







## EU MARKET ACCESS GUIDE FOR FISH AND FISHERY PRODUCTS









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This manual does not replace the national legislation nor the National Control Plans and Industry Standards of National Competent Authorities. It is a Guide to both the National Competent Authorities and Industries on Key EU Market Access requirements.

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# 1. THE OBJECTIVE OF THIS GUIDE

This publication aims to help fisheries and Competent Authority (CA) officers with certification responsibilities, as well as potential and present exporters, understand, on one side, the basics of the "technically oriented" market access certifications (IUU regulation and health) and some other key aspects of upcoming requirements.

This publication provides an updated guideline to the regulatory requirements for exporting seafood products to the European Union (EU). It describes the EU system of official assurances, the principal regulations, and the requirements for the Competent Authorities and operators along the value chain regarding health and "non-IUU" Catch Certification.

Each chapter opens with a "basics" section, and then further subsections develop some of the subject's most important topics.

Exporting seafood to the EU is not an obligation; it requires equal effort from the government authorities and the private sector of the exporting countries.

Compliance and understanding the required official assurance system are paramount to accessing the EU market.

It is intended that this publication be used as an introduction to the basics of IUU and health certification for the EU.

It is strongly recommended that the reader follow up on the references and research all the topics of interest.

# 2. REGULATORY BACKGROUND TO EU MARKET ACCESS FOR FISH AND FISHERY PRODUCTS

To understand EU Market Access, it is fundamental to understand the general policies and particular regulatory requirements governing this access.

The objective of this section is to facilitate that understanding.

#### 2.1 Overall Principle

One of the grounding ideologies of the EU is that of free trade. By the logic of free trade, any product produced under EU regulation in any European country can travel from one country to another without being subject to trade barriers (such as tariffs or non-tariff barriers to trade, different laws or regulations, subsidies, trade restrictions, import quotas, etc.).

This facilitates trade among EU countries. This principle is also extendable to four more countries (Iceland, Norway, Switzerland, and Liechtenstein) that form the European Free Trade Association (EFTA), which, together with EU countries, constitutes the Agreement on the European Economic Area.

The free trade principle is based on a robust regulatory framework that affects all the EU Member States (MS). Import rules for fish and fisheries products are harmonised, which applies to all EU countries. The European Commission is the negotiating partner for non-EU countries that defines import conditions and certification requirements.

The two principal regulations affecting fish and fishery products seek, among other objectives, to protect final consumers' health and close EU markets from products originating from Illegal, Unreported and Unregulated (IUU) fishing activities.

Under these regulations, all fishing products must be captured, manipulated, elaborated, transported and delivered following standards established by European legislators, considering European realities and addressed to European citizens.

While there are two "technical" regulatory sets (Health and IUU) and a trade one (Origin) that the exporting country needs to comply with, the most complex requirements are with health, so it is fair to say that the "main" authorisation requirement is that in place for health certification.

The EU sees aquaculture products from a "farming" perspective. Hence, their importation runs under a "parallel system" as the value chain from the farms to the processors must comply with the exact requirements of wild-caught fish. Still, they need to comply with an "extra" control system in the form of an annual control plan run by the CA on heavy metals, contaminants, residues of pesticides and veterinary drugs.

The foundation of the EU scheme is an obligation to comply with EU sanitary requirements and, thus, an expectation that the exporting country proves that it operates a control structure applicable to its seafood exports equivalent to those existing in an EU member country.

Hence, operationally, a non-EU country needs to be "authorised" by the European Commission (EC) and added to a positive list of countries from a seafood safety perspective before it can attest to the legality of the catch comprising those exports.

The main objective of this intervention is to fulfil the sanitary requirements; however, the issue of catch certification is important because exports to the EU must also be confirmed as legal from an IUU perspective.

#### 2.2 Health Certification

Consumer health and safety concerns led to the establishment of hygiene regulations across the EU in 1993. These were complemented in 2004 by regulations concerning importing food and feed, including fisheries and aquaculture products.

This comprised the "hygiene package," which has evolved and involves designated CA in EU MS and third countries, a network of Border Control Posts (BCP), and a system of sanitary certification and rapid alerts (e.g., RASFF).

Under the Health Certification system, third countries must guarantee that the exported product accomplishes what was established by the EU Member countries' regulations (EC) No. 178/2002, (EC) No. 882/2004 and (EC) No. 884/2004, commonly known as the "hygiene package." While these original legislations were since then repealed and replaced by the present (EC) No 625/2017 and (EC) No 1679/2024 respectively, the operating principles of the "hygiene package" have been maintained.

The third country CA must guarantee that all the participants in the production chain, from the producers (vessels, aquaculture farms, etc.) to the exporting establishments, passing by cold stores, processing establishments, etc., meet the requirements of the EU regulation, identifying all the components of this value chain using a proven traceability system.

The exporting country CA needs to assure compliance with three types of obligations:

- 1. **Obligations of resources:** i.e. instruments of production, Hazard Analysis Critical Control Points (HACCP) and prerequisites programme, traceability, etc.
- 2. **Obligations of results:** i.e. safety levels of the product (e.g. histamine, contaminants), etc.
- 3. **Obligations of control:** i.e. regulatory verification, data storage and management, legal support, etc.

Once the equivalence is established, the country could export to the EU market if the products exported have a Health Certificate issued by the CA of the country of origin together with a Catch Certificate.

Through its Food and Veterinary Office (FVO), the EU reviews, checks and makes sure that exporting countries' seafood safety regimes are equivalent to that of the EU itself. The FVO undertakes inspection missions to third countries to evaluate the CA's performance to determine the status of compliance with the EU regulation. After the inspection missions, FVO will publish a public report containing what they have found, references, and, if necessary, recommendations to facilitate compliance.

Regulation (EC) No. 625/2017 states what kind of official controls third countries CA must make to ensure that production chain components respect EU regulation. This regulation establishes that official controls can be carried out by the CA without warning, regularly, and with a frequency based on risk. The controls should also be done at any production stage including processing, distribution, exporting, etc.

In other words, establishments must be prepared to be the subject of official controls by CA at any moment, putting them at risk of being suspended or removed from the list of officially approved establishments if they are not able to prove that they are complying with the EU "hygiene package" regulation. They will lose the possibility of exporting to the EU market and/or providing their product to other establishments officially approved by the CA.

Besides the FVO, the EU has other tools to verify the accomplishment of its regulations by third countries.

All products entering the EU coming from third countries must enter via an EC-approved BCP under the authority of an official veterinarian. On their arrival, third-country products are subject to three types of checks:

- 1. A documentary check is done systematically.
- 2. An identity check is done systematically.
- 3. A physical check: done appropriately to the risk profiling of the consignment.

If any non-compliance with the EU legislation is found, the BCP notifies the EU MS through the RASFF, facilitating its detection on the European Market through the traceability system they must follow. If the product represents a danger to consumers' health (exceeding any regulatory level or containing non-authorized substances), the exporter, in conjunction with their resident CA, may decide whether to recover or destroy it.

In summary, the EU only permits imports from authorised countries, with each country having approved establishments under CA control. So, your country will need to be on the list first, and then your establishment needs to be approved and listed by the local CA.

#### 2.3 Catch Certification

Taking account of EU consumer concerns regarding the fact that "Illegal, unreported and unregulated (IUU) fishing constitutes one of the most serious threats to the sustainable exploitation of living aquatic resources and jeopardises the very foundation of the common fisheries policy and international efforts to promote better ocean governance" (preamble of the EU IUU Regulation), the EU decided to adopt the Regulation (EC) No. 1005/2008 establishing a Community system to prevent, deter and eliminate IUU fishing (EU IUU Regulation). This regulation is accompanied by implementing regulations and other tools.

The EU IUU Regulation prohibits trade with the Community in fishery products stemming from IUU fishing and states in its preamble,

"...to make this prohibition effective and ensure that all traded fishery products imported into or exported from the Community have been harvested in compliance with international conservation and management measures and, where appropriate, other relevant rules applying to the fishing vessel concerned, a certification scheme applying to all trade in fishery products with the Community shall be put in place."

The Catch Certification Scheme (CCS) was introduced on 1 January 2010, whereby fisheries products must be accompanied by a Catch Certificate (CC) declaring that the catch was made under applicable laws, regulations and international conservation and management measures.

The IUU regulation applies to all trade of marine fishery products, processed or not, originating from third-country fishing vessels and exported to the European Community by any means of transportation.

It also applies to any catches originating from EU fishing vessels to be exported to third countries. Transhipments and processing operations are also within the scope of the IUU certification scheme.

One of the critical aspects of this regulation is the complete traceability of marine products (which also has a relevant role in the regulation (EC) 178/2002 of the so-called "hygiene package", as seen in the previous section).

The system aims to record the origin of all the marine products arriving at the EU market: this means knowing who captured the fish, where it was caught, how much was caught when it was caught and how it was caught, and that all those activities took place in compliance with a verifiable regulatory framework.

As well as with the Health Certificate, the IUU regulation is based on the responsibility and commitments of third countries. The objectives of the Catch Certification scheme are threefold:

- 1. Ensuring product traceability at all production stages, from catch to marketing, including processing and transport.
- 2. Enabling Flag States to better monitor the fishing activities carried out by its vessels and support compliance with conservation and management rules and
- 3. Providing a legal basis for cooperation between Flag States, countries of processing and marketing and improving the dissemination of information.

As all the products entering the EU market must be accompanied by this certificate, the EC importer must ensure that the consignment to be imported has a validated certificate provided by the exporter before the importation to the EU. The responsible for issuing the CC should be the Fisheries Authority of the vessel's flag state.

In 2023, Council Regulation (EC) No 1005/2008 was amended by Regulation (EU) 2023/2842 of the European Parliament and of the Council of 22 November 2023<sup>1</sup>, introducing a series of updates, including the use of the CATCH EU-wide real-time IT system for the management of all procedures linked to the EU catch certification scheme.

<sup>1</sup> https://eur-lex.europa.eu/eli/reg/2023/2842/oj

The present EU CCS paper-based system will be valid until 26 January 2026. As such, the authenticity of any certificate can only be ascertained through a lengthy process involving direct communication and feedback requests from the authorities that issued the original—a process that falls under what the EU IUU Regulation refers to as "mutual assistance." Any such action by EU border authorities implies delays and demurrage costs to operators, regardless of whether the consignments are legal or illegal.

Yet, beyond 10 January 2026, the use of the CATCH system will be compulsory for EU importers for the submission of the catch certificates and related documents to the EU Member States' authorities.

Non-EU countries' exporters and authorities can use the system voluntarily.

#### 2.4 Relations between the Certifications

The certification regimes are as different as the work scopes of a Seafood Safety Inspector and a Compliance Fisheries Officer. Thus, a Health Certificate is irrelevant for validating a Catch Certificate, which relies only on compliance with conservation and management rules. Adversely, the Catch Certificates, as per the IUU Regulation, cannot be substituted for the Health Certificates.

However, it is important to note that the different documents (Catch and Health Certificates) cannot contain discordant information.

The table below compares some of the elements of the Health and Catch certifications covered in this guide, as well as the differences between the present and forthcoming Catch Certifications.

	Health Certification	Catch Certification until 10/01/26	Catch Certification after 10/01/26
Nature and extent of the problem	Small but significant number of alerts; small number of cases affecting EU consumer. Alerts published.	Extensive worldwide perception of IUU issues. No objective assessment of EU MS performance is published.	Same on IUU perception Centralised data base of certificates (CATCH) may help to identify EM MS performance
Aim	Protect the health of the European Consumers (and aquatic fauna in the case of live fish).	Avoid the importation of fisheries products obtained from IUU fishing and reduce the demand for such products.	Same
Scope	Fish and Fishery Products traded to EU Member countries from "authorised" countries.	All fishing vessels under any flag in all maritime waters, and all processed and unprocessed marine fishery products, traded to or from the EU (and EU nationals operating under any flag).	Same
Consistency with international instruments	Consistent with CODEX, WTO SPS Agreement etc.	Consistent with IPOA-IUU, UNFSA, FAOCA, APSM and partly with the voluntary guidelines for flag state performance.	Same

	Health Certification	Catch Certification until 10/01/26	Catch Certification after 10/01/26
Overall responsiblity	Authorised Exporting Country. The country must be in the list of "authorised" countries based on legal framework and the "competency" of the CA.	Flag State of the harvesting vessel (and/or a RFMO if the vessel/flag country is participant of a catch certification scheme recognised as compliant with the applicable regulation).	Same
Applicable EU regulations	Various, most notably Regulations: (EC) No 178/2002, No 852/2004, No 853/2004, No 625/2017, No 2073/2005 and their applicable amendments (see fig 1)	The regulation Reg. (EC) No 1005/2008 establishing a Community system to prevent, deter and eliminate IUU fishing, as amended by Reg (EU) 2023/2842 and various others	Same Plus, Regulation (EU) 2023/2842
Competent Authority EU MS	Coherent set of Border Control Points monitored and aided by DG SANTE; national systems within EU MS.	Responsibility on the Fisheries CA of the MS, Inconsistent methodology on entry into EU either through designated ports for Fishing Vessels, or through other ports for containers; little complementarity with sanitary controls; no standard methodology applied by DG MARE.	Same Yet with the support of the centralised CATCH database
Vetting and monitoring of EU MS CA	Not vetted; DG SANTE carries out standard audits and publishes results.	Not vetted; DG MARE carries out undefined audits or visits and does not publish results.	Same
Competent Authority in third country	Seafood safety CA varies depending on the country, for example it can be Ministry of Health, Fisheries, Agriculture, or Food Safety Authority.	Generally, is the Fisheries Authority of the flag country of the vessel but can be the veterinary services in charge of validating the health certificate.	Same
Vetting and monitoring of third country CAs	Vetted and monitored through published list of FVO missions, published audits and CA responses.	Nominations either accepted or not, unclear on nature of DG MARE audits or visits	Same Yet the CA could voluntarily be part of the CATCH Database
Contents of the certificate	Completed by the CA, and an officer of the CA of the country of processing or containerisation provides official guarantees that the consignment meets the EU regulations, or equivalent.  Standardised Certificate in the TRACES NT database for sanitary certification	Declaration by exporter; validation of transhipment; validation on export by CA; checks on arrival in the EU (authorisation); reexport certificate, transport details, and fishing details (save fishing area does not distinguish between high seas and EEZ, making licence verification difficult).	Same Yet the CA could voluntarily be part of the CATCH Database that is part of the TRACES NT.
Presentation of the Certificate	On product arrival at the Border Control Post. Electronic notification through TRACES before arrival; original on clearance.	By the importer on arrival. In case of direct landings in EU ports 3 days prior notice, with shorter periods for fresh products, air freight, and arrivals by road and train (2 to 4 hours).	Electronic CATCH (via TRACES) required from 10/01/26.

	Health Certification	Catch Certification until 10/01/26	Catch Certification after 10/01/26
Status of the operator (processing plant/ fishing vessel)	The operator must appear in a list of establishments (processing plants, vessels) published by DG SANTE, authorised and submitted by an accepted CA in a listed third country.	Vessel must fly the flag of a country whose notification has been listed. No list of approved vessels. Products of vessels in a list of IUU vessels (either by the EU or by RMFOs) are not allowed access.	Same
Role of the RMFO	None.	RFMO Catch Documentation Scheme may be approved to substitute the CCS under the EU IUU Regulation.	Same
Signatories	The authorised CA signs the certificate.	Notified CA validates Catch Certificate but port state authorities signs transhipment sections 7 and CA in processing State sign Processing and Non- Processing Statement.	Same Roles under CATCH unclear yet.
Controls on entry	Standard practices at BCPs and guidance to them; electronic record of all health certificates.	Varied practices and risk assessment on entry; no record of use of CCs and Processing Statements.	Same Yet under CATCH a record of CCs and Processing / Non- Manipulation Statements would be available
Action on rejection	Consistent methodology. RASFF	Sometimes returned, even though this is not provided for in the EU IUU Regulation.	Same
Controls on re- export and split consignments	EU MS issues new health certificate.	Re-export certificate completed by EU MS CA, but CC copied for consignment split, thus no control or traceability. No record of issue or use of re-export certificates.	Same Yet under CATCH a record of CCs and Processing / Non- Manipulation Statements would be available
Alerts	Comprehensive RASFF system, accessible by public, annual reports issued.	Provided for in the EU IUU Regulation, but not instituted.	Alerts via CATCH/TRACES NT
Single Liaison Office EU MS	Provided for, but not easily accessible.	Publication provided for in EU IUU Regulation, but not done to date; Third Countries do not have access to contacts in EU MS.	Same, yet under CATCH/ TRACES contacts may be available.
Traceability	Health certificate re-issued at each point in the chain; one-up-one-down principle applied. Traceability needs to confirm maintenance of EU supply chain.	Copies of CCs permitted; no record of their issue or use; port of landing not indicated; no traceability of product is possible.	Improved via CATCH/TRACES and the new rules applicable to Processing / Non- Manipulation Statements
Controls on vessels	In third countries and in EU MS need constant monitoring and improvement; EU distant water fleet controlled weakly.	Flag State responsibility paramount; coastal and port State controls bypassed at times.	Same for coastal states yet improved role for Port State in the new CC format.

	Health Certification	Catch Certification until 10/01/26	Catch Certification after 10/01/26
Training and support to third countries	Over 25 years of technical assistance by various bodies inside and outside the EC. Comprehensive long-term support through Better Training for Safer Food; plus other initiatives).	No formal support from DG MARE; some missions carried out but results not published; one initiative from DEVCO has ended. However, the EC have promised to co-operate administratively with and/ or support third countries in the implementation of this Regulation.	The EC have promised to co-operate administratively with and/or support third countries in the implementation of this Regulation.
Consequences of non-conformity	Product detained. Rapid Alerts Systems entry, report from the Country-of-Origin CA, product returned or destroyed. Possible reason for external audit of CA/ exporting country by DG- SANTE	Refusal of Importation. AC of MS may confiscate and destroy, dispose of or sell for charity. If the flag State refuse/fail to take corrective measures against the vessel, it could be potentially listed as IUU vessel. Flag State potentially listed as a Non-cooperating country.	Same
Black lists	No country blacklist. Countries must be listed. Certain products can be excluded, or EC can ask third country CA to suspend an establishment from its list of approved establishments. Potential loss of EU authorisation status.	There is provision for non-cooperating third States; CAs must be notified, and EC accepts notification by publishing list (though this is not legislated). IUU vessel list so far only compilation of RFMO lists.	Same
European Community Nationals	Nothing there.	Nationals of the EC shall neither support nor engage in IUU activities and the EC Member State concerned shall cooperate with the relevant third country to identify nationals supporting or engaging in IUU activities.	Same

# 3. WHAT DOES THE HEALTH CERTIFICATION IMPLY?

The European Commission is a member of the World Trade Organization (WTO) and takes the rules and agreements as binding for assessing and managing risks associated with food and feeds linked to trade. Concerning food and feed, the WTO Sanitary and Phyto-sanitary (SPS) Agreement and the supporting standards, guidelines and recommendations established by the World Organisation for Animal Health (OIE) and Food and Agriculture Organization / World Health Organization (FAO/WHO) Codex Alimentarius Commission are respected and form the basis of EU legislation.

#### 3.1 The hygiene regulatory package of the EU

The EU "hygiene package" has been designed to protect the health and safety of consumers, as well as address animal welfare, plant health and environmental protection. It follows the principles of the "farm to table" or food chain approach promoted by the WTO. Five broadly defined areas support the international food chain approach:

- The fundamental components of risk analysis, assessment, management and communication;
- Traceability of the food or feed from primary production through postharvest handling, processing and distribution to consumers;
- Harmonisation of all standards for fish safety and quality attributes to support the development of internationally agreed science-based standards;
- Equivalence in food safety systems in which similar levels of protection are developed against food-borne hazards and quality attributes irrespective of the method of control that is applied;
- An emphasis on risk avoidance and prevention at source within the whole food chain from farm or sea to fork or table. This also covers aquaculture and includes good practices, Prerequisite programmes and safety systems based on the preventive HACCP concept.

The "hygiene package" is characterised by regulations defining the sanitary requirements to be observed by the operators and controlled by the CAs (Regulations No. 852/2004 and No. 853/2004). They were developed with a focus on delegating responsibility for producing safe and wholesome food to the producers with support, monitoring and review activities from trade organisations and MS CAs.

Regulation (EC) No. 852/2004 on the hygiene of foodstuffs explains the obligations of the food business operators, including the duty of registering with the CA. It defines the most important terms regarding the food industry, while Regulation (EC) No. 853/2004 lays down specific hygiene rules on the hygiene of foodstuffs of animal origin.

Their equivalence means, in respect of different systems, being capable of meeting the same objectives. Furthermore, the specific hygiene requirements and the principles of the preventive Hazard Analysis and Critical Control Point (HACCP) system are explained.

With regards to the Official Control Systems to be in place, Regulation (EU) 2019/627 lays down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption under Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards to official controls, and includes the basic rules for the surveillance of food and the listing system for imports.

This system includes special rules for fishing vessels, factory vessels and freezer vessels flying the flag of a third country to control fishery products even when caught by one flag and processed in a different country. Furthermore, the regulation requires a Health Certificate that assures the imported products' safety at the Border Control Posts (BCP). Each authority issues a Certificate that the product passes through, even though its origin in customs terms may be in another country. Each MS and third country must nominate a CA responsible for managing all Sanitary and Phyto Sanitary (SPS) issues.

Regulations (EU) 2017/625 and 2019/627 cover official controls performed to verify compliance with feed and food law, animal health and animal welfare rules and demonstrate the principles of official controls and what those comprise and who executes control checks. The regulation states that imported goods should undergo the same controls defined for European goods. It shows the actions if the consignment from a third country does not fulfil the safety requirements. It has then either to be re-dispatched or destroyed. The food operator must bear the related costs.

Finally, binding requirements have been established for residue methods under Commission Decision No. 2002/657/EC. This regulation has harmonised the MS approach to validation, increasing the results' reliability.

It would be impossible to have referenced all legislation in one document and all the requirements in one simple list.

Figure 1 diagram outlines the key regulatory instruments and their interconnections; therefore, it can be used as a base to understand the systems and to find the required references.

#### 3.1.1 General principles and requirements of EU Food Law

Regulation (EC) No. 178/2002 outlining the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety was adopted in January 2002 and established the general principles and requirements of food law (last amended by Regulation (EU) 2019/1381). It provided a framework for supporting a coherent approach to food and feed safety legislation. The regulation also defines the role of EFSA and includes basic concepts of equivalence and traceability.

The key to understanding the principles and controls for feed and food law is Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.

#### **EC LEGISLATION - FISHERY PRODUCTS / PUBLIC HEALTH**

	Last amonded by	HYCIENE	OF FOODSTUFFS / HACCP
Regulation 852/2004	Last amended by Regulation (EU) 2021/382	ANNEX	X I: Primary Production eneral hygiene requirements
Regulation 853/2004	Last amended by Regulation (EU) 2024/1141		F FOOD OF ANIMAL ORIGIN ECTION VIII: Fishery Products
Regulation (EU) 2017/625	Last amended by Reg. 2021/1756	OFFICIAL CONTROL SYSTEMS - ORGANIZATIO  Verification of compliance: Feed and Food Law  Animal Health and Animal Welfare. Controls in  third Countries	
Commission Implementing Reg (EU) 2019/627	Practical arrangements for the performance of official controls in accordance with Reg. 2017/625, last amended by Reg. 2022/2503	OFFICIAL CONTROLS OF FISHERY PRODUCTS - TITLE VI	
HOR	IZONTAL	(a) organoleptic examinations;	Regulation (EU) 2019/627
		<ul><li>(b) freshness indicators;</li><li>(c) histamine;</li></ul>	
Water	Regulation 2020/2184	(d) residues and contaminants	
Food additives	Regulation 1333/2008	(e) microbiologica	
Labelling - Consumer Info	Regulation 1169/2011	checks; (f) parasites;	
Lot identification	Directive 91/2011	(g) poisonous fish products.	nery
Food Law, EFSA, RASFF, SCOFCAH, Traceability	Regulation 178/2002	Microbiological cr Histamine	riteria Regulation 2073/200
НАССР	Com Notice 2016/ C278/01	Contaminants Maximum Levels: heavy metals; tin i	l l
		canned foods; ben pyrene, dioxins/PC	
IMPORTS FROM	THIRD COUNTRIES	Sampling method criteria for analyt performance	ds & Regulation 333/2007
	ird countries n (EU) 2017/625	Methods for Sam & analysis for dio PCBs	
	Certificates		

This document provides an overview of the Community legislation, which, by its nature, is frequently updated. It does not necessarily represent the views of the European Commission and has no legally binding force. The latest texts may be accessed on the Internet site: https://eur-lex.europa.eu/homepage.html

Figure 1: Key regulatory instruments and their interconnections for sanitary market access



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#### This Regulation lays down rules for:

- 1. the performance of official controls and other official activities by the competent authorities of the Member States;
- 2. the financing of official controls;
- 3. the administrative assistance and cooperation between Member States in view of the correct application of the rules;
- 4. the performance of controls by the Commission in Member States and in third countries;
- 5. the adoption of conditions to be fulfilled with respect to animals and goods entering the European Union from a third country;
- 6. the establishment of a computerised information system to manage information and data in relation to official controls.

The objective is to ensure the application of food and feed laws, animal health and welfare rules, and plant health and plant protection products.

Therefore, this Regulation shall apply to the official controls performed for the verification of compliance with the rules, whether established at the European Union level or by the Member States, to apply European Union legislation in the areas of:

- 1. food and food safety, integrity and wholesomeness at any stage of production, processing and distribution of food, including rules aimed at ensuring fair practices in trade and protecting consumer interests and information, and the manufacture and use of materials and articles intended to come into contact with food;
- 2. deliberate release into the environment of Genetically Modified Organisms (GMOs) for the purpose of food and feed production;

- 3. feed and feed safety at any stage of production, processing and distribution of feed and the use of feed, including rules aimed at ensuring fair practices in trade and protecting consumer health, interests and information;
- 4. animal health requirements; (e) prevention and minimisation of risks to human and animal health arising from animal by-products and derived products;
- 5. welfare requirements for animals; (g) protective measures against pests of plants;
- 6. requirements for the placing on the market and use of plant protection products and the sustainable use of pesticides, with the exception of pesticides application equipment; (i) organic production and labelling of organic products;
- 7. use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed.

#### 3.2 List of Authorised Countries

Fish and Fishery products (as well as certain animals and goods), shall only enter the European Union from a third country which appears on a list drawn up by the European Commission for that purpose.

**For the inclusion in such a list of third countries**, the Commission shall approve according to appropriate evidence and guarantees that the products concerned from that third country **comply with the relevant or equivalent requirements.** 

Such listing conditions are set in Regulation (EU) 2017/625 (Articles 1, 126 and 127), while the operational requirements for food and food safety come from a set of hygiene and sanitary regulations usually identified as the hygiene package.

Article 126: Establishment of additional conditions for entry into the Union of animals and goods, under 2. (a) refers to the requirement that certain animals and goods shall only enter the Union from a third country or region of a third country which appears on a list drawn up by the Commission for that purpose; and as such, under <u>Article 127: Inclusion in the list of third countries</u> establishes the following conditions for the inclusion in the list:

- a. the third country's legislation in the sector concerned;
- b. the structure and organisation of the competent authorities of the third country and its control services, the powers available to them, the guarantees that can be provided with regard to the application and enforcement of the legislation of the third country applicable to the sector concerned, and the reliability of the official certification procedures;
- c. the performance by the competent authorities of the third country of adequate official controls and other activities to assess the presence of hazards for human, animal or plant health, for animal welfare or, in relation to GMOs and plant protection products, also for the environment;
- d. the regularity and rapidity of information supplied by the third country on the presence of hazards for human, animal or plant health, for animal welfare or, in relation to GMOs and plant protection products, also for the environment;
- e. the guarantees given by the third country that:
  - i. conditions applied to the establishments from which animals or goods are exported to the Union comply with requirements that are equivalent to those referred to in Article 126(1);

- ii. a list of the establishments referred to in point (i) is drawn up and kept up to date;
- iii. the list of establishments referred to in point (i) and updates thereof are communicated to the Commission without delay;
- iv. the establishments referred to in point (i) are the subject of regular and effective controls by the competent authorities of the third country;
- v. the findings of controls performed by the Commission in the third country in accordance with Article 120(1);
- f. any other information or data on the capability of the third country to ensure that only animals or goods which provide the same or an equivalent level of protection as that afforded by the relevant requirements referred to in Article 126(1) enter the Union.

#### and critically

The Commission shall delete the reference to a third country or a region of a third country from the list referred to in point (a) of Article 126(2) where the conditions for inclusion on the list cease to be met.

#### 3.3 The role of DG SANTE and the Food and Veterinary Office

DG SANTE is the Directorate of the EC in charge of protecting and improving public health and ensuring that Europe's food is safe and wholesome. It is also responsible for protecting the health and welfare of farm animals.

Regulations (EU) 2017/625 and 2019/627 provide the basis for the Food and Veterinary Office (FVO) activities and their oversight of third countries.

The FVO is an inspection service that oversees national audits within the EU MS and third countries. In its function as the eyes and ears of the Commission, the FVO verifies on-site that applicable requirements in food safety, animal health and welfare and plant health are correctly implemented and enforced by MS and third countries. By contributing to improving national control systems, the effective enforcement of requirements in the EU and third countries is enhanced.

The FVO checks the performance of essential stakeholders (e.g. CA, establishments handling FAPs or related vessels in MS). As the responsibilities have been delegated to the CAs and consecutive to the associated industries, there are only a limited number of controls carried out directly in the establishments. The audits comprise checks on the legislation structure and activities of CAs

Third countries, which are considered as compliant or equivalent to EU rules, will have the possibility to export FAPs into the EU. The reports of the FVO can be found on the Food and Veterinary Office website.

The FVO prepares an annual audit programme of premises and CAs in MS and third countries based upon data collated from previous inspections and information on notifications. Audit priorities are identified under careful consideration of several factors such as risk, legal requirements, trade and policy considerations, with risk being the main factor, and fully involving all relevant stakeholders in DG SANTE, while the MS are equally consulted. The audit programme may be altered as the year progresses when emergencies, other urgent issues and unforeseen circumstances arise. Audits in response to emergencies can only be made by cancelling or postponing other activities. In addition, the completion of specific audits will depend on the timely availability of resources.

Following the in-country audit, the FVO prepares an audit report containing recommendations. The CA comments on this and prepares an action plan for the identified non-compliances. All outcomes are made public and can be reviewed on the FVO website.

### 3.4 Certification, Listing of Countries and Approval of Establishments and Vessels.

Imports of animals and animal products into the EU must, as a rule, be accompanied by the Health Certification laid down in EU legislation. This sets out the conditions that must be satisfied and the checks that must be undertaken if imports are allowed.

The rules for certification are laid down in Commission Implementing Regulation 2020/2235 on the certification of animals and animal products. According to the Directive, the certification must be signed by an official veterinarian or official inspector (as indicated in the relevant certificate). Strict rules apply to the production, signing and issuing certificates as they confirm compliance with EU rules.

The original version of the certificate must accompany consignments on entry into the Community. Rules and principles applied by third country certifying officers should offer guarantees at least equivalent to those laid down in the Commission Implementing Regulation 2020/2235.

The listing of countries, establishments and fishing vessels, including processing vessels and freezing vessels, helps the inspectors at the BCP to check the incoming goods because fishery products coming from listed countries, establishments, and vessels will be checked mainly on the documentation. This reflects the EU principle for imported food intended for human consumption, which gives the primary responsibility to the authorities in the exporting countries. These must guarantee that the establishments or vessels conform to EU standards.

Establishments in a third country intending to export their FAP to the EU should be listed by the national CA. The listing procedure should be done according to EU legislation. The listing CA must also be authorised to guarantee that the structure and the execution of food/fish products are controlled at least to standards equivalent to the EU's.

The same principles and rules apply to fishing vessels (i.e. freezer vessels and factory vessels). Ice vessels and small-scale crafts also must be listed and approved internally by the CA (but notification to the EU is not required) with the EU requirements before they can be used to supply exporting establishments.

### 3.5 The Health Certificate and its contents as guidance for CAs and Industry

Fishery and Aquaculture products exported to the EU must be accompanied by a Health Certificate emitted by the CA of the country of origin.

This certificate is the official document between the exporting country and the EU that provides the official guarantees required.

The format and content of the certificate are to be respected as per Commission Implementing Regulation (EU) 2020/2235 and the EU health certificate defined in Article 14.

The <u>Public Health Attestation</u> of the certificate is a great tool to understand the requirements, as it states the following:

I, the undersigned, declare that I am aware of the relevant requirements of Regulation (EC) No 178/2002 of the European Parliament and of the Council, Regulation (EC) No 852/2004 of the European Parliament and of the Council, Regulation (EC) No 853/2004 of the European Parliament and of the Council and Regulation (EU) 2017/625 of the European Parliament and of the Council and hereby certify that the fishery products described in Part I were produced in accordance with these requirements, in particular that they:

- have been obtained in the region(s) or country(ies) ....... which, at the date of issue of
  this certificate is/are authorised for entry into the Union of fishery products in Annex IX to
  Commission Implementing Regulation (EU) 2021/405;
- come from (an) establishment(s) applying general hygiene requirements and implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004, regularly audited by the competent authorities, and being listed as an EU approved establishment;
- have been caught and handled on board vessels, landed, handled and where appropriate
  prepared, processed, frozen and thawed hygienically in compliance with the requirements laid
  down in Section VIII, Chapters I to IV of Annex III to Regulation (EC) No 853/2004;
- have not been stored in holds, tanks or containers used for other purposes than the production and/or storage of fishery products;
- satisfy the health standards laid down in Section VIII, Chapter V of Annex III to Regulation (EC)
   No 853/2004 and the criteria laid down in Commission Regulation (EC) No 2073/2005
- have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VII
   I of Annex III to Regulation (EC) No 853/2004;
- have been marked in accordance with Section I of Annex II to Regulation (EC) No 853/2004;

#### As well as its <u>health information</u> conditions:

- fulfil the guarantees covering live animals and products thereof, <u>if of aquaculture origin</u>, provided by the residue plans submitted in accordance with Article 29 of Council Directive 96/23/ECO, and the concerned animals and products are listed in Commission Decision 2011/163/ELJE for the concerned country of origin
- for the live animals from wild catch and products thereof monitoring arrangements are in place to control compliance with the Union legislation on contaminants; in accordance with Commission Regulation (EC) No 915/2023 in maximum levels of certain contaminants in food and on pesticide residues......;
- have satisfactorily undergone the official controls laid down in Articles 67 to 71 of Commission Implementing Regulation (EU) 2019/627

The first part of the attestation implies the need for a certifier (I, the undersigned...) whose duty relies on the body responsible for official guarantees (under the specific EU regulations), which, as previously mentioned, is the role of the CA.

Hence, seafood can be exported to the EU only from:

- Authorised countries
- Approved vessels and establishments (e.g. processing plants, freezer or factory vessels, cold stores generally called Food Business Operators)
- Approved Aquaculture establishments and Approved Areas

#### 3.5.1 Requirements for the Food Business Operators

Assuming that the country is on the list of authorised countries, the CA is responsible for approving Food Business Operators (FBOs) to export to the EU.

As exporting to the EU is not compulsory, the establishment decides to seek "approval" regarding the EU requirements that may be beyond applicable domestic standards.

The CA's assessment of the FBO's compliance with the EU standards defines the approval (or not) by assigning them a unique identification code.

#### 3.5.1.1 Approved Establishments

All establishments in the capture or aquaculture production chain (hatcheries, farms, vessels, plants, cool stores, etc.) must be approved by the CA regarding the EU requirements for the product they handle to be considered "eligible" for the EU.

The list of approved establishments in the progression from "raw material to product" is maintained by the CA and represents all the FBOs in the production chain that are allowed to provide to companies that export directly to the EU. CAs maintain EU internal (for indirect export to the EU) and EU External (approved for direct export to the EU) lists.

The establishments at the end of the chain (those that export directly to the EU) are to be included on a list of establishments authorised to receive a Health Certificate for their products. This list can consist of vessels, plants or cold stores if they export directly to the EU (or to another third country for further processing and then to the EU).

These establishments are given a unique identification code, usually called the "EU number".

The CA sends to the EC a "list" of authorised establishments, guaranteeing that they have been inspected and deemed to comply with the specific hygiene rules that correspond to the type of product processed.

Therefore, any changes or updates in this list must be communicated to the EC immediately. The approval and listing are not a "one-off" event; it is based upon continuous compliance by the establishments. If the level of compliance becomes so low that the CA cannot provide the required official guarantees, then the establishment can be suspended or removed.

When this happens, the establishment loses the right to export to the EU and provide raw materials and products to "listed" establishments.

#### 3.5.1.2 Requirements for the Establishments

As discussed, the CA certifies compliance with the requirements in the certificate's public health attestation. The second one is:

-"come from (an) establishment(s) applying general hygiene requirements and implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004, regularly audited by the competent authorities, and being listed as an EU approved establishment;

HACCP is a concept that has been introduced previously; there is a wide range of information on the subject worldwide. Therefore, this publication does need to explore it in detail. Food exporters should only process food with a fully functional HACCP plan that has been approved by the CA.

#### 3.5.1.3 Conditions of operators along the production chain

As mentioned, the whole value chain needs to be under the control of the CA with full compliance by the operators concerned. These requirements are evident from the following statement.

"have been caught and handled on board vessels, landed, handled and where appropriate prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Section VIII, Chapters I to IV of Annex III to Regulation (EC) No 853/2004;"

Most importantly, this provides the specific set of references in the legislation that the operators apply directly, namely Section VIII, Chapters I to IV of Annex III to Regulation (EC) No. 853/2004.

Furthermore, and very specifically, it requires that

'have not been stored in holds, tanks or containers used for other purposes than the production and/or storage of fishery products."

In many vessels, fish holds are used as temporary fuel reservoirs, which is not allowed.

The sections quoted above define the key requirements in terms of hygiene standards. These are relatively easy to comply with than any other requirements, such as those directly based on Codex Alimentarius.

#### 3.5.1.4 Requirements for all Fishery Products

The requirements for products are to be found in the following statements:

"satisfy the health standards laid down in Section VIII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down in Commission Regulation (EC) No 2073/2005"

This paragraph refers to the health standards for most fishery products. It includes organoleptic assessment, histamine, parasites, toxins, and microbiological standards, which are minimal and applied to ready-to-eat products only.

"have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VII I of Annex III to Regulation (EC) No 853/2004";

This refers to some elementary principles in terms of packaging and storage to avoid them becoming a source of contamination, and temperature controls (towards melting ice for fresh, -18°C for frozen products and -9°C for brine frozen fish to be canned), and how these same principles need to be maintained during transport.

"have been marked under Section I of Annex II to Regulation (EC) No 853/2004";

The identification-marking requirements are basic and refer primarily to product type and establishment of origin identification.

#### 3.5.2 Official Controls

Official controls are required under the following statement:

- "have satisfactorily undergone the official controls laid down in Articles 67 to 71 of Commission Implementing Regulation (EU) 2019/627"

Namely,

#### Art 67: Official controls on production and placing on the market

Official controls on the production and placing on the market of fishery products shall include verification of compliance with the requirements set out in Section VIII of Annex III to Regulation (EC) No 853/2004, in particular:

- a. regular checks on the hygiene conditions of landing and first sale;
- b. regular inspections of vessels and establishments on land, including fish auctions and wholesale markets, in particular to check:
  - i. whether the conditions for approval are still fulfilled;
  - ii. whether the fishery products are handled correctly;
  - iii. compliance with hygiene and temperature requirements;
  - iv. the cleanliness of establishments, including vessels, and their facilities and equipment, and staff hygiene;
- c. checks on storage and transport conditions

#### Article 68: Site of official controls (for vessels)

#### Article 69: Approval of factory, freezer or reefer vessels

#### Article 70: Official controls of fishery products

Official controls of fishery products shall include at least the practical arrangements laid down in Annex VI as regards:

- organoleptic examinations;
- freshness indicators;
- histamine;
- residues and contaminants;
- microbiological checks;
- parasites;
- poisonous fishery products.

In <u>Article 71: Decisions after controls</u>, is very specific on the CA's responsibility to declare fishery products unfit for human consumption if any of the above conditions is not met

Furthermore, EC 2019/627 focuses, among others, on specific requirements for audits by the CA in establishments handling products of animal origin as required in *Article 3: Requirements subject to auditing* 

- When auditing good hygiene practices in establishments, the competent authorities shall verify that food business operators handling products of animal origin apply procedures continuously and properly concerning at least the following:
  - a. the design and maintenance of premises and equipment;
  - b. pre-operational, operational and post-operational hygiene
  - c. personal hygiene;

- d. training in hygiene and in work procedures;
- e. pest control;
- f. water quality;
- g. temperature control;
- h. controls on animals or food entering and leaving the establishment, and any accompanying documentation.
- 2. When auditing procedures based on hazard analysis and critical control points (HACCP), as laid down in Article 5 of Regulation (EC) No 852/2004, the competent authorities shall verify that food business operators handling products of animal origin apply such procedures continuously and properly.
- 3. They shall, in particular, determine whether the procedures guarantee, to the extent possible, that products of animal origin:
  - a. comply with Article 3 of Regulation (EC) No 2073/2005 as regards microbiological criteria;
  - b. comply with Union legislation on:
    - the monitoring of chemical residues, in accordance with Council Directive 96/23/EC and Commission Decision 97/747/EC;
    - maximum residue limits for pharmacologically active substances, in accordance with Commission Regulation (EU) No 37/2010 and Commission Implementing Regulation (EU) 2018/470;
    - iii. prohibited and unauthorised substances, in accordance with Commission Regulation (EU) No 37/2010, Council Directive 96/22/EC, Commission Decision 1871/2019;
    - iv. contaminants, in accordance with Regulations (EC) No 2023/915 setting the maximum levels for certain contaminants in food; and respecting the sampling methods and criteria for analytical performance in accordance with Regulations (EC) No 333/2007 (last amended by Commission Implementing Regulation (EU) No 2022/2418) and also the methods for sampling and analysis for dioxins / PCBs in accordance with Regulation (EU) 2017/644.
    - v. pesticide residues, in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council;
      - do not contain physical hazards, such as foreign bodies.

Some of other vital requirements (but not the only ones) are that Official Control activities shall verify activities on the production and placing on the market of fishery products are aimed at assessing compliance by the processing establishments, in particular:

- 1. A regular check on the hygiene conditions of landing sites and the point of first sale;
- 2. Inspections at regular intervals of vessels and establishments on land, including fish auctions and wholesale markets, to check, in particular:
  - where appropriate, whether the conditions for approval are still fulfilled.
  - whether the fishery products are handled correctly
  - compliance with hygiene and temperature requirements
  - the cleanliness of establishments, including vessels, and their facilities and equipment, and staff hygiene
  - checks on storage and transport conditions.

In more practical terms, this implies that the establishments along the value chain would be "inspected" or "verified" by the CA against, for example, the requirements detailed below.

In terms of documentation:

- 1. General description of the company, facilities, products and processes
- 2. The description of operations followed
- 3. The documented pre-requisite programmes.
- 4. The HACCP plan
- 5. The system to provide guarantees for the product traceability
- 6. The documented and formalised withdrawal and recall procedures

In terms of physical settings, operational conditions, control strategies concerning the entire production process and the application of all pre-requisite programs by the operator:

- The general hygiene conditions of building and surroundings.
- The water supply and water quality management system, detailing the internal distribution network, treatment if any, quality monitoring plan and related data filing.
- Ice production, internal distribution and quality monitoring.
- The absence of cross contamination/air current risks (lay-out and infrastructure considerations).
- Personnel health and hygiene control (including training).
- Sanitary filtering of personnel arrangements, toilets and dressing facilities.
- Facilities and equipment cleaning and sanitation plans (methods, schedules, chemicals used and approvals).
- Raw materials' acceptance criteria and controls (freshness, temperature, transport, lot identification).
- Specifications for other inputs as ingredients, additives or packaging.
- Waste disposal system.
- Labelling system and lot codes, providing effective traceability.
- Pest control plan: Control of insects, rodents and other undesirable animals.
- Equipment and facilities preventive maintenance plan.

#### 3.5.3 Separation and Identification of Non-EU Eligible Product

Suppose a company listed with the EU holds products that are not eligible by origin (i.e. a non-approved vessel) or conditions (approved but in non-compliance). In that case, the operator must ensure the physical separation of EU-eligible from ineligible seafood products.

Where any assumed EU-eligible seafood products could not be distinguished from ineligible ones, the former is deemed ineligible and must be dealt with accordingly.

#### 3.5.4 Products with Imported Raw Materials

Based on the principle of official controls, EU Health Certificates for seafood products exported to the EU which are derived wholly or partly from raw materials products must:

- Have originated from a third country eligible to export the animal product to the EU;
- Have been derived from foreign premises eligible to export to the EU, (including vessels); and
- Be eligible to be exported to the European Community;.

A copy of the import certificate, or original export certificate, must be available on request by the CA.

#### 3.5.5 Laboratories to be used for Official Controls

It should be emphasised that the EU does not require analysis of the end product on a lot-by-lot basis, i.e. laboratory results for each exported batch are not a requirement of the EU.

The CA of the exporting country decides how it provides the necessary official guarantees to the EU over the exported products. Most countries establish monitoring programs maintained throughout the production chain and do not require analysis of the final product as a condition of certification but as verification of the effectiveness of the HACCP plan.

For an analytical result to have "official" validity, it must come from a laboratory accredited to ISO/ IEC 17025 for the parameters to be analysed. The standard specifies the general requirements for competence to carry out tests and/or calibration. It covers management and technical issues, with the critical objective of assuring the accuracy and quality of the results.

The accreditation allows the CA to "trust" the impartiality and accuracy of the results and, as a result, "approve" the laboratory for its testing results to be considered "official." Consequently, the "approved " status can only be maintained if the laboratory is accredited.

These requirements apply equally to government and private laboratories. Private sector laboratories are increasingly being used worldwide for regulatory purposes. Furthermore, there is no obligation for the laboratories to be in the same country.

#### 3.5.6 Traceability

Traceability refers to the ability to trace goods along the supply chain. It requires critical information to be linked with the physical flow of the product. Traditionally, this has been provided by physical labelling on the packaging and associated documentation supplied with the product.

The traceability system required depends on why you are implementing it. Traditionally, traceability systems in the seafood industry have been required for food safety. This has meant that companies have systems in place to identify the source of the product and to whom it was supplied, i.e. the principle is "one step backwards, one step forward". (From where and who does it come from, what is done with it, whom is it given to).

The CA should verify the efficiency of a traceability system adopted by an operator. Furthermore, the CA must manage and control the traceability chain from harvest to export.

In fact, (EC) No. 627/2019 Chapter II <u>Specific requirements for identification marking</u>, Article 5 states explicitly Compliance with the provisions of Regulation (EC) No 853/2004 concerning the application of identification marks shall be verified in all establishments approved under that Regulation, in addition to verification of compliance with other traceability requirements under Article 18 of Regulation (EC) No 178/2002.

#### 3.5.7 Labelling

Labelling is arguably the most dynamic field in the food regulatory framework. While this section provides information regarding the EU labelling requirement, as always, it is best to refer to the latest updates in regulations, your clients, and the CAs.

Regulation (EU) No 1379/2013 as amended (Common Market Organisation (CMO) Regs) explicitly states that it is necessary to ensure that imported products entering the EU market comply with the same requirements and marketing standards that EU producers must comply with. For certain aspects of labelling, the legislation includes explicitly imported products.

#### 3.5.7.1 Unprocessed and certain processed fishery products

The following requirements apply to the fishery and aquaculture products in Annex 1 (points a, b, c and e) of the CMO Regulation.

In short, these requirements apply to all unprocessed and some processed products (e.g. salted, smoked products, cooked shrimps in their shells). These products can be 'prepacked' and 'non-prepacked. The CMO Regulation (chapter IV) and Regulation 1169/2011 and also on Regulation (EU) No 1308/2013 on providing food information to consumers contains labelling and information provisions and applies to all food intended for retail sale or to supply mass caterers (FIC Regs); both apply.

The table below identifies a non-exhaustive list of the required information to be labelled with each lot of fish sent to the EU based on the present product range in the FFA membership.



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MANDATORY INFORMATION			
Labelling or Information Requirements	Further Detail		
Identification number of each lot	A unique number be allocated to each lot.		
Commercial designation and	Both the commercial and scientific names must be displayed.		
scientific names:	The FAO alpha-3 code of each species.		
	These names must match those on the official list drawn up and published by each EU country.		
	The commercial designation and the scientific name can either correspond fully with the name of the food (FIC Regulation) or partly, as would be the case where additional particulars must be added to the name.		
The production method, in particular by the following	This is to identify if the product is wild caught or aquaculture, etc. i.e. wild caught; or farmed; or caught in freshwater.		
words " caught" or " caught in freshwater" or " farmed"	Mixed products of the same species and different production methods must display the method of production for each batch."		
Catch area and Fishing gear where the product was caught	This will most commonly be a reference, for example, to the FAO area.		
	If the product was caught by the act of fishing, information on the specified gear type is also required.		
	It is possible to combine the production method, the area from which it was caught or farmed and the fishing gear in one sentence, e.g.		
	Wild Caught in Pacific Ocean, Area FAO 71 by Purse seine		
	NOTE – GEAR TYPES: On a mandatory basis, if the product was caught by any of the 7 gear types listed in Annex III of CMO Regs.		
External identification number, name, flag state and EU approval ID of catching fishing vessel	Full Identification of the harvesting vessels.		
The date of catches or the date of production	This is the catch or harvest date; it can include several days or one period of time corresponding to several dates of catches.		
Quantity	Usually expressed as the net weight or where appropriate the number of individuals.		
'Date of freezing' or 'Date of first freezing'	This requirement only applies to <b>unprocessed</b> products. The date must be indicated as follows: 'Frozen on day/ month/year'.		

MANDATORY INFORMATION			
Whether the product has been defrosted	This will only be relevant for any product that is sold to the EU in a chilled state that has previously been frozen and thawed.		
The date of minimum durability, where appropriate	This is likely to be a best before date for the majority of seafood products.		
Voluntary information			
Date of catch / harvest:	As per the appropriate documentation.		
Date of landing	As per the appropriate documentation.		
Port of landing	Name of the port where the fish was first landed.		
Flag state of vessel	Details on flag state of catching vessel.		

#### 3.6 Certification and TRACES

The "TRACES" acronym is "Trade Control and Expert System", and is the European Commission's (EC) online platform for animal and plant health certification required for importing animals, animal products, food and feed of non-animal origin and plants into the European Union (EU) and the intra-EU trade and EU exports of animals and certain animal products.

The most up-to-date version of TRACES is now called TRACES NT.

The main objective of the TRACES system is to streamline the certification process of all related entry procedures and to offer a fully digitised and paperless workflow.

But for this guide, TRACES NT is the EU's electronic Internet database related to the trade of seafood with the EU commodities, as they need to be produced and shipped from facilities listed on TRACES NT to be imported into the European Union (EU).

TRACES NT offers electronic certification for both EU and non-EU countries' authorities. This feature allows authorities to acquire an electronic seal, which allows official inspectors and certifying officers to apply it on official certificates and documents they issue in TRACES.

TRACES NT sends an electronic message from the departure point to the transfer point and the arrival point to notify that a consignment is arriving. Similarly, every concerned point sends a message to other points, which enables a well-developed follow-up of the consignment (goods or animals) movement.

It provides the ad-hoc EU legislation, manages the non-EU country establishment list<sup>2</sup>, which is the agreed-upon list for importing into the EU, and keeps on file the rejected consignments and the reason for rejection.

More than 113,000 users from over 90 countries worldwide are interconnected through TRACES, centralising all data, simplifying, and accelerating data exchange.

 $<sup>2 \</sup>quad https://food.ec.europa.eu/safety/biological-safety/food-hygiene/non-eu-countries-authorised-establishments\_en$ 

#### 3.6.1 Certification and Eligibility

An essential criterion not apparent on the certificate but because of official controls over the production chain and traceability is the eligibility of products and raw materials.

The nature of the official controls implies that the CA must approve ALL elements in the production chain.

Whoever issues the certificate in TRACES NT needs to have the capacity to assure that the product certified has been under officially controlled conditions in officially controlled establishments from origin to export.

If the raw materials were harvested or processing and handling at any production stages were performed in a non-compliant or non-verified establishment, that raw material or product is not eligible for export to the EU; hence, it cannot receive a certificate.

The fact that a product has been processed at an establishment with an "EU number" does not guarantee its eligibility to the EU market.

#### 3.6.2 Signing the Certificate

When the CA "signs" a Health Certificate in TRACES NT, it becomes official evidence that the establishments, operators, raw materials and products in the value chain comply with the requirements listed in the public health attestations.

Therefore, the Health Certificate must accurately describe the identity of the approved processor of the goods, the type of fish being shipped, the quantity of product being shipped, and the final destination of the goods.

#### 3.7 Once the fish consignment gets to the EU

#### 3.7.1 Designated Border Control Posts (BCPs)

Imports of seafood from non-EU countries must enter the EU via EC-approved BCPs under the authority of an official veterinarian.

At the BCP, the consignments are subject to three types of checks:

- A documentary check: this is done systematically and involves checking the export certificate accompanying the seafood consignments;
- An identity check: this is also done systematically and involves checking that the data on the export certificate is consistent with the product which is being imported;
- A physical check: this is done as appropriate to the circumstances of the consignment and involves examining the product, its packaging, the information on the label and the storage conditions;

The frequency and type of physical checks are determined for each category of product based on the intrinsic risk and results of checks carried out previously on the identical product of the exact origin.

This can include taking samples for laboratory testing randomly or based on records. If the consignment is found to be in non-compliance with the EU legislation for any reason, then the BCP notifies the non-compliance to the EU through the internal notification system of the EU, called the Rapid Alert System for Food and Feed (RASFF).

If the product exceeds any regulatory levels or contains non-authorised substances, it is up to the exporter in the country of origin to get the product back or let it be destroyed.

#### 3.7.2 Rapid Alert System for Food and Feed / RASFF

The RASFF is a tool that the EU uses to enable the quick and effective exchange of information between Member States and the Commission when risks to human health are detected in the food and feed chain. RASFF provides a round-the-clock service to ensure that urgent notifications are sent, received and responded to in the shortest time possible. The CE publishes a weekly summary of the notification under the RASFF system.

When a notification pertains to imported products, the CA of the country of origin must undertake a full investigation and report back to the EU on their results and measures to avoid recurrences.

# 4. WHAT DOES THE CATCH CERTIFICATION IMPLY?

Conceptually, at the time of its introduction, the EU IUU Catch Certification Scheme (CCS) has been a game changer. If the flag state cannot certify that the catch was legal, that fish is not allowed to enter the EU market.

While the total responsibility for the CCS is on the vessel's Flag State, the fisheries CA of the Port State where fish are transhipped, landed, stored and/or processed do play a role under the CCS.

The CA is expected to provide official assurances on the vessel's details, volumes and species being handled under their responsibility, and with the original catch certificate validated by the CA of the country where the harvesting vessel is flagged.

#### 4.1 What is IUU fishing?

It is not the intention of this guide to define and discuss the details of IUU fishing and its impact. However, under the scope of the IUU Regulation, the concept covers:

- Infringements to rules on management and conservation of fisheries resources in national and international waters;
- Fishing activities in high seas areas covered by a Regional Fisheries Management Organisation (RFMO) carried out by vessels without nationality or registered under a flag State which is a non-contracting or non-cooperating Party to the RFMO and in a manner contravening the rules issued by this organisation;
- Fishing activities carried out in high seas areas not covered by an RFMO in a manner inconsistent with state responsibilities for the conservation of fisheries resources under international law.
- Behaviours which shall be qualified as presumed IUU fishing activities. Under the IUU Regulation, a fishing vessel is notably presumed to be engaged in IUU fishing activities if it is shown that its operators have carried out activities in contravention with the conservation and management measures applicable in the area concerned, such as fishing without a valid licence, in a closed area, beyond a closed depth or during a closed season, or by using prohibited gear, as well as the failure to fulfil reporting obligations, falsifying its identity, or obstructing the work of inspectors.



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In very general terms, the "legality" of a fish can be defined by the existence of the responses within a legal framework of a series of basic questions: Who caught it? Where was caught? How much was caught? When was it caught? How was it caught?

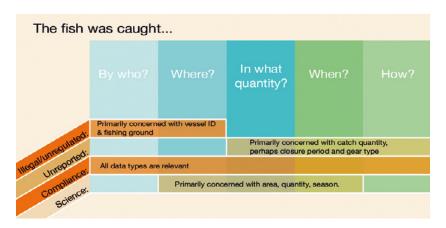


Fig 2: Schematic diagram of data types needed for compliance<sup>3</sup>.

The answers to these questions must be verifiable concerning the fisheries management framework of the harvesting vessel's flag state and subject to applicable laws and international conservation and management measures.

The "operating system" of this certification is based on the capacity of the fisheries CA of the vessel's Flag State to give official assurances about the existence and "legality" of the answers to these questions.

The CA, in turn, has a series of "programs" or tools within their scheme of Monitoring, Control and Surveillance (MCS) of fishing activities (e.g., fishing permits, fisheries observers, inspectors, VMS<sup>4</sup>, landing controls, etc.) that allow them to validate the accuracy of the information in the certificate.

<sup>3</sup> Adapted from: Best Practice Study of Fish Catch Documentation Schemes Phase 1 Report, 2009. MRAG Asia Pacific Pty Ltd for the UK Department of Environment, Food and Rural Affairs (DEFRA)

<sup>4</sup> Fishing Vessels Monitoring Systems. Usually satellite based, see http://www.fao.org/fishery/vms/en

# 4.2 The EU IUU Regulation and subsequent regulations

The EU IUU Regulation consists of a law (EC 1005/2008) passed in 2008 and an implementing regulation (EC 1010/2009) adopted in 2009. Both texts define a new legal EU regime to bar products derived from IUU fishing from entering the EU market. In its preamble, EC 1005/2008 states that this initiative is meant to respond to the tenets of the IPOA-IUU.

The regulation consists of a Catch Certification Scheme (CCS) requirement for all imports of marine fish into the EU and a separate but related rule involving the possible restriction of fisheries imports from countries identified as having unsatisfactory control of IUU fishing by their flag vessels, the so-called "yellow and red cards".

The scope of the EU IUU Regulation is broader than just control of imports. However, the core provisions aim at limiting the importation of IUU fishing products into the EU territory or directly landed by third-country vessels or imported by consignments. The main chapters that contribute to this aim are the following:

- 1. Chapter II Inspections of third country vessels in MS ports
- 2. Chapter III Catch Certification scheme for importation and exportation of fishery products
- 3. Chapter IV Community Alert System
- 4. Chapter V Identification of fishing vessels engaged in IUU fishing
- 5. Chapter VI Non-cooperating third countries
- 6. Chapter VII Measures in respect of fishing vessels and States involved in IUU fishing

Other chapters are also part of the system established by the EU to prevent, deter and eliminate IUU fishing activities (e.g. sanctions).

The focus of the EU IUU Regulation is on the priority of the responsibility of the flag State.

Often, vessels operate in distant waters where the flag State only sometimes has sufficient information to ensure the legality of the products caught. This underlines the importance of complementary Port State measures, such as inspections of landings and transhipment, and complementary coastal State measures. Some measures relate to nationals engaged in IUU fishing in Chapter VIII of the EU IUU Regulation.

Chapter III of the EU IUU Regulation contains the core provisions on FAP import requirements as it establishes the CCS. The importers must provide the CC to MS authorities, as provided by the exporters and validated by the CA of the flag State. EU importers must provide CCs for direct (Art 12) and indirect (Art 14) imports from third countries and from recognised Catch Documentation Schemes (Art 13). MS CAs must validate CCs for exports where these are required by third countries in the framework of the cooperation agreement (Art 15). MS CAs must receive CCs in advance and carry out checks on them (Art 16) and verifications (Art 17). Chapter III also contains provisions on refusal of consignments (Art 18), transit and transhipment (Art 19), flag State notifications (Art 20), re-exportation from the EU (Art 21) and record-keeping (Art 22).

Regarding direct importation from a third country (Art.12), consignments must be accompanied by a Catch Certificate according to Annex II of the EU IUU Regulation, which includes a statement from the master of the fishing vessel or his representative and which must be validated by the flag State of the fishing vessel.



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For indirect imports that have passed through a third country, if they are unprocessed (Art14.1), the consignment must be accompanied by the Catch Certificate(s) and documented evidence that the fishery products did not undergo operations other than unloading, reloading or any operation designed to preserve them in good and genuine condition, and remained under the surveillance of the competent authorities in that third country. This documented evidence can be a single transport document or document issued by the competent authorities of that third country.

If the products have been processed, they must be accompanied by a Processing Statement under Annex IV of the EU IUU Regulation following Art 14.2.

In 2023, Council Regulation (EC) No 1005/2008 was amended by Regulation (EU) 2023/2842 of the European Parliament and of the Council of 22 November 2023<sup>5</sup>, introducing a series of updates, including the use of the CATCH EU-wide real-time IT system for the management of all procedures linked to the EU catch certification scheme.

The new system introduces modifications to the content of documents and processes, such as punctual changes to ensure improved traceability along the supply chains and the correct functioning of the IT environment.

Specifically, it introduces changes to Chapter III: the IUUCCS, introducing CATCH: Article 12, general functionalities, access to CATCH, and timeframe for using CATCH, and it modifies the content of documents and processes such as Annex II, Article 14, Annex IV, detailed changes to catch certificates (CC) and related documents

The present EU CCS paper-based system will be valid until 26 January 2026. Yet beyond 10 January 2026, the use of the CATCH system will be compulsory for EU importers for the submission of the catch certificates and related documents to the EU Member States' authorities.

Non-EU countries' exporters and authorities can use the system voluntarily.

<sup>5</sup> https://eur-lex.europa.eu/eli/reg/2023/2842/oj

## 4.2.1 Role of Fisheries Administrations

The EU CCS relies on the cardinal principle of flag state validation, placing no formal emphasis on the role of coastal states and a limited role to be played by port, processing, and trading states.

This partly weakens its potential strength since these systems were conceived to overcome the ineffectiveness of control regimes limited to flag state enforcement and to tap the potential of port and market state jurisdictions and controls within a single, largely self-regulating and self-enforcing system.

Despite some weaknesses, the EU IUU Regulation provides valuable elements of good practice.

Equivalence is provided under the scheme for existing RFMO CDS, meaning that any products covered by RFMO certificates imported into the EU are exempted from the requirement to provide EU catch certificates. This is an essential first degree of coherence between unilateral and multilateral schemes. The EU system also allows for the recognition of equivalent national systems.

# 4.2.2 The designation of the CA in third countries

Article 20 of the EU IUU Regulation states that third countries should nominate their Competent Authority by providing a Flag State notification (see Annex III of EU IUU Regulation).

In the run-up to the implementation of the EU IUU Regulation and its first months, the EC (DG MARE) largely accepted the nominations of CAs from third countries without questioning whether these were the most appropriate authorities. In some countries, the authority nominated has been the CA nominated to validate the Health Certificate under the hygiene regulation. This arises from confusion in the terminology applied by the EC because the CA under the hygiene regulations were, in some cases, assumed by third countries to be the same CA under the EU IUU Regulation.

In most countries, the nominated CA is with the Fisheries Authority, which, while generally competent in IUU fishing and Monitoring and Control and Surveillance (MCS) measures, may need to be more familiar with the complexities of certification.

According to the wording of the EU IUU Regulation, the notification's acceptance is automatic and cannot be refused if the information requested in Article 20 is provided.

Explicit mention is made of the signature of Catch Certificates in Article 20. Yet, it does not mention CAs for signing Annex IV Processing Statements nor of the CAs in States that are processing products, not Flag States. There is a provision in the Processing Statement (Annex IV to the EU IUU Regulation) for endorsement by the Competent Authority. Still, there is yet to be an indication of which authority this should be. One might presume, from the fact that the Health Certificate number and date are requested on the form, that this CA is nominated under the Health Regulations.

Transhipments are authorised by authorities in third countries that have not had their CA notification published by the EC but have been informally allowed to sign.

# 4.3 The Catch Certification Scheme

Validated catch certificates must accompany all marine fishery products traded with the EC, including processed products.

It is up to the exporter to request a catch certificate for catches to be traded to the EC, complete it and transmit it to the competent flag State authority for validation.

The EC importer must ensure that the consignment to be imported is accompanied by a validated catch certificate transmitted by the exporter before the importation to the EC.



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## 4.3.1 Trade Flows

The catch certification scheme applies to all fishery products imports, exports and re-exports to and from the Community, irrespective of the means of transport (fishing vessel, other vessel, air or land transportation).

Some products are excluded from the scope of the IUU Regulation. However, these are limited and relate to freshwater species, marine species by-products and some invertebrates.

There is no minimum weight below which samples are exempted from the Regulation.

# 4.3.1.1 Indirect importation without processing in another third country

## (Article 14(1))

To ensure full traceability, the certification scheme also applies to situations where the fishery products are imported from another country than the flag State. As a result, products transported to another third country before reaching the Community must also be accompanied by a validated catch certificate and documented evidence that the products did not undergo any operations other than unloading, reloading or any operation designated to preserve them in a good and genuine condition.

# 4.3.1.2 Indirect importation with prior processing in another third country

#### (Article 14(2))

Where products are processed in a country other than the flag State, the importer in the Community shall submit a statement established by the processing plant in the other third country, as provided in Annex IV of the IUU Regulation.

The statement must give an exact description of the products and must indicate that the products originated from catches accompanied by a catch certificate. A copy of those catch certificates must be attached to this statement. The competent authorities in the processing State must endorse the statement.

N.B: Freezing is not regarded as processing but rather preservation. For freezing of products, Article 14(1) applies as explained in the previous paragraph. However, other conservation methods, such as drying, salting or smoking, are considered processing since such treatments significantly change the product's structure.

#### 4.3.2 What is CATCH?

CATCH is an EU-wide real-time IT system for managing all procedures linked to the EU catch certification scheme. It allows the submission of all catch certificates and related documents accompanying the fishery products to be imported into the EU under the EU IUU Regulation (Council Regulation (EC) No 1005/2008) as amended by Regulation (EU) 2023/2842 of the European Parliament and of the Council of 22 November 20231.

The main objective of CATCH is to streamline the catch certification process and all linked procedures and to offer a fully digitised and paperless workflow. It facilitates the exchange of data, information and documents between all involved trading parties and control authorities and, therefore, simplifies and speeds up administrative procedures.

CATCH is intended to improve the effectiveness of the EU IUU Regulation's catch certification scheme by ensuring a centralised digital management environment to identify and prohibit importation into the EU of fishery products obtained from IUU fishing.

EU importers must submit catch certification information through CATCH to Member States (MS) Cas. These, in turn, will carry out checks and verifications of the information received through CATCH and provide the decision about the authorisation of import to the EU importer and to customs, which will be integrated into the system in 2028.

#### 4.3.2.1 CATCH and TRACES

CATCH is part of the TRACES NT (discussed in subchapter 3.6 in the health certification chapter of this guide) and, as such, is only available to countries that have the EU sanitary authorisation from the sanitary perspective.

New users (for now, only EU importers and Member States' competent authorities) can apply for access directly through the system. The authorities with an EU Login in TRACES NT can also use it in CATCH. However, they will need to request an extra role to access CATCH.

The authorities that will be provided with a role in CATCH by the Commission will be those notified to the Commission under Article 20 of the IUU Regulation (flag State notification) and

other authorities in charge of implementing other provisions laid down in the EU IUU catch certification scheme (for example the endorsement of documents referred to in Article 14(1) and 14(2)).

The Commission will reach out to non-EU countries to collect information about authorities that will be provided credentials to access CATCH's different modules.

The first step is to create an EU login account if the CA still needs to create one. This is a mandatory security layer. Once an EU login has been formed, a request for access to TRACES NT as an Operator or Authority is made.

The Commission provides access only to the first user of the notified central CAs in the MS and non-EU countries. Subsequently, the process follows a delegated access management model (central competent authorities granting access to operators and its first users). This is a more efficient and secure method of managing access rights than if a central Commission helpdesk manages everything.

This means that an operator user (importer) will have to be linked to an operator company and be validated by its responsible authority. It should select in the system the central competent authority with CATCH domain in its country. The central competent authority should validate the request in TRACES NT.

# 4.3.2.2 CATCH use by Importers in the EU

EU importers will be mandated to use CATCH to submit the required documentation for the importation of consignments of fishery products to the CAs of the EU MS of importation, i.e. where the consignments are to enter the EU, which may or may not be the MS where the importer is based. CAs, in turn, are mandated to use CATCH to process submissions made by EU importers and provide feedback to them on the decision taken on the import.

#### 4.3.2.3 CATCH use by exporters to the EU

Non-EU countries' operators and authorities may also use CATCH voluntarily to create, validate and transfer CCs and related documents to the EU importer. In such cases, the EU importer will complete the importer declaration and submit the received CCs to the CA of the EU MS of importation.

If operators and authorities do not use the CATCH system, the assumption is that they must submit all using the present paper CA (plus some extra information as required by the new legislation discussed in section xxx). The EU importers will have to introduce data included on paper documents in CATCH themselves manually (and submit the scanned documents, too). This can lead to delays in import procedures. Any such action implies delays and demurrage costs to operators, regardless of whether the consignments are legal or illegal.

This, of course, will have a cost in time and resources to the importer, which indeed would, in turn, offer a lower price to those exported from a country not using CATCH.

Furthermore, the CAs in the importing country would be taking the information at face value, such that the authenticity of any certificate can only be ascertained through a lengthy process involving direct communication and feedback requests from the authorities that issued the original—a process that falls under what the EU IUU Regulation refers to as "mutual assistance."

# 4.3.2.4 Expected benefits of CATCH

Since its inception, the CCS has been criticised for its many intrinsic design failures by various organisations, including the EU Parliament itself, which in a 2013 study<sup>6</sup> noted among 22 other recommendations that:

"The existing paper-based system and the large number of CCs and Processing Statements involved mean it is impossible for EU MS to monitor, much less control, the use of CCs and Processing Statements individually. Each country is at liberty to design its own format. Collectively, this risk is compounded, as the same CCs and Processing Statements can be reused. The EP should call for the institution of a common computerised system, starting from the issuance of the standardised CC and the Processing Statements, aimed at monitoring the CCs and Processing Statements issued by all countries and entering the EU".

As such, to an extent, CATCH will address some of the deficiencies around the submission of the CCS data by:

- 1. Reduce the risk of fraudulent certificates
- 2. Facilitate controls and risk management
- 3. Harmonise procedures future link to customs IT
- 4. Speed up administrative procedures and facilitate the submission of data
- 5. When non-EU countries' authorities and operators choose to use the system directly, facilitate the entire process as the workflow becomes entirely digital.

# 4.4 The Catch Certification Scheme and its changes under CATCH

Central to the effectiveness of the regulation is the Catch Certificate (CC), a document not easy to handle, so this section will try to "reverse engineer" the ways each section is being handled by the different countries and the CA in the MS that receive them, to clarify its use.

The Regulation (EU) 2023/2842 that underpins the use of CATCH proposed changes in the content of the CC and processing statement to:

- 1. To address loopholes in key data elements relevant to traceability in the old CC
- 2. Incorporate key data related to fishing and to tracing trade flows
- 3. To ensure consistency of data collected
- 4. To ensure the same traceability data requirements for the same commodities in all cases.

While the changes are effective from 10 January 2026, "old" catch certificates and documents (those created and validated before 10 January 2026) will be admissible for an additional 24 months from the date of application (if submitted through CATCH).

# 4.4.1 The changes in each section of the Catch Certificate

There is no "standard understanding" of the interpretation of the CCS contents, and DG MARE does not interfere with the interpretation by EU MS.

As explained before, this guide is based on experience with the "old" certificate and the information available at present on the "new" certificate.

<sup>6</sup> European Union Parliament Study, 2013. "Compliance of Imports of Fishery and Aquaculture Products with EU Legislation"

This part of the guide aims to facilitate the understanding of the different sections of the CC by analysing them individually,

The "new" information requirements and changes are in light blue type, and new areas in the certificate have a light blue background, while the "old" ones without change maintain the white background.

#### 4.4.1.1 Section 1

This requires the details of the authority entrusted for this job (usually the fisheries authority) of the flag state. The authority must be "notified" by DG MARE, and it is assumed that under the new system, those authorities in exporting countries may access these "notification requirements" by becoming registered users of CATCH.

But there is a "catch 22" type situation between the requirements from the EU Catch Certification (CCS) and the Health Certification since some Flag States, while having a fisheries body, lack the EU DG SANTE's authorisation from a sanitary perspective to export, without which raw products sourced from such vessels will remain ineligible and as such are not part of DG SANTE's TRACES system (in which CATCH is based).

So, only the countries that are approved from a sanitary perspective get to be on the list of notified, even if they comply with all the "fisheries elements" of the CCS. This issue will become evident in the analysis of Section 7

The "new" Section 1 differs from the old regarding naming it the European Union Catch Certificate to avoid confusion

(i) EUROPEAN UNION COMMUNITY CATCH CERTIFICATE						
Document number	Validating Authority					
	te - 1000 100 100 100 100 100 100 100 100					
1. Name	Address		Telephone.			
	1		Fax			

Regarding the details above, it is assumed that the CA of the vessel flag State stays in charge of managing a unique consecutive numbering system for each cert. The complexity and structure of this system is up to the country.

While not listed, it is sensible for the CA of the vessel flag State to have a dedicated e-mail contact.

# 4.4.1.2 Section 2

The new elements in this section aim to increase the detail in the identification of the vessel and add the gear used for the harvesting of the fish in the consignment.

2. Fishing vessel name	Flag - hon number	ne port and registration	Call sign	IMO Alloyd's Number or, if not applicable, other unique vessel identifier (if applicable) (if issued)
Fishing licence no. – Valid to until		Inmarsat Mobile satellite service no Telefax no Telephone no. E-mail address (if issued)		
Fishing gear (1)				

The fishing gear code should be under FAO's International standard statistical classification of fishing gear (ISSCFG)<sup>7</sup>

However, the changes do not address the issues that the old system had, namely:

## 4.4.1.2.1 Many vessels and landings in one consignment

The CC is based on the volumes in the consignment exported; the consignment could consist of various landings of various vessels; hence, there could be 20+ vessels in one consignment in the paper system; there was no chance to put more than 2-3 vessels in this section.

To add more vessels, FFA members "invented" Annex B (see sub-section 4.4.1.2 in this chapter); hence, we assume that the new system may allow the addition of as many vessels as necessary for the consignment.

## 4.4.1.2.2 No role for coastal States

The fishing licence # and validity in the certificate refer to the flag state license and not the coastal state where the vessels may be operating.

Yet, the legality of the catch is associated with the conditions imposed by the coastal state and not only by the flag state. Furthermore, the validity may differ (yearly for the flag state, monthly for the coastal state), so it gets complicated, and the CCS remains silent on this. Based on this, the numbering of the licence and validity of the vessel by the flag state may not have any inference with the legality of the catch.

# 4.4.1.2.3 Charter Vessels

As discussed, the issuing and validating of the catch certificate is with the flag state fisheries authority. Yet, a significant part of the fishing world works on principles of "charter"; hence, vessels flagged in country "A" are based and operate in country "B" under its legislation and controls. Chances are that flag state "A" may not have seen that vessel in years and may not even know where it is, but under flag state responsibility is the flag state (A) that had to validate the catch certificates of the vessels that operate in country B.

So, in an ideal world, country "A" would establish an MoU with the Coastal States where the vessels operate and/or with the Port State where the fish is landed/transhipment and/or with the processing state where the fish is processed (note that all this can happen in one country or different ones). Once these MoUs are in place, a robust information-sharing system can be established, enabling the flag state to provide the required "official assurances" during validations.

In the real world, most of the countries that are utilising charter vessels are not those mainly responsible in terms of fishing compliance. Hence, they don't give much attention to these issues (in fact, there are very few such MoUs in place).

While initially, this was designed as a "Catch certificate" (hence certified the fish caught at the time of landing), it has always been used as an "export certificate" only for the fish being exported to the EU, in many cases not from processors based in the flag state of the harvesting vessel.

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<sup>7</sup> https://www.fao.org/fishery/en/knowledgebase/139

So this becomes a problem for the processors and exporters in the countries that process the fish being exported to the EU, as they depend on the willingness and efficiency of the flag state authority, even more so if the flag state CA does not use CATCH.

## 4.4.1.3 Sections 3 and 4

The changes in these sections aim to increase the catch area and date information available and clarify the issues of the weights to be presented in the CC, which was a matter of much confusion in the old one.

The catch area FAO area(s) refers to FAO's statistical catch areas8; furthermore, the information should include the identification of the exclusive economic zone(s) and/or high seas and where the catches took place.

3. Description of product	Type of processing authorised on board			4. References t		conservation and
Species	Product code	Catch area(s) and catch date(s) (from – to) (2)		ed <mark>live</mark> -weight to ded in kg (kg)	Estimated weight to be landed(Net catch weight in kg_)	Verified weight landed (net catch weight in kg) (3) where appropriate

In any case, the changes didn't address some of the old system's issues and remain somewhat mixed and complicated.

<u>Section 4</u> relates more to Section 2 in the conditions under which the vessel operates and catches fish; hence, it is analysed first.

It refers to the applicable Conservation and Management Measures (CMMs) relevant to the vessels and area of catches; this has been a confusing aspect, as an example; a vessel from a WCPFC member fishing in the area may be under the obligations of over dozens of CMMs9 that are incorporated into the fag state legislation (high seas permits, conditions related to leaving the flag state EEZ, observers, FADs, and all other CMMs applicable to the WCPFC in which that vessel operates) and/or the measures imposed by the coastal state (permit # and conditions, etc) which as discussed above seems absent.

In any case, it only relates to the relevant RFMO convention area(s), so one assumes that naming the WCPFC is sufficient.

Section 3 focuses on the products of the consignment.

<u>Product Description:</u> The product is described by using the species name, and the product code is the customs code used in the nomenclature implemented by the third country (however, in reality, it is the one that the client requested) in the sections below. However, some countries ask for the product's generic name to be listed (i.e. Tuna loins).

<sup>8</sup> https://fish-commercial-names.ec.europa.eu/fish-names/fishing-areas\_en

<sup>9</sup> https://cmm.wcpfc.int

<u>Catch dates and areas:</u> Dates of catch can be interpreted as the actual dates of fishing. However, a vessel may not catch every day, so certainty is required regarding whether this constitutes each active fishing date, the time between the 1st fishing operation (i.e. trawl, set, hook in the water, etc.) and the last one. This could also be from port departure to return or from empty hold to full hold, depending on how the vessel operates.

This is not defined; hence, it is potentially in the hands of the operators that complete this section to choose what they want, or it may also be subject to a directive from the fisheries authority defining what is required.

- Weights: The clarifications for this section, as explained in DG MARE's FAQ of May 202410, are very welcomed since the ones in the older system were complex and somewhat confusing. Question 48 of the FAQ states:
- 2. <u>"Estimated weight to be landed in kg"</u> this box will be used in direct landings of fishery products in the EU. It will contain data based on the fishing logbook.
- 3. <u>"Net catch weight in kg"</u> this box will be used in case of landings in third countries. It will contain data after completion of landing relevant for the products intended to be exported to the EU.
- 4. <u>"Verified weight landed (net catch weight in kg)"</u> this box will be used in case of landings having taken place under the supervision of an authority.

What often used to happen is that when fish from a vessel flagged in country "A" was unloaded in country "B" for processing, the whole volume of fish landed can be quoted in the "estimated" box. So now it is advised that this volume only applies to fish landed in the EU.

The weight that seems applicable to landing in 3rd countries is the "Net Weight"; the note does not go into details. Still, it would be great to assume this for the entire landing, and then the processing statement provides the details of the processed volume out of the landed. The CATCH system keeps track of this for each vessel's landing in the CC and incorporates some standard conversion factors/yields to keep subtracting the volumes processed of the volume landed until the total net volume is exhausted.

In terms of the verified weight landed, details need to be provided, yet one is to assume that this could apply to the port State authority if fish is landed in a country that is not the flag state.

While the present understanding is a step forward from the old one, some aspects will need further official clarification by DG MARE.

#### 4.4.1.4 Section 5

The changes here add the option of a licensee holder since masters were, in most cases, unavailable to sign.

# 5. Name of master of fishing vessel or of fishing licence holder - Signature Seal:

While it is ideal to make the master responsible for the fish caught, as is often the case, the certificate is raised when the product is ready to be exported, which usually means processed (not for the product caught).

<sup>10</sup> https://oceans-and-fisheries.ec.europa.eu/document/download/4b92c8f5-9f96-46ec-babc-3bc880ff4ad3\_en?filename=FAQ-amendment-IUU-Regulation\_en.pdf&prefLang=fr

This may happen in a different country and months after the vessel landed, and therefore, the master will not be available to sign the document.

In theory, this is something that the fisheries authorities should be validating. Yet, most operators have scans of the skipper's signatures available or add the concept of "authorised company representative" or something along those lines to the paper certificates.

#### 4.4.1.5 Section 6

Transhipments are permitted in various fisheries and under the fishing rules of the flag state and/or RFMO and/or coastal state.

6. Declaration of transhipment at sea Name of master of fishing vessel	Signature and date		Transhipment date/area/positi n	Estimated o weight (kg)
Master of receiving vessel	Signat	ure Vessel nam	e Call sign	IMO/Lloyds N number (if issued) or, if not applicable, other unique vessel identifier (if applicable)

Nevertheless, it is the Flag state's responsibility to attest to the legality of transhipment at sea. Hence, the Flag States should have processes and instruments to ensure the operations were legal and no underreporting occurred.

Some difficulties apply here in addition to the other elements of the CC. Completion of the paperwork may occur sometime soon after the event and be handled by the processors rather than by the fishers. So, in this case, how does the flag state know and validate the identity (and signature) of both masters?

While there is no definition of "transhipment at sea", it is almost obvious that it happens outside any port region, and many states have not defined the "format" in which the transhipment information is to be supplied.

Examples have been cited where the CC declares two dates and positions (start of the transhipment and finish). This may suggest the idea that there were two transhipments instead of one.

Indeed, there could also, in fact, be two consecutive transhipments by the same vessels separated by a few days.

Thus, it is essential that the validation authority clearly states how they require the information to be presented.

#### 4.4.1.6 Section 7

The changes here address a substantial failure of the old system, the need for a section for landings and an absence of Ports State Measures in the CCS.

Furthermore, the EU is a party to PSMA and actively participates in the FAO Technical Consultation that elaborated the 2022 Guidelines for Transshipment that agreed to the definition of transhipment and landing.

The new form correctly identifies the ports and the dates of transhipment or landing, as well as the details of the receiving vessels in case of transhipments.

7. Transhipment and/or landing auth			•					
Name	Autho rity	i g n a	Address	T el ep ho ne	Port of landing (as appropri ate)	Date of landing (as appropri ate)	Seal (stamp)	
		t u r e			Port of tranship ment (as appropri ate)	Date of tranship ment (as appropri ate)	Name and registration number of receiving vessel IMO number or, if not applicable, other unique vessel identifier (if applicable) of receiving vessel	Seal (stam p)

In any case, the changes do not address some of the old system's issues and must be clarified.

While not clearly explained in the regulations or manuals, this is the only part of the CC that requires the signature from the Port State instead of the Flag State.

When vessels flagged in Country "A" tranship or land at a port in Country "B". Country "A" is responsible for the validation of the CC, but Country "B "is responsible for authorising the transhipment or landing under PSM.

The transhipment or landing can occur before the CC certificates are raised and validated (because, in many cases, there is still no firm buyer for the fish) or because the fish has not been landed or processed at the destination, which may or may not be the Flag State.

This a difficulty for the Port State as under the paper system, if they were to sign Section 7 at the time of the transhipment or landing, they'd sign an empty CC unless the flag state is really "onto it" and able to provide a validated CC based on reliable estimates prior the transhipment (there is no evidence of this ever being the case).

Alternatively, they need to keep the records of the transhipment authorisation on file until such a time the processors of the fish that was transhipped/landed request the CC from the Flag State, who can then issue and validate the CC which can then go to the Port State for section 7 signature.

As it is now, the operational side of section 7 requires either jeopardy from the Flag State or the Port State.

It's only to hope that under CATCH, the communication between the flag state and port state may be working over the same CC initiated by the flag State. And, as discussed before, CATCH can incorporate countries that are not authorised from the sanitary perspective, something they cannot presently on TRACES.

#### 4.4.1.7 Section 8

8. Name and address of exporter	Signature	Date	Seal

There are no changes to this section, which is usually completed by the processor that fills Section 5, as the CC is prepared by the processors (which, as already discussed, defeats the purpose of a catch certification), so in general terms, there are no issues with this section.

#### 4.4.1.8 Section 9

9. Flag State authority validation:			
Name/Title	Signature	Date	Seal (stamp)

There are no changes to this section, which refers to the authority in charge of Section 1. However, a name and position are required.

Initially, it was believed that the details should be communicated to DG MARE. Yet, the CA of the EU MS evaluates the CC, and there needs to be a centralised system to verify (or not) the details of the CC. It is, therefore, up to the EU member state to decide whether to inform DG MARE.

#### 4.4.1.9 Section 10

#### 10. Transport details: See Appendix

There are no changes to this section, which is a rather illogic part of the certificate which could just be the appendix (transport details) or not referred to.

The "new" transport details appendix does, however, incorporate changes that refer to the documentation details, such as the Contract for the International Carriage of Goods by Road (CMR), the inclusion of a port of destination, and the instruction in the case of use of multiple modes of transport or multiple shipments, the information related to the transport has to be provided for each mode of transport used for each.

1. Country of exportation  Port/airport/other place- point of departure	2. Exporter signatu	re	3. Point of destination		
Vessel name and flag	Container	Name	Address	Signature	
Flight number/ airway bill number	number(s)				
Truck nationality and registration number					
Railway bill number	list attached				
Freight bill number					
Other transport documents (e.g. bill of lading,					
CMR <sup>(2)</sup> , air waybill)					

The appendix collects the information related to the transport details of the fishery products from the third country, having validated the catch certificate to the next destination, an EU Member State in case of direct importation or an intermediate country in case of indirect importation to the EU.



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Yet, as has been seen under part 7, if a transhipment in port happens in between vessels where the Port State is the Flag State, then this can also be construed as having the carrier as the de facto transport vessel. In this case, the carrier's details will be entered in this section.

There are also instances where the transhipment details being recorded in section 7 are the same details of the carrier being repeated in this section of transport details.

Acceptance of this practice may be one of those issues that is dependent on the practices of the authorities of importing EU MS at the time the consignment enters the country.

## 4.4.1.10 Processing Statement

The processing statement, as required by Annex IV of the IUU Regulation, has gone through a total change of understanding.

While it used to be only required for fish processed under a foreign catch certificate in a 3rd country, it will now be necessary even in cases where the processing and the flag state are the same.

From now on, processing statements will be required for ALL processed fishery products imported into the EU, regardless of where the processing occurs (in the flag State or another non-EU country).

This means that processing statements should also be endorsed in cases where the flag State of the fishing vessels that caught the fish and the country where the processing operation occurred are the same.

In addition, the template in Annex IV will include the obligation to apply a unique number provided by the authorities endorsing the statement (in case of direct use of CATCH, the system can generate such a unique number directly).

Notably, the processing statement should refer to the related catch certificates that will include the quantity of fish used as raw material to produce the processed products to be exported to the EU, which, as discussed before, hopefully, is checked in terms of the standards yields for the type of processing.

Catch certificate number	Vessel name(s) and flag(s)	Validation date(s)	Catch description	Total landed weight (kg)	Catch processed (kg)	Processed fishery product (kg)			
Name and addr	ess of the proc	essing plant	:						
Name and addr	ess of the expo	rter (if diffe	rent from the	processing pla	nt):				
Approval numb	er of the proces	ssing plant:							
Health certificat	Health certificate number and date:								

Responsible person of the processing plant	Signature	Date	Place
Endorsement by the competer	nt authority:		
Official:	Signature and seal	Date	Place

There are no significant issues regarding this document. From the practical and management point of view, it is essential for the CA of the processing state that validates this document to maintain a register of processing statements signed with a description of species, volumes and destiny.

# *4.4.1.11* A Non-Manipulation Statement?

The legislation did not stipulate a "non-manipulation statement", but it stated that:

To import fishery products constituting one single consignment, transported in the <u>same</u> <u>form to the EU from a 3rd country other than the flag State</u>, the importer shall submit to the authorities of the Member States of importation:

- (a) the catch certificate(s) validated by the flag State; and
- (b) documented evidence that the fishery products did not undergo operations <u>other</u> <u>than unloading, reloading or any operation designed to preserve them in good and genuine</u> <u>condition</u> and remained under the surveillance of the competent authorities in that third country.



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Documented evidence shall be provided by means of:

- 1. where appropriate, the single transport document
- 2. A document issued by the competent authorities of that third country:
  - a. giving an exact description of the fishery products, the dates of unloading and reloading of the products and, where applicable, the names of the ships or the other means of transport used and
  - b. an indication of the conditions under which the fishery products remained in that third country.

Hence, some FFA members developed a 'Non-Processing Statement" to cover all these issues and assist with their "fish accountancy". An example follows:

# Non-Processing Statement

Under the requirements of the EU Catch Certification Scheme

XXXXX, xx/xx/xxxx

To whom it may concern

We state that the following fishery products did not undergo operations other than unloading, reloading or any other operation designed to preserve them in good and genuine condition, and remained under the surveillance of the competent authorities while in the Solomon Islands:

Description of the products	ducts cer		Catch Produc certificate Weigh Number		Port a unloa	and Date of iding	Unloa	aded from: Vessel e, flag
Date reloading	Port / place or reloading	of	of Reloaded onto: Vessel name, flag or other means of transport used			Total product weight reloaded		
			7					
If product was sto	ored: Name and	d add	lress of sto	rage facilities		Stored fres	h	Stored frozen
1.11				l c:				
Name and addres	s of exporter			Signature	Signature		Date	
Authority Valid	ation							
Name/Title		Sigr	nature		Date		Seal (	(Stamp)

Under the new system, there would be an official template for this document (not yet published)

# 4.4.1.12 Annex B or attachment to Catch Certificate

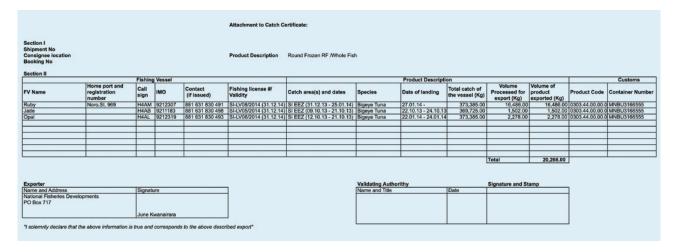
This form was not published in the original legislation; hence, it is not a compulsory form. In a note published by the EU on their website in July 2010, the EU welcomed the use of it for domestic products (i.e. products caught by the flag state vessels in this case). They do not standardise the contents. Hence, countries can adapt it to reflect their systems and the outcome based on traceability.

The EU noted: "Discussions are presently carried out with other third countries to provide similar information regarding domestic processing activities. The Commission welcomes the support received from third countries and their positive approach to implement the IUU Regulation". Hence, the third countries should use this to their advantage.

The certificate itself is still filled as usual, but then sections 2 and 3 will refer to the attachment or Annex B.

This form is handy when the consignment is made from various landings of various vessels (as is common in canneries), as the form can replace otherwise 30 "individual" certificates.

It is easier to set up the information in a readable way, including the volumes landed, the volumes processed, and the volumes exported. The Container number where that product is stored for dispatch, hence the whole traceability of the product is "visible" in one document; an example is presented below:



As discussed in Section 2 of the CC, it will depend on the facilities under the new CATCH system to add many vessels if applicable.

# 5. FORTHCOMING EU LEGISLATION THAT COULD IMPACT MARKET ACCESS

# 5.1 Directive on Corporate Sustainability due Diligence (CSDDD)

While the impact on fisheries will be highly variable depending on the size of the exporting companies, the recent publication of Directive (EU) 2024/1760 of the European Parliament and of the Council of 13 June 2024 on corporate sustainability due diligence (CSDDD) is worth mentioning in this section.

This legislation will be implemented gradually over the next few years, imposing mandatory human rights and environmental due diligence requirements on large EU and non-EU corporations operating in the EU.

The CSDDD aims to ensure that EU and non-EU companies are active in the EU:

"contribute to sustainable development and the sustainability transition of economies and societies through the identification, and where necessary, prioritisation, prevention and mitigation, bringing to an end, minimisation and remediation of actual or potential adverse human rights and environmental impacts connected with companies' own operations, operations of their subsidiaries and of their business partners in the chains of activities of the companies, and ensuring that those affected by a failure to respect this duty have access to justice and legal remedies."

Obligations under the CSDDD will apply in addition to other more specific or potentially stricter due diligence obligations under different EU laws, such as the Forced Labour Regulation<sup>11</sup> (see next section)

Except for the due diligence provisions relating to the identification, prevention and termination of adverse impacts, MS can go beyond the CSDDD and introduce stricter obligations or broader scope.

The thresholds for in-scope 'non-EU companies' (i.e., companies established outside of the EU) is that generated a 'net turnover in the Union' of more than EUR 450 million in the financial year preceding the last financial year, which may apply to companies in the tuna canning business.

The CSDDD also extends to EU and non-EU "ultimate parent companies" of groups of EU and/or non-EU companies – which, taken together as a group, meet the above thresholds.

<sup>11</sup> The CSDDD provides that if a provision conflicts with another EU legislative act pursuing the same objectives and providing for more extensive or more specific obligations, that other EU legislative act shall prevail. Article 1(3

These new rules will become applicable to companies according to a staggered timeline set out below to enable them to prepare. This means that it will be several years before the new rules take full effect; in the case of companies in the EUR 450 million threshold, the date of application is 26 July 2029.

In-scope companies must take steps to manage actual and potential adverse impacts of their activities on human rights and environmental matters arising from

- 1. their own operations,
- 2. the operations of their subsidiaries, and
- 3. the operations of their business partners in their chain of activities.

The "chain of activities" does not cover the disposal of products or activities of a company's downstream business partners related to the services of the company. However, it does cover:

- 1. The activities of the **company's upstream business** partners related to the production of goods or the provision of services by the company (including the design, extraction, sourcing, manufacture, transport, storage and supply of raw materials, products or part of the products and development of the product or the service).
- 2. The activities of a **company's downstream business** partners related to the distribution, transport and storage of the product where the business partners carry out those activities for the company or on behalf of the company.

The primary due diligence obligations under the CSDDD are "obligations of means", not "obligations of result".

Companies are not expected to guarantee that adverse impacts will not occur, nor will they always be prevented. But they are expected to take "appropriate measures": measures capable of achieving due diligence objectives.

These measures may involve the following: the development and implementation of a prevention action plan; the acquisition of contractual assurances from business partners, which are accompanied by measures to verify compliance; the implementation of necessary financial or non-financial investments, adjustments, or upgrades to operational processes and infrastructures; the modification of the company's own business plan, strategies, and operations, including purchasing, design, and distribution practices; the provision of targeted and proportionate support from SME business partners; or the provision of remediation.

The supervisory authorities of Member States will be responsible for enforcing the CSDDD. They can conduct investigations where they believe there are "substantiated concerns" and may request that companies provide information regarding suspected non-compliance with the obligations outlined in Articles 7 to 16.

In addition, national supervisory authorities will be obligated to "at least supervise" the adoption, design, and updating of companies' transition plans. Nevertheless, they are not obligated to oversee their execution. Additionally, there is no indication that such supervision will include the formal certification of transition plans. Nonetheless, an authority's assessment and determination of non-compliance could result in one of the consequences stipulated below.



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# **5.2 Forced Labour Regulation**

On 14 September 2022, the European Commission presented its proposal for a Forced Labour Regulation as part of a suite of regulatory changes aimed at cross-border supply chains. Then, in November 2023, the European Parliament adopted its position on the Commission's proposal, and the Council of the EU adopted its General Approach in January 2024.

Following intensive inter-institutional negotiations, the Council of the EU and the European Parliament (as EU co-legislators) reached a provisional agreement on the text of the Forced Labour Regulation on 5 March 2024. The Parliament adopted it on 23 April 2024.

The Forced Labour Regulation prohibits products made with forced labour (including child labour) from being placed on the EU market or exported from the EU. It establishes a framework for enforcement of the ban through investigations, new digital tools and cooperation amongst Member States and their national competent authorities.

The Regulation is part of the legislation addressing human rights in supply chains, flanking the recently adopted Corporate Due Diligence Directive (CSDDD), among others. Furthermore, the Regulation aligns with the aim of the International Labour Organization and the UN Sustainable Development Goals to eliminate all forms of forced labour.

The Regulation has an extensive scope and applies to all economic operators without considering their scale, revenue, place of establishment, or legal form. This distinguishes the Regulation from the CSDDD, which provides a threshold for turnover in the EU and company size.

Furthermore, the Regulation comprehensively understands the term "product." It applies to all types of products at any stage of the supply chain, with an effect on both the import and export of such products, as well as distance selling, such as online sales targeting end users in the EU.

The disclosure of information to customs authorities is one of the most significant obligations for economic operators that import or export products in the EU. The European Commission (is authorised to adopt delegated acts that specify the products for which additional information is required and to adopt implementing acts that define the specifics of the information to be shared, as per the Regulation.

Additional details regarding the product's manufacturer and supplier (e.g., name, trade name or registered trademark, contact information, unique identification number) as well as any product-specific information (e.g., name or brand of the product, specific requirements for product identification, such as serial number) would be disclosed. This information will assist the authorities in the identification of dubious products and the reconstruction of the supply chain.

The Regulation establishes a publicly accessible database to document the risk of compelled labour in specific geographic areas or concerning specific products or economic sectors, thereby supporting the disclosure. Nevertheless, this information cannot be traced to specific economic actors due to its anonymity.

The competent authorities designated by the Member States will implement and enforce the new rules. They will be responsible for conducting investigations into suspected use of forced labour and taking the final decision after the investigation.

Information regarding potentially violating products may be submitted to the Commission or the appropriate authorities of the member states by any individual or organisation. The authorities will initiate an investigation in the event of substantiated concern.

The Commission and the authorities of the member states will implement a risk-based approach to the enforcement of the Regulation, which is determined by the scale and severity of the suspected forced labour, the quantity or volume of suspected products on the European market, and the proportion of the final product that is suspected to have been produced using forced labour.

Once the investigation is concluded and forced labour is identified, the economic operator is prohibited from importing, selling, and exporting the infringing products on the European market. Additionally, the operator must remove the infringing content from sales via the Internet or withdraw the products from the market. The products must be disposed of.

The Regulation also allows member states to establish specific penalties. It is anticipated that the member states will leverage this entitlement to exert additional pressure on economic operators to adhere to the Regulation's obligations.

Penalties must be effective, proportionate, and dissuasive under the Regulation. Competent authorities must determine the penalties following the gravity and duration of the infringement, any relevant previous infringements by the economic operator, and the degree of cooperation with the competent authorities.

The Regulation does not establish an utmost time limit for the duration of investigations. Nevertheless, the Regulation instructs the authorities to strive for a decision within nine months of the investigation's commencement.

The Commission makes decisions to prohibit a product from the European market publicly available online, which could have a significant reputational impact on the economic operator and a particularly powerful impact in highly competitive economic sectors.

The European Council formally approves the Regulation to have a directly binding effect, which is expected in the second half of 2024.

Upon formal approval, the Regulation will be applicable 36 months from entering force (expected in 2027).

NOTES		



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