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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

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FINAL REPORT OF A MISSION

CARRIED OUT IN

CHILE

FROM 26 APRIL TO 06 MAY 2010

IN ORDER TO EVALUATE THE CONTROL SYSTEMS IN PLACE GOVERNING THE PRODUCTION OF FISHERY PRODUCTS AND LIVE BIVALVE MOLLUSCS INTENDED FOR EXPORT TO THE EUROPEAN UNION

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of a mission in Chile carried out by the Food and Veterinary Office from 26 April to 6 May 2010, as part of its programme of inspections in Member States and third countries.

The objective of the mission was to evaluate the public health conditions for the production of fishery products and live bivalve molluscs intended for export to the European Union. The mission scope covered the relevant European Union legislation for the public health sector.

The report concludes that the current organization of the Chilean Competent Authority and the control system implemented by the Competent Authority offer appropriate guarantees concerning the sanitary conditions of bivalve molluscs and fishery products for European Union export. However, to fully ensure that all exports to the EU of bivalve molluscs respect the requirements defined in Regulation (EC) No 2074/2005, as last amended, some improvements should be made, in particular concerning the classification and monitoring of productions areas including the official laboratory analysis methods used.

The Competent Authority has adequately addressed all recommendations of the previous mission report.

The report addresses to the Chilean Competent Authority a number of recommendations aimed at rectifying identified shortcomings and enhancing the control system in place.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
ASP	Amnesic Shellfish Poisoning
BM	Bivalve Molluscs
CA	Competent authority
CCA	Central competent authority
Cd	Cadmium
CS	Cold store/s
EC	European Community
EU	European Union
EU listed	Facilities approved and listed by the competent authority for participation in the EU FP export chain
FBO/s	Food business operator/s
FHD	Fish Health Department
FP	Fishery products
FV	Factory vessel
FVO	Food and Veterinary Office of the European Commission
HACCP	Hazard Analysis Critical Control Points
Hg	Mercury
INN	National Normalisation Institute (*Instituto Nacional de Normalizacion*)
ISO	International Organisation for Standardisation
ISP	Public Health Institute (*Instituto de Salud Publica*)
LBM	Live Bivalve Molluscs
MT	Mission team
NRL	National Reference Laboratory
OJ	Official Journal of the European Communities
PAC	Quality Assurance Programme (*Programa de Aseguramiento de Calidad*)

Pb	Lead
PP	Processing plant
PSP	Paralytic Shellfish Poisoning
RASFF	Rapid Alert System for Food and Feed
RET	Transport document
RFB/s	Regional Fishing Bureau/s
SANCO	Health and Consumers Directorate General of the European Commission
SERNAPESCA	National Fishing Service (*Servicio Nacional de Pesca*)
SMB	Shellfish Sanitation Programme
TC/s	Third country/ies

1 Introduction

The mission took place in Chile from 26 April to 6 May 2010 and was undertaken as part of the Food and Veterinary Office's (FVO) mission programme.

The mission team (MT) comprised two inspectors from the FVO and two experts from EU member states.

2 Objectives Of The Mission

The objectives of the mission were:

- to evaluate whether the official controls put in place by the competent authority (CA) can guarantee that the conditions of production of fishery products (FP) and live bivalve molluscs (LBM) in Chile destined for export to the European Union (EU) are in line with the requirements laid down in EU legislation, and in particular with the health attestations contained in the certificates of Appendix IV and Appendix V to Annex VI to Commission Regulation (EC) No 2074/2005;
- to verify the extent to which the guarantees and the corrective actions submitted to the Commission services in response to the recommendations of the previous FVO mission report of 2005 have been implemented and enforced by the CA.

In pursuit of these objectives, the MT proceeded as follows:

- an opening meeting was held on 26 April 2010 with the CA. At this meeting the MT confirmed the objectives of, and itinerary for the mission, and requested additional information required for the satisfactory completion of the mission;
- the following sites were visited:

Competent authority		
Central level	1	
District level	4	
Local level	1	
Laboratory visits		
Official control	5	
Primary production		
Aquaculture farms	1	
Fishing, carrier vessels	4	
Landing and first sale		
Landing sites	2	
Facilities handling FP		
Processing establishments	11	
LBM production areas		
Production areas	2	

- representatives from the CA accompanied the MT during the whole mission.

3 Legal Basis for the Mission

The mission has be carried out in agreement with the Chilean Authorities and under the general provisions of the Agreement on Sanitary and Phytosanitary measures (and in particular its Article 10) applicable to trade in animals and animal products, plants, plant products and other goods and

animal welfare - hereafter Agreement - (Annex IV of the Association Agreement between the European Community and its Member States of the one part and the Republic of Chile of the other part). The Association Agreement was approved by the Community with Council Decision 2005/269/EC[1] in February 2005.

In addition, general provisions of EU legislation were taken into account, in particular:

- Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;
- Appendix VII to the Agreement (Guidelines for conducting verifications).

Full legal references are provided in Annex I. Legal acts quoted in this report refer, where applicable, to the last amended version.

4 BACKGROUND

4.1 HISTORICAL BACKGROUND

Chile is presently listed in Annex I of Commission Decision 2006/766/EC establishing the list of third countries (TC) from which imports of live, frozen or processed bivalve molluscs (BM), echinoderms, tunicates and marine gastropods for human consumption are permitted and in Annex II of the same Decision establishing the list of TC and territories from which imports of FP in any form for human consumption are permitted. As regard to BM, Chile is only permitted to export to the EU frozen or processed BM.

Chile has applied to export chilled eviscerated BM to the EU.

Article 8(1) of the Agreement stipulates that fort products of animal origin the import conditions of the importing Party shall be applicable to the total territory of the exporting Party.

A previous mission covering this sector took place in 2005 (ref. DG(SANCO)/7551/2005) which highlighted deficiencies in relation to biotoxin testing, monitoring of the production areas, written procedures, inspection of fishing vessels, establishments' processing of LBM, and the the report – which is available on the Commission's Internet site at http://ec.europa.eu/food/fvo/ir_search_en.cfm – made a number of recommendations in respect of the actions required by the CA to improve the situation. Written guarantees were received from the CA in relation to the implementation of those recommendations.

4.2 PRODUCTION AND TRADE INFORMATION

According to information provided by the CA, the main FP exported to the EU are salmon and hake and the main BM exported to the EU are mussels, clams and scallops.

Imports of FP from Chile into the EU are authorised from a total of 169 processing plants (PPs), 54 cold stores (CS), and 17 factory vessels (FVs).

Imports of BM from Chile into the EU are authorised from a total of 162 classified LBM production areas. Presently Chile does not have any relaying area approved for LBM to be exported to the EU. It also does not have any dispatch centre or purification centre approved to export LBM to EU.

1See also Council Decision 2002/979/EC of 18 November 2002 on the signature and provisional application of certain provisions of an Agreement establishing an association between the European Community and its Member States, of the one part and the Republic of Chile, of the other part.

Table 1 summarises the exports in 2009 from Chile of FP and BM to the EU.

Table 1 - Exports of FP and BM from Chile to the EU (tons) (source CA)

Species (Common name)	Scientific Name	2009
Hake	*Merluccius australis, Micromesistius Australis, Merluccius Gayi Gayi, Macrouronus Magellanicus*	36,200
Salmon		23,400
Mussels	*Mytilus chilensis*	27,915
Clams	*Protothaca thaca, Mulinia edulis, Tawera gayi, Mesoderma donacium, Ensis macha, Tagelus dombelii.*	7069
Scallops	*Agropecten purpuratus*	2248
Others		12,868
	TOTAL	109,700

5 Findings And Conclusions

5.1 Legislation

Legal requirements

Article 46 of Regulation (EC) No 882/2004 states that Commission experts may carry out official controls in TCs in order to verify the compliance or equivalence of TC legislation and systems with the relevant Community legislation. Such official controls shall have particular regard, among others, to the legislation of the TC.

Point 1.2 of Appendix VII to the Agreement outlines that verifications should be designed to check the effectiveness of the controls of the auditee.

Findings

Details of the relevant national legislation are provided in the previous FVO mission report DG(SANCO)7551/2005.

The different sanitary programmes, manual of procedures and technical norms already described in the previous report have been updated and modified taking into account the current EU legislation applicable from 1 January 2006 and the recommendations of the previous FVO mission report.

The MT noted that the relevant national legislation, national programmes, manual of procedures and technical specifications can be considered as mostly equivalent to those of the EU.

However, Chilean technical norm SMB/NT2 foresees only the testing of shellfish flesh for the definition of B and C production areas (see also classification of production areas, Chapter 5.5.1). whereas points 4 and 5 of Chapter II of Annex II to Regulation (EC) No 854/2004 foresees the testing of shellfish flesh and intravalvular liquid.

Conclusions

Chilean legislation can, in general, be considered as in line with EU requirements The MT also noted an improvement in respect of the previous mission report. However, Chilean technical norm SMB/NT2 is not in line with points 4 and 5 of Chapter II of Annex II to Regulation (EC) No 854/2004.

5.2 COMPETENT AUTHORITY

Legal requirements

Article 46 of Regulation (EC) No 882/2004 states that official controls carried out in TCs by Commission experts shall have particular regard to the organisation of the TC's CA, their powers and independence. This Article also refers to other issues such as the training of staff in the performance of official controls, the existence and operation of documented control procedures and control systems based on priorities.

Point 4(d) of Part B of Appendix V to the Agreement outlines that the verification concerns the structure and organisation of the CA as well as the powers available regarding the implementation of importing Party's rules.

Article 5 of the Agreement defines that CA of the Parties are the authorities competent for the implementation of the measures referred to in the Agreement.

Findings

Structure and organisation

The organisation and structure of the CA is in general as was described in the previous mission report.

The CA at national level for FP and BM exports is the National Fisheries Service (SERNAPESCA). Within this body there are five technical departments, one technical unit (Aquaculture), a support unit (Human Resources) and two support departments (Legal and Finance), which direct and coordinate operations. All these departments are represented at regional level.

The Fisheries Health Department (FHD) is responsible for controlling the sanitary quality and food safety of FP and BM for export, and for issuing official sanitary export certificates.

The Regional Fishing Bureaus (RFBs) have a presence in every region of the country and represent SERNAPESCA at this level. In some regions there are also provincial and communal offices.

SERNAPESCA has 48 local offices located throughout the country, which are responsible for the implementation of the standards and guidelines established at central level.

Powers and independence

The framework law that regulates fishing and aquaculture activities in Chile is the General Fisheries and Aquaculture Law No. 18892 of 1989 (as modified by D.S. No. 430 of 1991).

Executive Decree DFL No. 5 of 1983, modified by DFL No. 1 of 1992, establishes the organization and powers of the SERNAPESCA and particularly of the FHD.

The above-mentioned national legislation confers competencies, powers and independence to the CA to carry out their tasks. In particular to:

Control the sanitary condition of fishery products for export and grant the relevant sanitary certificates, when requested to do so, in accordance with Chilean regulations or requirements established in International Agreements signed by the Government of Chile.

Adopt the measures necessary to prevent entry into Chilean territory of any substances used in fishing or aquaculture activities, which affects or may affect hydrobiological resources or products.

Control authorized entities to which SERNAPESCA has delegated functions of inspection, sampling and analysis of FP and BM for export.

Execute inspections to verify that all the aspects necessary to issue sanitary certificates of FP and BM to be imported and exported have been fulfilled in accordance with the law.

The law N.º 18575, Constitutional Organic Law for the General Bases of Public Administration (*Ley Organica Constitucional de Bases Generales de la Administracion del Estado*) lays down the rules of conduct and ethics applicable to all civil servants. This legal document encompasses requirements of independence, transparency, impartiality, confidentiality and freedom from conflict of interest applicable to CA officials. Sanctions to be applied to CA officials in case of non-compliance with these requirements are also laid down in that legal document. The CA informed the MT that no CA official has an activity that could be considered as a conflict of interest.

Supervision and authority to enforce legislation

The CA carries out the duties related to establishments, vessels, landing sites, production areas, etc listed by Chile as authorised to participate in the EU export chain (EU listed) according with their sanitary programmes and technical norms. Inspection reports are maintained in the establishments. When deficiencies are noted they are identified and deadlines for correction are set (normally the deadline for correction is immediate). The CA has the power to suspend not only health export certification but also the establishments.

Members of CA staff at central level audit different regional offices throughout the year on a regular basis. A standard checklist is used for these inspections and the resulting report is sent to the Regional Director. An internal audit unit assesses the operation of the different departments, regional and provincial offices.

Training

There is an induction manual covering all aspects of programmes and manuals of SERNAPESCA and newly recruited staff undergo for a training for a period no less than 3 months.

Annually at central level training is planned and provided to the inspectors. In 2009 the subject was heat treatments.

There is an annual meeting where inspectors discuss and share experiences gained during the year.

Records of newcomer training were provided to the MT.

Documented control procedures

Documented control procedures are set out in the manual of procedures, national programmes and technical norms. Checklists are used by the CAs (checklist for EU authorised facilities, checklist for fish farms, checklist for factory vessels and fishing vessels, approval forms, hygiene certificates application forms, etc). These documented procedures cover the FP and LBM production chains and include primary production, establishments, classification and monitoring of LBM areas, etc.

Official controls on imports

The MT observed that official controls on imports are carried out by SERNAPESCA officials. There is a programme for imports with an established documented procedure.

During the visits and interviews the MT noted that both Food Business Operators (FBOs) and CA inspectors are aware of the requirement that raw materials should only be obtained from EU-listed facilities.

Follow-up of Rapid Alert System Food and Feed (RASFF) Notifications

The MT reviewed the SERNAPESCA procedure following a RASFF. In all the cases looked at by the MT, the team noted that measures were taken to investigate the origin of the problem and corrective actions were also taken by the CA in the establishments affected.

Conclusions

The MT noted that the CA has power to enforce applicable legislation. The CA has developed an auditable official control system covering the entire FP and LBM production chain. The official control is based on national legislation and written procedures that can be considered as in line with EU requirements.

5.3 National Provisions and Procedures for Listing Establishments Exporting to the EU

Legal requirements

Article 8(6b) of the Agreement outlines that the import of animal products, the exporting Party shall inform the importing Party of its list of establishments meeting the exporting Party's requirements.

Appendix V to the Agreement lays down conditions and provisions for provisional approval of establishments.

Findings

Establishments must be approved by the CA to export to the EU. Establishments are approved according to Chilean requirements based on Regulations (EC) Nos 852/2004 and (EC) No 853/2004 which are set out in the CA programmes for each category of premises. Additionally to export to the EU an establishment must have an approved Hazard Analysis and Critical Control Points (HACCP) plan that is equivalent to the Chilean Quality Assurance Programme (PAC). Once the CA approves the HACCP plan an on the spot inspection visit is carried out by the CA to grant the final approval.

The approval of FP establishments is carried out by CA officials. Establishments are approved for one year.

Evaluation and approval of the HACCP plan is carried out once the establishment is approved, from a structural point of view by the CA. An assessment body (*Universidad de Chile*) is in charge of approving and verifying that HACCP plans are working properly before final approval. Once the HACCP plans are evaluated by the assessment body, the CA formally approves these plans, carries out an on-the-spot visit and grants the overall approval to the establishment to export to the EU. HACCP plan approval is granted for two years.

Fishing and carrier vessels providing FP to EU approved establishments must be registered and authorised by the CA. Fishing and carrier vessels complete and submit an application form to the CA. The CA evaluates the documentation and performs on-site visits to vessels in order to authorise

them to provide FP to EU listed establishments.

The MT reviewed several inspection reports related to approval of establishments and registration of vessels and they were found to be in order.

The CA is currently in the process of registering and approving landing sites handling material for FP for EU export. To date one landing site has been approved. The CA informed the MT that according to the implementation calendar for landing sites control, the stage of inspection and approval will fully start during July 2010.

Provisions and procedures for listing establishments approved for exporting FP and BM to the EU are followed and respected. There are also procedures and provisions to register vessels and landing sites providing FP or LBM to EU listed establishments. Approval and registration of establishments and vessels can be considered as in line with EU requirements.

5.4 Official controls of Fishery Products

5.4.1 Official controls of production and placing on the market

Legal requirements

In part II.1 of the model health certificate for imports of FP intended for human consumption (Appendix IV to Annex VI to Regulation (EC) No 2074/2005), established the FP requirements that are certified by the official inspector.

Findings

5.4.1.1 Primary production

One trout farm was visited by the MT. Fish farms providing raw material to EU listed establishments are registered and controlled by the CA. Fish farms authorized to export to the EU participate in the Chilean Residues Control Plan.

Fishing vessels (artisanal and industrial vessels) are inspected by the CA to check the hygiene requirements. Artisanal vessels are inspected by CA officials while industrial vessels are inspected by an external assessment body from Chile University authorized by the CA to carry out this task. There is an established frequency for these inspections.

The MT noted that inspection frequency is respected. Only vessels inspected and found in compliance with established requirements are allowed to provide FP to EU listed establishments. The MT also observed that the checklists used for these inspections cover EU requirements.

The MT verified several inspection reports and confirmed this information. The MT also visited one fishing vessel which was found to be acceptable. Three transport vessels were visited, on one of them deficiencies were noted.

5.4.1.2 Landing and first sale

Landing sites are in the process of approval. So far one landing site has been approved. The CA informed the MT that according to the implementation calendar for landing sites control, the stage of inspection and approval will fully start during July 2010.

Currently regular checks on the hygiene conditions at landing are not always carried out

by the CA. To date, when checks have been carried out, no records have been kept of these inspections by the CA.

5.4.1.3 Facilities, including vessels, handling FP

The eleven establishments visited were all approved by the CA and were included in the list of establishments included under the PAC.

PAC visits were carried out with the foreseen frequency.

CA inspection procedures and PAC visit procedures were found to be followed in most of the cases throughout the country.

Establishments are categorized taken into account previous reports perceived level of risk past performance. Inspection frequency is set out in accordance with establishment category.

The MT note that EU listed establishments are visited with the stipulated frequency.

During these visits a checklist based in EU requirements is used by the CA to verify if FBOs operate according to the legislation. The CA is also present when samples for official control are taken by authorized sampling bodies.

During visit the inspector fills an official logbook that is always kept at the establishment, recording the findings, the classification of deficiencies and the conclusions. Usually, deadlines are not prescribed because all the deficiencies must be corrected by the next planned inspection visit. In general establishments are visited at least once a month and when more than two serious deficiencies are noted, they are visited fortnightly.

However, the MT noted that in a few cases the details recorded in the checklist forms and the logbook did not match. It was also noted that a harmonised procedure for the filling of the checklists was not followed by the four inspectors in one region, which undermines the ability of the CA to apply the same standards during all visits and throughout all establishments. During the mission the local CA presented to the MT a newly drafted instruction for the harmonisation of checklist filling.

Reports presented also respected the frequency established in legislation. There are two kinds of reports focused on the general hygiene requirements and on HACCP plans respectively.

The MT visited eleven establishments for FP and BM. Eight can be considered as broadly in compliance with EU requirements (minor deficiencies); two establishments with more deficiencies considered partially in compliance and one establishment where the MT identified serious deficiencies.

Deficiencies noted by the MT when visiting establishments had not always been identified in earlier CA reports.

Establishments approved for the production of BM from "B" class areas applied the heat treatments described in Chilean standards. Studies performed by the FBOs concerning those heat treatments were validated by the FBOs and assessed and approved by the CA.

HACCP procedures were in place in all establishments visited and, with the exception

of minor deficiencies, can be considered as adequate.

Own-checks performed on the establishment were found adequate.

Factory vessels are also approved by the CA and subject to inspections at every landing. The MT did no visit any factory vessels. Inspection reports were checked in regional office and found to be in order.

Conclusions

Fish farms and fishing vessels are inspected and registered and were found to be generally in line with EU requirements.

A system to check regularly the hygiene conditions of landing of FP is not yet implemented.

The heat treatments applied to LBM at the processing establishments are in line with EU requirements and were found to be adequate.

The establishments were, in a majority of cases, in acceptable general hygiene conditions, and adequate HACCP plans were implemented. However, conditions were unsatisfactory in one establishment.

5.4.2 Official controls of FP

Legal requirements

Part II.1 of the model health certificate for imports of FP intended for human consumption (Appendix IV to Annex VI to Regulation (EC) No 2074/2005) establishes that the official inspector certifies that the FP have satisfactorily undergone the official controls laid down in Chapter II of Annex III to Regulation (EC) No 854/2004.

Findings

Organoleptic checks are carried out on final product by the CA when verifying the FBO own-checks control. However, the CA does not perform random organoleptic checks at all stages of production, processing and distribution as is required in part A, Chapter II of Annex III to Regulation (EC) No 854/2004.

Samples are taken, with an established frequency, and subject to laboratory tests to determine the levels of total volatile nitrogen and trimethylamine.

Histamine testing is organised with an established frequency in establishments where species with a high content of histidine are used. The MT did not visit any of these establishments. However, the CA has standards and provisions to test for histamine in line with EU requirements.

A monitoring system to control the level of contaminants and residues has been set up by the CA.

Microbiological checks are carried out systematically by the CA when verifying FBO own-checks. Parameters tested include among others *Listeria monocytogenes, E coli, Salmonella, S. aureus,* etc.

Conclusions

The CA has in place an official control system and a sampling programme covering almost all the elements included in Chapter II of Annex III to Regulation (EC) No 854/2004. However, official organoleptic checks cannot be considered fully in line with EU requirements.

5.5 Official controls of Live Bivalve Molluscs

5.5.1 Official controls of production and relaying

Legal requirements

Part II.1 of the model health certificate for imports of LBM intended for human consumption (Appendix V to Annex VI to Regulation (EC) No 2074/2005) establishes that the LBM have satisfactorily undergone the relevant official controls laid down in Annex II to Regulation (EC) No 854/2004.

Findings

Delineation of production areas

The procedures for the delineation of LBM production areas are defined in section 1 of the "Manual of Procedures No 2" of the "Shellfish Sanitation Programme" (SMB) - SMB/MP2/ May 2008.

In accordance with Chilean standards, the CA requires that the location and boundaries of LBM production areas on natural sea beds should be defined by the FBOs using at least three pairs of coordinates, which must be represented on a geographical chart and transmitted to the CA. If the LBM production areas are located in farming zones the FBOs must provide the CA with copies of the concession plan and of the Resolution issued by the Navy Sub-Secretary and a geographical chart of the area if it includes more than one farming zone.

In the production areas visited and from the evaluation of other production areas documentation (three in total) the MT noted that these procedures were followed by the FBOs and the CA.

Classification of production areas

The LBM production areas are classified by the CA based on the requirements defined in SMB/MP2/May 2008 and SMB/NT2/January 2009 ("Technical Norm No 2").

During the procedure of inclusion of a LBM production area in the SMB FBOs must provide the CA with a "Sanitary Inspection Report" of the production area concerned. This report includes among others an inventory of the sources of pollution (coast line inspection), effects of the meteorological, geographical and bathymetric characteristics on the distribution of the pollutants, an evaluation of the water pollution at specific points (sources of contamination) and an evaluation of all the compiled data. The CA assesses the report, gives a broad indication for the location of the sampling points (which must be then clearly identified by the FBOs and the specific geographic coordinates communicated to the CA) and defines a "classification programme". This "classification programme" comprises analyses carried out in shellfish sampled from the production areas concerned for microbiological parameters, *E. coli, Salmonella* and *Vibrio parahaemolyticus* (also for Norovirus in case of oyster production), biotoxins,

heavy metals and pesticides. It has a duration of sixteen weeks and the microbiological parameters are checked weekly with the exception of *Vibrio parahaemolyticus* which is checked fortnightly. All the analyses for the classification and monitoring programmes are under the responsibility of the FBOs and are supervised by the CA; the sampling is carried out by samplers authorised by the CA from a sampling entity also authorised by the CA; the analyses are performed in laboratories approved by the CA.

At the end of the "classification programme" the CA defines an area classification as A, B or C and establishes a monitoring programme for that area. The criteria for the classification of production areas are defined in SMB/NT2/January 2009 and consider the microbiological results of the "classification programme".

Periodically the CA evaluates the microbiological monitoring results of the classified production areas to identify the need for refinements of the existing classification. Once a year, the coast line inspection is repeated by the FBO in coordination with the CA. However, if during the monitoring programme an abnormal microbiological analysis result is obtained the classification of that area is immediately revised (downgraded if needed) and updated (see point Decisions after monitoring in this Chapter).

In the production areas visited and from the documentary evaluation of three production areas the MT noted that these procedures were in general followed by the FBOs and the CA.

Nevertheless, the MT found that the procedure for the classification of production areas as B or C categories, SMB/NT2/January 2009, foresees the testing for *E. coli* only in shellfish flesh instead of shellfish flesh and intravalvular liquid. In spite of this deficiency, the MT noted that in practice all the *E. coli* analyses carried on LBM use the shellfish flesh and the intravalvular liquid.

The MT also noted minor shortcomings in the "Sanitary Inspection Reports" related with the variation of pollution during the different periods of the year. In only one of the six reports reviewed by the MT was that variation considered. However for the others the evaluation of pollution was carried out during the period with the greatest pollution potential. In one of the studies the MT also observed different results for the same cadmium (Cd) testing, 1,14 µg/Kg in one table and 0,20 µg/Kg in the conclusions of the same study (the maximum limit of Cd in LBM is 1,00 µg/Kg).

Monitoring of classified production areas

The LBM production areas are monitored by the CA based on the requirements defined in SMB/MP2/May 2008, SMB/NT2/January 2009, LAB/MP1/December 2009 ("Laboratories Programme"), LAB/MP2/October 2009, LAB/NT1/December 2009, LAB/NT3/ March 2008 and LAB/NT7/October 2009. The monitoring system comprises several steps: sampling of shellfish and water; dispatch and transport to the analytical laboratories; arrival at the laboratories; analyses; online report to the CA; transmission of the report to the FBO; activation of contingency plan when required.

A monitoring programme is defined by the CA at the time of the area classification with defined frequencies for testing the microbiological quality of LBM, the presence of biotoxins in LBM, the presence of toxin-producing plankton in production waters and the presence of chemical contaminants on LBM and clearly identified sampling points.

This monitoring programme is followed by the FBOs who engage an authorized

sampler entity to perform the sampling. The FBOs must provide all the necessary means (i.e., boats) and ensure availability of resources to allow the sampling of LBM at the defined sampling points. These sampler entities are authorised by the CA and they must have authorised samplers in order to participate on the "Shellfish Sanitation Programme". The samplers are also authorised by the CA after the completion of an official training programme which is defined in the CA's written procedures and lasts for 30 hours. At the time of sampling a standard form containing the required information for the sample taken is completed by the sampler and accompanies the sample until it reaches the laboratory.

The tasks of the authorised sampler are supervised by the CA regional office of the production areas involved. Before sampling the authorised sampler must inform the local office of the monitoring programmes he intends to execute in that week in order to receive the sampling forms and he must also deliver the copies of the samplings performed the previous week. A completed copy of the sampling form is also given to the FBO.

The maximum delay allowed between the sampling and the arrival at the laboratory is defined in the CA procedures and is 24 hours for all regions except Magallanes region (48 hours in this case). The sampling techniques (when applicable), the size of the samples and the transport conditions are also defined in the CA procedures.

The MT assessed the monitoring data provided by the CA and the FBOs and found that the procedures were in general adequately followed. However, the MT noted that in one production area the samples for biotoxin and microbiological analyses were not taken at all the defined sampling points (only one sampling point was sampled instead of two). In another production area the MT noted that 4 out of 17 monthly samples for phytoplankton were taken at a considerable distance from the defined sampling point (approximately 1,100 meters).

The MT assessed the sampling of shellfish and water for the monitoring analyses in one production area and noted that the sampling of shellfish was not carried out in accordance with CA procedures, i.e. shellfish was collected at the sampling point from a specific depth instead of being collected at different depths, which can have an impact on the final result of analyses. Also the transport of the samples was not done in accordance with those procedures, i.e. the samples were placed inside plastic bags in direct contact with the icepack, which can influence significantly the result of the analyses (this could lead to a decrease of the quantity of *E. coli* found).

Microbiology

The testing for the microbiological quality of LBM comprises monthly analyses for *E. coli* and *Salmonella* and fortnightly for *Vibrio parahaemolyticus* for A areas and monthly analyses for *E. coli* for B and C areas. Analyses for the presence of Norovirus are performed weekly (A areas) in case of oyster production. These established frequencies are the same for the whole country.

If an FBO decides to suspend the production of LBM the CA can adopt a reduced monitoring frequency which includes monthly water phytoplankton analyses only. Nevertheless, the monitoring programme should start two weeks before the next production cycle. In the event of a production and monitoring suspension of more than four months the FBO must follow the procedures for an initial classification, i.e. "Sanitary Inspection", report of the "Sanitary Inspection" and "Classification Programme".

The analyses results of the microbiological monitoring are used by the CA to revise periodically the classification of the production areas, where a set of the last sixteen results is assessed. However, a defined frequency for that revision has not been established by the CA, but this does not indicate a deficiency because the CA has a procedure for a contingency plan whenever it finds results of the microbiological monitoring above set limits (see point Decisions after monitoring in this Chapter).

Other than the deficiencies already mentioned above concerning sampling the MT noted that the procedures and analyses frequency were in general followed by the CA and the FBOs. Nevertheless, the MT identified also a shortcoming related to the testing method for the determination of *E. coli* (see Chapter 5.7 Laboratories).

Biotoxins and phytoplankton

LBM are tested weekly for biotoxins (one sample by sampling point) in the whole country. These analyses comprise LBM testing for Paralytic Shellfish Poisoning (PSP), Amnesic Shellfish Poisoning (ASP), lipophilic toxins (okadaic acid, dinophysistoxins and pectenotoxins), yessotoxins and azaspiracids.

As for microbiology, if the FBO decides to suspend the production of LBM the CA can adopt a reduced monitoring.

The MT noted that the procedures were in general followed by the CA and the FBOs. Nevertheless, regarding the frequency of LBM sampling for biotoxin testing the MT noted that the CA was not following the procedures, i.e. when one production area has more than one sampling point for biotoxins, the CA divides the sampling points in two groups and instructs the FBOs to carry out fortnightly sampling in each one of the groups, alternating weekly, which gives an apparent weekly testing frequency for that production area. In addition, the MT also noted in one production area that the frequency established by the CA was not followed; i.e. only one out of two sampling points was sampled weekly.

Water is tested for the presence of toxic phytoplankton species with a weekly frequency for Atacama, Coquimbo, Aysen, Magallanes y Los Lagos Insular regions and with a fortnightly frequency for the remaining regions of Chile. A reduced monitoring plan, once a month, can be set up in case of absence of production.

Apart from the deficiencies already mentioned for the sampling the MT noted that the

procedures and analyses frequency were in general followed by the CA and the FBOs. The CA also informed the MT that up to now it was not possible to establish a relation between the toxic phytoplankton species and the occurrence of toxic episodes in LBM.

Chemical Contaminants

LBM are tested twice a year for the presence of heavy metals (mercury (Hg), Cd and lead (Pb)) and pesticides. All the test results observed by the MT were below the legal limits. The MT noted that in general the drafted procedures are followed by the CA and by the FBOs.

Decisions after monitoring

The CA has in place a contingency plan (defined in SMB/PT3/September 2009) to react whenever the analyses results shows the presence of biotoxins LBM and microbiological levels *(E. coli, Salmonella, Vibrio parahaemolyticus* and Norovirus) above the acceptable levels.

Regarding biotoxins the contingency plan is activated whenever the presence of toxins in LBM is detected. This leads to increased sampling of LBM for the quantification of PSP and ASP and a closure of the production area for Lipophilic toxins. If PSP and/or ASP levels in LBM are equal or below the sub toxic levels (600 µg/Kg for PSP and 15 mg/Kg for ASP) the increased sampling is maintained until two consecutive analyses results showing toxin absence (the samplings must have a minimum interval of two days between them). If PSP and/or ASP are above the sub toxic levels and/or in case of detection of Lipophilic toxins the production area is closed and sampling is performed in accordance with the quantity of toxin detected. The production area can only be reopened after two consecutive analyses results showing toxin absence (the samplings must have a minimum interval of two days between them).

Regarding microbiological levels the contingency plan is activated whenever the analyses results indicate the presence of *Salmonella, Vibrio parahaemolyticus* or Norovirus and/or levels above the limits for *E. coli.* This leads to a downgrading of classification of the production area. In case of declassification due to the presence of *Vibrio parahaemolyticus* increased sampling can be performed and the area can be reclassified again as A area if the results of five consecutive analyses indicates the absence of *Vibrio parahaemolyticus* (the sampling must have an interval of two or three days between them). If the declassification is due to the presence Norovirus, *Salmonella* or levels above normal of *E. coli* then the area can only be reclassified as A after 16 analyses results of weekly sampling indicates that those parameters respect the permitted levels.

The MT reviewed the decisions taken after monitoring by the CA and the FBOs for toxic episodes in LBM and for presence of *Vibrio parahaemolyticus* and found that the described procedures had been followed.

The MT also verified that a contingency plan is foreseen for chemical contamination of LBM.

Additional monitoring requirements

In case of closure of production areas there is cooperation between the CA and the Chilean Ministry of Health which also involve the Navy for the patrolling of the closed

production areas. In such a case the CA also request the FBOs to return the registration documents (see Chapter 5.5.2.) that they have in their possession and they do not supply new ones.

The MT team verified that the CA has in place a control system for final product analysis, which includes sampling performed by FBOs and sampling carried out under the supervision of the CA. Those analyses are performed with a frequency of one sampling for each fifteen production days and the CA supervises one in every four or every six samples (depending of the establishment's activity). The analyses cover EU requirements such as biotoxins, microbiological parameters, and chemical contaminants.

During the visits to the establishment the MT observed that the analyses were carried out for all parameters required under EU legislation. The sampling procedures and scope of analysis was in compliance with EU requirements. During the visits to the establishments the MT reviewed the official control sample results and verified that they were in accordance with the applicable requirements; the frequency and scope of analysis was also found to be respected.

Recording and exchange of information

The CA keeps an updated list of production areas approved for export to the EU. The CA has an on-line system available to all interested parties (such as producers, gatherers, FBOs, laboratories, CA ,etc.) with permanently updated information that includes the list of approved production areas, their classification or its closure.

This on-line system also includes the results of the analysis carried out for classifying or monitoring the production areas. The system allows the CA to act promptly where the controls indicate that a production area should be closed or reclassified or may be-reopened.

Conclusions

The procedures in place for the delineation and classification of production areas, the monitoring of classified production areas, the decisions after monitoring, the additional monitoring requirements and the recording and exchange of information are considered in general as equivalent to EU requirements and they were followed adequately by the FBOs and by the CA.

However, deficiencies were noted for the classification of production areas, in particular, in SMB/NT2/January 2009 and “Sanitary Inspection Reports”, the monitoring of classified production areas, in particular, the correct use of the sampling points, the sampling frequency for biotoxin testing in shellfish, the sampling techniques and sample transport for the microbiological testing in shellfish.

In spite of the deficiencies noted, the official control system of production of LBM can be considered, in general, as in line with EU requirements.

5.5.2 Official controls of harvesting and placing on the market

Legal requirements

Part II.1 of the model health certificate for imports of LBM intended for human

consumption (Appendix V to Annex VI to Regulation (EC) No 2074/2005) establishes that the official inspector certifies that the LBM:

- come from establishments implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;
- comply with the requirements laid down in Section VII, Chapters I to VIII 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 marked and labelled in accordance with Section I of Annex II to Regulation (EC) No 853/2004. Moreover, point A.4. of this Section refers to the compliance of FBOs with Article 18 of Regulation (EC) No 178/2002;
- have satisfactorily undergone the relevant official controls laid down in Annex II to Regulation (EC) No 854/2004.

Findings

Registration document

In their "Shellfish Sanitation Programme" procedures (SMB/MP2/May 2008) the CA foresees that LBM must be accompanied by a registration document (LBM Harvesting and Transport Registration Document (RET)) from the time of harvesting until they reach the first establishment. This RET includes all the necessary information to meet Community requirements and when issued an original and two copies are produced (carbon copy form). The CA prints the RET forms and then supplies them to the harvesters. Each RET form has a unique serial number. The CA has a system in place to control the delivery of the RET forms to, and their use by, the BFOs.

The MT observed that for each harvesting a RET is produced in accordance with the procedures, they contained all the required information, they were signed and dated and the originals and respective copies were available at the correct locations (establishment, harvester and CA).

Harvesting and transport

In their "Shellfish Sanitation Programme" procedures (SMB/MP2/May 2008 and SMB/NT2/January 2009) the CA defines the requirements applicable to the harvesting and transport of LBM. During their official control activities the CA staff perform the evaluation of the harvesting techniques (with a non-defined frequency). These visits can be performed during the "Sanitary Inspections" of the production areas, inspection visits to collecting boats/platforms and supervision of LBM monitoring sampling. The transport conditions are verified on the LBM's arrival at the processing establishments.

The MT verified that general information was present on the visit records to establishments and collection boats/platforms. The MT reviewed the harvesting technique in one production area visited and found that the practice used complied with established requirements.

Facilities handling LBM

In Chile there are neither dispatch nor purification centres for LBM. The CA annually performs official control inspections of the vessels that participate in LBM harvesting. The MT observed evidence of those visits. The harvesting platform visited by the MT

was in operation and can be considered as having in general adequate conditions. Nevertheless, it was noted that the platform did not have toilet facilities and the MT was informed by the FBO that if needed staff used the toilet located on land (10 to 15 minutes distance by boat).

For the findings and conclusions related with LBM processing establishments please refer to Chapter 5.4.1 above.

Conclusions

The procedures in place are considered in general as equivalent to EU requirements and they were followed adequately by the FBOs and by the CA.

The official control system for harvesting and placing on the market of LBM can be considered, in general, as in line with EU requirements

5.6 Official certification

Legal requirements

Article 9 of the Agreement lays down requirements for certification procedures.

The certificates shall meet the requirements set out in Annex VI to Regulation (EC) No 854/2004, and Appendix IV and Appendix V to Annex VI to Regulation (EC) No 2074/2005 includes the model health certificates for imports of FP and LBM, respectively, intended for human consumption.

Findings

SERNAPESCA has sanitary programme for certification of FP and BM for export to the EU. A detailed certification procedure is described in this programme.

The FBO has to submit for authorisation an export notification to the CA prior to export. Once the notification has been assessed by the CA the product is authorised for export.

For FP a document (*AOCS autorizacion en origen para certificacion sanitaria*) issued by the regional CA stating that the product complies with the requirements for export to the EU is presented to the certification office. For BM intended for EU export an additional document to declare that LBM are from an EU listed production area is also required prior to issuing the AOCS.

The MT visited four regional offices where export health certificates were issued. The MT noted that officials issuing export health certificates follow the prescribed procedures and that certificates are always accompanied by supporting documents to ensure that the exported product have been produced in line with EU requirements. The CA uses the export health certificate model set out in Regulation (EC) No 2074/2005.

However, the CA has issued EU export health certificate for products for which Chile is not authorised under Commission Decision 2006/766/EC.

Conclusions

The procedures in place for official certification are in line with EU requirements. The export health certificate model used by the CA meets EU requirements. However, the CA has certified for export BM which should not have been certified.

5.7 LABORATORIES

Legal requirements

Article 46(1)(d) of Regulation (EC) No 882/2004 states that Commission experts may carry out official controls in TCs in order to verify the compliance or equivalence of TC legislation and systems with the relevant Community legislation and that such official controls shall have particular regard to the resources including diagnostic facilities available to CAs.

Chapter 1 of Annex I to Regulation (EC) No 2073/2005 lays down the food safety microbiological criteria for FP and LBM, including the applicable sampling plans and the number of sample units giving values over or between the established limits.

Section II of Annex II to Regulation (EC) No 2074/2005 lays down the methods of sampling and analysis for the official control of the levels of Total Volatile Basic Nitrogen (TVB-N) in FP.

Annex III to Regulation (EC) No 2074/2005 lays down the recognised testing methods for detecting marine biotoxins.

Regulation (EC) No 1883/2006 lays down the methods of sampling and analysis for the official control of the levels of dioxins and dioxin-like PCBs in certain foodstuffs.

Regulation (EC) No 333/2007 lays down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, and benzo(a)pyrene in foodstuffs.

Findings

The MT visited five laboratories:

- The Public Health Institute (ISP) (the National Reference Laboratory for chemical, microbiological and toxicological testing of food);
- Two official laboratories - Biotoxins Laboratory of the Austral University (CERAM) and Biotoxins Laboratory of the Santiago University;
- Two private laboratories.

All laboratories visited by the MT were found to be well equipped and adequately resourced to undertake the necessary analyses.

The CA has designated laboratories for official control (verification laboratories) as well as for own-check analysis (service laboratories). These laboratories are periodically controlled by the CA.

All laboratories approved by the CA for analyses of FP and LBM are accredited to ISO standards 17025 by the National Normalisation Institute (INN). For FP the MT noted that the laboratories visited follow EU criteria regarding sampling and analyses methods used (Regulation (EC) No 2073/2005; Regulation (EC) No 2074/2005; Regulation (EC) No 1881/2006, Regulation (EC) No 333/2007).

For BM the MT noted that the laboratories visited follow in general EU criteria regarding sampling and analyses methods used (Regulation (EC) No 2073/2005; Regulation (EC) No 2074/2005; Regulation (EC) No 333/2007).

However, as mentioned under point 5.5.1 (Monitoring of classified production areas) the method for *E. coli* used in one of the laboratories visited is not the EU reference one and has not been validated against it. In fact the CA issued in October 2009 a note to the four laboratories belonging to the LBM microbiological laboratory network requesting the adoption of the Community

reference method for *E. coli* analyses in LBM. Nevertheless, the MT saw evidence that only two of the laboratories changed their testing method to the one prescribed by the CA. During the FVO mission, on the 4 of May, the CA sent a reminder to the laboratory visited by the MT requesting the immediate modification of the analyses method to be used for the determination of *E. coli* in LBM. Presently, and due to the recent earthquake, one of the four laboratories is not in operation and the microbiological analyses are carried out in one of the other three laboratories.

In one of the laboratories visited the MT also noted some shortcomings related to the LBM samples, i.e. the test sample preparation was carried out using ISO 6887-3 as reference method which differs from the ISO 16649-3 method in the number of dilutions and test tubes to be inoculated in each one of the dilutions (two dilutions each one with three test tubes in ISO 6887-3 instead three dilutions each one with five test tubes as described in ISO 16649-3); the laboratory sample being tested at the time of the visit was labelled with a sticker showing the name of the sampled production area, which does not allow a blind sample.

Analysis methods for biotoxins are in line with EU requirements. However, extraction of PSP is done without precise control of pH and standards used for PSP and ASP are not certified or calibrated against a certified one.

Biotoxin results of weekly reports are introduced in a software system called *mr-SAT*, that allows instant access to the information at national level.

No laboratory in Chile is accredited to date for phytoplankton monitoring, although CERAM has already requested accreditation for this purpose.

Most BM sampling is done weekly, although some areas are done fortnightly. With the exception of very dense blooms, especially for PSP toxins, in general, the sampling for monitoring purposes does not provide predictive information about the likelihood of a bloom. This trend is observed in most the phytoplankton sampling areas. The monitoring procedure has threshold values for certain species that would trigger the alert.

Most of the samples are carried out weekly, although some areas are done fortnightly. With the exception of very dense blooms, especially for PSP toxins, in general, the sampling of monitoring does not provide predictive information about the upcoming of a bloom. This is a trend observed in most of the sampling areas for phytoplankton. The monitoring procedure has threshold values for certain species that would trigger the alert.

The ISP organised proficiency testing for *E. coli Samonella, Listeria monocytogenes*, PSP and ASP. Laboratories approved by the CA for official control and for FBO own-checks participated in these proficiency tests with satisfactory results. However, the microbiological proficiency tests are carried out using a quantified lyophilized reference material instead of LBM matrix. This approach does not allow the normal matrix interference on the analysis result and impedes the evaluation of the performance of the laboratories studied in regard to this analyses factor.

Conclusions

The CA has designated laboratories for official control and FBO own-checks. The analyses methods used for analyses of FP and BM for export to the EU are, in general, in line with EU requirements. However, the *E. coli* detection method used in one laboratory visited is not the one foreseen in EU legislation and no validation of this method has been carried out as required in Regulation (EC) No 2073/2005.

Laboratories for official control and FBO own checks provide guarantees about reliability of analysis carried out as all the CA approved laboratories are accredited against ISO standards 17025

other than for phytoplankton monitoring.

5.8 Follow up of previous mission DG(SANCO)/7551/2005 on Fishery Products and bivalve molluscs

Legal requirements

Point 4.4 of Appendix VII to the Agreement lays down conditions and provisions for follow-up verifications.

Findings

The previous mission report contains nine recommendations for BM and four recommendations for FP.

The MT noted that all recommendations regarding FP and BM have been addressed by the CA.

Conclusions

The CA has adequately addressed all the recommendations of the previous mission report.

6 Overall Conclusions

In principle the current organization of the Chilean CA and the control system implemented by the CA offer appropriate guarantees concerning the sanitary conditions of production of BM and FP for EU export. However, to fully ensure that all the exports of BM to the EU respect the requirements defined in Regulation (EC) No 2074/2005, as last amended, some improvements should be made, in particular concerning the classification and monitoring of productions areas including the official laboratory analysis methods used.

The CA has adequately addressed all recommendations of the previous mission report.

7 Closing Meeting

During the closing meeting held in Santiago on 6 May 2010, the MT presented the findings and preliminary conclusions of the mission to the CA.

During this meeting, the CAs acknowledged the findings and preliminary conclusions presented by the MT and provided a commitment to correct the deficiencies. The CCA informed the MT that it had issued an instruction to the laboratories to use the Community EU reference method for testing for *E. coli*. The CA also informed the MT that from 4 May 2010 the certification of chilled eviscerated scallops for EU export had ceased.

8 RECOMMENDATIONS

The CA should provide Commission services with an action plan, including a timetable for its completion, within one month of receipt of the report, in order to address the following recommendations for FP and BM exported to the EU.

N°.	Recommendation
1.	The CA should ensure that national legal standards related to FP and LBM intended for export to the EU - in particular, Chilean technical norm SMB/NT2 - is in line with point 4 and 5 of Chapter II of Annex II to Regulation (EC) No 854/2004.
2.	The CA should ensure that official controls include regular checks on the hygiene conditions of landing of FP as is required in point 1 (a), Chapter I of Annex III to Regulation (EC) No 854/2004.
3.	The CA should ensure that official controls include random organoleptic checks of FP at all stages of production, processing and distribution as is required in part A, Chapter II of Annex III to Regulation (EC) No 854/2004.
4.	The CA should ensure that only establishments that meet equivalent conditions to those laid down in Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004 are EU listed (taking into account the requirements of Article 8 and Appendix V of the Agreement).
5.	The CA should ensure that all the designated sampling points in the production areas are monitored weekly for toxin analysis, in line with point 5 part B, Chapter II of Annex II to Regulation (EC) No 854/2004.
6.	The CA should ensure that all laboratories undertaking E .coli analysis for official EU BM export controls use the specified reference method (ISO TS 16649-3), or an alternative method formally validated against the EU reference method.
7.	The CA should ensure that export health certificates for export to the EU are only issued for processed or frozen BM in accordance with Commission Decision 2006/766/EC.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/ap/ap_cl_2010-8540.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dec. 2002/657/EC	OJ L 221, 17.8.2002, p. 8-36	2002/657/EC: Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results
Dec. 2006/766/EC	OJ L 320, 18.11.2006, p. 53-57	2006/766/EC: Commission Decision of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted
Dir. 95/2/EC	OJ L 61, 18.3.1995, p. 1-40	European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dir. 98/83/EC	OJ L 330, 5.12.1998, p. 32-54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
Dir. 2000/13/EC	OJ L 109, 6.5.2000, p. 29-42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
Dir. 2004/41/EC	OJ L 157, 30.04.2004, p.33 corrected and re-published in OJ L 195, 02.06.2004, p. 12	Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC

Legal Reference	Official Journal	Title
Reg. 2406/96	OJ L 334, 23.12.1996, p. 1-15	Council Regulation (EC) No 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004

Legal Reference	Official Journal	Title
Reg. 2076/2005	OJ L 338, 22.12.2005, p. 83-88	Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Reg. 1883/2006	OJ L 364, 20.12.2006, p. 32-43	Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
Reg. 1333/2008	OJ L 354, 31.12.2008, p. 16-33	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives