy metals or other contaminants. During random tests, shipments may be cleared and delivered to EU customers. However if the tests reveal any contamination, the establishment that sent the shipment in question will be put on "reinforced control status." This status is then communicated to all Member States as well as to the European Commission through the Rapid Alert System. When an establishment is on reinforced control status, the U.S. establishment's next ten consecutive shipments (of a commercial size, not sample) to any EU country, will be automatically tested. The products will be detained at border inspection posts until results are received. After ten shipments without positive results, the establishment in question is removed from the reinforced control list. The exporter may also choose to stop sending shipments to the EU for a three month period. This time period is equivalent to the ten consecutive shipments rule.

If a shipment is refused for non-compliance with EU legislation, the responsible party of the shipment has three options:

1. Destroy the products in question;
2. Re-dispatch these products to a non-EU country; or
3. Return the products to the originating country.

It is important to note that Regulation 882/2004 (Article 21) imposes a number of conditions for the two last options noted above:

1. The new destination has been agreed to by the EU based food business operator, i.e., consignee;
2. The consignee must inform the competent authority of the third country of origin or third country of destination, if different, of the reasons and circumstances that prevented sales of the food within the EU;
3. **And**, when the third country of destination is not the third country of origin, the competent authority of the third country of destination must signal its preparedness to accept the consignment.

F) Triangular Trade:

Triangular trade occurs when U.S. products are shipped from the U.S. to other third (non EU) countries for storage before being re-exported to the European Union at a later date. It also occurs when a product is imported into the U.S and then re-dispatched to the EU.

EU sanitary legislation requires:

1) The shipment must be stored in an EU-approved facility in the third country;
2) At the time of re-export to the EU, it must be accompanied by a sanitary certificate from the last country of dispatch, even if the products were not further processed in that country.

This second certificate must be based on the info included on the first certificate that was issued by the initial competent authority, if applicable.

The two sanitary documents to provide to EU border inspection post in the case of a U.S. shipment sent to a third country and then re-dispatched to the EU are:

1) From the U.S. to country of storage: **U.S. Certificate** (EU type or not) with final destination the country of storage **AND**
2) From the country of storage: **EU Certificate** with final destination in the EU.

V. Food and Feed Hygiene Legislation

Hygiene is part of the European policy on food safety, which also takes into account other sanitation aspects such as materials in contact with food, labeling, chemical substances, e.g., additives and food colorants, and ionization of foodstuffs, contaminants and residues.

While this Hygiene Package tends to simplify the previous very complex legislation, it also introduces the concept of "responsibility" for the food and feed operators throughout the entire food chain, in other words, "from farm to fork." This section summarizes the new legislation specifically addressing fishery products and bivalve mollusks.

A) Food Hygiene:

The Hygiene Package sets clear and strict rules on the sanitary conditions of foodstuffs, specific sanitation rules for food of animal origin, and specific rules for controls on products of animal origin intended for human consumption. While there are general rules for all food, there are specific measures that apply to fishery products and bivalve mollusks. Under this updated legislation, imported products will be required to meet the same standards as EU products.

The Hygiene Package is divided into 5 Regulations and Directives:

Hygiene 1: European Parliament and Council Regulation 852/2004 on the sanitation of foodstuffs. It includes general and technical requirements for primary production, including Hazard Analysis of Critical Control Points (HACCP).

Hygiene 2: European Parliament and Council Regulation 853/2004 are specific sanitary rules for food of animal origin. Specifically, Annex I - definition, and Annex III Section VII & VIII -bivalve mollusks and fishery products. This Regulation has been amended by Regulation 1662/2006. The last amendment modifies the conditions for exports of fishmeal into the EU.

Hygiene 3: Regulation 854/2004 outlines specific rules for the organization of official controls on products of animal origin that are intended for human consumption. Specifically, Chapter III, Annexes II, III and VI. This Regulation has been amended by Regulation 1663/2006. It modifies point 2 of annex VI of Regulation 854/2004 regarding health certificates languages.

Hygiene 4: Council Directive 2002/99/EC are health rules governing the production, processing, distribution and importation of products of animal origin.

Hygiene 5: Council Directive 2004/41/EC.

B) Subsequent Regulations:

U.S. exporters should be aware that Member States may have adopted additional measures that are specific and must be followed in addition to the requirements of the Hygiene Package.

Microbiological Criteria for Foodstuffs:

These criteria are fundamental for a comprehensive food sanitation framework. Regulation 2073/2005 last amended by Regulation 1441/2007, introduces new criteria for certain food borne bacteria, their toxins and metabolites (e.g., salmonella, histamine and listeria). These criteria are applicable to products during their entire shelf life. In addition, the Regulation sets down certain sanitation criteria regarding the production process.

Implementation Measures:

Implementing rules concerning the Hygiene Package (Commission Regulation 2074/2005) include certificates for certain products and testing methods for marine bio-toxins.

Implementing measures, described in Regulation 1664/2006, and subsequent Regulation 1250/2008, amending Regulation 2074/2005, have been in place since May 1, 2007. These measures include new certificates for fishery products and live bivalve mollusks. **These certificates do not apply to U.S fishery products and apply only partially for live bivalve mollusks.** Chapter IV of this report will identify the correct certificate to use to export fishery products to the EU.

Implications for Third Countries Exporting to the EU:

The European Commission developed a Guidance Document that addresses the key questions related to EU imports requirements. Food business operators will find the information they need regarding this new Hygiene regime on their businesses.

C) Feed Hygiene:

Contaminated feed has been responsible for many food crises. Council Regulation 183/2005 aims to ensure feed safety at all stages, including primary production. Effective January 1, 2006, it includes mandatory registration of feed growers, processors, packers and distributors with their competent authority. Note: in the U.S., it is the FDA and NOAA. However, in the absence of specific implementing rules concerning third countries, the existing rules on EU imports apply.

D) Food and Feed Controls:

The Food and Feed Regulation on Official Controls - Council Regulation 882/2004 – executes a harmonized EU controls system that includes: food and feed safety and animal health and welfare standards. Third countries must guarantee that products intended for the EU market meet the necessary standards. This section does not include animal welfare controls unless there are explicit animal welfare provisions in specific bilateral agreements.

Questions & Answers on Food Controls.

VI. Which Certificate for Which Product?

PRODUCT	CERTIFICATE-YES OR NO?	RELEVANT LEGISLATION
Fishery and Aquaculture Products (Including wild raw off scallops)	**YES**	• Decision 2006/199/EC • Regulation 1012/2012
Aquaculture Products - Live Fish • Eggs, gametes - for farming • For consumption	**YES**	• Decision 2003/858/EC • Decision 2004/454/EC • Regulation 1664/2006
Aquaculture Products - Mollusks • Eggs, gametes for growth, fattening, or relaying • For consumption	**YES**	• Decision 2004/319/EC • Decision 2004/609/EC • Decision 2004/623/EC • Decision 2005/409/EC
Bivalve Mollusks	**N/A**	Decision 2009/951/EC

A) Fishery Products:

Effective June 15, 2011, shipments of fishery and aquaculture products must be accompanied by a health certificate. U.S. exporters should consult the NOAA Seafood Inspection Program web site. This health certificate is covered by Commission Decision 2006/199/EC -for public health - and Regulation 1012/2012 for animal health. This health certificate is valid for both fishery and aquaculture products. Processed mollusks as well as frozen scallops are considered as fishery products and must have a health certificate.

B) Aquaculture Products:

The relevant EU legislation regarding aquaculture products:

- Commission Decision 2003/858/EC - identifies specific animal health conditions and certification requirements for imports of live fish, their eggs and gametes intended for farming. It also includes conditions for live fish of aquaculture origin and their products intended for human consumption; as amended by Commission Decision 2004/454/EC**.** This Decision has been partially repealed by Regulation 1664/2006.

- Commission Decision 2003/804/EC - identifies specific animal health conditions and certification requirements for imports of mollusks, their eggs and gametes, for further growth, fattening, relaying or human consumption; as amended by Commission Decision 2004/319/EC, Commission Decision 2004/609/EC, Commission Decision 2004/623/EC and Commission Decision 2005/409/EC.

C) Live Bivalve Mollusks:

Effective July 1, 2010, per Commission Decision 2009/951, imports of U.S. bivalve mollusks, in whatever form, are not permitted into the EU. Trade will resume once the US and the EU reach a Veterinary Equivalency Agreement.

VII. Fishmeal – Fish oil

A) Fishmeal:

A certificate "for processed animal protein not intended for human consumption," according to the model listed in Regulation 1069/2009 and its implementing Regulation 142/2011 (Chapter 1 certificate), must accompany U.S. exports of fishmeal.

For U.S. exporters, NOAA issues this certificate. Fishmeal exports intended for the EU must be produced by EU - approved establishments. The list of U.S. approved animal by-products establishments can be found through the link:
https://webgate.ec.europa.eu/sanco/traces/output/US/ABP-PET_US_en.pdf

B) Fish Oil:

Effective April 30, 2009, the amended Hygiene Legislation requires that fish oil intended for human consumption must meet the requirements for "regular" fishery products.
As such, U.S. fish oil shipments to the EU must be produced in EU-approved establishments and accompanied by the same public health certificate as the certificate for fishery products.
Fish oil products containing plant or other ingredients (wheat…) in quantity are to be considered composite products. Regulation 28/2012 is the framework Regulation covering composite products. Under this Regulation, establishments wishing to send composite products do not need registration and must use the certificate described in Annex I of the Regulation. U.S. Federal Agency (NOAA, FDA, USDA, FSIS, APHIS…) cannot issue such a document.
However, NOAA can issue a fishery product certificate for flavoured fish oil and fish oil containing plant-based antioxidants for human consumption. These products are not considered to be composite and must come from EU approved establishments

Shipments of fish oil not intended for human consumption are controlled by different legislations and must be accompanied by a certificate according to the regulation described in Regulation 142/2011 - Chapter 9 certificate - mentioned above.

For a complete overview of fish oil import requirements into the EU, see link below:
http://ec.europa.eu/food/animal/bips/docs/09-01-29Fish_oil.pdf

VIII. Duties and Trade Measures

A) Background:

All EU fish tariffs were consolidated under the Tokyo Round of GATT. The average EU duty for Chapters 3, 1604 and 1605 is 17.2%, one of the highest in the world. The tariff range is from 0% - live eels, to 25% - canned mackerel, bonito and anchovies. The primary legislation covering tariffs is Commission Implementing Regulation 1001/2013. However, the EU provides different mechanisms to reduce duties. It claims that its overall tariff average is then reduced to around 3 to 4%: An overall duty-free scheme applies to Africa-Caribbean-Pacific (ACP) countries, signatories of the Lomé Convention, for all seafood products imported into the EU from ACP countries. The Generalized System of Preferences (GSP), which applies to developing countries, applies to all seafood products in Chapter 3. Products are classified according to categories, e.g., *sensitive*, *semi-sensitive* and *very sensitive*.

The ANDEAN Group, composed of Bolivia, Colombia, Ecuador, Peru and Venezuela, enjoys duty-free rate on most of Chapter 3. "Access to Markets" for "Access to Resources" is the preferred EU strategy for fish trade negotiations. Some advantages are granted, product-

by-product, following signatures of fishing agreements. For example, Argentina has reduced duties for hake fillets and Morocco was granted duty-free status on canned sardines' imports. Recognizing its processing industry's requirements, the EU unilaterally reduces duties for certain quantities of its imports using two annual mechanisms, suspensions and autonomous quotas. Most of the products affected must be further processed within the EU. Requests for reduced duties must initially be made by the European importer.

Most products are also subject to "reference prices." The system of reference prices is based on an essential part of the CFP, the support of fishermen's incomes. Based on the previous year's landing prices, the EU fixes minimum prices on a yearly basis for a wide range of species. Depending on those prices, several financial mechanisms are allowed by Producers Organizations (POs) such as withdrawal prices and carry-over financial support.

B) Tariffs Quotas:

Tariffs Suspensions have been suspended since January 2013 and replaced by Autonomous Tariff Quotas (ATQs) that are granted for 3 years. These tariffs quotas are covered by Council Regulation 1220/2012.

Autonomous quotas are opened on an annual basis. Each product or group of products is subject to a quantitative limit. The quota remains opened until the limit is reached. Quantities and reduced duties may change every year depending on Member States' demands usually based on national industry requirements. Compromises are reached usually at the Ministerial level.

On a global scale, the U.S. Government continues to negotiate with the EU for a "zero for zero" approach to tariffs in the fisheries sector. The current discussions on a Transatlantic Trade & Investment Partnership (T-TIP) Agreement with the European Union include fishery products.

For questions on a specific duty rate, consult the following web site:
http://ec.europa.eu/taxation_customs/dds2/taric/taric_consultation.jsp?Lang=en&Screen=0&redirectionDate=20110203

IX. How Do I Label My Seafood Product?

A) Legislative Background:

Various crises within the food chain, such as Foot & Mouth disease, BSE, horsemeat misidentification incidents and detection of heavy metals in a product, have reinforced the critical need for information, communication and transparency for consumers from the producers, processors, and marketers.

The three primary Labeling Regulations are:

- Regulation 1169/2011 on the provision of food information to consumers.
- Commission Regulation 2065/2001/EC primarily targeting retail products. But additional Regulations are expected in the context of "public safety" and "organic food." Directive 2003/89, in force since November 2005, imposes the labeling of potential allergens.
- Food manufacturers must indicate the source allergen on the label, if it is used as an ingredient at any level in pre-packed foods. Directive 2006/142/EC adds "mollusks and products thereof" to the list of potential allergens.

All new EU Regulations are based to ensure the consumer's confidence and safety so that "the consumer will not be misled by any product or packaging."

For sanitary purposes and to allow traceability of seafood products, EU legislation requests that **all outer and inner packages** bear:

1. The country of origin,
2. The commercial denomination of the products, and
3. The approval number of the establishment of origin.

ALL OUTER & INNER PACKAGES MUST BEAR:

- Country of Origin
- Commercial Denomination
- Approval Number of the Establishment of Origin

Regulation 853/2004 (Annex II, point 7) requires that products intended for the final consumer such as canned products, must include the FDA approval number of the U.S. packer/processor/manufacturer as well as their address or that of the EU seller.

However, U.S. exporters should pay specific attention to article 5 of Commission Decision 2006/199 regarding products in bulk and those intended for further processing that introduces derogation to this rule.

Finally, Regulation 853/2004 (Annex II, paragraph 11) allows for minimal labeling instead of normal labeling requirements: *"For products of animal origin that are placed in transport containers or large packages and are intended for further processing, handling, wrapping or packaging in another establishment, the mark may be applied to the external surface of the container or packaging."*

Those two items must be written or printed "indelibly." The most desirable way would be to have them pre-printed on packages/cartons. In instances where stick-on labels may be used, they must not be easily destructible or removable. Labels must be in a language

"easily understandable" by users and at least in one of the official languages of the country of final destination (distribution). Labels may be in several languages.

Commission Regulation 2001/2065/EC identifies specific requirements for the labeling of fishery and aquaculture products intended for the **retail sector**. This Regulation only concerns products from Chapter 3 of the Tariff Harmonized System, and not products from Chapter 16, for example, canned products. **This legislation has been amended by Regulation 1379/2013.**

As of December 13, 2014 there will be new requirements for products intended to retail and mass caterers.

The required information on the label of all fishery and aquaculture products for sale at retailers and mass caterers is:

Compulsory Information on Labels for Retail Sector			
Commercial Name of Species	Production Method	Fishing Gear	Catch Area

The commercial name of the species. The Latin name is not mandatory on the label except if required by your client. The EC has established a list of applicable commercial names. This list is visible on DG Mare's website. (Note: the Latin name is required on other documentation such as the health certificate)

The production method, e.g., aquaculture or fishery product. The appropriate language is: "caught in..."; "caught in fresh water;" "farmed;" or "cultivated." However, it is up to Member States whether this information is required when the commercial designation and the area of capture make it obvious that the fish was caught at sea.

The fishing gear: The new legislation give the choice of seven fishing gears to be included on labels. In case of multiple fisheries, operators can put several fishing gears on the same label.

Operators that want to add additional voluntary information on the type of fishing gear can do so. Annex III of Regulation 1379/2013 provides a list of additional info for each type of gear.

Seines
Trawls
Gillnets and similar nets
Surrounding nets and lift nets
Hooks and lines
Dredges
Plots and traps

The catch area. Products caught at sea must identify the area of capture, which is taken from the FAO list. However, only the general area must be mentioned, e.g., Pacific Ocean. Products caught in fresh water require a reference to the Member State or third country of origin of these products. Farmed products must reference the Member State or third country in which the product underwent final stage of development. Operators may well choose to provide additional information regarding the area.

To ensure exact traceability at all stages of the marketing process, fisheries and aquaculture products must be accompanied by a document indicating the information described above as well as the Latin name of the products. The document concerned can be the invoice.

Effective January 2014, all seafood sold at RETAIL outlets must have nutritional information on the package. Regulation 1169/2011 identifies the minimum information that must be included on labels of products intended for retail or mass caterers. Exporters should pay specific attention to Article 9, the following articles as well as all annexes of the Regulation.

Other Regulations regarding ingredients, allergens and guidelines for the implementation of labeling legislation can be downloaded at:
http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/index_en.htm.

It is important to note that some Member States as well as countries that are part of the European Economic Area (EEA) may have additional requirements for seafood labeling. For further information on labeling, contact our office at the U.S. Mission to the European Union.

B) Specific Labeling Examples:

Fresh, Chilled Products:

1. Species
2. Country of Origin- Roman Letters, min. 2 cm
3. Presentation- Whole, Gutted, Fillet, etc.
4. Best Before Date- Not Mandatory per EU Legislation but Requested by Most Member States
5. Freshness, Grade & Size Category (for Species with Common Standards, min. 5 cm).
6. Net Weight in Kilograms (Kg)
7. Date of Grading and Dispatch
8. Name & Address (city + state + "FDA approval #" of Processor/Packer)
9. Freshness Grading is Only for Whole/Gutted Fresh Fish

Live Bivalve Mollusks:

1. Species- Common Name and Latin Name
2. Country of Dispatch
3. Date of Wrapping - at least Day and Month
4. Date of Durability or "These Animals Must Be Alive When Sold"
5. Net Weight - Kg.
6. Identification of the Dispatch Center by Its Approval Number
7. Name and Address – City & State of Packer + "FDA Approval #" Interstate Certified Shellfish Shipper #

Canned Products:

1. Name of Product
2. Country of Origin
3. Net Weight in Grams - or Liter for Liquid Products
4. Net Drained Weight- in Case of Solid Packed in a Usually- Not Consumed Liquid
5. List of Ingredients (added water is an ingredient)
6. Date of Minimum Durability - Year
7. Special Storage Conditions or Conditions of Use
8. Instructions for Use- If Not Obvious
9. Name and Address of Manufacturer, or EU Seller
10. "FDA Approval #" of Packer or Manufacturer/ Processor

Frozen Products:

1. **Species Followed by "Frozen"**
2. **Country of Origin**
3. **Presentation-** *may be included with the name of the species*
4. **Net Weight in Kg**
5. **List of Ingredients -** *unless it is only fish*
6. **Date of Minimum Durability -** *month/year, or "Best Before" date*
7. **Freezing date**
8. **Special Storage Conditions -** *"to be maintained at -18°C"*
9. **Instructions for Use** *- if not obvious, include "Do Not Freeze Again Once Thawed"*
10. **Name and Address of Manufacturer or EU Seller**
11. **"FDA Approval #" of Packer (CFN or FEI) or Processor**
12. **Lot #***- must begin with "L" or the word "LOT." Not always mandatory. The lot # is defined by the processor in order to trace a product history in case of problem. (It can be the production date).*

Deep-Frozen Products:

1. **Same Requirements for Frozen Products, plus...**
2. **Freezing Date**
3. **Storage Conditions and Maximum Period of Storage:**
   - *Between 0 and 5°C: 1 day*
   - *"*", or between -5 and 0°C: 1 week*
   - *"**", or between -12 and -6°C: 1 month*
   - *"***", or at least at -18°C: up to the best before date*

Lot # Example:

L8110B15 *may mean*

L = Lot
8 = 1998
110 = Day of Production
B15 = Production Line Number

X. Other legislation

In addition to the above-mentioned legislation, the EU sets various requirements for a wide range of issues. This includes legislation on:

- Additives, colorings, flavorings and sweeteners allowed within the EU.
  Per Directive 95/2/EEC (amended several times), additives such as STP - E338 to E 450 - are not allowed in fresh scallops, only in frozen and deep frozen scallops.
- Traceability of foodstuffs.
- Contaminants.
- Packaging materials: this legislation is important and relates to the characteristics of materials to not transfer substances to foodstuffs in quantities that may be harmful to human health, or change organoleptic properties.
- **Sport caught fish:** Commission Regulation 206/2009 identifies weight limits under which there is no need for health certificate for the import of fish for personal consumption. This limit has been raised from 1 kg to 20 kg. Article 2, paragraph c.

XI. Illegal, Unreported, and Unregulated (IUU) Legislation

In 2008, the EU adopted Council Regulation (EC) 1005/2008 aimed at eliminating Illegal, Unreported & Unregulated (IUU) fishing. Since January 1, 2010, all third countries wishing to export seafood to the EU must provide a catch certificate.

This catch certificate is required in addition to all other sanitary documentation.

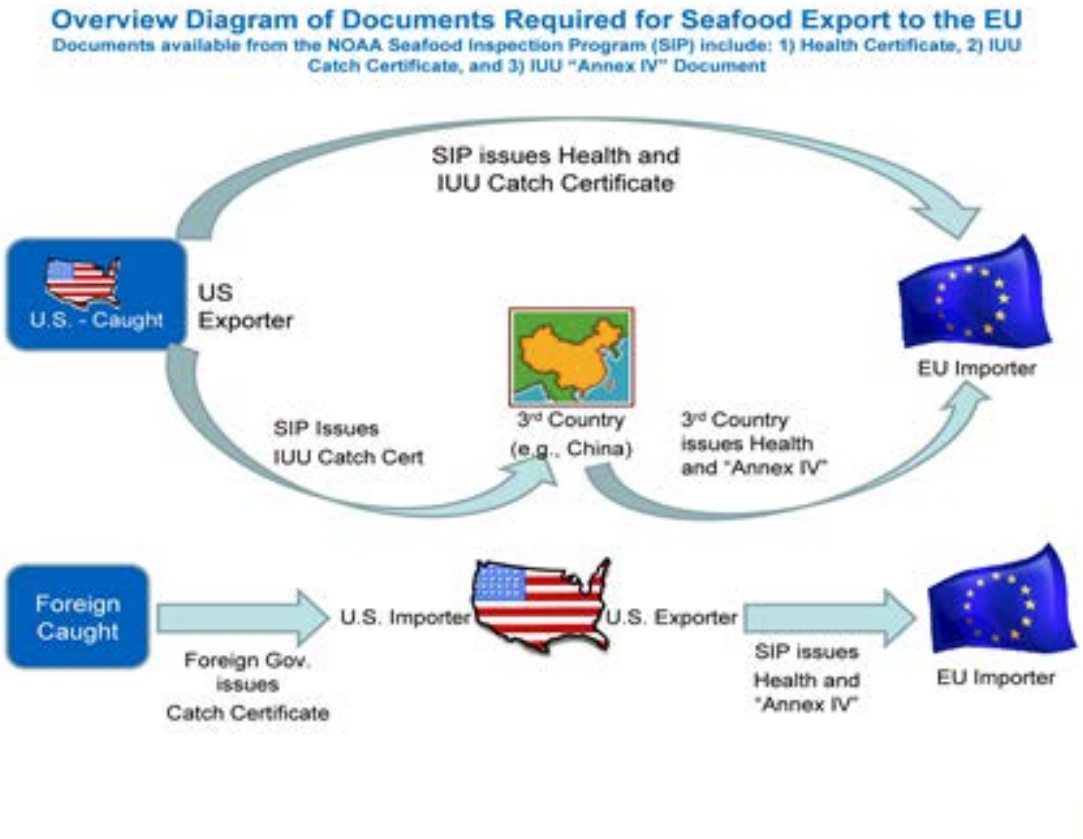
This Regulation has been amended by Regulation 86/2010 and Regulation 202/2011. These Regulations amend the list of products excluded by the scope of the catch certification system and identify specific agreements between the EC and third countries, including the U.S.

Catch Certificates are required for products of Chapter 3 and 16 of the Combined Nomenclature. For example, Fish Oil bearing HS code 1504 is Not subject to Catch Certification.

Implementing measures, list of products excluded by the IUU legislation, list of competent Member States (MS) authorities, and FAQs are all found on the EC-DG Mare web site below: http://ec.europa.eu/fisheries/cfp/illegal_fishing/index_en.htm

NOAA signed an agreement with the EC that allows for a U.S. specific catch certificate. NOAA is responsible for the issuance of both sanitary and catch certificates. U.S. exporters will find the necessary information regarding these catch certificates, as well as FAQs on the NOAA SIP web site.

Diagram of documents required for direct and indirect seafood exports to the EU (courtesy Linda Chaves):



Annex I: CERTIFICATION CHECKLIST

Establishment Listing:

- ☐ **Is your establishment on the EU list of U.S. approved establishments? If not (yet), DON'T SHIP!**
- ☐ **If yes, does it correspond to the one mentioned on the health certificate?**
- ☐ **No typos? Inversion of numbers?**
- ☐ **Is your third country supplier, if any, an EU approved establishment?**
- ☐ **Is there any restriction on products from that particular third country?**

Date of certificate:

- ☐ **Is your certificate dated prior to the bill of lading? If not, DON'T SHIP!**

Approval number:

- ☐ **Don't forget to mention your approval number on all (outer & inner) packages, irrespective of the final use of your product.**
- ☐ **Does the approval number on the health certificate match the one mentioned on your label?**

Identification of products:

- ☐ **Use the complete description of your products according to WCO nomenclature: *"raw dressed"* is not an accurate description of a product.**

Transport info:

- ☐ **Container and seal numbers not mandatory but highly recommended.**

Label:

- ☐ **Is your label complete?**
- ☐ **Does it match with box I.28 of your health certificate?**
- ☐ **No dual labeling?**

Annex II

XII. Points of contact

N.O.A.A. – National Marine Fisheries Service

Seafood Inspection Program:	Phone: (301) 427-8300
Timothy Hansen	Tim.hansen@noaa.gov
Steven Wilson	Steven.wilson@noaa.gov
Robert Downs	Robert.downs@noaa.gov
Regional Offices:	
North-East:	**Inspection** Steven Ross Phone: (978) 281-9228 Fax: (978) 281-9134
South-East	**Inspection** Brian Vaubel Phone: (727) 570-5383 Fax: (727) 570-5387
South-West	**Inspection** Laurice Churchill Phone: (562) 388-7346 Fax: (562) 388-7353
North-West	**Inspection** Eric Staiger Phone: (206) 526-4259 Fax: (206) 526-4264

Food and Drug Administration (FDA)

Office of Seafood (Washington, DC):	Phone: (202) 418-3160 Fax: (202) 418-3196
Johnny Braddy	Johnny.Braddy@fda.hhs.gov
Bruce Wilson	Bruce.Wilson1@fda.hhs.gov
Small Business Guide to FDA.	

Annex III - Useful links

EU List of U.S. FDA approved seafood producers/freezing & factory vessels/cold storage:
https://webgate.ec.europa.eu/sanco/traces/output/US/ABP-PET_US_en.pdf.

FDA list of approved shellfish growers/shuckers/packers:
https://www.accessdata.fda.gov/scripts/shellfish/sh/shellfish.cfm

EU Official Journal:
http://eur-lex.europa.eu/en/index.htm

DG SANCO - EU food safety legislation:
http://ec.europa.eu/food/food/index_en.htm

EU Tariffs database:
http://madb.europa.eu/madb/euTariffs.htm

DG Mare:
http://ec.europa.eu/fisheries/index_en.htm

European Food Safety Authority (EFSA)
http://www.efsa.europa.eu/

The European Free Trade Association
http://www.efta.int/

UK Seafish Organization
http://www.seafish.org

For More Information

The U.S. Commercial Service at the U.S. Mission to the European Union, can be contacted via email at: Stéphane Vrignaud, at stephane.vrignaud@trade.gov ; Phone: +32(2) 811-5831; Fax: +32(2) 811 5151; or visit our website: http://www.export.gov/europeanunion.

The U.S. Commercial Service – Your Global Business Partner

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