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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; 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 EU population is approximately 500 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 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 27 Commissioners named by their national governments but should be independent independent, heads the Commission.

The Council of the EU consists of ministers from the national governments of all the 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 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 Member States. The best known is the Committee of Permanent Representatives of the Member States, or COREPER.

The European Council refers to the formation of the heads of state in the European Union (EU) which hold regular meetings. This council is responsible for defining the general political direction and priorities of the Union.
In addition to the heads of states or government of EU member states, there is a semi-permanent President (with a 2 and ½ year term) and the President of the Commission. 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** 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 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** and the **Court of Auditors** are the two last EU institutions.

**D) 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 on 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 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 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 EU equivalent to the Office of the US 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. DG Mare and DG Environment are working together more closely due to the current status of worldwide fish resources. Fishery products are also subject to measures taken by DG Agriculture and DG Internal Market, and are supervised by DG Sanco. DG Agriculture handles the Common Agricultural Policy (CAP) and all “vertical” measures on raw material. All these DGs make proposals on all EU 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 on 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) which is 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 EU legislation.

A European Food Safety Authority (EFSA) was created on January 28, 2002. EFSA covers risk assessment as well as risk communication. The responsibility of risk management and decision-making remains in the hands of the EU's institutions.

Two main sets of legislation greatly influence US 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 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, and then reviewed in 1993 and amended in 2000 ([Council Regulation 104/2000](https://eur-lex.europa.eu/). 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), 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 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).
**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.

Since 2006, the US seafood inspection system has been recognized by the EU as equivalent as the European one. **This status does not apply yet to the export of live bivalve mollusks and their derived fishery products (scallops).** This recognition facilitates seafood trade between the US and the EU as it removes technical barriers such as 100% controls at border inspection posts and restricted circulation of US seafood products limited to the country of “first port of entry.” Furthermore, it creates a framework under which Member States do not have the possibility to impose national requirements on US seafood exporters in addition to EU harmonized legislation anymore. However, differences of interpretation amongst member states often lead to delays at border inspection posts.

**B) List of countries:**

**Commission Decision 2006/766/EC** lays down 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 US does not appear in the list of countries authorized to export bivalve mollusks, echinoderms, tunicates and marine gastropods. This means that, unlike for fishery products, the US inspection system for shellfish is not equivalent to the EU one. The US 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 US 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 US provided that they are wild caught. In this case, a public health certificate for fishery products complying with Decision 2006/199/EC is required.

**C) Approved establishments**

US 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 US competent authority for the approval of seafood establishments. Once they are approved, US 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

**Important Notice:**
US exporters **MUST NOT** send shipments to the EU before the EU list is published and is in force within the EU.

**D) Certification**

Each shipment of seafood products must be accompanied by both a sanitary and (since January 1, 2010) a catch certificate. You will find a separate chapter on the catch certificate in this report.

**Important Notice:**
Since June 2009, the US Department of Commerce (NOAA/National Marine Fisheries Service) is the unique competent authority for the certification of fishery and aquaculture products intended for the EU. 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.

US 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.**

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. Fresh and/or live products can be mentioned on the same certificate but frozen products need to be treated separately with another certificate. 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 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 Community languages other than its own. In practice, the Border Inspection Post (BIP) of the first point of entry into the EU 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, US seafood shipments must be accompanied by the same certificate as required by any EU member state. Such a certificate for Switzerland may be in French or English.

**E) Import controls:**


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 on the product itself (organoleptic control, packaging, temperature). This may include sampling and laboratory testing.

Products imported from “harmonized” countries, such as the US 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 such a consignment satisfies EU 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 US 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 in question;
2. Re-dispatch these products to a non-EU country; or
3. Ship the products back to 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 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.

**F) Triangular trade:**

Triangular trade occurs when US products are shipped from the US to other third countries, such as China, Republic of Korea or Japan, for storage before being re-exported to the European Union at a later date. EU hygiene legislation requires that the shipment be stored in an EU approved facility in that country and, at the time of re-export to the EU, be accompanied by a sanitary certificate from the last country of dispatch, even if the products haven’t been further processed in that given country. This certificate must be based on the first certificate issued by the US competent authority when the shipment first leaves the US.
The two sanitary documents to provide to EU border inspection post in that case are the following:

1) From the US to country of storage: US certificate (EU type or not) with final destination the country of storage **AND**
2) From the country of storage: EU certificate with final destination the EU.

**V. The food and feed hygiene 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), and 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.

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:** 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.

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. 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, and subsequent Regulation 1250/2008, 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.

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 US.

Questions & Answers on Food Controls.

VI. Which certificate for which product?

A) Fishery products:

Since June 15, 2011 shipments of fishery and aquaculture products must be accompanied by a certificate according to the model published on the NOAA Seafood Inspection Program web site. This new certificate is a combination of Commission Decision 2006/199/EC (for the public health part) and Regulation 1250/2008. This certificate is valid for both fishery and aquaculture products. Processed mollusks as well as frozen scallops are considered as fishery product and should be accompanied by the certificate.

B) Aquaculture products:

The EU legislation covering aquaculture products is made of the following:

- 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)


These three last amendments are of particular interest to US exporters. According to Commission Decision 2004/609/EC, the US 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 US 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:

Per Commission Decision 2009/951, imports of US live bivalve mollusks into the EU are not allowed since July 1, 2010. Trade will resume once the US and the EU will have reached 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), should accompany US exports of fishmeal. NOAA is the US competent authority for the issuance of such certificate. All exports of fishmeal must come from approved establishments. The list of US approved animal by-products establishments can be found through the link: https://webgate.ec.europa.eu/sanco/traces/output/ABP-FSB_US_en.pdf

B) Fish oil:

Since 30 April 2009, the amended hygiene legislation requires that fish oil intended for human consumption meets the requirements for “regular” fishery products. As such, shipments of fish oil have to come from US-EU approved establishments and be accompanied by the same public health certificate as the one used for fishery products. 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 Regulation 142/2011 (Chapter 9 certificate) above mentioned.
VIII. Duties and trade measures

A) Background:

All EU fish tariffs have been consolidated in the GATT agreement of the Tokyo Round. The overall average of EU 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 1006/2011. 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. 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 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 EU 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 EU 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 EU. 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 EU 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 1062/20009) 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 EU fixes minimum prices on a yearly basis for a wide range of species. Depending on those prices several aids are calculated to Producers Organizations (POs) like withdrawal prices and carry-over aids.
B) Tariff 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 a given product 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 when the importer cannot access the quota, and must pay a 15% duty;
- $110 when 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 2010-2012.

On a more global scale, the US 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 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:

Preceding crises such as Foot and Mouth disease, the BSSE crisis, and heavy metals have reinforced the critical need for information, communication and transparency towards consumers.

The three main Regulations with respect to labeling are:


- **Commission Regulation 2065/2001/EC** mainly 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. “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** adds “mollusks and products thereof” to the list of potential allergens.

All new EU Regulations 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.

Per Regulation 853/2004 (Annex II, point 7) that requirement also concerns products intended for the ultimate consumer (canned products) whereby the FDA approval number of the US packer/processor/manufacturer must be mentioned in addition to the address of such establishments (or of a seller in the EU). However, US exporters will pay specific attention to article 5 of Commission Decision 2006/199 regarding products in bulk and intended for further processing which introduces 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:

B) Concrete labeling examples:

1- Fresh, chilled products:
- Species
- Country of origin (roman letters, min. 2 cm)
- Presentation (whole, gutted, fillet, etc)
- Best before date (not mandatory per EU legislation but requested by most member states)
- Freshness grade and size category (for species with common standards, min 5 cm)
- Net weight in kilograms (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”
- Freezing date (if different from the production/catch date)
- 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°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.

For example: **L8110B15** may mean
- L = Lot
- 8 = 1998
- 110 = day of production
- B15 = production line number
3- For deep-frozen foods:

The above-mentioned requirements apply in addition to the following requirements:

- 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 EU
- "FDA approval #" of the packer or manufacturer/processor

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 US Mission to the European Union.
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, additives such as STP (E338 to E 450) are not allowed in frozen and deep frozen scallops.

- **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://www.fas.usda.gov/posthome/useu/woodpack.html](http://www.fas.usda.gov/posthome/useu/woodpack.html)

- **Sport caught fish**: Commission Regulation 2006/2009 sets up the weight limit 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 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 must provide since January 1, 2010.

This document comes in addition to all other sanitary documentation

This Regulation has been amended by Regulation 86/2010. This last document amends the list of products excluded by the scope of the catch certification scheme and identifies specific agreements between the EC and third countries, including the US. Implementing measures, as well as the list of products excluded by the IUU legislation, the list of competent Member States (MS) authorities and FAQs can be found through the EC-DG Mare web site below:

NOAA has signed an agreement with the EC that lays down a US specific catch certificate. NOAA is the unique competent authority for the issuance of both sanitary and catch certificates. Exporters will find all necessary information regarding these catch certificates, as well as FAQs on the NOAA SIP web site.

For any problems at EU border inspection posts or questions regarding the IUU Legislation please contact:

Mr. Stéphane Vrignaud
NOAA Fisheries
US Mission to the EU
Tel: (011) 322 811 5831
Fax: (011) 322 811 5151
Stephane.vrignaud@trade.gov
### XII. Points of contact

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

<table>
<thead>
<tr>
<th>Seafood Inspection Program</th>
<th>Phone (301) 427-8300</th>
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<tr>
<td>Timothy Hansen</td>
<td><a href="mailto:Tim.hansen@noaa.gov">Tim.hansen@noaa.gov</a></td>
</tr>
<tr>
<td>Robert Downs</td>
<td><a href="mailto:Robert.downs@noaa.gov">Robert.downs@noaa.gov</a></td>
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**Regional Offices:**

- **North-East:**
  - Inspection
  - Lawrence biondo
    - 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 (FDA):  
Center for Food Safety and Applied Nutrition

| Office of Seafood (Washington, DC): | Phone (202) 418-3160  
Fax (202) 418-3196 |
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<td>Johnny Braddy</td>
<td><a href="mailto:Johnny.Braddy@fda.hhs.gov">Johnny.Braddy@fda.hhs.gov</a></td>
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<td>Bruce Wilson</td>
<td><a href="mailto:Bruce.Wilson1@fda.hhs.gov">Bruce.Wilson1@fda.hhs.gov</a></td>
</tr>
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**Regional Offices**: click on the hyperlink.
Useful links

EU List of US FDA approved seafood establishments:

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

FDA list of approved shellfish production areas:
http://www.accessdata.fda.gov/scripts/EUCert/eumsgrl.htm

EU official Journal:

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

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

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

UK Department for Environment Food and Rural Affairs
http://www.defra.gov.uk/
For more information

The US Commercial Service at the US Mission to the EU can be contacted via e-mail at:
Stephane.vrignaud@trade.gov Phone: +322 811-5831; Fax: +322 811-5151 or visit our website:
http://export.gov/europeanunion/

The US Commercial Service — Your Global Business Partner

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

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