EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

Ares(2013)3473112

DG(SANCO) 2013-6721 - MR FINAL

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

CHILE

FROM 17 TO 26 APRIL 2013

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

Executive Summary

This report describes the outcome of a Food and Veterinary Office audit in Chile carried out from 17 to 26 April 2013 as part of its programme of audits in third countries.

The objectives of the audit were to evaluate the official control system put in place by the Competent Authority and the public health conditions for the production of live bivalve molluscs and fishery products derived therefrom intended for export to the EU. The audit covered the relevant EU legislation for the public health sector and the follow up of the corrective actions taken and implemented to address the previous audit report recommendations.

The report concludes that in principle the current organisation of Chilean competent authority, its standards and procedures can be considered as an adequate basis for carrying out official controls. The implementation observed by the Food and Veterinary Office team allows, in principle, the competent authority to provide adequate guarantees with regard to the sanitary conditions of live bivalve molluscs and fishery products produced therefrom to be imported by the EU.

However, a number of deficiencies have been identified in the report, which will require correction before the competent authority can fully ensure that all bivalve molluscs and products derived therefrom destined for export to the EU respect the requirements set out in the model health certificate as defined in Regulation (EC) No 2074/2005, as last amended.

The report also finds that all recommendations of the previous audit report were adequately followed up.

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

Table of Contents

Abbreviations and definitions used in this report

Abbreviation	Explanation
ASP	Amnesic Shellfish Poisoning
CA	Competent Authority (ies)
EC	European Community
EU	European Union
EU listed	Facilities approved and listed by the competent authority for participation in the EU fishery products export chain
EUROSTAT	Statistical Services of the European Union
FBO	Food business operator
FVO	Food and Veterinary Office of the European Commission
HACCP	Hazard Analysis Critical Control Points
HPB	Approval of establishments and factory vessels
INN	National Normalisation Institute
MPN	Most probable number
PAC	Quality Assurance Programme
PSMB	Shellfish Sanitation Programme
PSP	Paralytic Shellfish Poisoning
RASFF	Rapid Alert System for Food and Feed
RET	Harvesting and Transport Registration Document
SANCO	Health and Consumers Directorate General of the European Commission
SPS	Sanitary and Phytosanitary

1 Introduction

The audit took place in Chile from 17 to 26 April 2013 and was undertaken as part of the Food and Veterinary Office's (FVO) planned audit programme. The audit team (hereinafter the FVO team) comprised two inspectors from the FVO and two national experts from European Union (EU) member states.

An opening meeting was held in Valparaiso on 17 April 2013 with the Chilean competent authority (CA), the National Fisheries Service (SERNAPESCA - "*Servicio Nacional de Pesca*) which is under the Ministry of Economy, Development and Tourism - "*Ministerio de Economía, Fomento y Turismo*". At this meeting the FVO team confirmed the objectives of, and the itinerary for the audit, and requested additional information regarding the specific elements of the control system in place.

2 Objectives

The objectives of the audit were:-

• To evaluate whether the official controls put in place by the Chilean CA can guarantee that the conditions of production of live bivalve molluscs and fishery products derived therefrom destined for export to the 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 V and Appendix IV 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 an earlier FVO fishery products and live bivalve molluscs audit report of 2010 have been implemented and enforced by the CA.

In terms of scope the audit focused on the organisation and performance of the CA, the export certification procedure, the official control system in place covering production, processing and distribution chains applicable to live bivalve molluscs and fishery products derived therefrom to be exported to the EU. Accordingly, relevant aspects of the EU legislation referred to in Annex 1 were used as a technical basis for the audit.

In pursuit of these objectives, the following sites were visited:-

Competent Authority Visits/Meetings		
CA offices	3	Central Office – Valparaiso Regional Office of Los Lagos region – Puerto Montt Provincial Office of Chiloe Island – Castro
Laboratory visits		
Microbiology testing of bivalve molluscs	3	Santiago and Puerto Montt
Biotoxins testing of bivalve molluscs	3	Santiago and Puerto Montt
Phytoplankton testing	2	Chiloe Island and Puerto Montt
Classified production and relaying areas		

Live bivalve mollusc production areas	3	Includes the evaluation of one harvesting/landing activity.
FACILITIES HANDLING BIVALVE MOLLUSCS		
Dispatch centres	4	Part of the processing establishments visited.
Processing establishments	5	Two not in operation at the time of the FVO visit.

Representatives from the CA accompanied the FVO team during the whole audit.

3 LEGAL BASIS

The audit was carried out in agreement with the Chilean Authorities and under the general provisions of the Agreement on Sanitary and Phytosanitary measures (and in particular Article 10) applicable to trade in animals and animal products, plants, plant products and other goods and animal welfare (hereinafter "the 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 EU with Council Decision 2005/269/EC 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 1. Legal acts quoted in this report refer, where applicable, to the last amended version.

4 BACKGROUND

4.1 GENERAL BACKGROUND

Chile is presently listed in Annex I of Commission Decision 2006/766/EC establishing the list of third countries from which imports of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods for human consumption are permitted.

A previous audit took place in 2010 (ref. DG(SANCO)/2010-8540) which highlighted deficiencies in relation to the applicable Chilean standards, inspection of the hygiene conditions at landing, organoleptic checks of fishery products, classification of live bivalve mollusc production areas, the testing method used for *E. coli* determination in bivalve molluscs and export health certification. The report –published on the Health and Consumers Directorate-General (SANCO) Internet site at http://ec.europa.eu/food/fvo/ir_search_en.cfm – made a number of recommendations in respect of the action required of the CA. Written guarantees were received from the CA in relation to the implementation of those recommendations which were assessed by Commission services and found satisfactory. The follow-up of these recommendations is reported under the relevant parts of this

report.

4.2 Production and Trade Information

As per the lists[1] set up by the CA and available on SANCO's website (at http://ec.europa.eu/food/food/biosafety/establishments/third_country/index_en.htm on 05/03/2013 and valid from 18/03/2013) imports from Chile of bivalve molluscs (live and fishery products derived therefrom) are authorised from a total of 157 classified production areas (57 class A and 100 class B), 10 dispatch centres and 246 establishments (187 processing establishments and 59 cold stores). Chile does not have any class C production areas, relaying areas and purification centres.

According to information provided by EUROSTAT, fishery product exports to the EU amounted to approximately 127,000 tonnes in 2011 and 109,000 in 2012. Of these bivalve molluscs accounted for approximately 60,000 tonnes in 2011 and 42,000 in 2012 – mainly processed bivalve molluscs (more than 86%) produced from mussels (*Mytilus chilensis*). Chile has not exported to date live bivalve molluscs to the EU.

4.3 Rapid Alert System for Food and Feed (RASFF) Notifications

Since the last FVO audit 17 RASFF notifications were issued for bivalve molluscs and fishery products derived therefrom of Chilean origin. One of the notifications was due to an unauthorised irradiation treatment made in an EU member state, two of them due to the existence of levels of cadmium above the EU regulatory limits, one due to the presence of Norovirus and the remaining 13 were due to unsuitable organoleptic characteristics of frozen products or the rupture of the cold chain. Details on how these notifications were handled are presented in section 5.5.1 below.

5 Findings And Conclusions

5.1 Legislation

Legal requirements

Article 46(1)(a) of Regulation (EC) No 882/2004 states that Commission experts may carry out official controls in third countries in order to verify the compliance or equivalence of third countries legislation with the relevant EU legislation.

Article 11(4)(a) of Regulation (EC) No 854/2004.

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

In their response to the pre-audit questionnaire the CA stated that the General Fisheries and Aquaculture Law No. 18.892 of 1989, as modified by D.S. No. 430 of 1991 and Law No. 20.657 of 2013, regulates fishing and aquaculture activities in Chile. The FVO team noted that this law covers mainly policy for resource management in relation to wild caught fisheries, registration of fishing activities and aquaculture policy.

1 For live bivalve molluscs and fishery products.

The CA also stated that Executive Decree DFL No. 5 of 1983, as modified by DFL No. 1 of 1992, establishes the organisation and powers of the CA – SERNAPESCA – and identifies the Fisheries Health Department as the service in charge of the official controls of live bivalve molluscs and fishery products derived therefrom to be exported to the EU. A description of the CA's powers and organisation can be found in section 5.2.

In addition to the legal documents mentioned above the CA also adopted a Fishery Health Manual (*Manual de Sanidad Pesquera*) that encompasses the standards to be followed by the CA and food business operators (FBOs), for bivalve molluscs and fishery products derived therefrom to be exported and their production chain. This manual also describes the requirements and rules of Chile's Shellfish Sanitation Programme ("*Programa Sanitario Moluscos Bivalvos*" – hereinafter PSMB).

The FVO team noted that:-

- The legislation and standards applicable to bivalve molluscs can be considered as, in general, in line with the EU requirements.

- However, the CA has two different sets of requirements applicable to dispatch centres. One, HPB/NT3, requires that the FBOs running such centres implement HACCP based programmes and a second, CER/NT3, exempts establishments exporting live bivalve molluscs to the EU from having HACCP based programmes.

- The CA has taken the necessary actions to address Recommendation No 1 of the previous audit report. However, variances between Chilean national standards and EU requirements remain (e.g. Chilean requirement to test only shellfish flesh instead of shellfish flesh and intra-valvular liquid as required under EU rules).

Conclusions

The Chilean legislation and standards applicable to live bivalve molluscs and fishery products derived therefrom can be considered, in general, as in line with the EU rules. However, there is a lack of clarity in relation to the obligation for dispatch centres to implement HACCP based system and the sample requirements for the microbiological testing of live bivalve molluscs.

Recommendation No 1 of the previous audit report was adequately addressed.

5.2 Competent Authority

Legal requirements

Article 46 of Regulation (EC) No 882/2004 stipulates that EU controls in third countries shall verify compliance or equivalence of third countries systems with EU food law. These controls shall have particular regard to points (b) to (e), (g) and (h) of the aforementioned article.

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

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.

Findings

Structure and organisation

The CA in charge of official controls for the export of live bivalve molluscs and fishery products derived therefrom from is SERNAPESCA. Details of its structure and organisation have been set out in previous FVO audit reports.

Powers, Independence and Supervision

The powers of the CA are described in Executive Decree DFL No. 5 of 1983, as modified by DFL No. 1 of 1992. These powers range from the power to control the sanitary conditions of fishery products for export, the power to issuing the relevant sanitary certificates and the power to access premises and related documents.

As described in the previous audit report, Law N.º 18575 (Constitutional Organic Law for the General Bases of Public Administration) lays down the rules of conduct and ethics to be followed by all civil servants. This law requires independence, transparency, impartiality, confidentiality and freedom from conflict of interest and is directly 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 FVO team did not identify any activities that presented a conflict of interest for CA officials.

The CA has in place a system of internal audits covering their regional services. Audit reports were checked by the FVO team and it was noted that they covered aspects relevant to the organisation and implementation of official controls. Under an internal audit, when deficiencies are detected the region must set up an action plan to correct those deficiencies.

The CA also performs supervision of the entities approved for official sampling (including the approved samplers) and the laboratories that perform official control analyses.

Training – knowledge of EU requirements

In their response to the pre-audit questionnaire the CA provided information regarding the training programmes for CA officials.

The FVO team noted that those training programmes covered subjects relevant to the performance of official controls of live bivalve molluscs and fishery products derived therefrom, such as, organoleptic assessment, HACCP programmes, food safety and food safety risk analyses.

The annual workshop and meetings mentioned in the previous audit report are still carried out by the CA.

An induction training is provided for all newcomers at the time of commencing duties, followed by a period during which they are tutored by a senior CA official.

The FVO team noted that staff interviewed during the audit presented an adequate knowledge of the applicable EU requirements.

Resources available to the CA

The CA staff is located in adequate offices and have available the necessary means for the performance of their tasks, which include amongst others, access to relevant information (Fishery Health Manual with procedures, forms and checklist), GPS devices, protective clothing for inspections and material for sample collection.

The CA also has access to a network of approved laboratories for the performance of the official controls.

Documented Control Procedures

The CA has developed extensive procedures for the performance of official controls which are part of the Fisheries Health Manual.

This manual is divided into different programmes that set out the rules and procedures to be followed in the case of exports to the EU of live bivalve molluscs and fishery products derived therefrom, such as:-

- Programme for the approval of establishments and factory vessels (HPB).
- Quality Assurance Programme (PAC) (dealing with HACCP).
- PSMB.
- Control Programme for Residues (FAR).
- Programme for imports of raw material (IMP).
- Small scale fisheries Programme (SPA).
- Control of Laboratories Programme (LAB).
- Certification Programme (CER).
- Programme for traceability in fishery products (TPP).
- Programme for Inspections (INS).

The FVO team noted that all these procedures were available to the CA officials and were used and implemented in the course of their official tasks. Within the procedures the FVO team could find instructions, guidance, forms, checklists and report templates.

Conclusions

The CA designated for the official control of live bivalve molluscs and fishery products derived therefrom presents a structure, organisation and legal powers that allow for an adequate official

control and enforcement across the full production chain of products for EU export.

The resources made available to the CA allow for the satisfactory execution of official tasks and official staff presented adequate knowledge of the relevant EU rules and requirements.

The written procedures developed by the CA provide an appropriate basis for the CA to guarantee the implementation of adequate official controls of the sector.

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

Legal requirements

Article 8(6)(a) of the Agreement establishes conditions for the provisional approval of processing establishments. Such approval shall be consistent with the conditions and provisions set out in Appendix V.B to the Agreement. Point 4(b) of Appendix V.B outlines that the CA of the exporting Party has to provide satisfactory guarantees that the establishments appearing on its list meet the relevant health requirements of the importing Party.

Parts I.11 and I.28 of the model health certificate for imports of live bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption established in Appendix V to Annex VI to Regulation (EC) No 2074/2005.

Parts I.11. and I.28 of the model health certificate for imports of fishery products intended for human consumption established in Appendix IV to Annex VI to Regulation (EC) No 2074/2005.

Findings

The procedures in place for the listing of establishments exporting to the EU and the live bivalve molluscs production areas have not been changed since the last FVO audit.

The establishments that export to the EU are approved by the CA based on compliance with requirements equivalent to Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004. These requirements include the need for the FBOs to have and maintain an approved HACCP plan.

Once the establishment has been approved, from the structural point of view, by the CA an evaluation and approval of HACCP plans are carried out by an assessment body (Universidad de Chile).

Following approval of an establishment HACCP plan the CA performs an on the spot inspection visit to grant the final approval.

The FVO team noted that the procedures for approval had been followed appropriately in the premises visited.

However, as mentioned in section 5.1. there are conflicting requirements applicable to dispatch centres with regard to the need for HACCP based programmes.

The listing of live bivalve mollusc production areas for EU exports is also subject to the CA

procedures and only production areas included by the CA in the PSMB can be present on that list.

The FVO team noted that production areas that had been suspended by the CA from EU export (and removed from PSMB list) remained EU listed for long periods of time (up to two years) post suspension.

The procedures for listing do not include guidance or deadlines for requesting to the Commission services the de-listing of facilities/production areas from the EU list.

Conclusions

Provisions and procedures for listing establishments and production areas approved for exporting live bivalve molluscs and fishery products derived therefrom are adequately followed and can be considered, in general, as in line with EU requirements. However, the current procedures do not fully ensure that the EU list for production areas is up to date.

Recommendation No 4 of the previous audit report concerning EU listing of establishments can be considered as adequately addressed.

5.4 Official Controls of Live Bivalve Molluscs

Legal requirements

Part II.1 of the model health certificate for imports of live bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption established in Appendix V to Annex VI to Regulation (EC) No 2074/2005.

5.4.1 Obtained from Classified Production Areas

Classification of production and relaying areas

Findings

The definition of the location and boundaries of EU listed classified production areas is the responsibility of the FBOs concerned and needs to be made in accordance with the CA written procedures (SMB/MP2) and communicated to them. The FBOs need to provide to the CA geographical charts or maps with the location of the production areas. In the case of natural sea beds the FBO needs to indicate at least three pairs of geographical coordinates and for aquaculture farms (*centros de cultivo*) the FBO must provide the CA with a copy of the Resolution (concession authorisation) issued by the Navy Sub-Secretary. A single classified production area can have more than one aquaculture farm (concession).

In accordance with the CA procedures (SMB/MP2 and SMB/NT2), prior to the classification of an identified production area a Sanitary Inspection of the area is required. This Sanitary Inspection is the responsibility of the FBOs. The Sanitary Inspection includes, amongst other elements, a shoreline inspection which identifies pollution sources. This shoreline inspection must be performed by a CA authorised third party (usually a CA approved sampler) accompanied by a CA representative. The Sanitary Inspection also includes a description of hydrographic and

meteorological features (e.g. - tide amplitude and type, bathymetry, water circulation patterns, salinity, winds, rain) and an evaluation of the pollution sources. A report of the Sanitary Inspection must be drafted and delivered to the CA for assessment.

Based on the assessment of the Sanitary Inspection presented, the CA identifies and proposes the location of sampling points (and proposes their location) for live bivalve molluscs and water and establishes a classification programme. This programme has a four months duration during which live bivalve molluscs and water are tested in accordance with the following scheme:

- Live bivalve molluscs testing:
    - Microbiology: *E. Coli* and *Salmonella* (weekly); *Vibrio parahaemolyticus* (fortnightly) and Norovirus for oysters only (weekly).
    - Toxicology: Lipophilic toxins, amnesic shellfish poisoning toxins (ASP) and paralytic shellfish poisoning toxins (PSP) (weekly).
    - Contaminants: heavy metals and pesticides (in general two samples during the programme).
- Water testing:
    - Phytoplankton – count and identification.
    - Temperature, acidity or alkalinity (pH), salinity and oxygen.

All samples are taken at the defined sampling points (which in principle will be the ones for the monitoring of the classified production area) by CA authorised third parties and the samples are analysed in the laboratories approved by the CA for the performance of the required analyses (see section 5.7). In their procedures the CA indicates that the sampling frequency for the classification programme can be adjusted taking into consideration the results of the Sanitary Inspection.

Following the evaluation of the microbiological analyses results of the classification programme the CA decides on the classification of a production area. Production areas have three classification categories, A (direct human consumption), B (for human consumption after purification or heat treatment) or C (for human consumption after long relaying or heat treatment). The criteria to assess the analyses results include the levels of faecal contamination (*E. coli*) and are defined in the procedure SMB/NT2. The CA, after classifying the production area, informs the FBO on the classification of the production area concerned and the monitoring programme to be followed for the area to be maintained in the PSMB.

Under CA procedures, the classification of production areas may be reviewed periodically. When such a revision takes place the last 16 results of the monitoring programme are used to determine its classification. The CA procedures also indicate that an update of the shoreline inspection should be carried out every three years.

The classification of production areas can be changed following the results of the monitoring programmes. Any class A area that has been downgraded to class B or C due to the microbiological monitoring results can only be upgraded following 16 analyses results that comply with the regulatory limits for class A areas. Samples must be taken with no less than a weekly interval. If the

downgrade occurred due to the presence of *Vibrio parahaemolyticus* increased sampling can be performed and the area can be reclassified again as A area when the results of five consecutive analyses indicate the absence of *Vibrio parahaemolyticus* (each sampling must have an interval of two or three days between them).

The composition of any classified production area comprised of aquaculture farms may be modified at the request of the FBOs and in accordance with the CA procedures (e. g. - additions or deletions of farms). In the case of the addition of a farm, unless the new farm is included in the shoreline of other existing farms, a new shoreline inspection must be carried out before the modification of the composition of the area is sanctioned.

The FVO team noted that:-

- The procedures for the classification of production areas are in general in line with the EU requirements.

- The criteria and categories defined for the classification of production areas are in line with the EU requirements.

- All production areas visited during the FVO audit have been classified by the CA following their procedures. However, the water samples taken near the sources of contamination during the sanitary inspections did not take account of the most adverse contamination conditions (worst case scenario conditions), nor the variation of pollution during the different periods of the year[2].

- In one class A production area visited, the sampling point used for microbiological monitoring and classification purposes had been changed over time. This change was due to the incorporation of new farms (concessions) in the area. Although a shoreline inspection was carried out and the sampling point was relocated near to the pollution sources, the CA did not request the 16 consecutive weekly sample results in compliance with the regulatory limits for the area's classification and maintained its previous classification and the monthly monitoring for microbiological contamination was continued.

- One of the areas visited had a modification of its class status, returning to the previous one (class A), after 16 weekly results in line with class A requirements.

- While the FVO team noted that the classification of production areas is modified when necessary, it was not possible to ascertain if the CA evaluates regularly the past microbiological monitoring records of the areas with a view to a revision of the classification and the frequency of this evaluation.

- Shoreline inspections were in general performed in accordance with the set frequency – once every three years.

- In general only one species is harvested from each production area. The CA showed the FVO team the records of one production area with both mussels and oysters, which had two different classifications – one for each species. When in the same production area live bivalve molluscs and echinoderms are harvested, the live bivalve molluscs are used as the

2 As suggested in the EU reference laboratory's Guide to Good Practice.

indicator species for the microbiological monitoring of the area.

Monitoring of classified relaying and production areas

Findings

At least once a year, CA officials must visit the classified production areas to assess the harvesting of live bivalve molluscs and its sampling for the monitoring programmes (if taking place). During these visits the CA assesses the hygiene conditions of harvesting, the vehicles used in the transport of live bivalve molluscs to the establishments and the use of the registration documents.

Based on the outcome of the classification programme the CA establishes a monitoring programme for microbiology, biotoxins and environmental contaminants in live bivalve molluscs and phytoplankton in water. The monitoring programme consists of a sampling plan which is sent to the FBO for implementation, with an indication of the location of the sampling points and the sampling frequency for each parameter to be tested. Based on the availability of bivalve molluscs in the case of aquaculture farms the FBO sends the CA the exact location of the sampling points identified with geographical coordinates. The FBO implements the monitoring programme availing of the services of a CA approved sampler and a CA approved laboratory. The FBO is required to have molluscs available for sampling and to provide any necessary assistance to the approved sampler.

Sampling frequencies are defined in the CA procedures as follow:-

- Microbiology of live bivalve molluscs: *E. Coli* – monthly; *Salmonella* – monthly (only Class A areas); *Vibrio parahaemolyticus* – fortnightly (only class A areas); and Norovirus – weekly (only for oysters from Class A areas).

- Toxicology of live bivalve molluscs: Lipophilic toxins, ASP and PSP - weekly.

- Contaminants of live bivalve molluscs: heavy metals and pesticides – one sample every six months.

- Phytoplankton in water – weekly for Atacama, Coquimbo, Aysen, Magallanes and Los Lagos regions and fortnightly for the remaining regions.

The CA procedures require that the monitoring programmes are not interrupted – if monitoring sampling does not take place for more than one month the area is removed from the list of areas under the PSMB (hereinafter PSMB list). If a production area is not included in the PSMB list for more than four months then a new classification programme is required to be carried out before the area can be re-added to that list.

In addition to regular monitoring, the CA procedures also allow for a reduced monitoring in certain cases (e.g. - no harvesting for more than two months in aquaculture farms; prolonged biological closure for natural sea beds). The reduced monitoring consists of monthly sampling of water for phytoplankton testing. During the reduced monitoring no harvesting may take place and that is indicated in the PSMB list. Production areas that are subject to reduced monitoring must be sampled for all parameters two weeks before the commencement of harvesting followed by the implementation of the monitoring programme previously defined for that area.

The CA has in place procedures for sampling of bivalve molluscs and water (LAB/MP2 and

LAB/NT1) that should be followed by the approved samplers. The samples are collected by CA approved samplers hired by the FBOs. During one year the CA officials have to attend at least 1% of the samples taken. Sampling forms are filled in by the sampler, signed by the FBO (if the production area has aquaculture farms) and accompany the samples to the approved laboratories. All samples must reach the laboratory within 24 hours of sampling (with the exception of Magallanes Region for which the time limit is extended to 48 hours).

The CA has and makes available lists of approved samplers and approved laboratories. The CA only approves samplers after a candidate has passed a training course provided by the CA. The activity of the approved samplers should be regularly supervised by CA officials (at least once a year).

The FVO team noted that:-

- In general the procedures for the monitoring of production areas cover the EU requirements. The procedures for sampling adopted by the CA can be considered as fit for purpose.

- The parameters checked and the sampling frequencies were in general respected and are in line with EU rules (microbiology, biotoxins and chemical parameters for bivalve molluscs and phytoplankton for water).

- The sampling points used for the monitoring programme are in general the ones determined during the classification programme. Sampling points were defined by geographical coordinates for the collection of molluscs for microbiological, biotoxins and chemical testing and of water for phytoplankton.

- The microbiological monitoring results contribute to the maintenance or change of the classification but are not generally used as a tool for a predictive classification as it is advised in the Guide to Good Practice for the microbiological monitoring of bivalve molluscs harvesting areas[3] (hereinafter the "EU working Group Guide to Good Practice"). As already mentioned in the section for "Classification" the FVO team observed cases where following the results of the microbiological monitoring a production area changed its classification from A class to B and only returned to A class status after 16 consecutive analyses results in line with the requirements for A areas (samples taken with no less than one week interval).

- The phytoplankton species monitored in water are relevant for all groups of biotoxins. With the exception of very large algae blooms, in general, the monitoring of phytoplankton does not provide predictive information on the development of a bloom.

- In the records for different production areas the FVO team noted that reduced monitoring was applied. Two weeks prior to the commencement of harvesting in those areas sampling took place for microbiology, biotoxins and phytoplankton. The normal monitoring programme was then immediately resumed.

- Records of CA inspections of production areas were made available to the FVO team and they covered the points indicated in the CA procedures.

3 Issue 4 (August 2010) – EU working Group on microbiological monitoring of bivalve molluscs harvesting areas available on the website of the EU Reference Laboratory for live bivalve molluscs microbiology.

- The FVO team observed sampling made by three different samplers and noted that in general the CA procedures were followed adequately for the biotoxin testing of molluscs. However, with regard to the sampling of molluscs for microbiological testing the FVO team noted in one case practices that could have an impact on the analyses results, such as, washing and re-immersion of molluscs inside the container for the initial collection of the sample and sample plastic bags in direct contact with the ice packs for transport. During one sampling exercise shortcomings were also observed in the collection of water for phytoplankton testing, such as, incorrect sealing or closing of the collecting hosepipe and the recovery of the phytoplankton from the collection net.

Decisions after monitoring

Findings

The CA is only responsible for the authorisation of harvesting and subsequent export to the EU. The control at national level of the closure of the areas is the responsibility of the Ministry of Health.

The CA has in place a procedure to deal with non-compliant analyses results for biotoxins, microbiology and chemical parameters of bivalve molluscs and phytoplankton testing in water (SMB/NT3). This procedure also defines trigger levels for biotoxins in bivalve molluscs which will lead to an increased monitoring sampling for ASP and PSP toxins and a harvesting ban for lipophilic toxins. Trigger levels for phytoplankton are also defined which should activate an intensive monitoring of bivalve molluscs aimed at detecting the presence of biotoxins.

In case of analyses results above the regulatory limits for biotoxins the CA does not allow harvesting of bivalve molluscs and communicates the results to the services of Ministry of Health for a possible area closure. The harvesting ban is suspended when the analyses results of two consecutive samples taken with at least 48 hours interval present normal values for the biotoxin/s concerned.

In case of microbiological results above the limits for the area concerned, the CA immediately updates (downgrades) the area's classification (see details in the classification section (page 10)).

The FVO team noted that:-

- In general the procedures mentioned above are in line with the EU requirements and were adequately followed by the CA.

- Several cases of intensive monitoring and harvesting suspension were assessed by the FVO team and showed that the CA took adequate and timely actions.

Additional monitoring requirements

Findings

In order to ensure that no bivalve molluscs harmful to human health are exported to the EU, in the case of production areas closed for harvesting, the CA withdraws the movement documents from the FBOs and cooperates with the Ministry of Health in the supervision of the areas. The on-the-spot monitoring (patrols of the area) is the responsibility of the Ministry of Health and is performed by the Chilean Navy.

With regard to end product testing the CA has defined in its procedures the frequencies and the parameters to be tested.

The FVO team noted that:-

- End product testing is carried out by the FBOs for all relevant parameters every 15 days of production (one production date is selected). Every 4th sample is taken by the CA and is designated as an official sample (which means that the CA samples approximately once every two months).

Recording and exchange of information

Findings

The FVO team noted that the CA has and makes available to all stakeholders involved in the production of bivalves a comprehensive updated list of each production area and a detailed information on its approval number, location, composition (when the production area is comprised of aquaculture farms), classification (past and current), details on suspensions and monitoring programmes (e.g. reduced monitoring). This information can be accessed from the CA website and is also transmitted by email to interested parties.

Food business operators' own-checks

Findings

The FVO team noted that the CA does not apply the possibility given by point F of Chapter II of Annex II to Regulation (EC) No 854/2004 when it classifies the production areas.

Conclusions

The procedures in place for the classification of bivalve molluscs production areas and their implementation by the CA follow, in general, the principles of the EU rules (namely point A of chapter II of Annex II to Regulation (EC) No 854/2004) and the EU working Group Guide to Good Practice. However, the actions taken by the CA when there is change in the composition of aquaculture farms within the production areas do not follow adequately those principles and do not provide an equivalent level of guarantees.

The regular monitoring of production areas cover the relevant EU requirements, is performed adequately and provides satisfactory guarantees with regard to the attestations included in the Health Certificate for imports defined in Appendix IV (for fishery products derived from live bivalve molluscs) and V (for live bivalve molluscs) of Annex VI to Regulation (EC) No 2074/2005. However, the reduced monitoring does not allow the CA to ascertain the sanitary status of the production areas at that time and a single sample taken 15 days prior to the commencement of harvesting is not in line with the guidance provided in the EU working Group Guide to Good Practice for similar situations.

The decisions taken after monitoring, the additional monitoring requirements and the recording and exchange of information implemented by the CA are performed adequately and provide satisfactory

guarantees with regard to the attestations included in the Health Certificate for imports defined in Appendices IV and V of Annex VI to Regulation (EC) 2074/2005.

Recommendation No 5 of the previous audit report concerning the frequency of biotoxin monitoring can be considered as adequately addressed.

5.4.2 Pectinidae and Live Marine Gastropods not filter feeders Harvested Outside Classified Production Areas

Findings

In Chile *Pectinidae* are harvested from non-classified production areas in regions X (Los Lagos), XI (Aysén) and XII (Magallanes) with the biggest natural sea beds located in region XII. Marine gastropods are also harvested in region XII.

These natural sea beds, which are not covered by the PSMB, have a seasonal harvesting activity and are controlled for biotoxins by the services of the Ministry of Health. For control purposes the Ministry of Health has divided these areas into sectors.

The CA informed the FVO team that harvesting vessels go to the natural sea beds for the extraction of scallops following which a transport vessel collects the harvested scallops on a weekly basis (which can be from different harvesting vessels) and takes them to shore to be transported to the processing establishments.

From the information provided by the CA the FVO team noted that:-

- Due to the absence of a registration document for the movement of *Pectinidae* and gastropods harvested from non-classified production areas the CA cannot ensure that the FBOs comply with the applicable requirements. The commercial document used does not have all the necessary information.

- A network of sampling points has been established by the services of Ministry of Health for the control of biotoxins by sector. Each sector is sampled every 25 to 30 days. The Ministry of Health services also sample scallops from each landing (clustered by production sector). Samples of *Pectinidae* are analysed at the Ministry of Health laboratories for PSP only.

- No samples of gastropods are taken for the control of biotoxins.

- The CA requires EU listed FBOs to test each exported batch for the presence of toxins. Five samples are taken from one production batch (one exported batch may comprise several production batches).

- The FBOs producing these products must perform analyses at least once every 15 days of production. The products are to be tested for biotoxins in accordance with its origin: region X – all biotoxins; region XII – only PSP and lipophilic toxins; region XII only PSP. The reason presented for the variations in testing is the historical data concerning the detected biotoxins. One sample in every four FBO own-check production samples (roughly once

every two months) is taken by the CA (which constitutes an official control analysis).

Conclusions

The official controls in place do not allow the CA to provide guarantees that *Pectinidae* and gastropods harvested from non-classified production areas comply with the health standards laid down in Annex III, Section VII, Chapter V, to Regulation (EC) No 853/2004.

The CA is not in a position to provide guarantees that *Pectinidae* and gastropods harvested from non-classified production areas comply with standards equivalent to the requirements laid down in Annex III, Section VII, Chapter IX, to Regulation (EC) No 853/2004.

5.4.3 Production and Placing on the Market of Live Bivalve Molluscs

Registration document accompanying the batch

Findings

The PSMB procedures define that each batch of live bivalve molluscs must be accompanied by a registration document (Harvesting and Transport Registration Document (RET)) from the time of harvesting until they reach the first establishment. This RET includes all the necessary information regarding EU requirements and is issued in triplicate (original and two copies). Each RET has a unique serial number and the CA has in place procedures to control the delivery of RET to FBOs and their use.

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

During one visit the FVO team noted that the transit document that accompanied one RET had been altered between harvesting and its receipt at the establishment. The seal of the truck had been changed after the truck left the production area, however, this fact was not mentioned on the receipt records of the establishment and the product was admitted to processing. The CA evaluated this incident and requested additional information from the FBO concerned. After the analysis of the information and documentation provided, the CA declared the product ineligible for EU export and took appropriate measures with regard to the establishment's classification (see section 5.5 on details of establishment classification).

Facilities handling live bivalve molluscs

Findings

The CA has in place procedures to control and inspect facilities handling bivalve molluscs. The CA has to-date approved ten dispatch centres. However no exports of live bivalve molluscs have taken place.

The FVO team noted that:-

- The dispatch centres are included within existing approved processing establishments which have been approved by the CA for this new activity in accordance with the applicable requirements. Official controls took place to assess this new operation.

- In general the structures and equipment of the establishments visited can be considered as adequate.

- HACCP based procedures were absent or not correctly implemented in all dispatch centres visited.

- The packages and methods of sealing to be used could not be fully evaluated due to the fact that the establishments are not producing live bivalve molluscs. The FBOs provided a demonstration of their new activities for the FVO team visit and the practices observed appeared adequate.

- The documentary requirements for live bivalve molluscs were observed in the course of the evaluation of the remaining activities of the establishments.

Health standards and microbiological criteria

Findings

In accordance with the rules for the approval of establishments and the requirements to be complied with, FBOs are obliged to test their products with a defined frequency (in general one sample taken within a period of 15 production days) for all the relevant parameters.

The FVO team noted that:-

- In all establishments visited the sampling programme required under CA procedures was adequately followed.

- In case of detection of non-conforming results the relevant batch was segregated in order to prevent its export to the EU and further investigations were performed to allow the CA to decide on the actions to be taken.

- In case of results above EU limits for lipophilic toxins by the mouse bioassay method a further test was performed using the chemical method (see section 5.6.). All the results obtained with the chemical method were in line with the EU requirements and the batches were considered eligible for EU export.

Pectinidae and Marine Gastropods which are not filter feeders harvested outside classified production areas

Findings

The background information and the activities description for this section can be found in section 5.4.2. No FBO processing this type of product was visited.

From the information provided by the CA the FVO team noted that:-

- There is no registration document for the movement of *Pectinidae* and gastropods harvested from non-classified production areas. There is a commercial document that does not have all the information required by Annex III, Section VII, Chapter IX, point 4(a), to Regulation (EC) No 853/2004.

- FBOs own-checks are described in section 5.4.2 above. Final products have to be tested for biotoxins in accordance with their origin: region X – all biotoxins; region XII – only PSP and lipophilic toxins; region XII only PSP. One sample is taken within a period of 15 production days.

Conclusions

In general the official control of production and placing on the market of live bivalve molluscs is adequately implemented by the CA and follows the EU requirements.

However, the failures detected with regard to *Pectinidae* and marine gastropods which are not filter feeders harvested outside classified production areas do not allow the CA to provide adequate guarantees concerning the compliance of those products with standards equivalent to those of the EU.

5.5 Official Controls of Fishery Products

5.5.1 Production and Placing on the Market

Legal requirements

Requirements contained in point II.1 of the model health certificate for imports of fishery products intended for human consumption established in Appendix IV to Annex VI to Regulation (EC) No 2074/2005.

Article 11(4) and (j) of Regulation (EC) No 854/2004 establishes that EU controls carried out in the context of drawing up or updating lists of third countries from which imports of products of animal origin are permitted, shall have regard to any experience of marketing of the product from the third countries and the results of any import control carried out.

Findings

Official controls system in place

The CA inspects the establishments following the programmes indicated in section 5.2. These inspections verify for the requirements indicated in each programme (such as HACCP, structures, equipment and hygiene practices) and with defined frequencies. Each establishment is visited for the PAC and HPB programmes. After each visit a report is produced and a classification is assigned to the establishment. The classification obtained will determine the frequency for future visits and whether or not the establishment can export to the EU. In general HPB inspections occur every year (can be reduced to once every two years) and PAC inspections take place from fortnightly to once

every two months.

The requirements to be respected by the FBOs are indicated in the different documents associated with each programme and the CA procedures are also defined in those programmes, in particular in the Programme for Inspections.

Facilities handling fishery products

The FVO team noted that:

- All establishments visited during the audit had been inspected by CA officials for the applicable programmes (PAC and HPB). Inspection reports were available and the deficiencies detected were identified and categorised (applicable categories vary from minor to critical) in those reports. The CA requests the correction of the deficiencies identified or an action plan for that correction. Follow-up of the correction of deficiencies occurs during the next inspection or at the expiry of the deadline set.

- CA officials followed adequately the procedures and visit frequencies were in general respected.

- In one of the establishments visited (which had been recently suspended for EU exports) the FVO team noted deficiencies with regard to structural and layout requirements.

- In another establishment the FVO team observed important deficiencies with regard to water condensation on ceilings and noted that this deficiency had also previously been identified by the CA and that attempts were being made to correct the problem but as yet no definitive solution had been found.

- The remaining establishments visited by the FVO team can be considered as in general in compliance with requirements equivalent to those of the EU.

- HACCP plans were available in the processing establishments visited and were broadly in line with EU requirements. Furthermore relevant own-check analyses programmes were correctly implemented by the FBOs.

- In all establishments processing bivalve molluscs originated from class B areas adequate heat treatments were applied. Those heat treatments were validated by the FBOs and their parameters were in line with EU requirements.

Import controls of fishery products

The FVO team was informed by the CA that there are no imports into Chile of bivalve molluscs for further processing and subsequent export to the EU. In the establishments visited the FVO team found that exports to the EU consist of fishery products derived from bivalve molluscs originated in Chile.

Follow-up of RASFF notifications

The CA informed the FVO team that the Economic Directorate of the Ministry of Foreign Relations

is the contact point for RASFF notifications. This service then passes the RASFF notification to the responsible bodies.

The CA on receipt of a RASFF notification requests that the FBO concerned undertake an investigation on the causes of the notification and if necessary CA officials visit/inspect the establishment to check the investigation performed.

In two RASFF cases evaluated (heavy metals contamination) the FVO team noted that the cascade of information worked in one case and the CA requested the FBO to evaluate the RASFF notification and to provide reasons for that notification. In another case the information was not passed to the CA by the relevant service but the FBO, which was informed directly, performed an investigation and presented the outcome to the CA. In both cases it was not possible to determine the origin or the cause of the RASFF notification.

Conclusions

Official controls of fishery products are adequately implemented by the CA, follow their procedures and are in general in line with EU requirements, allowing the CA to provide the guarantees required by the export health certificate.

The implementation of the actions taken to address recommendation No 2 of the previous audit report concerning landing of fishery products was assessed on the basis of a documentary check and can be considered as satisfactory.

5.5.2 Fishery Products

Legal requirements

Point II.1 of the model health certificate for imports of fishery products intended for human consumption established in Appendix IV to Annex VI to Regulation (EC) No 2074/2005, in particular official controls laid down in Chapter II and III of Annex III of Regulation (EC) No 854/2004.

Findings

The FVO team noted, for products evaluated during the audit, that official controls of fishery products derived from live bivalve molluscs were adequately implemented by the CA and they covered environmental contaminants and microbiological criteria such as *Salmonella*, *E. Coli* and *Staphylococci* coagulase-positive.

The frequency of these official control analyses is the one mentioned in section 5.4.2. for end-product testing.

In general, the results observed by the FVO team were in compliance with the EU requirements.

Conclusions

The official control analyses of fishery products derived from live bivalve molluscs is carried out

adequately and in line with EU requirements.

The implementation of the actions taken to address recommendation No 3 of the previous audit report concerning organoleptic checks was assessed on the basis of a documentary check and can be considered as satisfactory.

5.6 Laboratories

Legal requirements

Article 46(1)(d) and (c) of Regulation (EC) No 882/2004 stipulate that Community controls shall have particular regard to the resources including diagnostic facilities available to CAs and the training of staff in the performance of official controls.

Points 41 and 42 of Guidelines of Codex Alimentarius CAC/GL 26-1997 on the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.

Chapter 1 of Annex I to Regulation (EC) No 2073/2005.

Section II of Annex II and Annex III to Regulation (EC) No 2074/2005.

Regulations (EC) No 333/2007 and (EU) No 252/2012.

Findings

The CA has access to a laboratory network for the performance of official control analyses.

The CA drafted procedures for the approval of laboratories (LAB/MP1) and supervision of their tasks. In general each laboratory is audited by the CA every quarter.

The CA has approved laboratories for official control (verification laboratories) as well as for own-check analyses (service laboratories). All laboratories approved by the CA for analyses of live bivalve molluscs and fishery products derived therefrom are accredited to ISO standards 17025 by the National Normalisation Institute (INN) and must be authorised by the Public Health Institute.

The Public Health Institute acts as National Reference Laboratory and carries out activities for harmonizing techniques, methods and procedures for water and food testing. On an annual basis, this laboratory organises proficiency testing.

In order to maintain its authorisation laboratories must be audited by the CA, participate in the proficiency tests organised by Public Health Institute and present the results of the yearly audit of INN.

The FVO team visited seven laboratories and noted that:

- The laboratory performing only analyses on water for phytoplankton is accredited to ISO 17025 and was approved by the CA. The laboratory has adequate facilities and equipment and staff are well trained and up-to-date. Standard Operating Procedures are in place and adequately used by staff. Analyses reports are adequate and results are communicated without delay. The CA supervises the laboratory within the scheduled frequency and in

general no deficiencies were detected.

- Due to the specificity of the methodology for biotoxins determination the laboratories performing these analyses are at the same time verification laboratories and service laboratories.

- Laboratories performing analyses for lipophilic toxins (using the mouse bioassay methodology), PSP and ASP:-

  - The laboratories visited are accredited to ISO 17025 and were approved by the CA.

  - Both laboratories were regularly supervised by the CA and in general no deficiencies had been noted.

  - They participated in proficiency tests for PSP and ASP organised by the Public Health Institute with satisfactory results.

  - No proficiency testing is organised for lipophilic toxins. However one of the laboratories performs internal controls of the essay method employed every six months using certified reference material.

  - The analytical methods used and their performance criteria are in line with the EU requirements.

  - Analyses are speedily performed and the results are promptly made available to the CA. The analyses reports issued are adequate.

  - One of the laboratories also performs phytoplankton analyses. These analyses are included in the scope of the accreditation and are performed adequately.

- Laboratory performing lipophilic biotoxin analyses with the chemical methodology (LC-MS/MS):-

  - The methodology used is not included in the scope of the accreditation to ISO 17025. The laboratory was approved and is regularly supervised by the CA.

  - This laboratory is used mainly to confirm or challenge the results of analyses that showed results above the EU limits with the mouse bioassay methodology. If the results obtained by this method are in line with the EU requirements the analysed batch is considered as EU compliant.

  - In a recent CA audit report (21/12/12) several deficiencies were identified as important shortcomings. In subsequent follow-up visits made (26/03/13 and 02/04/13) the deficiencies were still present. Nevertheless, the laboratory was allowed to continue to perform official control analyses.

  - The LC-MS/MS method validation was not performed according to international rules (e.g. limits of detection, limits of quantification, calibration curve).

  - The LC-MS/MS method used does not conform to the SOP EU-HARMONISED-SOP-

LIPO-LC-MS/MS, VERSION 4, JULY 2011 (matrix effect, sample weight, second ion/product signal).

- The lipophilic toxins reporting results are not in line with EU requirements.

- No proficiency tests for the LC-MS/MS method were performed.

- Laboratories for microbiological analyses:-

  - All three laboratories visited are accredited to ISO 17025 and the relevant analytical methods were included in the scope of the accreditation (*E. Coli* - ISO/TS 16649-3, version in standards of Chile NCh 3056.Of 2007; and *Salmonella* - ISO 6579 version in standards of Chile NCh 2675.Of2002).

  - All laboratories had been audited by the CA following adequately the procedures and in line with the scheduled frequencies. However, the forms used for the audit did not allow the CA to detect deficiencies noted during the FVO team visit.

  - The laboratories participated in proficiency tests for *Salmonella* with adequate results.

  - The proficiency tests organised by the Public Health Institute for *E. coli* did not specify the use of a five tube format for MPN (most probable number) and did not evaluate the interpretation of tube combination nor the MPN table used. As a result all laboratories used a three tube MPN format in this evaluation. The result of this proficiency test was satisfactory for all laboratories.

  - The laboratories use six individual animals for the sample preparation instead of the ten required in EU Regulation (EC) No 2073/2005.

  - One of the laboratories that had been authorised by the CA on 22/11/11 performed one official analysis in a sample collected on 30/11/11 with a method that is not the Chilean official method for *E. coli* and is not equivalent or validated against the EU reference method. By the time of another analyses of a sample performed on 01/02/12 the laboratory was using the correct method but the report concerned mentions the other non-official method. These shortcomings were detected by the CA during the laboratory audits and corrective measures have been implemented.

  - Most staff of the laboratories showed adequate knowledge and experience in microbiological analyses and in particular the methods used. However in one laboratory one operator did not know the correct MPN table. This was detected in several samples taken in the context of PSMB in this laboratory during 2011 and 2012 and had an impact on how the results were expressed. However, this shortcoming had no impact on the safety of the products or on the classification of the area.

  - In one laboratory the shelf-life for a specific media (TBX agar plates prepared in-house) was defined but was not in line with ISO 16649-3 standard.

- In some of the laboratories visited the FVO team also evaluated the performance of analyses for heavy metals detection. No deficiencies were detected in this regard.

Conclusions

The laboratories performing laboratory analyses for phytoplankton in water and biotoxins in live bivalve molluscs allow the CA to provide the required guarantees with regard the compliance of the exported products to the EU health standards for biotoxins.

The CA is not in a position to ascertain the reliability of the results provided by the laboratory performing lipophilic toxin analyses using the chemical method.

The reliability of the analytical results with regard to the laboratories performing microbiological testing of live bivalve molluscs are weakened due to the shortcomings detected and do not allow the CA to provide full guarantees with regard the EU microbiological health standards for live bivalve molluscs.

Recommendation No 6 of the previous audit report concerning the analytical method used for *E. coli* determination can be considered as adequately addressed.

5.7 Official Certification

Legal requirements

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

Article 14 of Regulation (EC) No 854/2004.

Article 6 of Regulation (EC) No 2074/2005, in particular the model health certificate for imports of fishery products intended for human consumption established in its Appendix IV to Annex VI and the model health certificate for imports of live bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption established in Appendix V to Annex VI.

Findings

As indicated in section 5.2 the CA has in place a specific programme for certification of live bivalve molluscs and fishery products derived therefrom for export to the EU. A detailed certification procedure is set out in this programme and has not changed since the previous FVO audit (see previous FVO audit report).

The FVO team noted during the visits that the certification procedure was adequately followed by the CA officials and that certificates are always accompanied by supporting documents to ensure that the exported products have been produced in line with EU requirements. The CA uses the export health certificate model set out in Regulation (EC) No 2074/2005.

Conclusions

The procedures in place for official certification are in line with EU rules and provide adequate guarantees with regard to compliance of the exported products to the applicable EU requirements.

Recommendation No 7 of the previous audit report concerning certification can be considered as adequately addressed.

6 Overall Conclusions

In principle the current organisation of Chilean CA, its standards and procedures can be considered as an adequate basis for carrying out official controls. The implementation observed by the FVO team allows, in principle, the CA to provide adequate guarantees with regard to the sanitary conditions of live bivalve molluscs and fishery products produced therefrom to be imported by the EU.

However, a number of deficiencies have been identified in the report, which will require correction before the competent authority can fully ensure that all bivalve molluscs and products derived therefrom destined for export to the EU respect the requirements set out in the model health certificate as defined in Regulation (EC) No 2074/2005, as last amended.

All recommendations of the previous audit report were adequately followed.

7 Closing Meeting

During the closing meeting held in Santiago airport on 26April 2013, the FVO team presented the findings and preliminary conclusions of the audit to the CA.

During this meeting, the CA acknowledged the findings and preliminary conclusions presented by the FVO team with the exception of the conclusions related to the laboratory performing lipophilic biotoxins testing using the chemical method. The CA provided a commitment to correct the deficiencies and actions to be taken to correct the failures detected in the laboratories performing microbiological testing of live bivalve molluscs.

8 Recommendations

The CA should provide Commission services with an action plan, including a timetable for its completion, within one month of receipt of this report, in order to address the following recommendations for live bivalve molluscs and fishery products derived therefrom intended for export to the EU.

N°.	**Recommendation**
1.	In order to provide all the guarantees required by the Health Certificate for imports defined in Appendices IV and V of Annex VI to Regulation (EC) 2074/2005 the CA should ensure that standards at least equivalent to the EU ones are applied to dispatch centres approved for EU exports, in particular as regards the obligation for FBOs to implement and maintain HACCP based systems as required in Article 5 of Regulation (EC) No 852/2004.
2.	The CA should ensure that the standards applicable to live bivalve molluscs and fishery products derived therefrom intended for export to the EU are in line with Annex II, Chapter II, part A, points 4 and 5, to Regulation (EC) No 854/2004, in particular with regard to the requirements applicable to live bivalve mollusc samples to be analysed (i.e. flesh and intravalvular liquid).

N°.	Recommendation
3.	In order to provide the guarantees required by Article 12, point 1, of Regulation (EC) No 854/2004, the CA should ensure that the lists of live bivalve mollusc production areas are promptly updated as necessary.
4.	The CA should ensure that, when a production area is modified (e.g. incorporation of new farms), the re-classification is performed following requirements at least equivalent to the ones indicated in point A of chapter II of Annex II to Regulation (EC) No 854/2204, in order to provide all the guarantees required by the Health Certificate for imports defined in Appendices IV and V of Annex VI to Regulation (EC) No 2074/2005.
5.	The CA should ensure that all classified production areas are periodically monitored for all the parameters defined in point B of chapter II of Annex II to Regulation (EC) No 854/2204, in order to provide all the guarantees required by the Health Certificate for imports defined in Appendices IV and V of Annex VI to Regulation (EC) No 2074/2005, in particular, when there is irregular harvesting from production areas, the CA should ensure that at the time of commencement of harvesting the microbiological quality of the live bivalve molluscs has been in line with the classification of the area during the previous month.
6.	In order to provide all the guarantees required by the Health Certificate for imports defined in Appendices IV and V of Annex VI to Regulation (EC) No 2074/2005 the CA should ensure that Pectinidae and gastropods harvested from non-classified production areas comply with the health standards laid down in Annex III, Section VII, Chapter V, to Regulation (EC) No 853/2004 and with standards equivalent to the requirements laid down in Annex III, Section VII, Chapter IX, to Regulation (EC) No 853/2004.
7.	In order to provide all the guarantees required by the Health Certificate for imports defined in Appendices IV and V of Annex VI to Regulation (EC) No 2074/2005 the CA should ensure that analyses performed on live bivalve molluscs are carried out in accordance with the requirements established in Regulation (EC) No 2073/2005 with regard to the number of individual animals to be used when forming the sample for analysis.
8.	The CA should ensure that all laboratories performing official control analyses use EU reference methods (or alternative methods validated to the EU reference ones), have performance criteria for the methods used in line with EU rules, are assessed and that adequate quality controls are in place to provide for the reliability of test results (Codex Alimentarius, CAC/GL 26-1997), in particular for microbiology and lipophilic toxins testing (chemical method).

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6721

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Dec. 2005/269/EC	OJ L 84, 2.4.2005, p. 19-20	2005/269/EC: Council Decision of 28 February 2005 on the conclusion of the 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
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
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

Legal Reference	Official Journal	Title
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
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. 252/2012	OJ L 84, 23.3.2012, p. 1-22	Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006