



Imports of fishery products into the EC: sanitary approval for third countries

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Introduction

European Community (EC) legislation and, in particular, its Council Directives 91/493/EEC and 91/492/EEC on fishery products and live shellfish respectively, clearly lay down the required sanitary conditions and procedures to be followed by both Third countries and EC Member states, in order to put their products on the EC market. **These conditions aim at protecting the health of European consumers.**

It is important to recall that the EC legislation is, in fact, inspired in the *Codex Alimentarius* Codes of Practice for Fish and Fishery Products. In practical terms, this means that the EC, as a member of the World Trade Organisation (WTO) and signatory of the Agreement on the Application of Sanitary and Phytosanitary Measures, accepts any Third Country's legislation based on the Codex. This EC legislation is currently being up-dated and simplified by the legislation services of the European Commission.

But, how is a Third Country allowed to export its fishery products to the European market? What is expected from it? How does the authorisation procedure operate in practice?

List of Countries: Third Countries must be on the EC lists of authorised importing countries

All Third Countries intending to export fishery products to the EC must be authorised by the European Commission and be included on any of the two Lists of Commission Decision

97/296/EC. Only countries appearing in any of these lists are permitted to export their fishery products to the EC. As of autumn 1999, there are 45 countries on List I and 56 on List II. The same system operates for shellfish (Commission Decision 97/20/EC), however, tighter restrictions are imposed, given the higher risks of these products (7 countries on list I and 6 on list II).

List I: Countries are included on List I on a definitive basis, after a compulsory on-the-spot evaluation of the country's system of control of fishery products by the European Commission services. When the result of this evaluation is found to be satisfactory, the procedure of inclusion is launched (see point 7).

If the required sanitary conditions are not maintained and pose a threat to public health, the country is withdrawn from the list until the conditions are restored. Nevertheless, when the problem concerns a certain establishment or consignment, the competent authority of the Third Country can avoid this withdrawal of the whole country from the list, by taking immediate action to control the problem. Such a rapid reaction (e.g: temporary suspension of the establishment's authorisation), is perceived positively by the EC and helps to re-establish its confidence in the Third Country.

List II: This is a "temporary list" that will expire on the 31st December 2000. The countries on this list have provisional authorisation to export their products solely to those EC Member states, which accept their products. Listed here are two kinds of Third Countries, those previously subjected to an on-the-spot evaluation and not found to be in full compliance, and those still awaiting an EC inspection visit, but considered acceptable after an analysis of their legislation and the written information on the country's sanitary system of control of fishery products (documentary evaluation).

The aim of the EC services is to finalise the full evaluation of such countries before the expiry of the deadline. Then, after January 2001, only countries on list I will be allowed to export to

the EC and the remaining countries will be forced to cease exporting until they comply with all necessary requirements for inclusion on the list.

Evaluation/audit of the sanitary system of control of fishery products/shellfish by the European Commission services

Any country intending to put its fishery products on the European market must formally request to the European Commission for its inclusion on the list of authorised countries to export to the EC. This request must be addressed specifically to the Food and Veterinary Office (FVO) of the Health and Consumer Protection Directorate-General, as the responsible authority. The headquarters of the FVO are in Dublin (see below). The normal procedure is the submission of a formal letter by the competent authority for fishery products of the Third Country to the Director of the FVO.

Then, the competent unit for fishery products in the FVO starts working on the dossier and the responsible FVO auditors contact the country's authorities to initiate a dialogue. Complete written information on the country's sanitary system of control of fishery products and/or shellfish will be requested and bilateral meetings will be held whenever possible. The aim of this phase is the collection of high quality data and information in order to adequately plan the subsequent evaluation/audit mission of the FVO team to the country.

The dynamics of an "on-the-spot evaluation mission" by the FVO always follow a pattern

This kind of mission normally takes one week for an 'average' country. Several issues will be addressed under the scrutiny of the FVO team:

- the performance of the competent authority;
- the comparison of the Third Country legislation with EC legislation;

- sanitary conditions in the production of fishery products/live shellfish;
- hygienic conditions in the production areas (e.g. fish-farms);
- hygienic conditions in the establishments handling these products; and
- controls, such as physical inspection, inspection of HACCP (Hazard Analysis and Critical Control Points) systems or laboratory checks, carried out by the competent authority.

In practical terms, the above are carried out through meetings with the national competent authority and other related authorities, documentary inspection, on-the-spot inspection of processing plants, cold stores, freezer vessels, factory vessels, production areas and laboratories.

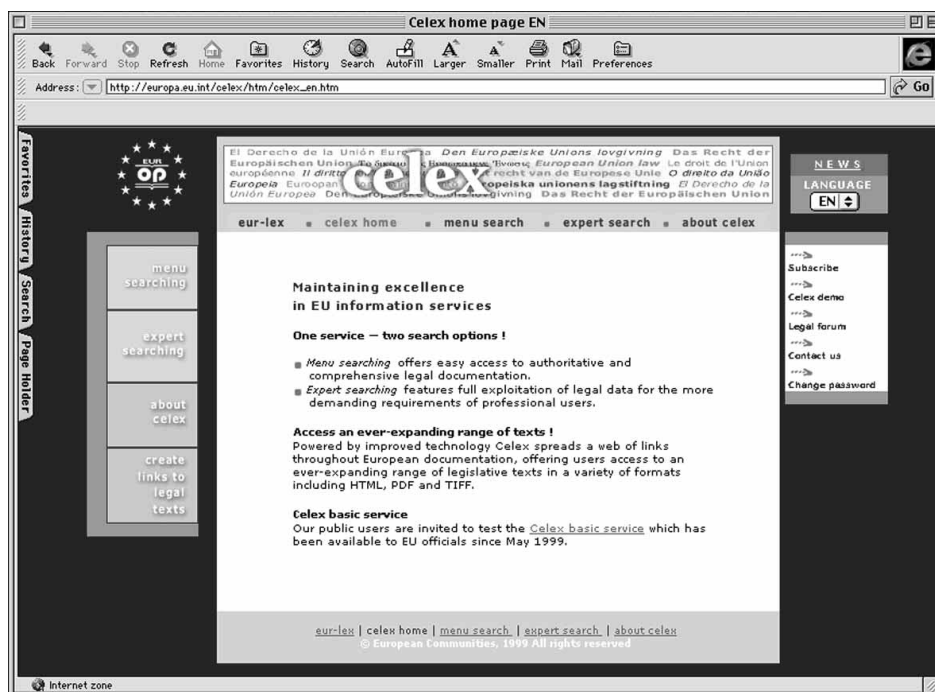
Before the FVO team leaves the country, the competent authority receives a preliminary briefing of the evaluation and its conclusions in a final meeting. This final meeting is one of the key points of the mission, because it provides an opportunity for some clarification in cases of doubt and also offers the competent authority a chance to give preliminary guarantees of compliance. Deadlines for submitting further information or guarantees after the mission are also jointly set in this meeting.

It is important to point out that, after authorisation, verification of the maintenance of the sanitary conditions by the Third Country is carried out by further on-the-spot inspection missions by the FVO.

The aim of the EC evaluation is to ascertain that the competent authority of the exporting country is reliable

A mutually satisfactory outcome of an evaluation mission depends on several factors, but the most important is good collaboration between the FVO team and the competent authority of the country. The transparency of the national system in place is an important factor for establishing such collaboration. An accurate and realistic result can only be achieved through a thorough and effective evaluation. Since systems of control are constantly evolving, what today represents non-conformity, may tomorrow be easily solved, if detected in time. One of the tasks of the auditors is to achieve sufficient guarantees of compliance after their evaluation. These guarantees can only be accepted when the competent authority is shown to be responsible, reliable and committed to improvement.

In any case, if the FVO mission has ascertained full compliance with sanitary standards, it will be recommend up-grading of the exporting country to list I. If major risks to human health exist, however, the EC takes immediate protec-



CELEX: http://europa.eu.int/celex/htm/celex_en.htm

tive measures, which could lead to a ban of imports of fishery products from the country in question.

The post-mission period still offers opportunities

After the FVO mission, and provided no major risks to human health have been detected, there are two possible options open in relation to a country on list II that still has not achieved full compliance: depending on the situation, the FVO may decide either

- to accept the guarantees and wait until improvements have been made and communicated, or
- to re-visit the country.

Draft report: When the FVO auditors return from the mission, they draft their report, which also includes their conclusions and recommendations both for the Third Country and other Commission services. This draft report is sent to the competent authority of the country concerned thus giving it the opportunity to comment on the report. This is done with the aim of detecting possible errors or differences in position of both authorities. This period can also be used to receive further information on the improvements made after the mission, or further guarantees.

Final Report and information to the EC Member States: Upon receipt of the comments of the competent authority, they are included in or attached to the report and the final report is produced. This final report is presented to the 15 Member States meeting at the Standing Veterinary Committee (SVC) for their informa-

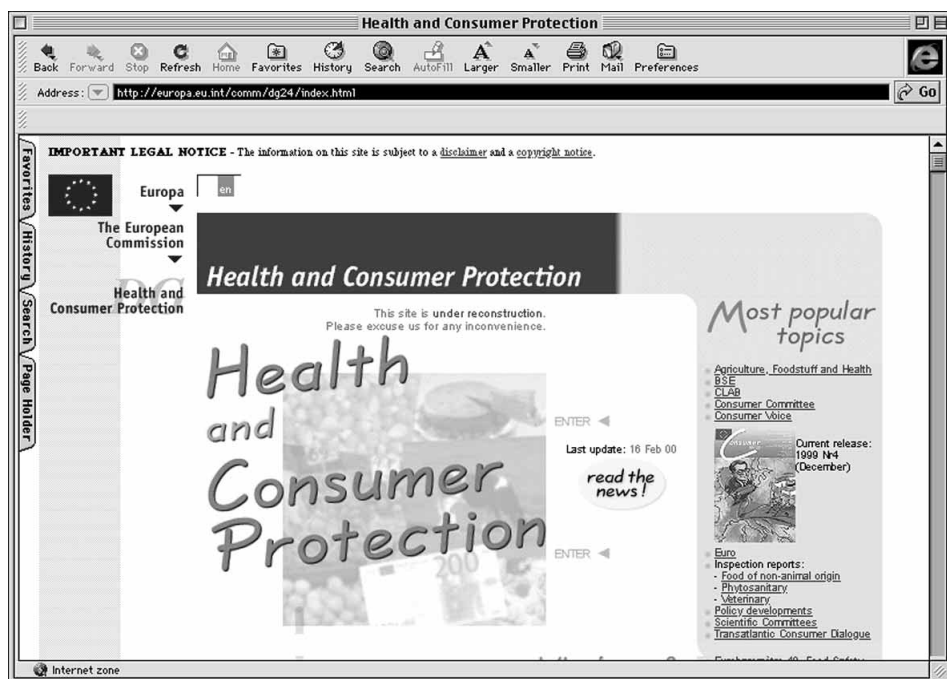
tion. At the conclusion of this process, the final report, together with the comments of the competent authority, is published on the Internet to assure the transparency of the system. Any later improvements to the system of control of fishery products after the publication of the report are not published. This implies that the Internet report only gives an instant picture of the country's situation at the time of and immediately after the visit.

A country is only listed after a Specific Commission Decision (its specific approval)

Commission Decision: The FVO cannot take official decisions. It is only the 15 Member states in the SVC who, based on a proposal from the Commission services (including the FVO), can decide in the first instance. These decisions must be finally adopted by the Commission and published in the Official Journal of the EC. When the outcome of the evaluation is considered satisfactory, a specific European Commission Decision is produced for the country, allowing it to export to all EC Member States. No further bilateral negotiations are required. The country is automatically included in the List of Countries (list I).

Standard content of this Decision: The Decision always covers the following issues, namely:

- Which Competent Authority for fishery products in the Third Country is recognised by the EC (only one authority is accepted);
- What is the Sanitary Mark that all products coming from the said country must bear



Website for Consolidated Texts: http://europa.eu.int/celex/consleg/home_en.htm

(ISO code of the country and approval number of the establishment of origin);

- The model Certificate of Import into the EC that must accompany all the consignments;
- The List of Establishments approved for export to the EC by the national competent authority.

The List of Establishments, another list

As mentioned above, one of the main reasons for establishing a specific Commission Decision for a Third Country is to identify the list of establishments approved for export to the EC by the competent authority. This list is unique and only the listed establishments are permitted to export to the EC. To be included, the establishment must make the request to the competent authority of the country in which the establishment operates. The responsible officials inspect the establishment and audit its HACCP system, to verify that the sanitary conditions are met and to give an approval number to the establishment in question.

It is important to clarify that the meaning of "establishment" in EC terminology includes processing plants, cold stores, factory vessels and freezer vessels. Therefore, all of these intending to export to the EC should be included on the list.

After the EC evaluation, and once the competent authority is recognised, the EC services accept the list proposed by the Third Country. Once published in the Commission Decision, this list becomes official in all EC Member States. Every establishment must be identified by an official approval number. The fishery

products of other establishments not included on the list are not allowed into the EC.

One of the characteristics of this list is that it can be subject to modification. Any modification must be notified to the EC services (see below) in Brussels. When an establishment fails to maintain the sanitary conditions the competent authority must remove it, either temporarily or permanently, from the list. There is also a provision for the addition of new establishments.

Conclusion

In conclusion one could say that, basically, a Third Country should

- be in a position to apply legislation that is at least equivalent to the EC legislation;
- have a competent authority organised in such a way that it can guarantee the effective implementation of the relevant legislation through inspection and control of all parts of the chain of production of fishery products;
- have sanitary practices and controls in the field of fishery products, which demonstrate the effective implementation of the sanitary standards in terms of safety of the products for the consumers.

Penetrating the EC market is a big achievement for a Third Country, but we must not forget that, apart from the economic benefit that exports give, there is a much more important associated benefit: the protection of consumer's health.

The joint effort of the authorities of Third Countries and its industry to improve their

sanitary systems of control of fishery products under external pressure, provides them with new tools and know-how, such as the use of HACCP techniques. Thus, their own systems are effectively improved and the industry becomes more competitive and better equipped to offer safe and higher quality products to the external world.

Finally, an additional advantage of improving systems of control and sanitary conditions in order to obtain an export authorisation, can be seen in the Third Country itself. It may have a direct or indirect impact on the health of its own consumers. Third Countries can use the effort to knowledge and skill improvements, organisation and control that authorisation for exports require, to improve their own country's sanitary situation. Sometimes it is not only a question of financial resources but of effective use of knowledge, human resources and improved work organisation.

Summary of key information

1. Website addresses for the Regulations are of three types: 'EUR-Lex' contains all legal texts in the format of the Official Journal starting in 1998; 'EUDOR' provides all legal texts in the format of the Official Journal between at least 1981 and end 1997; 'CELEX' provides all main texts with all amendments, which have been made over time, but will not show the annexes of the main texts:

- EUR-Lex:
<http://europa.eu.int/eur-lex/en/index.html>
- EUDOR:
<http://www.eudor.com:8444/EUDOR/PROC/orientation?LANGUAGE=english>
- CELEX:
http://europa.eu.int/celex/htm/celex_en.htm
- Website for Consolidated Texts:
http://europa.eu.int/celex/consleg/home_en.htm

2. Website address for the publications of inspection reports:
<http://europa.eu.int/comm/dg24/index.html>
3. Address of the Food and Veterinary Office (FVO): Belfield Office Park, Beech Hill Road, Dublin 4, Ireland
4. Address for notification of changes on the list of authorised establishments: The Director, Directorate D of Health and Consumer Protection Directorate-General, European Commission, 200 rue de la Loi, B-1049 Brussels, Belgium. ■