European Union: *How to export Seafood to the European Union*

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TABLE OF CONTENTS

I- Introduction 3
A) Scope of the report: 3
B) Background: 3
C) The Institutions: 3
D) European legislative process: 4
E) What are the different types of measures? 4
F) Cross-cutting responsibilities 5
II- The Common Fisheries Policy (CFP) 6
A) Overview: 6
B) The Common Organization of the Market in Fishery and Aquaculture Products: 7
III- The food and feed hygiene legislation: 8
A) Food Hygiene: 8
B) Subsequent Regulations: 9
C) Feed Hygiene: 10
D) Food and Feed Controls: 10
IV - Exporting seafood to the EU: 10
A) General provisions: 10
V- Which certificate for which product? 14
A) Fishery products: 14
B) Aquaculture products: 14
C) Live bivalve mollusks: 15
VI- Fishmeal – Fish oil: 16
VII- Duties and trade measures: 16
A) Background: 16
B) Tariff suspensions: 17
VIII- Labeling: 18
A) Legislative background: 18
B) Concrete labeling examples: 20
C) Future labeling legislation: 21
IX- Other legislation: 22
X- Points of contact 24
Annex 1 26
Annex 2 28

I- Introduction

A) Scope of the report:

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

B) Background:

Twenty-seven countries compose the European Union (E.U.). The current Member States (MS) are Austria, Belgium, Bulgaria, 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 E.U. population is approximately 485 million people since the accession of Bulgaria and Romania on January 1, 2007. The decision to integrate Turkey is still in discussion.

C) The Institutions:

The E.U. has six different institutions that function in many ways as the different branches of the U.S. government. Among these institutions are the European Commission, the Council of the European Union, the European Parliament and the European Court of Justice.

- The **European Commission** is the E.U. executive body. It has three main tasks: to initiate E.U. policies, to act as the guardian of E.U. treaties and to supervise implementation of E.U. law. The Commission is divided in 32 directorates general (DG), of which DG Mare, DG Sanco for food safety consumer policy and public health protection. A college of 26 Commissioners, named by their national governments but supposedly independent, heads the Mission.

- The **Council of the EU** consists of ministers from the national governments of all the EU Member States. Each MS is in his turn president of the Council for six months. The Council shares with the European Parliament the responsibility for passing laws and taking policy decisions. It also bears the responsibility for what the EU does in the field of the common foreign and security policy and for EU action on some justice and freedom issues. The Council has working parties and permanent or special committees consisting of representatives from MS. The best known is the Committee of Permanent Representatives of the Member States, the COREPER.

- The **European Parliament** 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 and the proposals for new laws come from the European Commission. It has the power to dismiss the European Commission. The European Parliament gained power over time.

From an advisory-only body, it can now veto legislation in certain areas such as consumer protection, health, environment or the single market. Most of EU Legislation is now adopted according to the co-decision procedure of which the European Parliament is one of the two pillars.

- The **European Court of Justice** rules on disputes involving interpretation and application of the E.U. 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.

D) European legislative process:

All EU decisions regarding fisheries involve a consultation procedure. In this procedure, the legislative work is shared between the Commission and the Council: the Commission, which has the power of initiative, submits proposals and the Council makes the final decision. These proposals are initially discussed within the Permanent Representative Committee (COREPER). Before any decision is adopted by the Council, various stages must be completed which, depending on the field concerned, also involve the European Parliament, the Committee of the Regions and the Economic and Social Committee in addition to the Commission and the Council.
For food safety related matters, the co-decision procedure is required. This procedure usually takes longer than the consultation procedure.
The Treaty of Amsterdam designed the co-decision procedure to create “equality of arms” between the Council and the Parliament. The Council can adopt no decision without reaching a compromise with the Parliament. Given the complexity of the co-decision procedure, the most important thing to notice at that stage of the report is that it usually takes more than a year between the first reading of the Commission’s proposal and its final adoption by the Council.

E) What are the different types of measures?

Regulations:
A Regulation is a law that is binding and directly applicable in all Member States without any implementing 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 binding on the Member States as to the result to be achieved, but the choice of method is their own. In practice, national implementing legislation in form deemed appropriate in each Member State is necessary in most cases.
This is an important point, as businesses affected by a directive have to take account of the national implementing legislation as well as the directive.
All directives set a date by which Member States have to transpose it in National legislation.

After that date, in case of non-implementation, the Directive should remain the basis in case of dispute. The Commission can act against Member States that have not implemented the Directive in time.
Example: Council Directive 91/493 laying down the health conditions for the production and the placing on the market 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. Since 1995, the European Parliament can be associated to the adoption process on a limited number of issues.
Example: Commission Decision 95/328 laying down certain transitional measures concerning the certification of fishery products from third countries in order to facilitate the switchover 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.

F) Cross-cutting responsibilities

DG Mare handles negotiations of international fishing agreements, resources management, aquaculture, fleet management, and makes the Common Fishery Policy (CFP). It also makes proposals for tariff reduction, tariff suspensions and import quotas. It acts as aid to DG Trade, part of which is the E.U. equivalent to the Office of the U.S. Trade Representative for WTO matters.

Some species are subject to trade restrictions under the Convention on International Trade of Endangered Species, which is covered by DG Environment. So DG Mare and DG Environment are working closer and closer due to the current status of worldwide fish resources.
But fishery products are also subject to measures taken by DG Agriculture and DG Internal Market, and to the supervision of DG Sanco. DG Agriculture handles the Common Agricultural Policy (CAP) and all “vertical” measures on raw material. All these DGs make proposals on all E.U. measures concerning sanitary legislation and inspection, by type of products (beef, pork, poultry, vegetables, seafood, etc).

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

The FVO principal missions are to monitor the observance of food hygiene, veterinary and plant health legislation within the European Union, and to contribute towards the maintenance of confidence in the safety of foods offered to European consumers. The FVO is responsible for auditing Member States' competent authorities, and to inspect third countries for compliance and/or equivalency to E.U. legislation.

A European Food Safety Authority (EFSA) has been formally created on January 28, 2002. EFSA covers risk assessment as well as risk communication. The responsibility of risk management a decision-making remains into EU's Political Institutions' hands.

Two main sets of legislation greatly influence U.S. seafood exports to the EU: 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 influence imports of seafood from third countries such as the U.S.
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 minimum EU's hygiene standards.

II- The Common Fisheries Policy (CFP)

A) Overview:

With a production of approximately 6.9 million tons of fish (in reduction compared to previous years), the E.U. is the world's largest fishing power after China and Peru. However being one of the largest markets, the E.U. has a trade deficit of some 4.3 million tons of seafood products, worth about USD 23 billion.
The Common Fisheries Policy (CFP) is the EU's instrument for the management of fisheries and aquaculture. Justification for the Community's involvement in fisheries is based on Articles 38 and 39 of the Treaty of Rome signed in 1957. It means there must be common rules adopted at Community level and implemented in all Member States, covering all aspects of the fishing industry from the sea to the consumer.

The CFP deals with the biological, social and economic dimensions of fisheries. To integrate those multiple areas, it relies on five instruments:

- The policy and conservation management of resources (allocations of Total Allowable Catches and quotas, recovery plans, technical measures on fishing gears...).
- The structural policy for fisheries (modernization of the fleet, adaptation of activity vis a vis depletion of resources).
- The Common Organization of the Markets (prices of withdrawal, distinction between fishery products and aquaculture products, quality strategies...).
- The international relations (participation of the EU in several international and regional conventions, fisheries agreement with third countries).

- The monitoring and inspection policy (of growing importance within the CFP framework).

The Agenda 2000 has introduced new guidelines for a better CFP, where concepts such as "responsible fishing" and "sustainable development" have been constantly reminded.
In March 2001, the Commission published a "Green Paper" intending to reform the CFP. The overall objective of this future Common Fishery Policy would be to reduce the European fleet and developing its aquaculture industry while paying more attention to environmental and consumer protection.
The first decisions on the reform of the Common Fisheries Policy were adopted by the Council of Ministers on December 2002.
This first legislative package concentrates on four dimensions:

- A multi-annual approach to Total Allowable Catches (TAC) and quotas
- A new fleet policy
- The control of fishing activities
- A new governance

In October 2005, the European Commission tabled a three-year action program to simplify EU legislation. An Action Plan for simplifying the Common Fisheries Policy over the period 2006-2008 is the first sectoral action plan adopted in this context. It identifies a series of priority initiatives in two main areas, i.e. conservation and control. The regulations that will be targeted include instruments dealing with quotas and fishing effort, technical measures for the protection of young fish, collection and management of data, monitoring measures, reporting obligations and authorizations to fish outside EU waters.

In 2008, the European Commission launched a review of the CFP. This review will be based on an analysis of the success and failures of the current policy. A great attention will be paid to other fisheries management systems (right-based management for instance) to explore new plans of action.

B) 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, and then reviewed in 1993 and amended in 2000 (Council Regulation 104/2000). Its purpose is to stabilize the market, to guarantee a steady supply of quality products and 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 for imports.
- Producers' organizations (associations to which fishermen belong on a voluntary basis), officially recognized, they 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 to make sure that fishing quotas are respected.
- Interbranch Organizations and Agreements aiming at facilitating a total integration of the sector (from the producer to the 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 to be sold when market improves, or they can be processed.
- Trade with third countries in order to insure an adequate supply to the Community market of raw material intended for the processing industry (customs duties, tariff quotas, autonomous suspensions).

III- The food and feed hygiene legislation:

Since January 1, 2006, the EU has a new and updated food & feed legislation.
Hygiene is part of the European policy on food safety, which also takes into account aspects such as material in contact with food, labeling, chemical substances (additives and food colorants), ionization of foodstuffs, contaminants and residues.
If this Hygiene Package tends to simplify previous complex legislation, it also introduces the concept of "responsibility" of all food and feed operators throughout the entire food chain: "from farm to fork". This report intends to summarize this new legislation with specific indication regarding fishery products and bivalve mollusks.

A) Food Hygiene:

The Hygiene Package sets clearer and stricter rules on the hygiene of foodstuffs, specific hygiene rules for food of animal origin, and specific rules for controls on products of animal origin intended for human consumption. While general rules are laid down for all food, specific measures are targeting fishery products and bivalve mollusks.

Under this updated legislation, imported products will be required to meet the same standards as EU goods.
The Hygiene Package is divided into 5 Regulations and Directives instead of 17 previously:
Hygiene 1: European Parliament and Council Regulation 852/2004 on the hygiene of foodstuffs. It includes general and technical requirements for primary production, including HACCP.

Hygiene 2: European Parliament and Council Regulation 853/2004 lays down specific hygiene 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. This last amendment modifies the conditions for exports of fishmeal into the EU.

Hygiene 3: European Parliament and Council Regulation 854/2004 lays down specific rules for the organization of official controls on products of animal origin 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 on the languages of health certificates.

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

Hygiene 5: Council directive 2004/41/EC repeals 17 existing Directives.

B) Subsequent Regulations:

In addition to this minimum Hygiene Package, Member States have adopted additional measures that cover more detailed aspects.

Microbiological Criteria for Foodstuffs:

These criteria are fundamental for a coherent food hygiene framework. Commission Regulation 2073/2005 (last amended by Regulation 1441/2007) introduces new criteria for certain important food borne bacteria, their toxins and metabolites (such as salmonella, histamine and listeria). These criteria are applicable to products placed on the market during their entire shelf life. In addition, the Regulation sets down certain process hygiene criteria to indicate the correct functioning of the production process.

Implementation measures:

Implementing rules concerning this Hygiene Package (Commission Regulation 2074/2005) include certificates for certain products, testing methods for marine biotoxins.
Implementing measures, described in Regulation 1664/2006, amending Regulation 2074/2005, are 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 guide you on the correct certificate to use while exporting fishery products to the EU.

Until December 31, 2009 the EU allows transitional arrangements to facilitate the transition phase between old and new food hygiene legislation. The transitional measures are laid down in Commission Regulation 2076/2005 last amended by Regulation 1666/2006.

Implications for third countries exporting to the EU:

The Commission has developed a Guidance Document addressing the key questions related to EU imports requirements. Food business operators will find all necessary information they need as to the consequences of this new regime on their activity.

C) Feed Hygiene:

Contaminated feed has been responsible for many food crises. Council Regulation 183/2005 aims at ensuring the safety of feed at all stages, including primary production.
This legislation introduces compulsory registration of feed operators by their competent authority, while feed businesses dealing with more sensitive substances continue to require approval.It became applicable on January 1, 2006. However, in the absence of specific implementing rules concerning third countries, the existing rules on EU imports continue to apply.

Questions & Answers on Feed Hygiene.

D) Food and Feed Controls:

The Food and Feed Regulation on official controls - Council Regulation 882/2004 - sets out harmonized EU controls systems, covering both food and feed safety, and animal health and welfare standards. Concerning import controls, third countries have to guarantee that products intended for the EU market meet the necessary standards. This section does not include animal welfare controls except when there are explicit animal welfare provisions in specific bilateral agreements, which is not the case for the U.S.

Questions & Answers on Food and Feed Controls.

IV - Exporting seafood to the EU:

A) General provisions:

As a general principle, seafood can be exported to the EU only by approved countries and approved establishments (processing plants, factory or freezing vessels, brokers). For aquaculture products (including live bivalve mollusks), only approved establishment can export from approved production zones or areas.
On March 10, 2006, the EU published a new set of Decisions recognizing the U.S. seafood inspection system as equivalent as the European one. **This status does not apply yet to the export of live bivalve mollusks.**

This recognition facilitates seafood trade between the U.S. and the EU as it removes technical barriers such as 100% controls at border inspection posts and restricted circulation of U.S. seafood products limited to the country of “first port of entry”.
Furthermore, it creates a harmonized framework under which Member States do not have the possibility to impose national requirements on U.S. seafood exporters in addition to EU harmonized legislation anymore.

B) List of countries:

Commission Decision 2006/766/EC establishes 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 in the list of countries authorized to export bivalve mollusks, echinoderms, tunicates and marine gastropods. It means that, unlike for fishery products, the U.S. inspection system for shellfish is not equivalent to the EU one.
Consequently, each EU member state can accept or refuse imports of shellfish from the U.S. (the majority still refuse).
However, article 1, paragraph 2 of the Decision 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 that case, a public health certificate for fishery products complying with Decision 2006/199/EC is required.

C) Approved establishments

U.S. operators who wish to export seafood to the EU need to be approved and registered by their National competent authority. The Food & Drug Administration (FDA) is the U.S. competent authority 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. This process can take up to three months.
The list of FDA district offices in charge of the approval process can be found below:
http://www.fda.gov/ora/fed_state/Small_Business/sb_guide/regions.htm

U.S. exporters **MUST NOT** send shipments to the EU before the EU list is published **and** is in force within the EU. For further information on the US-EU list of approved establishments, see the following link:
https://sanco.ec.europa.eu/traces/output/listsPerCountry_en.htm#

D) Certification

Each shipment of seafood products must be accompanied by a sanitary certificate.
As of June 17, 2009, the US Department of Commerce (NOAA/National Marine Fisheries Service) will be the unique competent authority for the certification of fishery and aquaculture products intended for the E.U.
There are different types of certificates according to the products (wild fishery products, aquaculture products, live bivalve mollusks…) and sometimes according to their destination.
A certificate may be issued for goods produced in different establishments, but can only be made to one consignee. A certificate may be issued for several containers of the same product considered to be a single lot.

U.S. exporters should pay specific attention to the fact that health certificates must be issued and signed before the shipment leaves the control of the competent authority of the country of dispatch. In other words, bills of lading should always be dated the day of, or after issuance of the health certificate.
For further information of the concrete implementation of this measure within EU Member States, please contact the European Office of NOAA Fisheries Services.

It must be noted that a certificate defines a lot. Therefore a rejection may be decided for all goods covered by the same certificate, even if only a part of it presents a sanitary or documentary problem.
Instructions regarding the language of certificates can be found at the end of Regulation 1663/2006 (mentioned in chapter III). In summary, certificates must be issued in one of the official languages of the country of entry into the E.U. territory, and if necessary in the language of the country of destination. However a member state may consent to the use of an official Community language other than its own.

In practice, the Border Inspection Post (BIP) of the first point of entry into the E.U. does 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 as to be in at least the language or in one of the languages of the border inspection post where the products coming from third countries are introduced into the Community and in the language or in one of the languages of the country of destination of the product.

Important Notice:
Since April 1, 2007 Switzerland has adopted EU sanitary legislation regarding import requirements for fishery products. Therefore, U.S. seafood shipments must be accompanied by the same certificate as required by any EU member state. Such certificate 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 E.U. territory and in approved border inspection posts.

Import controls are done in three consecutive steps:

- Documentary check: examination of the health certificate;
- Identity check: visual inspection to confirm consistency between documents and products, verification for the presence of required sanitary marks (country of origin, approval number);
- Physical check: check on the product itself (organoleptic control, packaging, temperature), it 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 E.U. territory. When such a consignment satisfies E.U. requirements, it can be marketed freely in all EU member states.

If the documentary and the identity checks must be performed on all consignments, the frequency of physical checks is reduced for products from “harmonized” countries from a theoretical 100 per cent to a theoretical 20 percent for fish products in hermetically sealed containers, for fresh and frozen fish, for dry and/or salted products, to 50 percent for other fishery products and for bivalve mollusks.

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 the Customs Authorities before the import process occurs.

European border inspection posts may randomly conduct specific analysis on shipment being presented to them for clearance. These analyses can target residues, heavy metals or any other contaminants
During these random tests, shipments may still be cleared and delivered to EU customers. However, if the tests reveal any contamination, the U.S. 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, its ten next consecutive shipments (that could be small shipments such as samples) to any country of the EU will be systematically tested. During these tests, and until the results are known, products will be detained at border inspection posts. After ten shipments without negative results, the establishment in question will be lifted from the reinforced control list. The exporter may also choose to stop sending shipments to the EU for a three months period. This period is equivalent to the ten consecutive shipments rule.
If a shipment is refused for non-compliance with EU legislation, the responsible of the shipment has three options:

1. Destroy the products concerned,
2. Re-dispatch these products to a non-EU country,
3. Ship the products back to originating country

It is important to note that Regulation 882/2004 (Article 21) imposes conditions for the two last options.

1. The destination has been agreed with the food business operator responsible of the consignment,
2. The food business operator has first informed the competent authority of the third country of origin, or third country of destination, if different, of the reasons and circumstances preventing the placing on the market of the food concerned within the Community,

3. **And**, when the third country of destination is not the third country of origin, the competent authority of the third country of destination has notified the competent authority of its preparedness to accept the consignment.

V- Which certificate for which product?

A) Fishery products:

Shipments of (wild) fishery products must be accompanied by a public health certificate according to Commission Decision 2006/199/EC.
Processed mollusks as well as frozen scallops are considered as fishery product and should be accompanied by the above mentioned certificate.

B) Aquaculture products:

In the field of aquaculture, the relevant legislation covers any placing on the market within each individual Member State (MS), the intra-community trade and imports into the European Union. It means that products coming from aquaculture within the EU and from any third country must broadly be equivalent in terms of animal health requirements.
The animal health conditions governing the placing on the market of aquaculture animals and products are defined in Directive 2006/88/EC**.**
Since May 1, 2004 new rules are in place for the imports of aquaculture products or animals. **These new procedures require that each shipment of aquaculture products be accompanied not only by a public health certificate (Decision 2006/199) but also by an animal health attestation (Regulation 1664/2006 last amended by Regulation 1250/2008)**.

The legislation covering aquaculture products is made of the following Regulations:
Commission Decision 2003/858/EC laying down the animal health conditions and certification requirements for imports of live fish, their eggs and gametes intended for farming, and live fish of aquaculture origin and products thereof intended for human consumption; as amended by Commission Decision 2004/454/EC**.** This Decision has been partially repealed by Regulation 1664/2006 (described on page 10)
Commission Decision 2003/804/EC laying down the 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.

These three last amendments are of particular interest to U.S. exporters.
According to Commission Decision 2004/609/EC, the U.S. is authorized to exports mollusks (from aquaculture) not only for human consumption (2004/319/EC) but also for further growth, fattening or relaying.

However, Commission Decision 2005/409/EC reduces the number of U.S. regions from which the export of live mollusks for further growth, fattening, or relaying and for further processing before human consumption. As indicated in the previous chapter, these specific products cannot be exported to the EU until further notice.
Commission Decision 2004/623/EC suppresses the need for an animal health attestation – in addition to a public health certificate – for mollusks intended for direct human consumption, under some labeling conditions.

C) Live bivalve mollusks:

As for fishery products, Regulation 853/2004 is the main legislation concerning live bivalve mollusks, tunicates, marine gastropods and echinoderms (named bivalve hereafter). It defines conditions for placing those live animals on the market for immediate consumption. It also set criteria concerning production areas, harvesting and transportation, relaying and purification. In general terms, the E.U. and the U.S. legislation are very similar when defining several categories of production areas. The main difference remains in the method of control to qualify those areas. The E.U. requests tests to be performed on animal flesh, where the United States relies on water tests. E.U. officials unofficially state that both methods appear to be in good correlation for bivalve mollusks such oysters and mussels. Results differ for clams in general.

Following an audit from the EU Food and Veterinary Office (FVO), the import into the EU on live bivalve mollusk, echinoderms, tunicates and marine gastropods, for further growth, fattening or relaying is not allowed.
U.S. establishments can only export live bivalve mollusks intended for direct human consumption (retail) and provided that they are packed and labeled accordingly.

Certificates included in Regulation 1664/2006 will be delivered only for products originated from U.S. establishments listed in the FDA Interstate Certified Shellfish Shippers list and from FDA approved production areas.
The list of approved establishments and production areas can be found through the link below:
http://www.cfsan.fda.gov/~frf/sfeuexp.html

For non-harmonized countries, of which the United States is one, E.U. Member States may or may not accept live bivalve mollusks to be imported for immediate human consumption.
Since August 2002, the following Member States have indicated their national requirements:

France:
Live bivalve mollusks must be imported in closed packages that may be sold as such to retailers. The French measure is intended to prohibit the relaying of imported mollusks in their coastal area to avoid development of “exotic” diseases. It is advisable to use packaging of less than 15 kg. The so-called “Re-shippers”, according to FDA definition, cannot be listed in Part II of the certificate, as they are not considered as the establishment of origin.
Italy:
Italian authorities made clear that no live bivalve mollusks would be accepted on the Italian territory unless the European Commission has approved the country of origin (List I).

VI- Fishmeal – Fish oil:

A) Fishmeal:

A certificate "for processed animal protein not intended for human consumption", according to the model listed in Regulation 668/2004, should accompany U.S. exports of fishmeal. NOAA is the unique U.S. competent authority that issues such certificate.
In theory, all exports of fishmeal must come from approved establishments. However, in the absence of EU harmonization on the subject, some Member States accept fishmeal without referring to such a list of approved establishments.
It is recommended to contact our NOAA office at the U.S. Mission to the EU for guidance before shipping.

B) Fish oil:

As of 30 April 2009, the amended hygiene legislation will require that Fish oil intended for human consumption meet the requirements for "regular" fishery products. As such, shipments of fish oil will have to come for U.S.-EU approved establishments and will have to be accompanied by the same public health certificate as the one used for fishery products.
During the transitional period, food business operators in Member States may continue to import fish oil from establishments in third countries under the regimes that were in place in that Member State prior to requirements for fish oil being included in the hygiene Regulations.
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

Shipments of fish oil not intended for human consumption fall under another set of legislation and should be accompanied by a certificate according to the model described in chapter 9 of Commission Regulation 668/2004.

VII- Duties and trade measures:

A) Background:

All E.U. fish tariffs have been consolidated in the GATT agreement of the Tokyo Round. The overall average of E.U. duties for Chapters 3, 1604 and 1605 is 17.2%, one of the highest in the world.
The tariff range goes from 0% (live eels) to 25% (canned mackerel, bonito and anchovies). The main legislation covering tariffs is Commission Regulation 1031/2008. However, the E.U. 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.

- The Generalized System of Preferences (GSP), which applies to developing countries, covers all seafood products of Chapter 3. Products are classified according to different categories (sensitive, semi-sensitive, sensitive and very sensitive).
- The ANDEAN group, meant to help those countries to combat drugs, enjoys duty-free rate on most of Chapter 3 lines.

- "Access to markets" for "Access to Resources" is the preferred E.U. strategy of fish trade negotiations. Some advantages are so granted, product-by-product, following signatures of fishing agreements (Argentina: reduced duty for hake fillets; Morocco: duty-free imports of canned sardines...)

Recognizing the needs of its processing industry, the E.U. unilaterally reduces duties for certain portions of its imports using two yearly mechanisms, suspensions and autonomous quotas. Most of the products concerned must be further processed within the E.U.

For a better impact, reduced duties must be requested first by the European importer.
Suspensions, set on a yearly basis, provide better access for raw material needed by the E.U. industry on an unlimited basis (Alaskan Pollack fillets blocks, hard fish roes). Applied duties may be a full suspension (duty-free) or a reduced duty. Many products are subject to a reference price.
Autonomous quotas (Council Regulation 824/2007) are opened on a yearly basis. Each product (or group of products) is subject 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 (following national industry requirements) and the compromise reached usually at ministerial level.

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 past years landing prices, the E.U. fixes on a yearly basis minimum prices for a wide range of species. Depending on those prices are calculated several aids to Producers Organizations (POs) like withdrawal prices, carry-over aids.

B) Tariff suspensions:

Council Regulation 1255/96/EC, last amended by Council Regulation 1/2009, covers tariffs suspensions.
To be entitled to a tariff suspension or reduction, importers must buy the concerned product at a "free-at-frontier" price (C&F) higher than the reference price. Otherwise, products may be imported, but the full conventional rate applies. For example, an autonomous quota is opened for product A with a reduced duty of 5% instead of the conventional 15%, subject to the respect of a reference price of $100. If the C&F price paid by the importer is:

- $ 95: the importer cannot access the quota, and must pay a 15% duty;
- $ 110: the importer can access the quota and will pay a 5% duty.

In October for suspensions, and December for autonomous quotas, the European Commission consults the twenty-seven Member States to know about the needs of each national industry.

Summing the different needs, a proposal is sent to all governments to be discussed in various committees.
It is quite impossible to request a suspension at once for a product not yet entitled to a reduced duty. But a product may be moved from the list of autonomous quotas to the list of suspensions, or quantities of a quota may be increased and its duty further reduced.

It is also possible to open new autonomous quotas.
Once a reduced duty has been obtained, the product can be petitioned for a move to a suspension of the tariff. However, the move from reductions to suspension is difficult to obtain.
The EU Fisheries Council of December 1999 adopted the final text for the renewal of the EU Common Organization of Markets for fish and fishery products (2000/104/EC). Some products (surimi, Alaskan Pollock fillets and meat blocks) considered as essential to the EU processing industry to remain competitive will enjoy total or partial suspension of customs duties. For some other products (H&G cod, tuna loins, herring flaps), pluri-annual autonomous quotas at a reduced duty rate have been decided for the period 2007-2009.

On a more global scale, the U.S. Government is permanently negotiating with the EU a "zero for zero" approach to tariffs in the fisheries sector. Unfortunately, the slow progresses of current Doha negotiations do not predict a rapid agreement on this issue.
For any questions on a specific tariff rate, you may look at the following web site:
http://europa.eu.int/comm/taxation_customs/dds/cgi-bin/tarchap?Lang=EN

VIII- Labeling:

A) Legislative background:

Foot and mouth disease, BSE crisis, heavy metals...All these preceding crisis have reinforced the critical need for information, communication and transparency towards consumers.

The three main Regulations with respect to labeling are Council Directive 2000/13/EC (last amended by Directive 2003/89/EC on ingredients present in foodstuffs) and Commission Regulation 2065/2001/EC. 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. "Fish and products thereof" and "crustaceans and products thereof" that were included on the list of potential allergens have been removed from this list per Commission Directive 2007/68/EC.

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 (applicable as of December 2008) adds "mollusks and products thereof" to the list of potential allergens.
All new EU Regulation is (and will be) based on consumer confidence and safety in such a way that "the consumer will not be misled by any product or packaging".

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

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

U.S. exporters will pay specific attention to article 5 of Commission Decision 2006/199 regarding products in bulk and intended for further processing which introduces a derogation to this rule.
Finally, Regulation 853/2004, Annex II, paragraph 11 allows for a 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 cases where stick-on labels may be used, they must not be easily destructible when attempts are made to remove them, i.e. tear into small pieces.
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 imposes specific requirements for the labeling of fishery and aquaculture products intended to the retail sector. This Regulation only concerns products from Chapter 3 of the Tariff Harmonized System, and not products from Chapter 16 (canned products for instance).

Three sets of information are now compulsory on the label of any fishery and aquaculture products on sales at retailers:

- The Commercial name of the species (the Latin name is not compulsory on the label except if your client requires it). Each Member State has established a list of commercial names applicable. These lists are visible on the EU web site.

- The production method (aquaculture or fishery product). The proper language to use is "caught in...", "caught in fresh water", "farmed" or "cultivated". However Member States may decide 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 catch area. Products caught at sea have to show the area of capture (taken from the FAO list, Annex of the above Regulation). However, only the general area has to be mentioned (Pacific ocean for example). The FAO Area code can be mentioned on a voluntary basis. Products caught in fresh water require a reference to the Member State or third country of origin of these products. As for farmed products, the reference is to the Member State or third country in which the product undergoes the final stage of development. Operators may well choose to provide additional information on the area.

To ensure a perfect traceability at all stages of the marketing process, fisheries and aquaculture products have to 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.

Other sets of Regulations regarding ingredients, allergens and guidelines for the implementation of labeling legislation can be downloaded from DG Sanco's website at: http://europa.eu.int/comm/food/food/labellingnutrition/foodlabelling/comm_legisl_en.htm

B) Concrete labeling examples:

1- Fresh, chilled products:

- Species
- Country of origin (roman letters, min. 2 cm)
- Presentation (whole, gutted, fillet, etc)
- Freshness grade and size category (for species with common standards, min 5 cm)
- Net weight in kg (except for standard boxes, average net weight is enough)
- Date of grading and dispatch
- Name and address (city + state) + "FDA approval #" of processor/packer

Freshness grading is only for whole/gutted fresh fish.

2- Frozen products:

- Species followed by the word "frozen"
- Country of origin
- Presentation (may be included with the name of the species)
- Net weight in kg
- List of ingredients (except if fish only)
- Date of minimum durability (month/year) or "best before" date.
- Special storage conditions (to be maintained at - 18^{o} C)
- Instructions for use (if not obvious), incl. "do not freeze again once thawed"
- Name and address of the manufacturer, or of a seller in the EC
- "FDA approval #" of the packer (CFN or FEI) or processor.
- Lot # (it must begin by "L" or the world "LOT") (not always mandatory).
- The lot # is defined by the processor in order to be able to trace a product history in case of problem. It can be the production date.

  Example: L8110B15 may mean
  L = Lot
  8 = 1998
  110 = day of production
  B15 = production line number

3- For deep-frozen foods: (All of the above plus)

- Freezing date
- 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.

4- Live bivalve mollusks:

- Species (common name and Latin name)
- Country of dispatch
- Date of wrapping (at least day and month)
- Date of durability or "these animals must be alive when sold"
- Net weight (kg)
- Identification of the dispatch center by its approval number
- Name and address (city + state) of packer + "FDA approval #" (Interstate Certified Shellfish Shipper #)

5- Canned products:

- Name of product
- Country of origin
- Net weight in grams (or liter for liquid products)
- Net drained weight (in case of solid packed in a usually-not-consumed liquid)
- List of ingredients (added water is an ingredient)
- Date of minimum durability (year)
- Any special storage conditions or conditions of use
- Instructions for use (if not obvious)
- Name and address of the manufacturer, or of a seller established within the E.U. "FDA approval #" of the packer (CFN or FEI)

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

C) Future labeling legislation:

The EU has planned to review its entire food labeling system between 2006 and 2008, with a first set of proposals expected in the course of 2008. See link below:
http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/proposal_regulation_ep_council.pdf

This exercise, aiming at reconciling industry views with consumers' expectations, is predicted to be quite difficult. Consumer groups would like everything to be on the label while the food industry finds EU labeling rules too expensive of a burden.

It is already clear to all operators involved in this process (business operators, consumers, legislators) that the debate will focus on what information should be on a label. What is essential versus what is not? The majority agrees to call for the implementation of the so-called "KISS" principle: Keep It Small and Simple!

On March 10, 2006, the Commission (DG Sanco) published a discussion paper entitled "Labeling: Competitiveness, Consumer Information and Better Regulation for the EU". This document is designed to facilitate exchanges between stakeholders but other contributions are welcome.
The consultation paper can be downloaded from DG Sanco's website at: http://europa.eu.int/comm/food/food/labellingnutrition/betterregulation/competitiveness_consumer_info.pdf

IX- Other legislation:

Besides the above-mentioned legislation, the E.U. sets various requirements for a wide range of issues. It includes legislation on:

- Additives, colorings, flavoring and sweeteners allowed within the EU.
- Traceability of foodstuffs.
- Contaminants.
- Packaging materials: regarding their stability to not transfer substances to foodstuffs in quantities that may be harmful to human health, or change organoleptic properties; regarding waste standardizing information systems for recycling to contribute to environmental protection.
- **Wood packing materials**: In 2004, the EU adopted Commission Directive 2004/102/EC on protective measures against the introduction into the Community of organisms harmful to plants or plants products and against their spread within the Community. On January 17, 2006, the European Union Standing Committee on Plant Health (SCPH) voted to delay until January 1, 2009, the requirement that imported wood packaging material (WPM) is debarked. After further review, the debarking requirement was postponed again to July 1, 2009. For more information on this specific subject, consult the following web site: http://useu.usmission.gov/agri/woodpack.html

- **IUU catch certificate:** In 2008, the EU adopted Council Regulation (EC) 1005/2008 aiming at eliminating Illegal, Unreported & Unregulated (IUU) fishing. This Regulation introduces a catch certificate that all third countries wishing to export seafood to the EU will have to provide by January 1, 2010. This document comes in addition to all sanitary documentation already provided and appears to be very complex to produce. The U.S. Government is currently discussing with EU authorities to propose an amended document that would allow U.S.-EU seafood trade not to be disrupted by this additional paperwork.

X- Points of contact

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

Partnership & Communication	**Phone (301) 713-2379** **Fax (301) 713-2384**
Christopher Moore **John Ward**	**Chris.moore@noaa.gov** **John.M.ward@noaa.gov**
Inspection Service	**Phone (301) 713-235** **Fax (301) 713-1081**
Tim Hansen **Steven Wilson**	**Tim.hansen@noaa.gov** **Steven.wislon@noaa.gov**
Regional Offices:	
North-East:	**Inspection**
	David Moisan Phone (978) 281-9292 Fax (978) 281-9134
South-East:	**Inspection**
	Robert J. Buckley Phone (727) 570-5383 Fax (727) 570-5387
South-West:	**Inspection**
	Eric Staiger Phone (323) 526-7412 Fax (323) 526-7417
North-West: **Trade**	**Inspection**
Rick Ranta Phone (206) 526-6114 Fax (206) 526-4461	Brian Vaubel Phone (206) 526-4259 Fax (206) 526-4264

Food and Drug Administration – Office of Seafood
http://www.cfsan.fda.gov/seafood1.html

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**
Regional Offices: click on the hyperlink.	

For More Information

The U.S. Commercial Service at the U.S. Mission to the EU can be contacted via e-mail at: Stephane.vrignaud@mail.doc.gov Phone: +322 508-2842; Fax: +322 513-1228 or visit our website: www.buyusa.gov/europeanunion.

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

With its network of offices across the United States and in more than 80 countries, the U.S. Commercial Service of the U.S. Department of Commerce utilizes its global presence and international marketing expertise to help U.S. companies sell their products and services worldwide. Locate the U.S. Commercial Service trade specialist in the U.S. nearest you by visiting http://www.export.gov/.

Annex 1

USA - Certification conditions:

1. For fishery products of aquaculture origin either intended for retail, providing they comply with the rules applying to packaging and labeling laid down in Regulation (EC) n°853/2004:

Consignments shall be accompanied by the public health attestation defined in Commission Decision 2006/199/EC of 22 February 2006 laying down specific conditions for imports of fishery products from the United States of America.

2. For fishery products of aquaculture origin when originating from fish and crustaceans, other than those mentioned in paragraph 1 above:

Consignments shall be accompanied:
- By the public health attestation defined in Commission Decision 2006/199/EC of 22 February 2006 laying down specific conditions for imports of fishery products from the United States of America, and
- By the animal health part of the certificate defined in Appendix IV to Annex VI of Commission Regulation (EC) No 1664/2006 of 6 November 2006 amending Regulation (EC) No 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and repealing certain implementing measures. **To be replaced by Regulation 1250/2008 as of July 1, 2009.**

3. For fishery products other than those mentioned in paragraph 1 and 2 above:
Consignments shall be accompanied by the public health attestation defined in Commission Decision 2006/199/EC of 22 February 2006 laying down specific conditions for imports of fishery products from the United States of America.

4. For processed bivalve mollusks belonging to the species *Acanthocardia Tuberculatum*:

Consignments shall be accompanied:
- By the public health attestation defined in Commission Decision 2006/199/EC of 22 February 2006 laying down specific conditions for imports of fishery products from the United States of America, and
- By the additional public health attestation defined in Appendix V to Annex VI part B of Commission Regulation (EC) No 2074/2005 as last amended by Regulation (EC) No 1664/2006.

5. For live bivalve mollusks, echinoderms, tunicates and marine gastropods intended for retail, providing they comply with the rules applying to packaging and labeling laid down in Regulation (EC) n°853/2004:

For consignments certified after 31 October 2007 shall be accompanied by the public health attestation of the public health and animal health certificate defined in Appendix V to Annex VI to Commission Regulation (EC) No 2074/2005 as last amended by Regulation (EC) No 1664/2006.

6. For live bivalve mollusks, echinoderms, tunicates and marine gastropods intended for human consumption, other than those mentioned in paragraph 5 above:

For consignments certified after 31 October 2007 shall be accompanied by the joint public health and animal health certificate defined in Appendix V to Annex VI to Commission Regulation (EC) No 2074/2005 as last amended by Regulation (EC) No 1664/2006. **To be replaced by Regulation 1250/2008 (Appendix V to Annex VI) as of July 1, 2009.**

7. For mollusks, their eggs and gametes for further growth, fattening, relaying :

Consignments shall be accompanied by the corresponding animal health certificate defined in Commission Decision 2003/804/EC of 14 November 2003 laying down the animal health conditions and certification requirements for imports of mollusks, their eggs and gametes for further growth, fattening, relaying or human consumption.

8. For live fish, their eggs and gametes intended for farming, and live fish of aquaculture origin:

Consignments shall be accompanied by the corresponding animal health certificate defined in Commission decision 2003/858/EC of 21 November 2003 laying down the animal health conditions and certification requirements for imports of live fish, their eggs and gametes intended for farming, and live fish of aquaculture origin and products thereof intended for human consumption.

Annex 2

Useful links

EU List of U.S. FDA approved seafood establishments:
https://sanco.ec.europa.eu/traces/output/listsPerCountry_en.htm#

FDA list of approved shellfish establishments:
http://www.cfsan.fda.gov/~ear/shellfis.html

FDA list of approved shellfish production areas:
http://www.cfsan.fda.gov/~frf/sfeuexp.html

NOAA Seafood Inspection Program:
http://www.seafood.nmfs.noaa.gov/

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://ec.europa.eu/taxation_customs/dds/cgi-bin/tarchap?Lang=EN

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

NOAA Fisheries:
http://www.nmfs.noaa.gov/sfa/PartnershipsCommunications/tradecommercial/index.html