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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

CHINA

FROM 14 TO 20 NOVEMBER 2013

IN ORDER TO EVALUATE THE CONTROL SYSTEMS IN PLACE GOVERNING THE PRODUCTION OF 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 Food and Veterinary Office audit in China carried out between 14 and 20 November 2013, as part of its programme of audits in third countries.

The objective of the audit was to evaluate the public health conditions for the production of scallops from the Zhangzidao production area intended for export to the European Union as frozen scallops' adductor muscle roe-on and roe-off. The audit covered the relevant EU legislation for the public health sector. This was also a follow-up inspection to a previous Food and Veterinary Office audit carried out from 7 to 11 September 2009.

The report concludes that since the 2009 FVO audit, improvements have been noted in the official controls of scallops from the Zhangzidao production area. However, weaknesses remain in the way sanitary surveys and phytoplankton monitoring are conducted. Moreover, deficiencies, which undermine the reliability of test results, were noted in the laboratory in charge of analysing monitoring samples from the Zhangzidao production area.

The report addresses to the Chinese Competent Authorities 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
AQSIQ	General Administration of Quality Supervision Inspection and Quarantine of the PRC
ASP	Amnesic Shellfish Poisoning
C/CA/s	Central/Competent Authority/ies
CIQ	Entry-Exit Inspection and Quarantine Bureau
CNAS	China National Accreditation Service for Conformity Assessment
CNCA	Certification and Accreditation Administration of the PRC
Community Guide	Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regard to Regulation 854/2004.
DSP	Diarrhoeic Shellfish Poisoning
EC	European Community
ELISA	Enzyme-linked immunosorbent assay
EU	European Union
FBO/s	Food Business Operator/s
FVO	Food and Veterinary Office of the European Commission
ISO	International Organisation for Standardisation
MoA	Ministry of Agriculture
NMEMC	National Marine and Environment Monitor Centre
MPN	Most probable number
MS	Member State/s of the European Union
OFB	Ocean and Fishery Bureau
OJ	Official Journal of the European Communities
PAHs	Polycyclic Aromatic Hydrocarbons
Pb	Lead
PCBs	Polychlorinated Biphenyls
PRC	People's Republic of China
PSP	Paralytic Shellfish Poisoning
RASFF	Rapid Alert System for Food and Feed
SANCO	General Directorate for Health and Consumers
SOP/s	Standard Operating Procedure/s
ZZD	Zhangzidao

1 Introduction

The audit took place in China from 14 to 20 November 2013 and was undertaken as part of the Food and Veterinary Office's (FVO) planned audit programme. The FVO team comprised two inspectors from the FVO and one national expert.

An opening meeting was held in Beijing on 14 November 2013 with the Competent Authorities (CAs) within the scope of this audit. At this meeting the FVO team confirmed the objectives of, and itinerary for the audit, and requested additional information regarding the specific elements of the control system in place. Representatives from the CA accompanied the FVO team during the whole audit.

2 Objectives and Scope

The objectives of the audit were:-

- To evaluate whether the official controls put in place by the CA can guarantee that the conditions of production of certain bivalve molluscs in China 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 certificate of Appendix IV to Annex VI to Regulation (EC) No 2074/2004. More precisely this concerns scallops (*Patinopecten yessoensis*) originating in Zhangzidao (ZZD) classified production area in Liaoning province intended to be exported to EU as frozen scallops' adductor muscle roe-on and roe-off;
- Verify the extent to which the guarantees and the corrective actions submitted to the Commission services in response to the recommendations of the previous bivalve molluscs report of 2009 have been implemented and enforced by the CA (ref. DG(SANCO)/2009-8348).

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 bivalve molluscs to be exported to the EU. Accordingly, relevant aspects of the EU legislation referred to in Annex 1 were used as technical basis for the audit.

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

Competent authority		
Central level	3	Meeting in Beijing with the General Administration of Quality Supervision Inspection and Quarantine of the PRC (AQSIQ), the Certification and Accreditation Administration of the PRC (CNCA) and the Ministry of Agriculture (MoA).
Provincial level	2	Meeting in Dalian (Liaoning province) with the Dalian Ocean and Fishery Bureau (OFB) and the Liaoning Entry-Exit Inspection and Quarantine Bureau (CIQ).
Laboratory visits		

Provincial level	2	The Liaoning CIQ laboratory (end-products testing before export) and the National Marine and Environment Monitor Centre (NMEMC) laboratory (analysing monitoring samples of the ZZD production area)
Primary production		
Production areas	1	The Zhangzidao production area
Fishing Vessels	2	1 scallops harvesting vessel and 1 transport vessel
Landing sites	1	Zhangzi island
Food processing facilities		
Processing establishments	1	Zhangzi island: newly built processing establishment preparing scallops

3 Legal Basis

The audit was carried out in agreement with the Chinese Authorities and under the general provisions of EU legislation and, 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.

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 General background

Currently China is not listed in Commission Decision 2006/766/EC, Annex I – List of third countries from which imports of bivalve molluscs, echinoderms, tunicates and marine gastropods are permitted.

Following a request of the Chinese Authorities concerning scallops originating from the ZZD production area and intended for export to the EU as frozen scallops' adductor muscle roe-on and roe-off, an FVO audit took place in 2009 (ref. DG SANCO/2009/8348). The 2009 FVO report highlighted several deficiencies in relation to the classification and monitoring of the ZZD production area and the reliability of laboratories involved in the testing. As a result, the official control system was not deemed adequate to meet the standards equivalent to those of the EU.

4.2 Production and trade information

The FVO team noted that:

- The ZZD production area, with a surface area of 70,000 hectares located 44.4 km from the mainland, is one of the 27 production areas under the jurisdiction of the Dalian Ocean and Fishery Bureau (OFB). The ZZD production area is the main producing area of scallops in Dalian, using a bottom sowing farming method.

- Dalian coastline is 1906 kilometres long and the sea area under its jurisdiction is over 29,000 square kilometres. Dalian is the most important shellfish production zone in China, covering about 330,000 hectares, with an annual shellfish production of about 10% of the total Chinese marine shellfish output. The main species harvested are scallops, clams, oysters and mussels.
- Shellfish produced in Dalian are mainly exported to the U.S., Japan, South Korea, Australia, New Zealand, Hong Kong and Taiwan.

5 Findings And Conclusions

5.1 Introduction

The bivalve molluscs audit referred to in Chapter 2 above was conducted in parallel with a fishery products audit, which took place from 3 to 13 November 2013.

For this reason, cross-references to the fishery products report DG(SANCO)/2013-6718 are made in this report, in particular regarding:-

- The general structure, organisation and competencies of the CAs involved in the official controls of fishery products, including bivalve molluscs (see Point 5.3).
- Official controls of production and placing on the market of bivalve molluscs (see Point 5.6)

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

Findings

Since the last FVO audit, the following laws concerning the sanitary supervision of the food of animal origin have been amended:

- The food safety law, of 1 June 2009; and its implementing rules, of 20 July 2009;
- The law on the inspection of imported and exported commodities, of 29 June 2013.

Specific administrative rules have also been adopted, such as:-

- AQSIQ Order No 135, dated 1 June 2011, setting out measures for inspection and quarantine administration of imported and exported fishery products, including bivalve molluscs; and its implementing rules (AQSIQ Notice 2011.286);
- AQSIQ Order No 142, dated 26 July 2011, concerning measures on import and export food safety management approach;
- The AQSIQ Order No 144, dated 1 March 2012, concerning measures on registration of exporting food processing establishments.

With regards to exports of frozen scallops from the ZZD production area, the relevant EU requirements are taken into account by the different CAs involved in the official controls. The FVO team noted that translated Chinese versions of legal provisions laid down in the EU "food and

hygiene package" were available for the staff involved in these controls.

Conclusions

The Chinese legislation and standards applicable to frozen scallops from the ZZD production area intended to be exported to the EU can be considered, in general, in line with the EU rules.

5.3 Competent Authorities

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.

Findings

The general structure, organisation and competencies of the CAs involved in the official controls of fishery products, including bivalve molluscs are already described in details in the fishery products report DG(SANCO)/2013-6718.

Regarding scallops intended for export to the EU, the Dalian OFB is, at municipal level, the competent service for the classification and the monitoring of the ZZD production area, targeting EU requirements.

The FVO team noted that, in July 2010, the Dalian OFB commissioned the National Marine Environmental Monitoring Centre (NMEMC) to carry out on the basis of an annual contract, sanitary surveys in the ZZD production area. This contract also includes:

- An annual review of the data,
- The monitoring of the ZZD production area based on an annual monitoring plan for *E.coli, Salmonella* and phytoplankton on a monthly basis,
- The monitoring of marine biotoxins (lipophilic toxins, PSP and ASP) on a weekly basis and chemical contaminants (lead, mercury, cadmium) every six months.

At provincial level, the Liaoning CIQ, within AQSIQ, is responsible for the official controls and certification of bivalve molluscs intended for export. It also implements its own monitoring of production areas.

Regarding the issue of lack of coordination between the Liaoning CIQ and the Dalian OFB, which was raised in the previous FVO report, the FVO team noted the following:-

- A "cooperation Agreement" was signed on 19 November 2007 between Liaoning CIQ and Dalian OFB to set down a general cooperation framework between the two services involved in the controls of bivalve molluscs intended for the domestic market and for export;
- On 20 January 2011, a specific Memorandum in relation to scallops originating from ZZD production area and intended for export to the EU, was also signed between Liaoning CIQ and Dalian OFB in order to strengthen cooperation and information exchange;
- Examples of communication between the two CAs related to the monitoring of production areas (closure/re-opening) and alerts notifications were available. Furthermore, since 2011, inter-comparison exercises are carried out regularly between NMEMC laboratory and Dalian CIQ laboratory.

Conclusions

The CAs in charge of the official controls and certification of scallops from the ZZD production area intended for export to the EU are clearly identified. Cooperation agreements exist between the two CAs. Examples of cooperation and information exchanges have been noted by the FVO team. Consequently, recommendation No 1 can be considered as satisfactorily addressed.

5.4 National provisions and procedures for listing establishments exporting to the EU

Legal requirements

Article 12(1) and (2) of Regulation (EC) No 854/2004; part I.11. 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; and, part I.11 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.

Findings

China is not yet authorised to export scallops to the EU; therefore, there was no list of EU approved classified production areas or processing establishments available.

However, the FVO team noted that national provisions and procedures for the approval and the listing of establishments intending to export to the EU are in place, namely the AQSIQ Order No 142, 2011 and the CNCA Order No 15, 2002. These administrative procedures have already been implemented for fish sector establishments approved and listed for export to the EU.

Conclusions

National provisions and procedures for listing establishments for export to the EU are in place.

5.5 Official controls on live bivalve molluscs from classified production and relaying areas

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.

5.5.1 Classification of production areas

Findings

The Dalian OFB is in charge of the classification of production areas. According to the "Marine bivalve culture area classification plan of Dalian", the Dalian OFB had established 27 classified production areas, the ZZD production area being the biggest of them with a surface area of 77,000 hectares. The ZZD production area has been classified as class 1 according to Chinese requirements, which can be regarded as equivalent to EU class A standard (Annex II, Chapter II, A, 3 of Regulation (EC) No 854/2004).

The Dalian OFB commissioned the National Marine Environmental Monitoring Centre (NMEMC) to carry out a sanitary survey on the ZZD production area and a preliminary document was finalised in August 2010.

The FVO team noted that:-

- The sanitary survey included an inventory of the sources of pollution carried out in June 2010, together with a set of microbiological analyses collected between 14 and 25 July 2010, from samples of seawater (70 stations), sediment (52 stations) and live scallops (17 stations).
- The survey did not examine the quantities of organic pollutants which are released during the different periods of the year, according to the seasonal variations of both human and animal populations in the catchments area, rainfall readings, waste-water treatment, etc.
- The characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle was carried out in a broad area, which does not take into account the precise features of the ZZD production area.

The FVO team noted as well that the classification monitoring frequency for *E.coli* has been established on a monthly basis, which is considered acceptable under guidance produced by the EU Reference Laboratory.

Conclusions

The procedures in place for the classification of live bivalve molluscs production areas and their implementation by the CA follow, in general, the EU principles; namely the requirements laid down in Article A, Chapter II, Annex II to Regulation (EC) 854/2004 and the guidelines of the Community Guide.

However, the sanitary survey in the ZZD production area, initiated in June 2010, is not fully in line with the requirements laid down in Point 6, (b) and (c), Article A, Chapter II, Annex II to Regulation (EC) 854/2004. Consequently, Recommendation No 2 cannot be considered as fully addressed.

5.5.2 Monitoring of production areas

Findings

Dalian OFB commissioned the National Marine Environmental Monitoring Centre (NMEMC) to carry out the monitoring on the ZZD production area on the basis of an annual monitoring plan for *E.coli, Salmonella* and phytoplankton on a monthly basis, marine biotoxins (PSP, lipophilic toxins and ASP) on a weekly basis and heavy metals (lead, mercury, cadmium) on half a year basis.

Monitoring sampling is carried out by NMEMC staff.

In addition, the FVO team was informed that CIQ has implemented in the ZZD production area additional monitoring covering *E.coli* and marine biotoxins in scallops on a monthly basis, heavy metals (lead, cadmium and mercury) and contaminants (Polychlorinated Biphenyls [PCBs], dioxins and Polycyclic Aromatic Hydrocarbons [PAHs]) on a half year basis. Samples are analysed by Dalian CIQ laboratory (not visited by the FVO team) and for contaminants by the Chinese Academy of Testing in Beijing.

<u>Microbiological monitoring</u>

The FVO team noted that:

- Microbiological (*E.coli, Salmonella*) monitoring is carried out regularly on a monthly basis in one sampling station per harvesting areas; the coordinates of each sampling station are not fixed and vary according to the place of harvesting. In 2013, there were two active harvesting areas.
- The *E.coli* method used for the monitoring of the ZZD production area is the EU reference one: ISO/TS 16649-3.

- The timeline between testing and results reporting is on average a week, which can be considered acceptable.

Phytoplankton monitoring

The FVO team reviewed phytoplankton sampling operations during the visit to the ZZD production area.

The FVO team noted that:

- Phytoplankton monitoring is carried out regularly on a monthly basis from 29 sampling stations, with fixed geographical coordinates;
- Three samples of about 1 litre of seawater are collected in each station, two of them are taken respectively at surface and bottom level; the last one is taken using a plankton net;
- The sampling equipment is not fit for purpose as the plankton net mesh size (77 mm) used is not appropriate for the routine detection of small size toxin-producing species (i.e. *Alexandrium, Dinophysis,etc.),* which can pass through the net without being retained;
- The delay between testing and results reporting is an average of three weeks which cannot be considered acceptable for forecasting (early warning system).

Marine biotoxins monitoring

The FVO team noted that:

- Marine biotoxins (lipophilic toxins, PSP and ASP) monitoring is carried out regularly on a weekly basis in one sampling station of each harvesting area; the coordinates of each sampling station are not fixed and vary according to the place of harvesting. In 2013, there were two active harvesting areas;
- The method used for the monitoring of lipophilic toxins in the ZZD production area is mouse bioassay (GB/T 5009.212-2008), which can be considered in line with EU requirements;
- The PSP method used for the monitoring of the ZZD production area is a mouse bioassay method (GB/T 5009.213-2008), which can be considered equivalent to the EU reference method;
- The ASP method used for the monitoring of the ZZD production area is a HPLC method (GB/T 5009.198-2003), which can be considered equivalent to the EU reference method;
- The timeline between testing and results reporting is on average weekly for the mousse bioassay test; concerning ASP, results are only sent by NMEMC to Dalian OFB every month, which cannot considered acceptable.
- Monitoring results suggesting an accumulation of toxins in molluscs was followed by intensive sampling.

Chemical Contaminants monitoring

The FVO team noted that:

- Heavy metals (lead, mercury and cadmium) monitoring is regularly carried out by NMEMC every 6 months; the coordinates of each sampling station are not fixed and vary according to the place of harvesting. In 2013, there were two active harvesting areas;
- Regarding scallops originating from the ZZD production area, a set of 27 results of tests for cadmium (from December 2010 until July 2013) was provided to the FVO team. The following part of the scallop was analysed: adductor muscle roe-on together with gills; out of the 27 results, 25 showed a value between double and triple the EU legal limit (1 mg/kg), albeit this limit was not exceeded (according to data provided to the FVO team) in the edible

part (adductor muscle roe-on and roe-off) being proposed for EU export[1];

- Other contaminants, including PCBs, dioxins and PAHs are monitored by Dalian CIQ every 6 months. Samples are sent to the Chinese Academy of Testing in Beijing. Monitoring results were made available to the FVO team, who noted that:

    1. PAHs monitoring does not cover all the requirements laid down in Regulation (EC) No 1881/2006 as amended, which also requires the monitoring of benzo(a)antracene, benzo(b)fluorantene and crisene;
    2. PCBs monitoring does not cover all the requirements laid down in Regulation (EC) No1881/2006 as amended, which also requires the monitoring of PCB 28, PCB 52, PCB 101, PCB 138, PCB 153, PCB 180.

Conclusions

In general, the regular monitoring of the ZZD production area covers the relevant EU requirements, is performed adequately and provides satisfactory guarantees with regard to the attestation 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 sampling equipment used for phytoplankton monitoring is unsuitable for the routine detection of small size toxin-producing species (*Alexandrium, Dinophysi*s, etc.)

Regarding heavy metals, all parameters tested during the last three years were below the EU limits, except cadmium. Not all the requirements laid down in Commission Regulation (EC) No 1881/2006 as amended are monitored.

Consequently, Recommendation Nos 3, 4 and 6 of the 2009 FVO report can be considered as satisfactorily addressed. However, Recommendation No 5 cannot be considered as addressed.

5.5.3 Decisions after monitoring

Findings

The FVO team reviewed all the monitoring data concerning microbiology, marine biotoxins and contaminants from August 2010 until October 2013 and noted the following:-

- One unique case of PSP exceeding the EU limits occurred following the sampling carried out on 25 April 2011. The information was immediately forwarded by NMEMC to Dalian OFB and immediate action was taken. The ZZD production area was closed by the Dalian OFB and re-opened two weeks later following two consecutive results below the regulatory limit. An official notification was sent to the relevant stakeholders by Dalian OFB.
- For chemical contaminants, as already said above, exceeding limits laid down in Commission Regulation (EC) No 1881/2006 (noted by the FVO team for cadmium) does not trigger any specific action where the national maximum levels, (higher than the EU limits: 4 mg/kg) are exceeded[2].

Conclusions

1 In their response to the draft report the Competent Authority stated that regarding the results that are provided to FVO, all samples are molluscs with visceral mass removed and include mantle. However products intended for export to EU will not include gills. Test results of separate adductor muscle roe-on. and adductor muscle have not exceeded the EU legal limit (1 mg/kg).

2 In there response to the draft report the CA stated since no products have been exported yet to the EU, no action has been taken in relation to scallops with cadmium above the EU threshold. All samples monitored so far have results below the Chinese standard (4mg/kg). Should sample results exceed the Chinese limits measures to prevent such products being placed on the market would be taken in line with Dalian Ocean and Fishery Bureau procedures.

The procedures in place for taking decisions after monitoring can be considered in line with EU requirements.

Consequently, Recommendation No 7 can be considered as addressed.

5.5.4 Additional monitoring requirements

Findings
The FVO team noted that the Liaoning CIQ carries out tests to verify food operator's compliance with requirements on end-product intended for export, including microbiological testing (*E. coli, Salmonella*) and marine biotoxins testing (Lipophilic toxins, PSP and ASP) on a monthly basis, and heavy metals (lead, cadmium and mercury) and contaminants (PCBs, dioxins and benzo(a)pyrene) on a half year basis.

Conclusions
A control system to verify the food business operators (FBOs)' compliance with requirements on end products intended for export is in place.

Consequently, Recommendation No 8 is satisfactorily addressed.

5.5.5 Recording and exchange of information

Findings

The FVO team noted that:-

A map of the 27 approved production areas with details of the location and boundaries as well as the class in which the production area is classified was available.

Examples of prompt actions and communication between the two CAs, related to the monitoring of production areas (closure/re-opening, changes) and alerts notifications sent to the relevant stakeholders were available.

Conclusions
Recording and exchange of information are in line with EU requirements.

5.6 Official controls of production and placing on the market of 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.

Introduction

As indicated in the previous 2009 FVO report, the audit mainly focussed on the conditions of production of scallops in the ZZD production area including their harvesting and transport to the processing establishment located on the Zhangzi island. The conditions and the official supervision of the processing establishment where the scallops are processed were partially looked at as these aspects were covered by the fishery products audit DG(SANCO)/2013-6718.

Findings

China is not yet authorised to export scallops to the EU; as such no processing establishment has so far been approved.

During the visit of the ZZD production area, the FVO team attended the harvesting and the landing operations of scallops and noted the following:-

- The FBO harvesting the live scallops also operates the processing establishment receiving these shellfish, and a single CA supervises the establishment concerned. For these reasons, a registration document is not necessary.
- The landing site presented good structural and hygiene conditions preventing the contamination of live scallops when unloaded.

The FVO team visited one harvesting vessel and one transport vessel (live scallops from the harvesting vessels are transhipped by sea). Once the scallops are harvested, they are put in plastic crates and then put into the ship's hold where they are covered with refrigerated sea water. The same system applies in the transport vessels.

The FVO team paid a short visit to a newly built processing establishment and observed processing operations (reception, calibration, evisceration, freezing and packaging) being carried out. These operations met standards equivalent to EU requirements.

Conclusions

The harvesting, landing and processing operations observed by the FVO team during the visit of the ZZD production area can be considered equivalent to EU standards.

5.7 Laboratories

Legal requirements

Article 46(1)(d) of Regulation (EC) No 882/2004 stipulate that Community controls shall have particular regard to the resources including diagnostic facilities available; Chapter 1 of Annex I to Regulation (EC) No 2073/2005; Articles 2 and 3, Section II of Annex II and Annex III to Regulation (EC) No 2074/2005; Regulations (EC) Nos 1883/2006 and 333/2007; and Regulation (EU) No 252/2012.

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.

Findings

The FVO team visited two laboratories:

- the Liaoning CIQ laboratory responsible for the official testing of scallop end-products intended for export;
- the NMEMC laboratory in charge of analysing monitoring samples from the ZZD production area.

In general, the staff from these two laboratories were found to be professional and well informed and the facilities and equipment (except phytoplankton sampling equipment) of good quality and satisfactory for the testing being performed.

5.7.1 The Liaoning CIQ laboratory

The laboratory has two departments:

- The Food Inspection Centre dealing with microbiological (*E. coli, Salmonella*) and heavy metals (lead, cadmium and mercury);
- The Animal and Plant Centre dealing with marine biotoxins (PSP, ASP, lipophilic toxins) testing.

Samples are collected by Dalian CIQ staff.

Quality system

The FVO team noted that:-

- The laboratory was accredited by the China National Accreditation Service for conformity assessment (CNAS) according to ISO/IEC 17025 standard. CNAS is a member of the International Laboratory Accreditation Cooperation (ILAC). The accreditation granted on June 2012 is valid until June 2015.
- All the methods used for the analysis of scallop end-product samples are within the scope of its accreditation except the ASP HPLC method.
- None of the copies of results reports seen by the audit team contained the logo of the accreditation body. The FVO team was informed by the CA that the stamp of the accreditation body was only added to copies upon request of the stakeholder[3].

Microbiological laboratory

The FVO team noted that:

- The laboratory uses the EU reference method for testing of *E. coli* (ISO TS 16649-3) and *Salmonella* (EN/ISO 6579);
- The laboratory has participated in April 2013 in proficiency tests organized by CNAS for *E. coli* in adductor muscle of scallops with satisfactory results.

Biotoxins laboratory

The FVO team noted that:

- The lipophilic toxin method used is a mouse bioassay method (GB/T 5009.212-2008), which can be considered in line with EU requirements;
- The PSP method used is the mouse bioassay method (GB/T 5009.213-2008), which can be considered equivalent to the EU reference method; the PSP standardisation is correctly performed on a quarterly basis: March, June and September records were available;
- The laboratory does not have a breeding section for the mice, which are provided by the Dalian CIQ laboratory upon request; mice are kept in good conditions before use[4];
- The ASP method used is a ELISA method (SN/T 2663-2010), which can be considered in line with the EU requirements as a screening method; the laboratory has the equipment, the reference material and the SOPs available for the ASP HPLC EU reference method: this method was recently accredited by CNAS in June 2013;
- In 2013, regarding bivalve molluscs originating from Dalian production areas, about 600 analyses concerning lipophilic toxins and PSP were carried out; very few exceeding results concerning scallops (2 DSP/2 PSP) were found; none of them originating from the ZZD production area;

3 In their response to the draft report the Competent Authority stated that every official paper version is issued with the stamp of the accreditation body.

4 In their response to the draft report the Competent Authority noted that the laboratory is able to feed the mice and has a license for using experimental animals. The laboratory is not a producer of experimental animals which are provided by Dalian Medical University upon request.

- Proficiency tests were available for ASP (ELISA method, organized by CNAS in June 2013); for lipophilic toxins (mouse bioassay, organised by CNAS in May 2013) and PSP (mouse bioassay, organized by CNAS in June 2013), all of them with satisfactory results.

Heavy metals laboratory

The FVO team noted that:-

- Heavy metals (lead, cadmium and mercury) method is the ICP-MS, with can be considered in line with EU requirements.
- In 2013, regarding end-product scallops originating from Dalian production areas, no results concerning lead and mercury were available; 33 results concerning cadmium were available, all of them meeting EU requirements.
- Proficiency tests were available for lead, mercury and cadmium in mussels meat (organized by CNAS in April 2007), all of them with satisfactory results.

5.7.2 The NMEMC laboratory

Samples are collected by the laboratory staff.

Quality system

The FVO team noted that:

- The laboratory was accredited by CNCA (Certification and Accreditation Administration of the PRC) according to a standard (GB/T 15481-2000) considered equivalent to ISO/IEC 17025 standard. CNCA is not a member of ILAC[5];
- All the results reports showed the stamp of the accreditation body; even though some methods are not included within the scope of accreditation.

Microbiology laboratory

The FVO team noted that:

- The laboratory uses the EU reference method for testing of *E. coli* (ISO TS 16649-3); but the EU method is not within its scope of accreditation and no proficiency test result was available. The whole flesh of ten scallops is used for *E. Coli* testing, which is in line with EU requirements[6];
- The timeline between testing and results reporting is on average a week.

Phytoplankton laboratory

The FVO team noted that:

- The count methodology (full species counted under light microscopy) is defined by the GB/T 15481-2000 method. A standard operating procedure is in place and the method is within the scope of CNCA accreditation.
- Regarding phytoplankton testing and reporting, the FVO team noted the following:-
    1. The filtering system used to concentrate the surface and bottom samples (50 mm mesh size) is not fit for purpose, as small size toxin-producing species remain

5 In their response to the draft report the Competent Authority noted that CNCA is a government authority with laboratory qualification and that the certification standards of both CNCA and CNAS, which is a member of ILAC, are equivalent.

6 In their response to the draft report the Competent Authority stated that in April 2014, this EU reference method method will be added to the scope of accreditation.

undetected.

2. No proficiency testing is carried out.
3. Result reports do not provide information on the presence of toxic species as well as on population trends as required in Point 7, Article B, Chapter II, Annex II to Regulation (EC) No 854/2004.
4. Result reports do not provide information on changes in the composition of plankton containing toxins and their geographical distribution; moreover, results suggesting an accumulation of toxins in mollusc flesh are not followed up by intensive sampling as required by in Point 4, Article B, Chapter II, Annex II to Regulation (EC) No 854/2004;
5. The time-lag between testing and results reporting is on average three weeks which cannot be considered acceptable as an early warning tool.

Biotoxins laboratory

The FVO team noted that:-

- The lipophilic toxin method used is a mouse bioassay method (GB/T 5009.212-2008), which can be considered in line with EU requirements; this method is within the scope of accreditation.
- The PSP method used is the mouse bioassay method (GB/T 5009.213-2008), which can be considered equivalent to the EU reference method. However, the PSP standardisation is not performed, which undermines the reliability of the test and the validity of the result. Furthermore, this method is not within the scope of accreditation.
- The ASP method used is a HPLC method (GB/T 5009.198-2003), which is the EU reference method. This method is within the scope of accreditation.
- None of the methods described above have undergone proficiency testing; nevertheless, since November 2010, twice a year inter-comparison exercises have been carried out with Dalian CIQ laboratory for the three groups of marine biotoxins; all reports provided to the FVO team showed satisfactory results.
- Lipophilic toxic analyses are carried out using the muscle together with the roe, which is not in line with the requirements laid down in Point 4, Article B, Chapter III, Annex III to Regulation (EC) 2074/2005, which requires the inoculation with an extract equivalent to 5g hepato-pancreas or 25g whole body;
- The time-lag between testing and results reporting for lipophilic toxins and PSP is on average one week. However for ASP, results are only sent by NMEMC to Dalian OFB every month, which cannot be considered acceptable.

Heavy metals laboratory

The FVO team noted that:

- Lead and cadmium analyses are carried out using Atomic Absorption (AA) method (lead: GB 5009.12-2010, cadmium: GB/T 5009.15-2003); while mercury is performed using Direct Mercury Analyser which can be considered in line with EU requirements. These methods are not within the scope of accreditation.
- Proficiency test results were available for cadmium and mercury (organised by the State Oceanic Administration every two years). The matrix used was water for cadmium and mussels for mercury. All results were satisfactory.

Conclusions

The Liaoning CIQ laboratory, responsible for the official testing of bivalve molluscs end-products intended for export, can be considered in line with EU requirements with regards to accreditation, analytical methods, proficiency testing, etc.

The NMEMC laboratory, in charge of analysing monitoring samples from the ZZD production area, cannot be considered fully in line with EU requirements, taking into account:

- The phytoplankton quantitative method and reporting (information of toxic species, population trend and turnover), which are not in line with the requirements laid down in Point 4 and 7, Article B, Chapter II, Annex II to Regulation (EC) 854/2004.
- The lack of standardisation of the PSP analytical method, which undermines the reliability of the test and the validity of the result;
- The lipophilic toxins analytical method, which is not carried out in line with the requirements laid down in Point 4, Article B, Chapter III, Annex III to Regulation (EC) 2074/2005. This aspect undermines the reliability of the test.

Consequently, Recommendations Nos 9 and 10 can be considered as addressed. However, Recommendation No 11 has not been fully addressed.

6 Overall Conclusions

Since the 2009 Food and Veterinary Office audit, improvements have been noted in the official controls of scallops from the Zhangzidao production area.

However, weaknesses remain in the way sanitary surveys and phytoplankton monitoring are conducted. Moreover, deficiencies, which undermine the reliability of test results, were noted in the laboratory in charge of analysing monitoring samples from the Zhangzidao production area.

7 Closing Meeting

During the closing meeting held in Beijing on 20 November 2013, the FVO team presented the findings and preliminary conclusions of the audit to the CAs.

During this meeting, the CAs acknowledged the findings and preliminary conclusions presented by the FVO team.

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 scallops from the ZZD production area intended to be exported to the EU as frozen scallops' adductor muscle roe-on and roe-off.

N°.	Recommendation
1.	The CA should ensure that the sanitary survey of the Zhangzidao production area is carried out in line with the requirements laid down in Point 6, (b) and (c), Article A,

N°.	Recommendation
	Chapter II of Annex II to Regulation (EC) No 854/2004.
2.	The CA should ensure that the sampling equipment to check for the presence of toxin-producing plankton in production areas, the phytoplankton quantitative method used and the related laboratory reporting respect standards equivalent to the requirements laid down in Points 4. (a), 5 and 7, Article B, Chapter II of Annex II to Regulation (EC) No 854/2004.
3.	The CA should ensure that PAHs monitoring is carried out in line with the requirements laid down in Regulation (EC) No 1881/2006, as last amended.
4.	The CA should ensure that PCBs monitoring is carried out in line with the requirements laid down in Regulation (EC) No 1881/2006, as last amended.
5.	The CA should ensure that the PSP analytical method used in the NMEMC laboratory includes a standardisation process, in order to guarantee the reliability of the test and the validity of the result, in line with the requirements laid down in Chapter I of Annex III to Regulation (EC) No 2074/2005.
6.	The CA should ensure that the lipophilic toxins analytical method used in the NMEMC laboratory is carried out in line with the requirements laid down in Point 4, Article B, Chapter III of Annex III to Regulation (EC) 2074/2005.

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=2013-6821

Annex 1 - Legal References

Legal Reference	Official Journal	Title
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. 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
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

Legal Reference	Official Journal	Title
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
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. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
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
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

Legal Reference	Official Journal	Title
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
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
Dec. 2002/226/EC	OJ L 75, 16.3.2002, p. 65-66	2002/226/EC: Commission Decision of 15 March 2002 establishing special health checks for the harvesting and processing of certain bivalve molluscs with a level of amnesic shellfish poison (ASP) exceeding the limit laid down by Council Directive 91/492/EEC