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## *Exporting Seafood to the EU*

*Contents*

*Introduction*

*Some Basics*

*The Health Certificate*

*Other Requirements*

*EU Regulations*

*Annexes*

This bulletin provides a guideline on how to export seafood products to the EU. It describes, *inter alia*, the required EU system of official assurances, the main regulations and requirements for the Competent Authorities and operators along the value chain.

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**Abbreviations and acronyms**

AH	—	Animal Health
ARMP	—	Aquaculture Residue Monitoring Programme
BIP	—	Border Inspection Post
CA	—	Competent Authority
CCA	—	Central Competent Authority
EC	—	European Commission
EU	—	European Union
FAO	—	Food and Agriculture Organization of the United Nations
FP	—	Fish and fishery products
FVO	—	Food and Veterinary Office
HACCP	—	Hazard Analysis and Critical Control Point (System)
ITC	—	International Trade Centre
NPC	—	National Control Plan
PH	—	Public Health
RASFF	—	Rapid Alert System for Food and Feed
SPS	—	Sanitary and Phytosanitary (measures)
TRTA	—	Trade-Related Technical Assistance
UNCTAD	—	United Nations Conference on Trade and Development
WTO	—	World Trade Organization

## Foreword



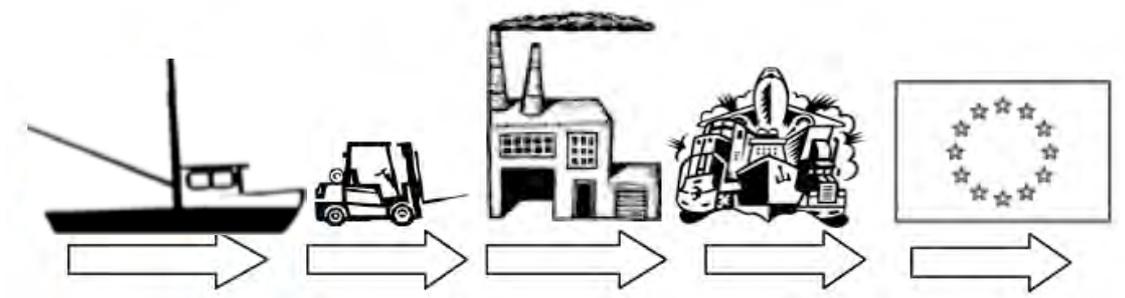
*“There is no way to escape some reading if you want to export to the European Union (EU).*

*Exporting to the EU is not an obligation and it requires an equal amount of effort from the governmental authorities and from the private sector.*

*However, if the idea of accessing over 495 million consumers in 27 countries at once is not worth understanding around hundred pages, then the EU may not represent a priority market for you and your country.*

*Compliance and understanding of the required system of official assurances is paramount to access the EU market”.*

Francisco Blaha.



## **Contents**

	<b><u>Page</u></b>
1 Some Basics.....	6
1.1 The world trade of fish .....	6
1.2 Is it worth to export to the EU?.....	6
2 The Health Certificate.....	7
2.1 Public Health Attestation.....	8
2.1.1 Food and Veterinary Office (FVO).....	9
2.2 Approved countries .....	9
2.3 Requirements for the food business operators .....	10
2.3.1 Approved Establishments.....	10
2.3.2 Requirements for the establishments.....	11
2.3.3 Conditions of operators along the production chain .....	11
2.3.4 Requirements for all fishery products.....	12
2.3.5 Specific requirements for aquaculture products .....	12
2.4 Official Controls.....	14
2.5 The official guarantees and the Health Certificates .....	17
2.5.1 Which countries will accept this certificate? .....	18
2.5.2 Border Inspection Posts .....	18
2.5.3 Rapid Alert System for Food and Feed .....	19
2.6 Certification, traceability and eligibility .....	20
2.7 Traceability guidelines .....	21
2.7.1 Separation and Identification of non-EU eligible product.....	21
2.7.2 Products with imported raw materials .....	22
2.8 Foreign flagged vessels landing in your country.....	22
2.8.1 Chartered Vessels.....	23
2.8.2 Independent Vessels.....	23
3 Other requirements.....	24
3.1 Labels .....	24
FAO Catch Area.....	25
3.2 Laboratories to be used for official controls .....	25
3.3 Potable water .....	26
4 What about the regulations?.....	27
5 Acknowledgments. ....	27
6 Annex I – Key regulatory framework .....	28
7 Annex I- Formal steps towards approval for imports.....	30
8 Annex III - Useful web-sites.....	31
9 Annex IV – Model Health Certificate.....	32
10 Annex V - Trade-Related Technical Assistance (TRTA) .....	33

# 1 Some Basics

## 1.1 *The world trade of fish*

The value of the international fish trade increased from \$15.5 billion in 1980 to over \$71 billion in 2004, according to FAO.

Developing countries have particularly benefited from this boom, with their net earnings (exports minus imports) increasing from \$3.4 billion to over \$20 billion over the same period. This income exceeds the net foreign exchange revenue they earn from any other food commodity, including coffee and tea.

Currently, around 77 % of fish consumed worldwide as food is supplied by developing countries.

The European Union (EU) is the biggest single market for fish and fishery products worldwide, as a consequence of an increased consumption per capita and its enlargement to 27 member states.

For example Spain (US\$5.2bn) is the world's third largest importer<sup>1</sup>, followed by France (US\$4.2bn), Italy (US\$3.9bn), Germany (US\$2.8bn) and the United Kingdom (US\$2.8 bn). (FAO data<sup>2</sup>)

These figures are particularly important, because all EU Member Countries<sup>3</sup> share the same market access rules for seafood products.

## 1.2 *Is it worth to export to the EU?*

While the idea of accessing many wealthy customers is very tempting, as a producer, your decision to export to the EU is to be based on a cost benefit analysis.

If your potential incomes justify the expenses you may incur, in terms of infrastructure upgrades, knowledge and capacity building then go ahead, but without forgetting that there would be on going costs to maintain the system

The European Community (EC) has laid down joint conditions for imports of foodstuffs of animal or plant origin, taking into account of the need not only to protect consumer health but also to protect the territory of the Union from the introduction of animal or plant diseases.

The European Commission's Directorate-General for Health and Consumer Protection (DG SANCO) is responsible for food safety in the EU, its import rules for fishery products seek to guarantee that all imports fulfil the same high standards as products from the EU Member States, with respect to hygiene and consumer safety and, if relevant, also the animal health status.

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<sup>1</sup> Detrás de Japón y USA

<sup>2</sup> <http://www.fao.org/newsroom/en/news/2006/1000301/index.html>

<sup>3</sup> A good resource to understand the structure and workings of the EU can be found at [http://europa.eu/abc/12lessons/index\\_en.htm](http://europa.eu/abc/12lessons/index_en.htm)

Hence, it is very important that interested countries and business should understand the fundamental principles and philosophy of the European Food Law, which form the basis for EU import rules, in order to ensure that imports can take place smoothly and efficiently<sup>4</sup>.

The EU bases its systems on government-to-government assurances, without the intervention of any private type certification, neither standards such as ISO.

So, the producer efforts are conditional to the good performance of whichever authority (the Competent Authority - CA) in your country assumes the responsibility of giving the EU the *official guarantees* it requires.

The CA in the country of origin is the responsible of giving these official guarantees to the EU in regards compliance and conformity to all the requirements of its legislation.

One way to understand some of the key issues around EU market access and the systems of *official guarantees* is based on the attestations that the CA signs in the *official health certificate* required to enter the EU.

## 2 The Health Certificate

Seafood products that are exported to the EU must be accompanied by a health certificate emitted by the *Competent Authority* of the country of origin<sup>5</sup>.

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

As the format and content of the certificate are to be respected, the attestation is a great tool to understand the requirements.



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<sup>4</sup> Some information reported in this bulletin is reproduced from the publication “EU import conditions for seafood and other fishery products”, EC Health and Consumer Protection, Directorate-General.

<sup>5</sup> The model certificate is presented as an annex and can be found as part of regulations (EC) No 1664/2006 of 6 November 2006, [http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l\\_320/l\\_32020061118en00130045.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_320/l_32020061118en00130045.pdf) Annex IV.

## 2.1 Public Health Attestation

*"I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No. 178/2002, (EC) No. 852/2004, (EC) No. 853/2004 and (EC) No. 854/2004 and certify that the fishery products described above were produced in accordance with those requirements, in particular that they:*

- come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulations (EC) No. 852/2004,*
- 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,*
- 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 Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs,*
- have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VIII 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,*
- the guarantees covering live animals and products thereof, if from aquaculture origin, provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled,*
- and*
- have satisfactorily undergone the official controls laid down in Annex III to Regulation (EC) No. 854/2004."*

Let's start to understand the first attestation:

*"I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and certify that the fishery products described above were produced in accordance with those requirements, in particular that they:"*

This statement implies the need of a certifier whose duty relies on the body responsible for *official guarantees*, the *Competent Authority*.

The EU requires that the *official guarantees* in terms of compliance of seafood exports from a third country should be given by a *Competent Authority* which means the "...central authority of a State competent for the organisation of official control..."<sup>6</sup>

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<sup>6</sup> Reg (EC) No 882/2004. Art 2

This statement has to be read in terms of the *official controls* as required in terms of food safety, production standards, and others as specified for seafood in the relevant EU legislation.

The EU legislation emphasises that...*"The competent authorities for performing official controls should meet a number of operational criteria so as to ensure their impartiality and effectiveness. They should have a sufficient number of suitably qualified and experienced staff and possess adequate facilities and equipment to carry out their duties properly"*<sup>7</sup>...

Where governments are unwilling or unable to assure the consumer safety of exported food, the EU will not accept such products.

### **2.1.1 Food and Veterinary Office (FVO)**

As part of the market access conditions, EU experts (Food and Veterinary Office - FVO) assess the equivalency of an exporting country's seafood safety regime and determine the conditions required to be met for seafood from that country. The FVO determines the status of compliance of the CA in terms of the required official guarantees. FVO inspection missions are currently undertaken in all exporting countries and they are the basis for establishing confidence between the EU Commission and the CA of the exporting country. All inspection visit reports are publicly available and published on the FVO website<sup>8</sup>. They contain findings, references and (*if necessary*) recommendations to facilitate compliance.

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

- Approved countries
- Approved vessels and establishments (e.g. processing plants, freezer or factory vessels, cold stores)
- Approved Aquaculture establishments and Areas

## **2.2 Approved countries**

The EU takes three criteria into account when drawing up the list of approved countries:

- The recognition of the equivalence of the relevant CA of the third country to the national authorities of the Member States.
- The health status of the exporting country as regards animal diseases, which are transmissible through animal products.
- The submission by the country concerned of an annual residue-monitoring plan for the products concerned.

While summarising all that the EU requires for a country evaluation would be quite difficult, it is safe to say that the local system is to be equivalent (or equal)

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<sup>7</sup> Reg (EC) No 882/2004. 1. (6)

<sup>8</sup> [http://ec.europa.eu/food/fvo/ir\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm)

to what is established majorly by *Regulations (EC) No 178/2002, (EC) No 882/2004, and (EC) No 854/2004.*<sup>9</sup>

However, we could summarise that the CA is required to assure compliance to three types of obligations:

- **Obligations of resources:** i.e. Instruments of production, Conditions of handling/processing, HACCP and Pre-requisite programmes, Traceability.
- **Obligations of results:** Safety levels of the products (i.e. Histamine, Contaminants, Micro levels).
- **Obligations of control:** i.e. Regulatory verification effectively implemented by the CA, Strict control of certification of products.

So, if a country is assessed as approved for export to the EU, it means that it has legislative instruments, structure, knowledge and systems that are able to provide the reliable official assurances required.

### **2.3 Requirements for the food business operators**

As we have seen so far, the first and most important condition, required for a food business operator (FBO) to export to the EU, does not depend on the FBO at all, but rather on the CA that regulates it.

So, assuming that the country is on the list of approved countries, then the CA is responsible to authorise you to export to the EU.

The CA must in principle have a complete register of all establishments under its jurisdiction.

As exporting to the EU is not compulsory, it's the establishment's decision if they seek "approval" in terms of EU requirements in order to access its market.

The CA's assessment of compliance is the one that defines the establishments in line with the EU standards, and approves them, or not usually by assigning them a unique identification code.

#### **2.3.1 Approved Establishments**

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

The list of approved establishments is maintained by the CA and represents all the elements in the production chain that are allowed to provide to companies that export directly to the EU.

The establishments that export directly to the EU need to be included on a list of establishments authorised to receive a health certificate for their products. This list can include vessels, plants or coolstores on the condition that they export directly to the EU.

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<sup>9</sup> Updated and consolidated versions of all this regulations can be found at:  
[http://www.fsai.ie/legislation/eu\\_hygiene\\_regs/index.asp](http://www.fsai.ie/legislation/eu_hygiene_regs/index.asp)

These establishments are given a unique identification code, usually known as the “EU number”.

The CA sends to the EC the list of *authorised establishments*, with the guarantee that they have been inspected and deemed to comply with the specific hygiene rules, which correspond to the type of product processed. Therefore any changes or updates in the list composition needs to be communicated to the EC immediately.

The EC evaluates the list and communicate them to the Member States (ME) , as appropriate, once the recommendations have been accepted as complying with the requirements. The processing of the applications and changes can take between one to three months.

The lists are then adopted by the Commission after an opinion of the Member States and sent to the Border Inspection Posts (BIPs) in the Community.

The approval and inclusion in the list is not a “one off” event, it is based upon compliance by the establishments. If the level of compliance becomes so low that the CA is unable to provide the required official guarantees, then the establishment can be suspended or taken out of the list. In this way the establishment loses the right to export to the EU.

### **2.3.2 Requirements for the establishments**

As discussed, the CA certifies compliance to a series of requirements, which are listed in the public health attestation of the certificate. The first one is:

- *“come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,”*

HACCP<sup>10</sup> should not be anything new these days; in general no company should be processing food if they haven't a full HACCP functional plan.

The plan and its pre-requisite programmes are “living documents” and they need to represent in reality your operations, and not just paper exercises only to be given to the inspector once in a while.

Compliance systems must be written to be used and applied by the company and not just to be read by the CA. Hence, coherence and user friendliness are very important to make the system effective, beyond what is just written.

### **2.3.3 Conditions of operators along the production chain**

As mentioned, the whole value chain needs to be under the control of the CA and in compliance by the operators. These requirements are evident on the following statement.

- *“have been caught and handled on board vessels, landed, handled and where appropriate prepared, processed, frozen and thawed, hygienically in*

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<sup>10</sup> Basic information on HACCP is available from an ITC bulletin, EQ 71 “Introduction to HACCP”, ITC (2002).

*compliance with the requirements laid down in Section VIII, Chapters I to IV of Annex III to Regulation (EC) No 853/2004,”*

But most importantly, it provides the specific set of references in the legislation that are of direct application by the operators, namely *Section VIII, Chapters I to IV of Annex III to Regulation (EC) No 853/2004.*

These few pages are actually the ones defining the key requirements in terms of hygiene requirements, and in reality, are not more difficult to comply with, than any other type of requirements such as those directly based on *Codex*.

#### **2.3.4 Requirements for all fishery products**

The particular requirements for the 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 Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs”*

This particular paragraph refers to the health standards for most fishery products such as organoleptical, histamine, parasites, toxins and so on. As well as the microbiological standards, which are quite minimal, applying so far to ready-to-eat products.

*- “have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VIII of Annex III to Regulation (EC) No.853/2004,”*

In this case it refers to some very simple 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 in accordance with Section I of Annex II to Regulation (EC) No 853/2004,”*

These identification-marking requirements are very basic and refer mostly to type of product and establishment of origin identification.

#### **2.3.5 Specific requirements for aquaculture products**

Besides all the requirements listed so far, the following statement applies specifically to products originated from aquaculture practices.

*- “the guarantees covering live animals and products thereof, if from aquaculture origin, provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled.”*

Countries, wishing to export aquaculture products to the EU, need a particular approval, which is given upon compliance with Veterinary residue monitoring requirements as outlined in Articles 29 and 30 of Council Directive 96/23/EC. In particular, Article 29 (1) of the Directive states that a third country must submit a plan setting out the guarantees which it offers as regards the monitoring of

the groups of residues and substances referred to in Annex I of Council Directive 96/23/EC.

The guarantees provided by third countries must:

1. Meet the requirements of Article 4 and specify the particulars laid down in Article 7 of this Directive, and
2. Meet the requirements of Article 11 (2) of Council Directive 96/22/EC as amended by Directive 2003/74/EC.

The key points are:

- Article 4 of Council Directive 96/23/EC, that specifies, *inter alia*, that there must be a centrally co-ordinated residue monitoring plan in place;
- Article 7 (indent 1) of Council Directive 96/23/EC, that requires a description of the legislation governing the authorisation, distribution and use of veterinary medicinal products;
- Article 7 (indent 6) of Council Directive 96/23/EC, that states that the number of samples taken should be in accordance with the sampling levels and frequencies laid down in Annex IV of that Directive;

The initial plan submitted by a third country must include:

- Information on the structure of the CA
- A description of the legislative framework
- A list of approved laboratories for residues controls and the accreditation status of these laboratories;
- Rules covering the collection of official samples;
- Details on measures to be taken in the event of an infringement;

The residue-monitoring programme is submitted by the CA of the country of origin to the EC for initial approval and needs to be presented annually for evaluation and renewal.

The aim of the evaluation is to assess whether the third country regulatory systems described for the control of contaminants, veterinary residues, the authorisation of veterinary medicinal products, and the control plan offer guarantees which are at least equivalent to those provided by the Community legislation.

It should be noted that a favourable evaluation is based on the guarantees received on paper. If a subsequent inspection carried out by the FVO, to assess the implementation of residues and veterinary medicines controls, demonstrates that the paper guarantees cannot be relied upon, the status of the third country on the list could be revised.

Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals.

## **Animal Health**

From August 2008 [\*Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals\*](#) will come in place

This directive establishes the need of a recognised CA that should perform their functions and duties in accordance with the general principles laid down for food safety, but in terms of animal health of aquaculture species and management of infectious or contagious aquatic animal diseases in its territory, particularly the notifiable diseases, listed by the World Organisation for Animal Health (OIE).

This directive requires from 3<sup>rd</sup> countries, great capacity of control, including among other obligations, zoning in terms of diseases, registry of establishments, accreditation of laboratories and several requirements but that exceed the scope of this publication, but should not be ignored.

The scope of these requirements applies to: live fish, their eggs and gametes intended for aquaculture in the EU, and for raw materials or products intended for further processing in the EU.

*However, they do not apply aquaculture products intended for retail.*

But is as well important to understand that that responsibility of these requirements, may or may not fall under the scope of the CA for official controls in terms of food safety and trazability.

For further info:

[http://ec.europa.eu/food/animal/liveanimals/aquaculture/index\\_en.htm](http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm)

## **2.4 Official Controls**

Official controls are required under the following statement:

- *“have satisfactorily undergone the official controls laid down in Annex III Regulation (EC) No 854/2004.”*

However, under this last paragraph, we should firstly focus on the official controls done by the CA as per EC 854/2004<sup>11</sup>.

Some of these key requirements (but not the only ones) are that *Official Control* activities carried out:

- On a regular basis and with a frequency based on risk
- Without prior warning (as a general rule)
- At any stage of production, processing and distribution
- To include imports/exports.

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<sup>11</sup> Official controls of production and placing on the market (Chapter I), Official controls of fishery products (Chapter II), Decisions after controls (Chapter III).

Some operational criteria to be satisfied by CA activities are:

- Official controls must be effective
- Adequate laboratory capacity
- Adequate facilities and equipment; continual training of staff
- Legal powers
- Verification procedures
- Documented procedures and transparency
- Internal audits
- Reports

As seen, these are all issues that rely on the performance of the CA.

However, these *Official Control* activities on the production and placing on the market of fishery products are aimed at assessing compliance by the establishments, in particular:

- a. A regular check on the hygiene conditions of landing and first sale;
- b. Inspections at regular intervals of vessels and establishments on land, including fish auctions and wholesale markets, to check, in particular:
  - (i) where appropriate, 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

and
- c. 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<sup>12</sup>.

In terms of **documentation**:

- General description of the company, facilities, products and processes.
- The description of operations followed.
- The documented pre-requisite programmes.
- The HACCP plan (whenever necessary).
- The system to provide guarantees for the product traceability.
- The documented and formalised withdrawal recalls procedures.

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<sup>12</sup> Not exhaustive list.

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

- The general hygiene conditions of building and surroundings.
- The water supply and water quality management system, detailing the internal distribution net, 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 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.

In terms of **characteristics of the products**, the official controls are to include at least the following regulatory elements as described in the EC Directives:

- Random organoleptic checks must be carried out at all stages of production, processing and distribution.
- When the organoleptic examination reveals any doubt as to the freshness of the fishery products, samples may be taken and subjected to laboratory tests to determine the levels of total volatile basic nitrogen (TVB-N) and trimethylamine nitrogen (TMA-N).
- Random testing for histamine is to be carried out to verify compliance with the permitted levels laid down under Community legislation.
- Monitoring arrangements are to be set up to control the levels of residues and contaminants in accordance with Community legislation.
- Where necessary, microbiological checks are to be performed in accordance with the relevant rules and criteria laid down under Community legislation.

- Random testing is to take place to verify compliance with Community legislation on parasites.
- Checks are to take place to ensure that the following fishery products are not placed on the market:
  - Poisonous fish of the following families: *Tetraodontidae*, *Molidae*, *Diodontidae* and *Canthigasteridae*;
  - Fishery products containing biotoxins such as Ciguatera (or ciguatoxin ) or other toxins dangerous to human health<sup>13</sup>.

So, basically, the above is what the Health Certificate implies.

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

## **2.5 The official guarantees and the Health Certificates**

The EU Health Certificates can only be issued for products processed in establishments that are listed on the EU Approved Establishment list<sup>14</sup>. The information published on the EU List must match the information about the exporting establishment, reported on the Health Certificate and the product labels (in terms of product and establishment of origin identification, production dates, batch codes, etc.)

The certification procedures must be well documented, as they are audited by the FVO inspection team in the exporting country and must not be amended without the agreement of the Commission.

The format and content of the Health Certificate are laid down in the EU legislation and must be respected. The model Health Certificate for imports of fishery products intended for human consumption is attached as **Annex IV**.

A single, original, fully completed EU Health Certificate printed in the language of the Border Inspection Post (BIP) of entry into the EU (*regardless of the language of final destination*) must accompany each shipment. The Directives (and hence the model certificates) are published in all languages of the member countries.

The Health Certificate must provide an accurate description of 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.

An Export Health Certificate, once produced and signed by a certification officer, must not be modified with alterations, deletions, additional declarations or endorsements.

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<sup>13</sup> However, fishery products from bivalve mollusks, equinoderms, tunicates, and marine gastropods, can be commercialized if they have been produced in conformity with section VII of annex III , and bullet 2 of chapter V of the same section of Regulation CE no 853/2004.

<sup>14</sup> [https://sanco.ec.europa.eu/traces/output/listsPerCountry\\_en.htm](https://sanco.ec.europa.eu/traces/output/listsPerCountry_en.htm)

Commercial information such as contract numbers and bank arrangements must not be entered on an export certificate.

The date entered must be the actual date of issue of the export certificate and not any other, and cannot be a date after the product has left the country.

Certificates need to be signed and stamped in ink that is of a different colour than the remaining text on the certificate.

### **2.5.1 Which countries will accept this certificate?**

The following countries are presently<sup>15</sup> Member States of the EU: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France (including Guyana, Martinique, Guadeloupe and Réunion), Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain (including Andorra and Canary Islands), Sweden, and the United Kingdom.

While Switzerland, Norway and Iceland are not official EU Member States, they have adopted EU requirements and fish exported to these countries are subject to the same requirements listed below.

Products landed in either Norway or Iceland may proceed to EU Member States without any additional import controls.

### **2.5.2 Border Inspection Posts**

Imports of seafood from non-EU countries must enter the EU via an EC approved BIP under the authority of an official veterinarian. Hence, checks on seafood imported into the Community must be carried out before entering Community territory at a BIP.

There are around 300 authorised BIPs, at ports, airports and land borders.

In order to be authorised, a BIP must meet a number of requirements like staff, facilities, storage premises, cold stores, testing laboratory, which can differ depending on the type of products imported.

There are therefore BIPs specialising in certain animal products or products of animal origin which cannot receive all products.

The Commission gives its approval after the BIP has been inspected and given a positive assessment by the FVO.

At the BIP the consignments are subject to three types of checks:

- *The documentary check:* it is done systematically; it involves checking the export certificate accompanying the seafood consignments.
- *The identity check:* it is also done systematically; it involves checking that the data on the export certificate are consistent with the product, which has been imported.

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<sup>15</sup> As of July 2008

- *The physical check*: it is done as appropriate; it 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 on the basis of the intrinsic risk and results of checks carried out previously on the same product of the same origin, and it can include taking samples for laboratory testing on a random basis or on the basis of past records.

If the consignment is found to be in non-compliance with the EU legislation, for any reason, then the BIP 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).

The BIP initially detains the product, until the CA of the country of origin clarifies the situation.

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

### 2.5.3 Rapid Alert System for Food and Feed

The Rapid Alert System for Food and Feed (RASFF)<sup>16</sup> 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 notifications<sup>17</sup> under the RASFF system.

The notifications can be either *Alerts or Information*:

- *Alert notifications* are sent when the food or feed presenting the risk is already on the market and immediate action is required. For example, from the 934 alerts received during 2006<sup>18</sup>, the majority (62%) related to products originating in the EU, and most of these problems were detected by controls carried out directly on the market. Among the risks most reported through these alerts were the presence of potentially pathogenic micro-organisms, heavy metals (such as mercury in fish) and mycotoxins.
- *Information notifications* are sent when a risk has been identified but immediate action by other Member States is not necessary, as the

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<sup>16</sup> For more information on RASFF: [http://ec.europa.eu/food/food/rapidalert/index\\_en.htm](http://ec.europa.eu/food/food/rapidalert/index_en.htm)

<sup>17</sup> Por ejemplo: [http://ec.europa.eu/food/food/rapidalert/reports/week8-2008\\_en.pdf](http://ec.europa.eu/food/food/rapidalert/reports/week8-2008_en.pdf)

<sup>18</sup> Source: [http://ec.europa.eu/food/food/rapidalert/report2006\\_en.pdf](http://ec.europa.eu/food/food/rapidalert/report2006_en.pdf)

product has not reached their market (e.g. consignments stopped at the BIPs).

When a notification pertains to imported product, then the CA of the country of origin has to make a full investigation and report back to the EU on their results and measures to avoid recurrences.

The EU publishes a yearly Report on RASFF. The Annual Report provides useful data on the number of notifications received during the year, as well as details on the origin of the notifications, the products and countries involved, and the identified risks. It also details the follow-up actions carried out in response to various food safety problems<sup>19</sup>.

## ***2.6 Certification, traceability and eligibility***

A very important criterion not really obvious on the certificate per se, but as a consequence of official controls over the production chain and traceability is the issue of eligibility of products and their raw material.

The nature of the official controls implies that all elements<sup>20</sup> in the production chain need to be approved for purpose by the CA.

This critical issue has important ramifications, as the different stages of production may be under different authorities<sup>21</sup>.

In any case, the various “sub CAs”, and/or the Central CA need to act as one in terms of the offering of official guarantees to the EU. If a country has four different authorities dealing with the fisheries production chain, this cannot be used as an excuse for non-compliance, as mechanisms should be enacted for coordinated official controls.

Good coordination is fundamental in order for certification to be meaningful, as the certification process should be centralised, although the fishery operators and the CA’s inspection activities tend to be geographically fragmented.

Good IT practices are increasing the norm in terms of proving traceability, inspection results and certification of food products.

In particular, the design and maintenance of proper database structures enhancing the information sharing and integration between the CAs can be very important to provide some consistency in the certification process.

Whoever signs the certificate, 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.

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<sup>19</sup> The reports are downloadable from [http://ec.europa.eu/food/food/rapidalert/index\\_en.htm](http://ec.europa.eu/food/food/rapidalert/index_en.htm)

<sup>20</sup> Vessels, landing sites, transporters, cold stores, processors, etc for Fishery Products. Feed producers, hatcheries, farms, transporters, processors, etc for Aquaculture Products.

<sup>21</sup> For example: Vessels, landing sites under the Fisheries authority, aquaculture operations and veterinary medicines under the Agriculture authority, processing sites under the Health authorities.

If the raw materials harvest or any production stages were performed in a non-compliant or non-verified<sup>22</sup> establishment, then 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 a “EU number”, this fact alone, does not guarantee its eligibility to the EU market

## **2.7 Traceability guidelines**

The CA should verify the efficiency of a traceability system adopted by an operator.

The principle is “one step backwards, one step forwards”. From where/who I get product, what I do with it, who I give it to.

To make it possible, the system should be clearly documented and followed. The following are some of the key points to be observed:

- All products entering the establishments should be allocated with a unique batch code.
- Products should be identifiable by a batch code while in the control of the operator.
- Products consigned to another operator should be identifiable by a batch code.

As a minimum, systems of traceability should record the following essential information in relation to each and/every batch.

There should be documented evidence to support these indications:

- Name of supplier
- Date and time of receipt
- Divisions/additions to batch
- Name of consignee
- Date and time of dispatch

### **2.7.1 Separation and Identification of non-EU eligible product**

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

Operators must have procedures and methods in place to distinguish ineligible seafood products from EU-eligible seafood products.

Where any assumed EU-eligible seafood products cannot be distinguished between ineligible seafood products then the former are deemed to be ineligible and must be dealt with accordingly.

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<sup>22</sup> Against EU standards or officially equivalent ones.

### **2.7.2 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, 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.

### **2.8 Foreign flagged vessels landing in your country**

The foreign flagged vessels landing in other countries are a difficult issue for the CAs and the Industry, worldwide.

In principle, foreign flagged vessels should be under the control of the CA of the country of flag.

If the country of origin of the vessel is as well authorized to export to the EU, then the legislation contemplates some options<sup>23</sup>. One of them is a Memorandum of Understanding (MoU) in between the CA for verification of conformity against the same EU requirements

However, this is not the case in many countries, as vessels are flagged in a country with no CA or have been outside the jurisdiction of their country of origin for an extended period of time.

This is the usual scenario on the tuna canning industry, with fleets with great mobility, fleet operations in distant waters and the use of contracted reefer vessels.

In these cases, while not official, some potential strategies could be used to maintain the required level of official controls.



<sup>23</sup> Guidance on this issue is found in the provisions of article 15 of the Corrigendum to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption.

### 2.8.1 Chartered Vessels

When vessels are under long-term charter arrangements with local companies, and incorporated under local law, there are provisions in the Vessels Charter Contracts relating to compliance to regulations, licenses, permission and approvals under the local regulations.

Under this principle, the local CA could incorporate them under their scope for the purposes of approval and official guarantees, however it could not list the vessel as a direct exporter.

### 2.8.2 Independent Vessels

When vessels are not in charter agreement with locally based companies, then the following conditions shall apply:

- i) Fishery products imported from a factory or freezer vessel flying the flag of a third country shall come from vessels that appear on a list drawn up and updated in accordance with the procedure set out in the EU regulations in the country of origin.
- ii) However, if a vessel is not on the list of vessels approved for exports, it may also be eligible if, on the basis of a joint communication from the local CA and the one in the country of which the vessel is flagged, on condition that:
  - The third country appears on the list of third countries from which imports of fisheries products are permitted;
  - All products are unloaded in the receiving country
  - The CA of that third country has inspected the vessel and has declared that it complies with Community requirements;or
  - Under a MoU with the CA of the country of origin, the local CA is delegated to regularly inspect the vessel to ensure that it continues to comply with Community requirements, while operating in local waters.



**Note:**

These requirements have an impact on non-food safety related issues.

For example, a vessel engaged in Illegal, Unreported and Unregulated (IUU) Fishing Activities by its nature, is unlikely to be under the control of any authority, hence its fish would not be eligible for the EU market, curbing in this way the profitability of its activities.

Recently (June 2008) the EU parliament adopted a non-binding report on the proposal for a regulation establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated (IUU) fishing<sup>24</sup>.

This initiative is based on two main principles; the first one is to oblige providing countries to intensify their controls over the fishery, if there is no cooperation product would be received. And the second is to transfer the burden of proof of the legality of the captures to the providing country.

Hence organizations wanting to export to the EU, need to provide official assurances on the legality of the fish.

Under this proposal the new regulation will introduce a certification regime, to guarantee that fishery product from countries that are able to assure that their fish and fishery product have been harvested legally.

### **3 Other requirements**

Other examples of important requirements to consider for gaining or maintaining EU market access follow:<sup>25</sup>

#### **3.1 Labels**

Requirements for labelling are to be based on Council Directive 2000/13/EC on *labelling, presentation and advertising of foodstuffs* to the final consumer.<sup>26</sup>

Its aim is to ensure that the consumer gets all the essential information as regards the composition of the product, the manufacturer, methods of storage and preparation, etc.

The labelling needs to be presented in a language to be understood by the consumers, normally the language of the member country of destiny, but as well it can be in various languages to allow intra EU trade.

All units to be used are to be expressed in accordance with the international metric system.

Some aspects to consider on the labels are:

- The name under which the product is sold.

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<sup>24</sup> See [http://www.europarl.europa.eu/news/expert/infopress\\_page/033-30825-156-06-23-904-20080604IPR30756-04-06-2008-2008-false/default\\_en.htm](http://www.europarl.europa.eu/news/expert/infopress_page/033-30825-156-06-23-904-20080604IPR30756-04-06-2008-2008-false/default_en.htm)

<sup>25</sup> Not exhaustive list.

<sup>26</sup> Reference and updates to be found at [http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/comm\\_legisl\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/comm_legisl_en.htm)

- The net quantity of prepackaged foodstuffs.
- The date of minimum durability consisting of day, month and year in that order and preceded by the words ‘best before’ or ‘best before end’ or the ‘use by’ date for highly perishable goods.
- The name or business name and address of the manufacturer, packer or EU seller.
- Particulars of the place of origin or provenance
- Lot identification.

The processing and/or freezing dates, and the type of enumeration used must be the same as expressed in the certificate.

Once in the EU, Regulation (CE) No 2065/2001<sup>27</sup> requires all information concerning the commercial designation, the production method and the catch area shall be available at each stage of marketing of the species concerned.

This information together with the scientific name of the species concerned shall be provided by means of the labelling or packaging of the product, or by means of a commercial document accompanying the goods, including the invoice.

### **FAO Catch Area**

The producer/exporter needs to provide information over the capture area/areas of the species exported.

One way to inform over the capture area is to express it under the internationally normalized FAO Fishing Areas for Statistical Purposes.<sup>28</sup>

But this information cannot be on the health certificate, and it is a commercial matter as to how the exporter provides the information to the EU operator.

### **3.2 Laboratories to be used for official controls**

For an analytical result to have “official” validity, it must come from a laboratory accredited to ISO/IEC 17025 for those parameters to be analysed<sup>29</sup>.

The standard specifies the general requirements for the competence to carry out tests and/or calibrations, it covers management and technical issues, and the key objective is to assure the accuracy and quality of the results.

The accreditation is what allows the AC to “trust” the impartiality and accuracy of the results, and as a result “approve” the laboratory for its results to be considered “official”. As a consequence the status of “approved” can only be maintained as long as the laboratory holds the accreditation.

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<sup>27</sup> See: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:278:0006:0008:ES:PDF>

<sup>28</sup> See: <http://www.fao.org/fishery/statistics/programme/3.3,4/en>

<sup>29</sup> Regulation (CE) 882/2004 art 12.

These requirements apply equally to government and private laboratories, in fact private sector laboratories are increasingly becoming more used worldwide for regulatory purposes.

The results of independent privately-owned laboratories are acceptable as “official” as long as they are accredited to an internationally traceable standard, normally done by means of requesting accreditation against ISO/IEC 17025 in the parameters to be determined.

If a laboratory has not yet gained accreditation for a specific parameter, the CA will provide an interim approval based on a verifiable accreditation plan with clearly defined time milestones to be followed; however, this approval is only valid until 31/12/2009.<sup>30</sup>

### **3.3 Potable water**

An important topic that often does not get the right attention is the compliance of the water in contact with product and/or personnel.

Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption<sup>31</sup>, defines the characteristics of the water to be used by the food industry and the minimal sampling frequencies based on volumes used.

Is important to note that from the EU perspective, product can only be in contact with potable water and ice made from potable water (or clean sea water for vessels), therefore the addition of chlorine beyond the defined values for potable water becomes a no conformity and makes the affected product not eligible for the EU.



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<sup>30</sup> Ref: Derogation for accreditation (SANCO/2952/2005 rev 4 March 06)

<sup>31</sup> See: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:330:0032:0054:EN:PDF>

## 4 What about the regulations?

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

There is no way to escape reading regulations, but be aware that they change and get updated.

The two graphic representations in **Annex I** resume the key regulatory instruments, their interconnections, and they can be used as a base to understand the systems and to find the required references.

## 5 Conclusions

One of the first lessons I was told when I started to work on fishing boats was that to have good fish you needed to be *“cold, clean, and gentle, and when you can't be cold be fast”*.

Big part of EU requirements for wild caught fish products are a “glorified” version of that same basic principle.

If you can prove as a producer that you have followed those principles as per the requirements, and your CA can verify them and provide the necessary official guarantees requested by the certificate, then you are in a good way into the EU market.

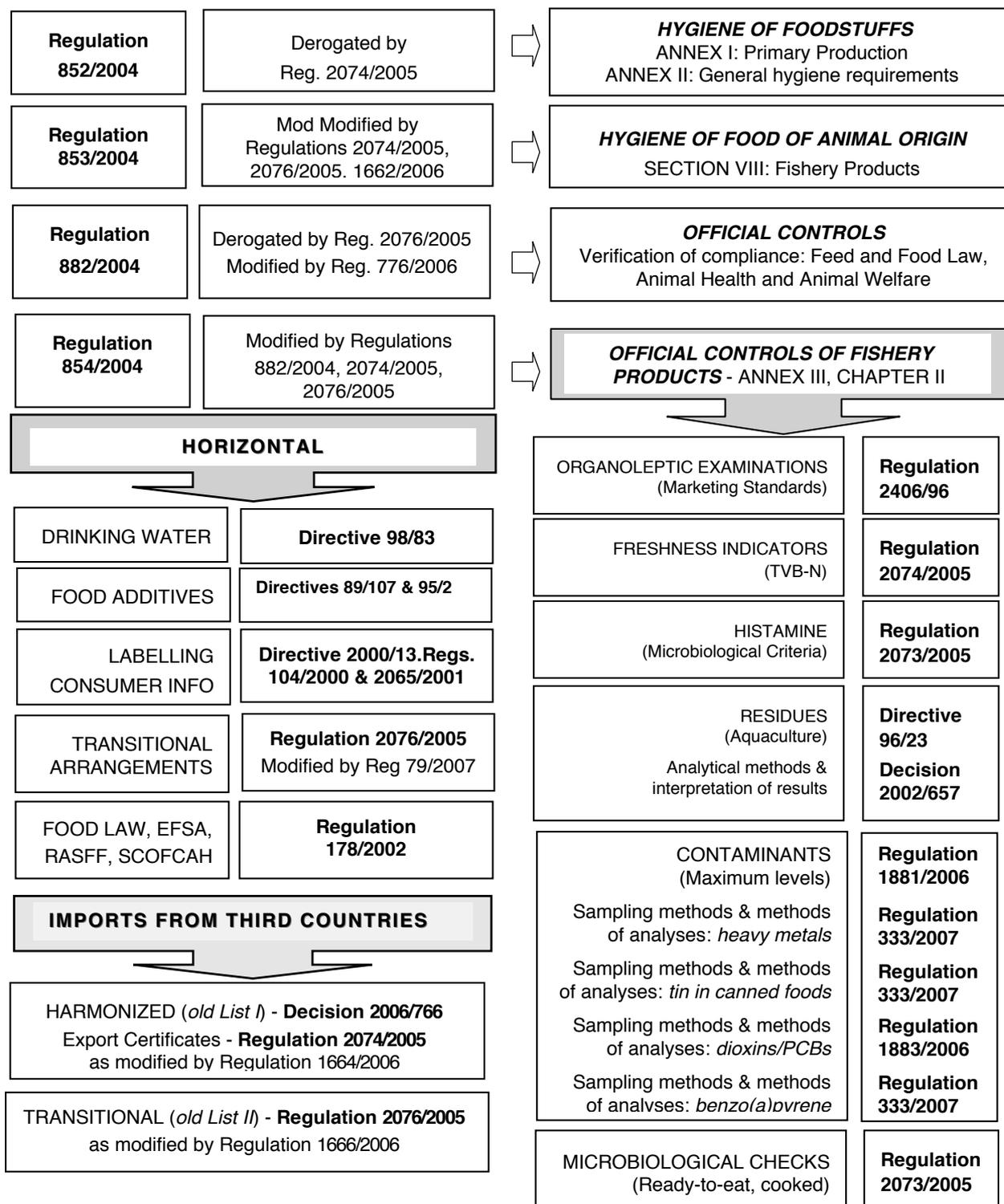
## 6 Acknowledgments.

The author wants to thank the feedback and support of the following people: Ludovica Ghizzoni, Paolo Caricato, Jacky Le-Gosles, Paulo Luciano y Aurora de Blas.



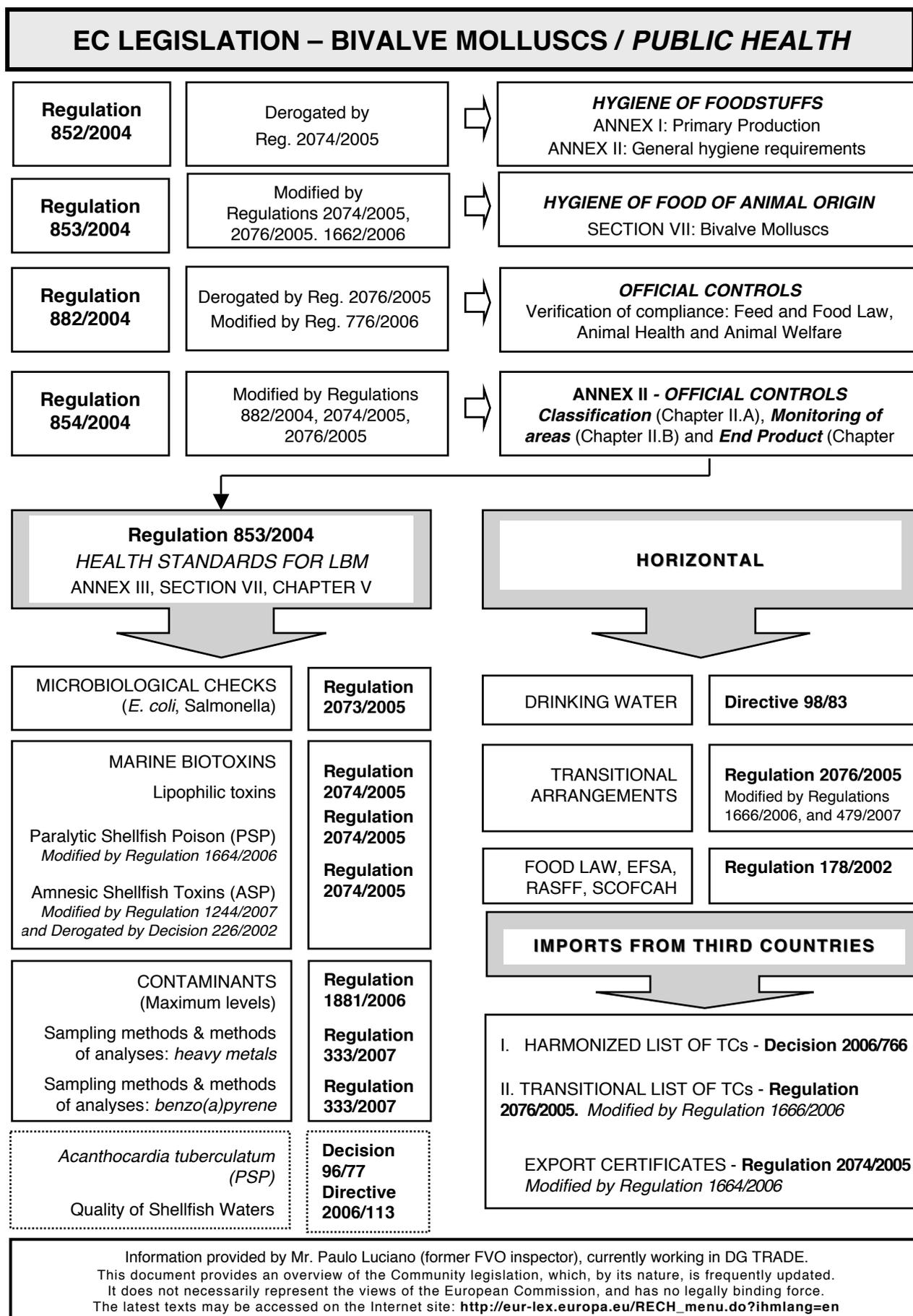
## 7 Annex I – Key regulatory framework

### EC LEGISLATION - FISHERY PRODUCTS / PUBLIC HEALTH



Information provided by Mr. Paulo Luciano (former FVO inspector), currently working in DG TRADE.  
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: [http://eur-lex.europa.eu/RECH\\_menu.do?ihmlang=en](http://eur-lex.europa.eu/RECH_menu.do?ihmlang=en)

## Annex II (cont.)



## 8 Annex I- Formal steps towards approval for imports

The EU has designed a procedure for the evaluation of the eligibility of third countries for exporting fishery products to the EU.<sup>32</sup>

1. The national authority of a third country must submit a formal request to the Directorate-General for Health and Consumer Protection of the European Commission to export fish, fishery products to the EU. The request should contain confirmation that the authority can fulfil all relevant legal provisions to satisfy EU requirements.
2. The Directorate-General for Health and Consumer Protection sends out a questionnaire, which should be completed and returned. Information on relevant legislation, competent authorities, hygiene and many other elements are requested.
3. For aquaculture products, a residue monitoring plan of the exporting country must also be submitted and approved at this stage.
4. After the evaluation of the paper submission, an FVO inspection may be carried out to assess the situation on the spot. Such an inspection is mandatory for high-risk products like shellfish.
5. Based on the results of the evaluation / inspection, and the guarantees given by the exporting country, the Directorate-General for Health and Consumer Protection proposes the listing of the country, the specific conditions under which imports from the country will be authorized and the list of approved establishments in the country. These are then discussed with representatives of all EU Member States.
6. If the Member States have a favourable opinion on the proposal, the European Commission adopts the specific import conditions. Lists of eligible establishments can be amended at the request of the exporting country and are made available for the public on the internet:

[http://ec.europa.eu/food/food/biosafety/establishments/third\\_country/indexen.htm](http://ec.europa.eu/food/food/biosafety/establishments/third_country/indexen.htm)

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<sup>32</sup> Extracted from the bulletin entitled: "EU import conditions for seafood and other fishery products", Health & Consumer Protection Directorate-General available at [http://ec.europa.eu/food/international/trade/im\\_cond\\_fish\\_en.pdf](http://ec.europa.eu/food/international/trade/im_cond_fish_en.pdf).

## 9 Annex III - Useful web-sites

As a first step, companies wishing to export seafood or other fishery products to the EU should contact the relevant national authorities in their country to become authorised.

In any case these are some of the most useful web sites available:

### From the EU:

*The Food Safety web-site of DG Health & Consumer Protection:*

[http://ec.europa.eu/food/index\\_en.htm](http://ec.europa.eu/food/index_en.htm)

*Detailed information on import conditions for animals and animal products:*

[http://ec.europa.eu/food/animal/animalproducts/index\\_en.htm](http://ec.europa.eu/food/animal/animalproducts/index_en.htm)

*Expanding Exports – online helpdesk managed by DG Trade:*

[http://ec.europa.eu/trade/issues/global/development/thd\\_en.htm](http://ec.europa.eu/trade/issues/global/development/thd_en.htm)

*Food and Veterinary Office (FVO) and inspection reports:*

[http://ec.europa.eu/food/fvo/index\\_en.htm](http://ec.europa.eu/food/fvo/index_en.htm)

*Legislation search engine:* [http://eur-](http://eur-lex.europa.eu/RECH_menu.do?ihmlang=en)

[lex.europa.eu/RECH\\_menu.do?ihmlang=en](http://eur-lex.europa.eu/RECH_menu.do?ihmlang=en)

*Third Country Establishments' Lists:*

[https://sanco.ec.europa.eu/traces/output/listsPerCountry\\_en.htm](https://sanco.ec.europa.eu/traces/output/listsPerCountry_en.htm)

*Residues of Veterinary Medicinal Products - Third Countries:*

[http://ec.europa.eu/food/food/chemicalsafety/residues/third\\_countries\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/residues/third_countries_en.htm)

*Official controls on products of animal origin intended for human consumption:*

<http://europa.eu/scadplus/leg/en/lvb/f84003.htm>

*Food Labelling - Community Legislation:*

[http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/comm\\_legisl\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/comm_legisl_en.htm)

*EU Exporter HelpDesk:*

<http://exporthelp.europa.eu/>

### Others:

*Strengthening Fishery Products Health Conditions in ACP/OCT Countries:*

<http://www.sfp-acp.eu/EN/index.htm>

*EU Food Law News:* <http://www.rdg.ac.uk/foodlaw/index.htm>

*INFOFISH:* <http://www.infofish.org/>

## **10Annex IV – Model Health Certificate**

Model Health Certificate for Imports of Fishery Products intended for Human Consumption

Appendix IV to Annex VI, Commission Regulation (EC) No 1664/2006 amending Regulation (EC) No 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and repealing certain implementing measures.

([http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l\\_320/l\\_32020061118en00130045.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_320/l_32020061118en00130045.pdf))

## 11 Annex V - Trade-Related Technical Assistance (TRTA)

The following information gives some examples of TRTA provided in the seafood sector by ITC and the EC. The information is an illustrative one and it is far from being exhaustive as several other technical cooperation agencies and organisations provide TRTA in the fishery sector.

### A. International Trade Centre (ITC)

ITC provides technical assistance to three target groups: (i) to enterprises to strengthen their international competitiveness; (ii) to trade-support institutions to develop capacity to provide a more comprehensive service to their clients; (iii) to policymakers, *inter alia*, to support the integration of the business sector into the global economy.

There are various areas in which ITC intervenes to achieve its objectives. As far as the export of seafood is concerned, ITC provides assistance to developing countries to meet the requirements related to food safety and hygiene in export markets. For example:

- Asia Trust Fund<sup>33</sup> (ATF) projects:
  - Philippines: “Upgrading BFAR<sup>34</sup>’s Capability in Fish Inspection Services”
  - Indonesia: “Improving the inspection capabilities and status of vessels and establishments in the Indonesian fishery sector”
  - Malaysia: “Upgrading the capability of the Competent Authorities’ and fish facilities in Malaysia of meeting EU fishery requirements”

ITC has recently completed the implementation of three above-mentioned ATF projects in the Philippines, Indonesia and Malaysia. The one-year duration projects helped the countries address some of the urgent deficiencies along the fishery supply chain highlighted by the latest European Commission FVO missions regarding fish exports to the EU.

The projects’ reports are available at the ATF website.

- Standards and Trade Development Facility<sup>35</sup> (STDF) 69 project:

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<sup>33</sup> The Asia Trust Fund (ATF), co-financed by the European Commission (EC) and the International Trade Centre (ITC) and managed by ITC, has been a channel to provide quick delivery of short-term Trade-Related Technical Assistance, in response to an immediate need identified by a national government or regional organization. The ATF programme reached its end in December 2007 (for more information on ATF visit: <http://www.intracen.org/atf>).

<sup>34</sup> BFAR - Bureau of Fisheries and Aquatic Resources in the Philippines.

<sup>35</sup> The Standards and Trade Development Facility (STDF) is a global programme in capacity building and technical co-operation established by the Food and Agriculture Organization of the

“Improved capacity for ensuring the quality and safety of Yemeni seafood products”

In February 2007 ITC was granted observer status for STDF.

ITC is currently providing supervisory services to a STDF project in the fisheries sector in Yemen. The overall objective of the project is to enable the Yemeni Seafood Exporters Association (YSEA) to develop the capacity of its members to better meet SPS requirements and thereby improve the quality and safety of seafood products emerging from Yemen. The two-year project started in September 2007. YSEA is directly implementing the project.

## **B. European Commission (EC)**

The EC provides technical assistance and facilities for institutional capacity building to help developing countries comply with EU rules. For example, DG SANCO’s “Better Training for Safer Food” initiative runs training for official control staff of developing countries on EU standards for fishery and aquaculture products.

Furthermore, national and regional development programmes of the EU are available in individual countries and regions, as well as bilateral aid projects of the Member States. The EU delegations can provide detailed information on these programmes<sup>36</sup>.

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United Nations (FAO), the World Organization for Animal Health (OIE), the World Bank, the World Health Organization (WHO) and the World Trade Organization (WTO). The STDF acts both as a co-ordinating and a financing mechanism (for more information on STDF and the related funding opportunities, visit: <http://www.standardsfacility.org>).

<sup>36</sup> For more details on EC technical assistance programmes, see [http://ec.europa.eu/food/training/index\\_en.htm](http://ec.europa.eu/food/training/index_en.htm) and [http://ec.europa.eu/external\\_relations/delegations/intro/web.htm](http://ec.europa.eu/external_relations/delegations/intro/web.htm)

Appendix IV to Annex VI

MODEL HEALTH CERTIFICATE FOR IMPORTS OF FISHERY PRODUCTS INTENDED FOR HUMAN CONSUMPTION

COUNTRY

Veterinary certificate to EU

<b>Part I: Details of dispatched consignment</b>	I.1. Consignor Name  Address Postal code Tel No.		I.2. Certificate reference number		I.2.a.	
			I.3. Central Competent Authority			
			I.4. Local Competent Authority			
	I.5. Consignee Name  Address Postal code Tel No.		I.6.			
	I.7. Country of origin		ISO code	I.8. Region of origin		Code
				I.9. Country of destination		ISO code
				I.10.		
	I.11. Place of origin  Name Address		Approval number		I.12.	
	I.13. Place of loading		I.14. Date of departure			
	I.15. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification: Documentary references:		I.16. Entry BIP in EU		I.17.	
I.18. Description of commodity				I.19. Commodity code (HS code)		
				I.20. Quantity		
I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				I.22. Number of packages		
I.23. Identification of container/Seal number				I.24. Type of packaging		
I.25. Commodities certified for Human consumption <input type="checkbox"/>						
I.26.			I.27. For import or admission into EU <input type="checkbox"/>			
I.28. Identification of the commodities  Species (Scientific name)      Nature of commodity      Treatment type      Approval number of establishments      Manufacturing plant      Number of packages      Net weight						

## COUNTRY

## Fishery products

<b>Part II: Certification</b>	<b>II.</b>	<b>Health attestation</b>	<b>II.a.</b> Certificate reference number	<b>II.b.</b>
	<b>II.1.</b>	<p><b>Public health attestation</b></p> <p>I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and certify that the fishery products described above were produced in accordance with those requirements, in particular that they:</p> <ul style="list-style-type: none"> <li>— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,</li> <li>— 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,</li> <li>— 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 Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs,</li> <li>— have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VIII of Annex III to Regulation (EC) No 853/2004,</li> <li>— have been marked in accordance with Section I of Annex II to Regulation (EC) No 853/2004</li> <li>— the guarantees covering live animals and products thereof, if from aquaculture origin, provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled</li> </ul> <p style="text-align: center;">and</p> <ul style="list-style-type: none"> <li>— have satisfactorily undergone the official controls laid down in Annex III to Regulation (EC) No 854/2004.</li> </ul>		
	<b>II.2.</b>	<p><b>(<sup>1</sup>) [Animal health attestation for products of aquaculture origin</b></p> <p>I, the undersigned, declare that the fishery products described above originate from fish or crustaceans that were clinically healthy on the day of harvest, and have been transported under conditions that do not alter the animal health status of the products and certify, in particular that:</p> <ul style="list-style-type: none"> <li>— (<sup>1</sup>)(<sup>2</sup>) if from species susceptible (<sup>3</sup>) to ISA and/or EHN, they: <ul style="list-style-type: none"> <li>— (<sup>1</sup>) [originate from a source (<sup>4</sup>) considered free from ISA and/or EHN in accordance with the relevant EU legislation or OIE Standard (<sup>5</sup>)],</li> <li>— (<sup>1</sup>) [have been slaughtered and eviscerated]].</li> </ul> </li> <li>— (<sup>1</sup>)(<sup>6</sup>) if from species susceptible (<sup>3</sup>) to VHS and/or IHN, they: <ul style="list-style-type: none"> <li>— (<sup>1</sup>) originate from a source (<sup>4</sup>) considered free from (<sup>1</sup>) VHS/(<sup>1</sup>) IHN in accordance with the relevant EU legislation or OIE Standard (<sup>5</sup>)],</li> <li>— (<sup>1</sup>) [have been slaughtered and eviscerated]]].</li> </ul> </li> </ul>		

**Notes****Part I:**

- Box reference I.8: Region of origin: For products of aquaculture origin and if appropriate, indicate zones as listed in Commission Decisions 2002/308/EC and 2003/634/EC. For frozen or processed bivalve molluscs, indicate the production area.
- Box reference I.11: Place of origin: name and address of the dispatch establishment.
- Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in the event of unloading and reloading.
- Box reference I.19: Use the appropriate HS codes: 03.01, 03.02, 03.03, 03.04, 03.05, 03.06, 03.07, 05.11.91, 15.04, 15.18.00, 16.03, 16.04, 16.05.
- Box reference I.23: Identification of container/seal number: only where applicable.
- Box reference I.28: Nature of commodity: specify if aquaculture or wild origin.  
Treatment type: live, chilled, frozen, processed.  
Manufacturing plant: includes factory vessel, freezer vessel, cold store, processing plant.

**Part II:**

- Part II.2 is not relevant for consignments intended for retail, provided they comply with the rules applying to packaging and labelling laid down in Regulation (EC) No 853/2004.
- (<sup>1</sup>) Delete as appropriate.
- (<sup>2</sup>) This part of the animal health certificate is only relevant if the consignment comprises species referred to as susceptible to ISA and/or EHN. The requirement applies to exports to all Member States, whereby one of the two statements should be retained, unless the consignment is intended for further processing in an approved import centre.
- (<sup>3</sup>) Known susceptible species
 

<b>Disease</b>	<b>Susceptible host species</b>
EHN	Redfin perch ( <i>Perca fluviatilis</i> ), rainbow trout ( <i>Oncorhynchus mykiss</i> )
ISA	Atlantic salmon ( <i>Salmo salar</i> ), rainbow trout ( <i>Oncorhynchus mykiss</i> ), brown trout ( <i>Salmo trutta</i> ),
VHS	Atlantic cod ( <i>Gadus morhua</i> ), Atlantic herring ( <i>Clupea harengus</i> ), brown trout ( <i>Salmo trutta</i> ), chinook salmon ( <i>Oncorhynchus tshawytscha</i> ), coho salmon ( <i>O. kisutch</i> ), grayling ( <i>Thymallus thymallus</i> ), haddock ( <i>Melanogrammus aeglefinus</i> ), Pacific cod ( <i>Gadus macrocephalus</i> ), Pacific herring ( <i>Clupea harengus pallasii</i> ), pike ( <i>Esox lucius</i> ), rainbow trout ( <i>Oncorhynchus mykiss</i> ), rockling ( <i>Rhinonemus cimbricus</i> ), sprat ( <i>Sprattus sprattus</i> ), turbot ( <i>Scophthalmus maximus</i> ), whitefish ( <i>Coregonus</i> sp.)
IHN	Rainbow or steelhead trout ( <i>Oncorhynchus mykiss</i> ), the Pacific salmon species (chinook salmon ( <i>O. tshawytscha</i> ), sockeye salmon ( <i>O. nerka</i> ), chum salmon ( <i>O. keta</i> ), masou salmon ( <i>O. masou</i> ), pink salmon ( <i>O. rhodurus</i> ) and coho salmon ( <i>O. kisutch</i> )), and Atlantic salmon ( <i>Salmo salar</i> ).
- (<sup>4</sup>) Source may be a country, zone, or an individual farm.
- (<sup>5</sup>) Freedom according to the provisions laid down in Annex B or C to Directive 91/67/EEC, and Commission Decisions 2001/183/EEC and 2003/466/EC. Freedom according to the most current edition of the OIE Code and Manual is also recognised.
- (<sup>6</sup>) This part of the animal health certificate is only relevant if the consignment comprises species referred to as susceptible to VHS and/or IHN. In order for the consignment to be authorised into a Member State or part thereof (boxes I.9 and I.10 of Part I of the certificate) declared free from VHS, and/or IHN, or undergoing a programme for such freedom, one of the two statements must be retained, unless the consignment is intended for further processing in an approved import centre.  
  
A list of such Member States and zones are listed in Commission Decisions 2002/308/EC and 2003/634/EC.
- The colour of the stamp and signature must be different from that of the most particulars in the certificate.

**Official inspector**

Name (in capitals):  
Date:  
Stamp:

Qualification and title:  
Signature: