

Exporting Seafood to the European Union February 2022 Update



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I. Introduction

A) Scope of the Report:

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

B) Background:

Twenty-seven countries compose the European Union (EU). The current Member States (MS) are: Austria, Belgium, Bulgaria, Croatia, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Romania, Spain, Sweden, Latvia, Lithuania, Estonia, Poland, Malta, Cyprus, Hungary, Slovenia, Slovakia and the Czech Republic. The EU population is approximately 448 million people since the accession of Croatia on July 1, 2013.

The European Free Trade Association (EFTA) is the intergovernmental organization of Iceland, Liechtenstein, Norway and Switzerland. These countries although not members of the European Union, fully implement EU food safety legislation.

Brexit:

Since Brexit took place, seafood trade with the UK operates under specific rules.

The UK authorities have created a step-by-step web site for third countries operator wishing to export food to the UK:

<https://www.gov.uk/import-goods-into-uk>

For the list of U.S. establishments approved to export animal products to the UK please go to the following link:

<https://data.gov.uk/dataset/4698a65d-1a3b-42d1-981e-df869e04185b/export-of-animals-and-animal-products-to-the-uk>

Additionally, Seafish's web site contains very useful information for U.S. operators wishing to export seafood products to the UK:

<https://www.seafish.org/trade-and-regulation/>

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 Sante* share responsibility for food safety consumer policy and public health protection.

A college of 27 Commissioners who are named by their national governments but should make decisions independently, head the Commission.



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



The [European Council](#) is the EU institution that defines the general political direction and priorities of the European Union. It consists of the **heads of state or government of the Member States**, together with its President and the President of the Commission.

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

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



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

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

D) What are the different measures?

Regulations:

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

Directives:

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

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.

Recommendations:

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

II. How Fishery Policies are handled at the EU Level

DG Mare is responsible for negotiating international fishing agreements, resources management, aquaculture, fleet management, the Common Fisheries Policy (CFP), ocean governance and maritime affairs. It also sets Autonomous Tariff Quotas (ATQs) that allow third countries such as the U.S. to export fishery products to the European market at a reduced duty. It supports DG Trade, part of which is the EU equivalent to the Office of the US Trade Representative for WTO matters.

Some fish species are subject to trade restrictions under the Convention on International Trade of Endangered Species. DG Environment is the “Chef de File” for this subject matter. DG Mare and DG Environment work together closely due to the status of worldwide fish resources. Fishery products are also subject to measures introduced by DG Agriculture and DG Internal Market and are supervised by DG Sante. DG Agriculture is responsible for the Common Agricultural Policy (CAP) and all “vertical” measures on raw materials. These DGs initiate proposals on all EU measures concerning sanitary legislation and inspection by type of products (beef, pork, poultry, vegetables, seafood, etc.).

DG Mare	DG Environment	DG Agriculture	DG Grow	DG Sante
<ul style="list-style-type: none"> •Negotiates international fishing agreements, resources management, aquaculture, fleet management & Common Fisheries Policy (CFP) •Proposes tariff reductions, and import quotas •Supports DG Trade in fisheries related matters •Works with DG Environment to manage worldwide fish resources 	<ul style="list-style-type: none"> •Monitors trade restrictions on species that fall under the Convention on International Trade of Endangered Species •Works with DG Mare to manage worldwide fish resources 	<ul style="list-style-type: none"> •Responsible for Common Agriculture Policy (CAP) •Responsible for all "vertical" measures on raw materials 	<ul style="list-style-type: none"> •Responsible for "horizontal" measures for processed products •Proposes legislation on additives, microbiological criteria, colorings, antibiotics, and labeling in conjunction with DG Sante 	<ul style="list-style-type: none"> •Proposes legislation on additives, microbiological criteria, colorings, antibiotics, and labeling •In charge of EU food and feed legislation •Handles import controls for food and feed •Includes the Food & Veterinary Office (FVO)

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

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

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

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

Common Fisheries Policy (CFP)

- Legal basis for regulation of fisheries & aquaculture activities
- Manages fleet and quotas
- Directly affects imports of seafood from third countries (i.e., US)

Food Hygiene Legislation

- Guarantees safe food to European consumers
- Makes sure imported food complies with EU's minimum hygiene standards

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

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

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

- ✦ Marketing standards and consumer information for fresh products for quality, grades, packaging and labeling for domestic production as well as imports.
- ✦ Producers' organizations (voluntary fishermen associations) are officially recognized and are set up to help stabilize markets fluctuations. Their role is to protect fishermen from sudden changes by adjusting supply to demand. They also help to improve product quality and ensure that fishing quotas are respected.
- ✦ Interbranch Organizations and Agreements are aimed at facilitating a total integration of the sector from producer to consumer.
- ✦ Prices and Intervention by which certain species cannot be sold below a given price.
- ✦

IV. Exporting Seafood to the EU

A) General Provisions:

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

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

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

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

B) List of Countries:

[Commission Implementing Regulation 2021/405](#) is the list of countries and territories from which imports of fishery products and bivalve mollusks, echinoderms, tunicates and marine gastropods are permitted. One may note that only two U.S. States (Washington and Massachusetts) appear on the list of countries authorized to export bivalve mollusks, echinoderms, tunicates and marine gastropods. This means that, unlike fishery products, the U.S. inspection system for shellfish has not been recognized as totally equivalent to the EU’s inspection system. Similarly, the U.S. only recognizes two EU Member States as being equivalent to the U.S. (The Netherlands and Spain). Negotiations between the U.S. and the EU to resume transatlantic trade in shellfish are currently underway.

However, the exports of wild roe-off scallops to the EU from the U.S. are still authorized, per Article 12 of the Regulation referred above. In this case, a regular health certificate for fishery products is required.

C) Approved Establishments

U.S. operators that wish to export seafood to the EU must be approved by and registered with their National competent authority. The Food & Drug Administration (FDA) is the U.S. agency

responsible for the approval of seafood establishments. Once they are approved, U.S. exporters are included on the FDA list, which is updated every quarter. This FDA list is then sent to the EU for validation. The EU list of U.S. approved fishery products establishments can be found below:

https://webgate.ec.europa.eu/tracesnt/directory/publication/establishment/index#!/view/US/FISHERY_PRODUCTS/31

Although the production is allowed from the date the request for listing a new establishment has been confirmed by the European Commission services, no health certificate can be issued by the competent authority overlooking that establishment before the amended published EU list of approved establishments enters into force.

D) Certification

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

U.S. exporters should pay specific attention to the fact that health certificates must be issued and signed by USDOC-NOAA **before** the shipment leaves the U.S.

Bills of lading should always be dated the day of or after issuance of the health certificate.

See Certification Checklist in Annex

Important Notice:

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

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

Since December 14, 2019, the EU has modified the template of official certificates for certain animal and goods. This Regulation **does not** apply to our existing U.S. fishery products certificate (article 4, paragraph 4 of the pre-mentioned Regulation) except for imported (foreign sourced) products that have not initially produced/processed in the U.S. and that are re-dispatched to the EU without further processing. It also modifies and restricts the conditions for a replacement certificate.

In practice, the Border Control Post (BCP) at the first point of entry into the EU conducts the documentary check and issues a Common Veterinary Entry Document (CVED).

This CVED must be:

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

Important Notice:

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

E) Import Controls:

Principles for veterinary checks are laid down in [Regulation 2017/625](#). Inspections of consignments originating from third countries must be carried out on all consignments, at the first point of entry into the EU territory and at approved border control posts.

Import controls are done in three consecutive steps:



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

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

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

European border control posts may randomly conduct specific analysis on shipments presented to them for clearance. The analyses can target residues, heavy metals or other contaminants. Normally products will not be allowed to leave the BIP pending test results.

In cases where samples are taken for analysis and the results will not be known for at least a few days, consignments will not be given a CVED and will not be able to leave the BCP if:

- ✚ The testing is for a substance or pathogenic agent which presents a direct or immediate animal or public health risk; or
- ✚ The testing has been carried out because of information on previous unfavorable test results.

The veterinary authorities for the area of destination should be advised of any pending test results by TRACES,

Consignments which are sampled as part of the Veterinary Monitoring Directive (VMD) non-statutory sampling plan and those taken as part of routine sampling at the Border Control Post or the national monitoring plan do not need to be detained pending the results of the analysis.

However, if the tests reveal any contamination, the establishment that sent the shipment in question will be put on “reinforced control status.” This status is then communicated to all Member States as well as to the European Commission through the Rapid Alert System. When an establishment is on reinforced control status, the U.S. establishment’s next ten consecutive shipments (of a commercial size, not sample) to any EU country will be automatically tested. The products will be detained at border control posts until results are received. After ten shipments without positive results, the establishment in question is removed from the reinforced controllist. The legal text describing reinforced control procedures is [Commission Implementing Regulation \(EU\) 2019/1873](#).

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

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

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

1. The new destination has been agreed to by the EU based food business operator, i.e., consignee.
2. The consignee must inform the competent authority of the third country of origin or third country of destination, if different, of the reasons and circumstances that prevented sales of the food within the EU.

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

F) Triangular Trade:

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

EU sanitary legislation requires:

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

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

If the products are destined to a third country with temporary storage in a specially approved customs warehouse on the EU territory, they need to be presented to the EU border control post of arrival for transit controls. They should at least be accompanied by the health certificate requested by the third country of destination and the BCP will issue a Common Veterinary Entry Document (CVED). A second CVED will be issued when the goods leave the customs warehouse and travel to the country of destination. This is applicable for most fishery products; however, for fish and crustaceans of aquaculture origin, the health certificate needs to be provided to the entry BCP as such transit consignments must fulfil animal health conditions.

Certification procedures for re-dispatch to another third country are then of the responsibility of the member states where the goods are stored. Some may issue a certificate; some will refuse to do so. In any case, please contact NOAA EU office before shipping.

V. Food and Feed Hygiene Legislation

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

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

A) Food Law:

The [General Food Law Regulation](#) establishes that only safe food and feed can be placed on the Union market or fed to food producing animals. It also sets basic criteria for establishing whether a food or feed is safe.

The General Food Law Regulation defines [traceability](#) as the ability to trace and follow food, feed, and ingredients through all stages of production, processing and distribution. It affects importers who are required to be able to identify from whom the product was exported in the country of origin. It also obliges businesses to be able to identify at least the immediate supplier of the product in question and the immediate subsequent recipient, with the exemption of retailers to final consumers - one step back-one step forward (unless specific provisions for further traceability exist).

Rules on hygiene of foodstuffs were adopted in April 2004 by the European Parliament and the Council (Regulation (EC) No 852/2004, 853/2004 and 854/2004). They became applicable on 1 January 2006. With the coming into force of Regulation (EU) 2017/625 (the Official Control Regulation) on 14 December 2019, Regulation (EC) No 854/2004 was repealed. Provisions on official controls in products of animal origin can be found in:

- [Commission Delegated Regulation \(EU\) 2019/624](#) (Official controls of products of animal origin)
- [Commission Delegated Regulation \(EU\) 2019/625](#) (Import conditions),
- [Commission Implementing Regulation \(EU\) 2019/627](#) (Practical arrangement official controls products of animal origin)
- [Commission Implementing Regulation \(EU\) 2020/2235](#) (Import certificates)
- [Commission Implementing Regulation \(EU\) 2021/405](#) (Lists of third countries authorized to import products of animal origin)

B) Subsequent Regulations:

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

Microbiological Criteria for Foodstuffs:

These criteria are fundamental for a comprehensive food sanitation framework and are applicable to products during their entire shelf life. In addition, the corresponding [legislation](#) sets down certain sanitation criteria regarding the production process.

Contaminants:

Contaminants are substances that have not been intentionally added to food. These substances may be present in food because of the various stages of its production, packaging, transport or holding.

They also might result from environmental contamination. Since contamination generally has a negative impact on the quality of food and may imply a risk to human health, the EU has taken measures to minimize contaminants in foodstuffs. European Union measures (establishment of maximum levels) have been taken for the following contaminants ([consolidated Regulation 1881/2006](#)):

- ✓ mycotoxins (aflatoxins, ochratoxin A, fusarium-toxins, patulin, citrinin)
- ✓ metals (cadmium, lead, mercury, inorganic tin, arsenic)
- ✓ dioxins and Polychlorinated Biphenyls (PCBs)
- ✓ Polycyclic Aromatic Hydrocarbons (PAH)
- ✓ 3-MCPD
- ✓ melamine
- ✓ erucic acid
- ✓ nitrates

C) Feed Hygiene:

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

D) Food and Feed Controls:

The Food and Feed Regulation on Official Controls ([Regulation 2017/625](#)) establishes a harmonized EU controls system that includes: food and feed safety and animal health and welfare standards. Third countries must guarantee that products intended for the EU market meet the necessary standards. This section does not include animal welfare controls unless there are explicit animal welfare provisions in specific bilateral agreements.

A consignment of live animals or animal products can only enter the EU, if it has satisfactorily undergone the specific checks and a Common Health Entry Document (CHED) is issued from [TRACES](#) (TRAdE Control and Expert System). TRACES is a centralized database which allows the monitoring of consignments of live animals and animal products checked at the Border Control Posts.

The lists of designated veterinary BCPs are available through the link below:

https://ec.europa.eu/food/animals/veterinary-border-control/contact-details-bcps-veterinary_en#EEA

VI. Which Certificate for Which Product?

A) Fishery and Aquaculture Products:

Shipments of fishery and aquaculture products must be accompanied by a health certificate. Seafood products caught or farmed raised in the U.S., further processed or not, and shipped directly to the EU must be accompanied by a “simplified” certificate. Foreign sourced material must be accompanied by a regular EU type certificate. U.S. exporters should consult the [NOAA Seafood Inspection Program](#) web site for further information regarding the right template to use. Note that wild roe-off scallops are considered as fishery products and must be accompanied by a fishery product health certificate.

B) Live Bivalve Mollusks:

On February 4, 2022, the United States and European Union (EU) concluded negotiations to allow for resumption of bilateral trade in bivalve molluscan shellfish. For the first time since 2011, U.S. producers, beginning in the states of Massachusetts and Washington, are eligible to export live, raw and processed bivalve molluscan shellfish to the EU, including oysters, clams, mussels, and whole or roe-on scallops. EU producers in Spain and the Netherlands are also now eligible to export live and raw bivalve molluscan shellfish to the United States.

The bilateral [sanitary certificate](#) for shellfish, published on February 7, 2022, will enter into force on February 27, 2022.

VII. Fishmeal – Fish oil

A) Fishmeal:

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

For U.S. exporters, NOAA issues this certificate. Fishmeal exports intended for the EU must be produced by EU - approved establishments. The list of U.S. approved animal by-products establishments can be found through the link below:

https://webgate.ec.europa.eu/sanco/traces/output/non_eu_listsPerCountry_en.htm

B) Fish Oil:

The amended Hygiene Legislation requires that fish oil intended for human consumption must meet the requirements for “regular” fishery products.

As such, U.S. fish oil shipments to the EU must be produced in EU-approved establishments and accompanied by the same public health certificate as the certificate for fishery products. Fish oil

products containing plant or other ingredients (wheat...) in quantity are to be considered composite products. [Regulation 2020/2235](#) is the framework Regulation covering composite products. Under this Regulation, establishments wishing to send composite products do not need registration and must use the certificate described in Annex I of the Regulation. **Due to legal complexities regarding this specific certificate, no U.S. Federal Agency (NOAA, FDA, USDA, FSIS, APHIS...) can issue such a document yet.**

However, NOAA can issue a fishery product certificate for flavored fish oil and fish oil containing plant-based antioxidants for human consumption. These products are not considered to be composite and must come from EU approved establishments.

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

For a complete overview of fish oil import requirements into the EU, see link below:
https://ec.europa.eu/food/sites/food/files/animals/docs/bips_guidance_fish-oil_en.pdf

VIII. Duties and Trade Measures

A) Background:

All EU fish tariffs were consolidated under the Tokyo Round of GATT. The average EU duty for Chapters 3, 1604 and 1605 is 17.2%, one of the highest in the world. The tariff range is from 0% - live eels, to 25% - canned mackerel, bonito and anchovies. The primary legislation covering tariffs is [Commission Implementing Regulation 2021/1832](#). However, the EU provides different mechanisms to reduce duties. It claims that its overall tariff average is then reduced to around 3 to 4%: An overall duty-free scheme applies to Africa-Caribbean- Pacific (ACP) countries, signatories of the Lomé Convention, for all seafood products imported into the EU from ACP countries. [The Generalized System of Preferences](#) (GSP), which applies to developing countries, applies to all seafood products in Chapter 3. Products are classified according to categories, e.g., *sensitive*, *semi-sensitive* and *very sensitive*.

The Lobster agreement:

On August 21, 2020, the U.S. and the EU agreed on a package of tariff reductions that increased market access for hundreds of millions of dollars in U.S. and EU exports. These tariff reductions are the first U.S.-EU negotiated reductions in duties in more than two decades.

Under the [agreement](#), the EU have eliminated tariffs on imports of U.S. live and frozen lobster products; lobster meat and processed products of Chapter 16 are not subject to this agreement. The EU has eliminated these tariffs on a Most Favored Nation (MFN) basis, retroactive on August 1, 2020. The suspension of tariffs is for a period of five years and the European Commission will initiate procedures aimed at making the tariff changes permanent. The United States have reduced by 50% its tariff rates on certain products exported by the EU worth an average annual trade value of \$160 million, including certain prepared meals, certain crystal glassware, surface preparations, propellant powders, cigarette lighters and lighter parts. The U.S. tariff reductions operate under an MFN basis and retroactive on August 1, 2020. For more information on this agreement and potential reclaim of duties, contact the NOAA EU Office.

B) Tariffs Quotas:

Tariffs Suspensions have been suspended since January 2013 and replaced by Autonomous Tariff Quotas (ATQs) that are granted annually for a period of for 3 years. These tariffs quotas are covered by [Council Regulation 2020/1706](#) for the period 2021-2023.

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

For questions on a specific duty rate, consult the following web site:

http://ec.europa.eu/taxation_customs/dds2/taric/taric_consultation.jsp?Lang=en&Screen=0&redirectionDate=20110203

IX. Labeling of Seafood Products?

A) Legislative Background:

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

The three primary labeling Regulations are:

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

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

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

ALL OUTER & INNER PACKAGES MUST BEAR:

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

1. The country of origin,
2. The [commercial denomination](#) of the products, and
3. The approval number of the establishment of origin

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

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

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

Those two items must be written or printed “indelibly.” The most desirable way would be to have them pre-printed on packages/cartons. In instances where stick-on labels may be used, they must not be easily destructible or removable. Labels must be in a language “easily understandable” by users and at least in one of the official languages of the country of final destination (distribution). Labels may be in several languages.

Commission Regulation 2001/2065/EC identifies specific requirements for the labeling of fishery and aquaculture

products intended for the **retail sector**. This Regulation only concerns products from Chapter 3 of the Tariff Harmonized System, and has been amended by [Regulation 1379/2013](#).

Since December 13, 2014, there are new requirements for products intended to retail and mass caterers.

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

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

The commercial and Scientific name of the species. The EC has established a list of applicable commercial and scientific names. This list is visible on [DG Mare’s website](#). (Note: the Latin name is also required on other documentation such as the health certificate)

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

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

EC [Guidance document](#) on labels for retail.

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

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

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

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

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

Other Regulations regarding ingredients, allergens and guidelines for the implementation of labeling legislation can be downloaded at:

https://ec.europa.eu/food/safety/labelling-and-nutrition/food-information-consumers-legislation/guidance-documents_en

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

B) Specific Labeling Examples:

Fresh, Chilled Products:

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

Live Bivalve Mollusks:

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

Canned Products:

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

Frozen Products:

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

Deep-Frozen Products:

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

Lot # Example:

L8110B15 may mean

L = Lot

8 = 1998

110 = Day of Production

B15 = Production Line Number

X. Other legislation

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

- ✦ [Additives](#), colorings, [flavorings](#) and sweeteners allowed within the EU. Per Directive 95/2/EEC (amended several times), additives such as STP - E338 to E 450 - are not allowed in fresh scallops, only in frozen and deep-frozen scallops.
- ✦ [Packaging materials](#): this legislation is important and relates to the characteristics of materials to not transfer substances to foodstuffs in quantities that may be harmful to human health or change organoleptic properties.
- ✦ **Sport caught fish**: [Commission Delegated Regulation 2019/2122](#) identifies weight limits under which there is no need for health certificate for the import of fish for personal consumption. This limit has been raised from 1 kg to 20 kg. Article 7, paragraph b.

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

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

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

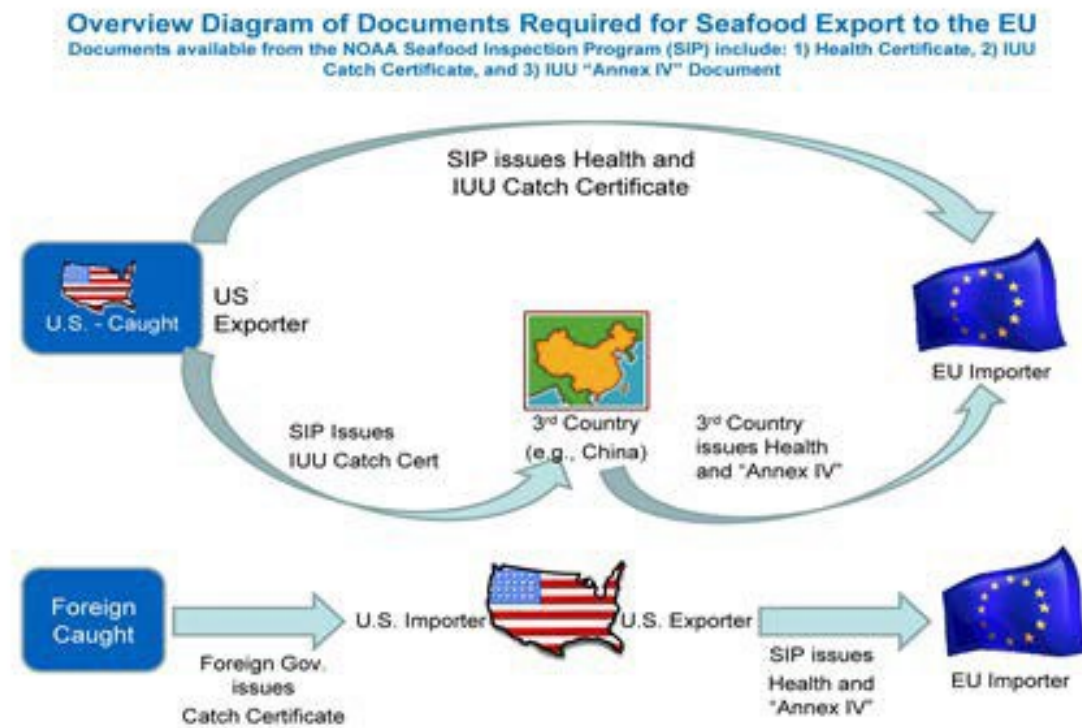
This Regulation has been amended by [Regulation 86/2010](#) and [Regulation 202/2011](#). These Regulations amend the list of products excluded by the scope of the catch certification system and identify specific agreements between the EC and third countries, including the U.S.

**Catch Certificates are required for most products of Chapter 3 and 16 of the Combined Nomenclature.
For example, fish oil bearing HS code 1504 is not subject to Catch Certification.**

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

NOAA signed an agreement with the EC that allows for a U.S. specific [catch certificate](#). NOAA is responsible for the issuance of both sanitary and catch certificates. U.S. exporters will find the necessary information regarding these catch certificates, as well as FAQs on the NOAA SIP web site. **Since March 1, 2020, NOAA has a new certificate of legal harvest that includes catching vessels.**

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



Annex I: CERTIFICATION CHECKLIST

Establishment Listing:

- ┆ Is your establishment on the EU list of U.S. approved establishments?
- ┆ If yes, does it correspond to the one mentioned on the health certificate?
- ┆ No typos? Inversion of numbers?
- ┆ Is your third country supplier, if any, an EU approved establishment?
- ┆ Is there any restriction on products from that specific third country?

Date of certificate:

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

Approval number:

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

Identification of products:

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

Transport info:

- ┆ Container and seal numbers not mandatory but highly recommended.

Label:

- ┆ Is your label complete?
- ┆ Does it match with box I.28 of your health certificate?

Annex II

XII. Points of contact

[N.O.A.A.](#)

[National Marine Fisheries Service](#)

[NOAA Seafood Inspection Program](#)

[Food and Drug Administration \(FDA\)](#)

Annex III - Useful links

EU List of U.S. FDA approved seafood producers/freezing & factory vessels/cold storage:
https://webgate.ec.europa.eu/sanco/traces/output/non_eu_listsPerCountry_en.htm

FDA list of approved shellfish growers/shuckers/packers:
<https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list>

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

DG SANTE - EU food safety legislation:
https://ec.europa.eu/food/safety/biological-safety/food-hygiene_en

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

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

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

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

For More Information

The U.S. Commercial Service at the U.S. Mission to the European Union, can be contacted via email at: Stéphane Vrignaud, at stephane.vrignaud@trade.gov; Phone: +32(2) 811-5831; Fax: +32(2) 811 5151; or visit our website: <https://useu.usmission.gov/mission/useu/sections-offices/>

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