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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

CHINA

FROM 04 TO 13 NOVEMBER 2013

IN ORDER TO EVALUATE THE CONTROL SYSTEMS IN PLACE GOVERNING THE  
PRODUCTION OF FISHERY PRODUCTS 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 from 4 November to 13 November 2013 as part of its programme of audits in third countries.*

*The primary objective of the audit was to evaluate whether the official controls put in place by the Competent Authority can guarantee that conditions of the production of fishery products in China intended to be imported into the European Union are in line with the requirements laid down in European Union legislation. The audit also verified the implementation of the recommendations of the previous audit in 2009 on fishery products.*

*The audit was conducted in combination with DG (SANCO) audit 2013-6821 on official controls of the production of bivalve molluscs intended for export to the European Union.*

*The report concludes that there is an efficient official control system in place for the production of fishery products for export to the EU. The current organisation of the competent authorities and the control system implemented offer sufficient guarantees concerning the sanitary conditions of fishery products for EU export.*

*Only minor shortcomings were detected (e.g. number of histamine samples, listing data for one establishment) which should be corrected to ensure that all fishery products for export fully respect the requirements set out in the EU's model health certificate.*

*Improvements in the implementation of official controls since the previous FVO audit in 2009 has been noted and the recommendations of this report have been adequately addressed.*

*The report addresses to the Chinese competent authority a number of recommendations aimed at rectifying identified shortcomings and enhancing the control system in place.*

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## ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

<b>Abbreviation</b>	<b>Explanation</b>
AQSIQ	Administration of Quality Supervision, Inspection and Quarantine
CA	Competent Authority
CIQ	Entry/Exit Inspection and Quarantine Bureau
CNCA	Administration for Certification and Accreditation
DG SANCO	Health and Consumers Directorate General of the European Commission
EC	European Community
EU	European Union
FVO	Food and Veterinary Office of the European Commission
GMP	Good Management Practice
HACCP	Hazard Analysis Critical Control Points
HPLC	High Performance Liquid Chromatography
ISO/IEC	International Organisation for Standardisation
FVO	Food and Veterinary Office of the European Commission
MoA	Ministry of Agriculture
OJ	Official Journal of the European Union
PAH	Polycyclic Aromatic Hydrocarbons
PCBs	Polychlorinated Biphenyls
RASFF	Rapid Alert System for Food and Feed
SOP	Standard Operating Procedure

## 1 INTRODUCTION

The audit took place in China from 4 to 13 November 2013 and was undertaken as part of the Food and Veterinary Office's (FVO) audit programme. The audit team comprised two inspectors from the FVO.

## 2 OBJECTIVES AND SCOPE OF THE AUDIT

The objectives of the audit were:

- to evaluate whether the official controls put in place by the competent authority (CA) can guarantee that the conditions of production of fishery products in China destined to be imported into 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 health certificate laid down in 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 the previous FVO audit report of 2009 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 fishery products 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 audit team proceeded as follows: an opening meeting was held in Beijing on 4 November 2013 with the CA. At this meeting the audit team confirmed the objectives of, and itinerary for the audit, and requested additional information required for the satisfactory completion of the audit;

In pursuit of these objectives the audit team visited the following sites:

<b>COMPETENT AUTHORITY</b>		
Central level	1	Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), Ministry of Agriculture (MoA)
Regional level	3	Fujian, Ningbo City, Shandong
<b>LABORATORY VISITS</b>		
Official laboratories	3	Fujian CIQ Lab, Ningbo CIQ lab, Shandong CIQ lab
<b>PRIMARY PRODUCTION</b>		
Aquaculture farms	1	Fujian Province
Fishing vessels and landing sites	2 1	Dongshan County, Fujian Province
<b>FACILITIES HANDLING FISHERY PRODUCTS</b>		
Processing Plants	6	Fujian, Ningbo City, Shandong

Representatives from the (CCA/CAs) accompanied the audit team during the whole audit.

### **3 LEGAL BASIS FOR THE AUDIT**

The audit was carried out 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.

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

### **4 BACKGROUND**

#### **4.1 GENERAL BACKGROUND**

China is presently listed in Annex II to Commission Decision 2006/766/EC establishing the list of third countries and territories from which imports are permitted of fishery products for human consumption, other than those covered by Annex I.

China is also listed in the Annex to Commission Decision 2011/163/EU, indicating that the residue monitoring plan is approved in accordance with Council Directive 96/23/EC and therefore can export aquaculture fishery products to the EU.

A previous audit took place in 2009 (ref. DG(SANCO)/2009/8108) which highlighted deficiencies in relation to import controls, the supervision of freezer vessels and the accreditation of official laboratories. The report of this audit - published on the Health and Consumers Directorate-General (SANCO) Internet site at [http://ec.europa.eu/food/fvo/ir\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm) - made a number of recommendations in respect of the action required by the CA. Written guarantees were received from the CA in relation to the implementation of actions aimed at addressing those recommendations. The follow-up of these recommendations are reported under the relevant parts of this report.

#### **4.2 PRODUCTION AND TRADE INFORMATION**

According to information provided by the CA, in 2012, the main fishery products exported to the EU were as follows: cod, tilapia, salmon, flatfish, squid and shrimp mainly from aquaculture. The major importing Member States are (by decreasing order): Germany, Spain, United Kingdom, France, Netherlands, Belgium, Italy and Poland. In fact, China exports some fishery products to all EU Member States.

According to data provided by the CA, fishery products exported to the EU amounted to 526,656 tons in 2012, comprising mainly of imported/processed and re-exported cod and salmon. Flatfish, squid and shrimp are the main species from China's own production exported to the EU.

According to the list established by the CA and available on the DG SANCO website (list valid as of 9/10/2013, imports of fishery products from China into the EU are authorised from a total of 625 establishments (these include 280 establishments processing only or partially materials derived from aquaculture, three cold stores, 226 freezer vessels, and 14 factory vessels).

This list is available on the SANCO web site at the following address:

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

### 4.3 RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) NOTIFICATIONS

In 2012 twenty-one RASFF notifications were issued by MS concerning imported fishery products from China. Half of them were related to temperature control during transport. Others covered mislabeling, several *Anisakis* infestations one high level of cadmium and one of mercury as well as some for residues such as sulfonamide and sulfadiazine.

## 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 concerning the legislation on products of animal origin of a third country.

Article 11(4)(k) 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 the results of EU controls carried out in the third country, in particular the results of the assessment of the CAs, and the actions they have taken in the light of the recommendations addressed to them following a EU control.

#### Findings

The audit team reviewed the information provided by the CA in response to the pre-audit questionnaire and handed over during the FVO audit and noted that several pieces of legislation covering the official controls of fishery products for export to the EU had been revised or enacted since the last FVO audit in 2009. These included:

- The revised Law of Import and Export Commodity Inspection (29 June 2013) establishes new rules for the execution of commodity inspections by CIQ and introduces specific compulsory import and export checks for listed commodities.
- The implementation of Food Safety Law (20 July 2009) establishes the general principles for the safety of food.
- The Measures on the Inspection and Quarantine Administration of Entry and Exit of Fishery Products (AQSIS Order No 135, 1 June 2011) establishes the specific control requirements for imported and exported fishery products.
- The Measures on the record management of export food production enterprises (AQSIS Order No 142, 26 July 2011) sets out the administrative rules for application and approval of export facilities.
- The Measures on Import and Export Food Safety Management approach (AQSIS Order No 144, 1 March 2012) lays down the rules/ procedures concerning the standards, documents and control steps that imported food has to undergo when entering China.
- The Measures on the register management of imported food from overseas production enterprises (AQSIS Order No 145, 1 May 2012) sets out the administrative measures to guarantee the traceability of imported food.

- On the issuance of export food production enterprise safety and health requirements and product catalogue notice (CNCA Announcement No 23, 1 October 2011) defines rules for export establishments and the list of commodities to be controlled if exported from China.
- Administrative Measures of Food Processing Establishments Applying for Overseas Registration (CNCA Announcement NO 15, 2002) lays down the rule for application for export establishments.

For fishery product exports to the EU, a set of standards for maximum limits concerning microbiology, residues and contaminants are in place in line with EU requirements.

## **Conclusions**

From the limited review of the Chinese legislation and standards applied to EU exports the FVO team concluded that they are largely equivalent to EU rules. They provide an adequate framework for the controls by competent authorities to provide the necessary guarantees with regard to EU requirements.

### **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.

#### **Findings**

##### Structure and organisation

The following CAs are involved in the control chain for fishery products exported to the EU:

AQSIQ which is directly under the State Council, is an independent administrative body of the MoA, which is responsible for, inter alia, the entry-exit commodity inspection and for the overall food safety of imported and exported food. AQSIQ has 20 departments, including the Import and Export Food Safety Bureau, which is responsible for the implementation of the national controls on the safety and quality of fishery product imports and exports. Aquaculture farms listed for export to the EU fall under the responsibility of AQSIQ.

The Administration for Certification and Accreditation (CNCA) is the competent body authorised by the State Council for drafting regulations concerning sanitation registration of food imports and exports, organising the inspection, audit, approval and follow-up supervision on food imports and exports, as well as registration for EU listing of qualifying establishments, freezer and factory vessels.

The actual controls are implemented by 35 provincial branches, the CIQs. They have divisions for Food Safety Supervision and Facility Registration. The controls in establishments are done by the local branches of CIQs.

The Department of Fisheries Management is responsible for legal compliance and safety inspections of fishing vessels, both those involved in the domestic and EU export markets, under the relevant national rules and legislation. Based on different regional practices, local governments appoint executive bodies to manage landing sites.



## Powers, Independence and Supervision

The legal framework empowers the CAs to gain access to establishments and fishery vessels. They may grant and seize permits, approvals and registrations. The audit team saw evidence that the CAs can withdraw approvals and suspend activities.

The staff of the CAs are civil servants and may not have economic relationships with exporting establishments. A part of the controls is conducted by mixed teams from different levels and entities to ensure transparency and a consistent approach.

## Training

AQSIQ provided the FVO team with information regarding the training events and programmes in place. The training activities were planned annually at central level for China and refined and implemented at provincial levels according to their particular needs. The courses comprised, inter alia, auditing, sampling and inspection techniques, HACCP evaluation, EU standards, infringement procedures, microbiology, contaminants and parasites. In 2010 there were also several joint training activities organised in conjunction with the EU for biotoxins and residues under the EU's Better Training for Safer Food Initiative (BTSF). The FVO team examined several CIQ staff training files which showed evidence for regular participation in training. The minimum level of qualification for AQSIQ inspectors is a master's degree.

## Documented Control Procedures

Documented control procedures are drafted at central and provincial level of AQSIQ/CIQ and are in use at the premises visited by the audit team. They comprise checklists and Standard Operation Procedures (SOPs) for different levels of inspections at establishments, ice plants, freezer and factory vessels. They cover the registration, approval, suspension and withdrawal of establishments. For freezer and factory vessels SOPs are in place for approval and handling of fishery products, including the control of HACCP and automatic temperature registration.

For fish farms (primary production) AQSIQ/CIQs have issued procedures for approval requirements, water quality, veterinary drug and feed use, residue testing and traceability for those wishing to be listed for EU export. The audit team noted also standardised checklist for vessel inspection issued and used by the Fishery Bureau Inspection Services of the MoA. This covered checks on the health status of the crew, the hygiene conditions of vessels, chilling equipment, temperature registration and storage conditions. Landing sites are checked by the MoA using standard checklists.

## **Conclusions**

The CAs responsible for official controls on fishery products are clearly designated at central, provincial and local level with sufficient numbers of competent staff, with adequate powers to perform official controls, which can be considered to be in line with EU requirements. Official staff has had appropriate training and obtained a satisfactory knowledge of EU requirements.

### **5.3 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.

## **Findings**

The CIQ has procedures in place to register and list processing establishments, freezer vessels, factory vessels and cold stores for EU exports. Landing sites are approved by local governments and administered by their nominated executive bodies. Ice plants fall under the control of the Ministry of Public Health.

Food business operators must apply to the CA for approval. The approval is given by the CA based on a documentary assessment and an inspection visit to evaluate the level of compliance with the rules for export facilities. These rules comprise the necessity to have Good Manufacturing Practices and HACCP plans in place. The approval is valid for four years. If the establishment introduces changes to production or facilities with relevance for the food safety the approval has to be renewed immediately. To maintain their approval and listing for EU export, food business operators must apply for a renewal every four years. The renewal procedure is identical to the approval procedure. There is also a procedure in place to suspend or withdraw approval/ listing. Fishing vessels are registered and approved after an inspection by the CA. The approval procedure is similar to establishment procedure and is also valid for four years.

The list of EU approved facilities is sent to the Commission Services and updated regularly.

Approval documentation was available at all establishments visited by the audit team. This documentation identified the range of activities for which the establishment is approved.

The audit team found during cross-checks of the listings that one establishment was listed for processing aquaculture products on the EU list, but, according to the CA, does not process these products.

## **Conclusions**

The rules and procedures for the listing of facilities and freezer and factory vessels for the EU export are adequate and provide satisfactory guarantees. Though minor discrepancies were found on the listing they do not call into question the system as such.

### **5.4 OFFICIAL CONTROLS OF PRODUCTION AND PLACING ON THE MARKET**

#### **Legal requirements**

Article 12(2) of Regulation (EC) No 854/2004.

Requirements contained in point II.1 and point II.2 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) 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 take particular account of the extent and operation of official controls on imports of animals and their products.

Article 11(4) (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 and the assurances, which the third countries can give regarding equivalence to EU requirements.

Commission Decision 2002/994/EC requires aquaculture fishery products to be tested on certain residues prior to export certification to the EU.

#### *5.4.1 Official control system in place*

### **Findings**

The official control system is implemented by the CA by administrative orders, work instructions and an annual sampling plan. The system covers the entire production chain including imports with the exception of primary production fishing vessels and landing sites. The distribution of competencies are as follows:

- CIQ is responsible for the control of farms producing aquaculture products intended for export. The MoA is responsible for all aquaculture farms supplying the domestic market. As the residue limits are different for the Chinese and export markets the checks are executed in parallel by both CAs. They cover traceability, hygiene and the monitoring of residues of veterinary residues and contaminants. MoA exchanges monitoring information with AQSIQ, but has no role in the transmission of non-compliant sampling test results to the local CIQs. However, the local agricultural departments plan to share food safety related monitoring information (including fishery product sampling results) with local CIQs through a food safety monitoring information exchange platform established by local governments. The results will be published online. Once the sharing process is established, the whole process of taking samples, testing, result review and the publication of results should take a maximum of 30 days.
- The Fishery Bureau of MoA is responsible for the inspection of fishery vessel and landing sites for the domestic market and export. They issue permits for the vessels which certify, inter alia, the hygiene status and the sea area the vessel is allowed to fish.
- CIQ is responsible for the controls of EU listed establishments and for import and pre-export certification checks.
- CNCA is responsible for the listing of all facilities for export and the approval, audit and monitoring of freezer and factory vessels for export.

The CIQ carries out regular control visits to exporting aquaculture farms which include residue sampling. Regular audit and inspection visits are undertaken in approved export establishments with a set frequency depending on the risk status applied. There are four risk levels (1-4) with one being the lowest level. The frequencies depend on the type of inspection and are at least twice a year for exporting aquaculture farms by CIQ; vessels for primary production are inspected at least twice a year by MoA; processing establishments are inspected by CIQ four times a year for routine inspections and twice a year for periodical inspections. Freezer and factory vessels are checked by CIQ before each departure. Reports are drawn up of visits with copies to operators in case of non-compliances. The audit team reviewed inspection reports at the establishments visited and found them compliant concerning the models used and the frequency of visits.

#### *5.4.2 Primary production*

The three main sources of fishery products intended for export premises are:

- imported fishery products from foreign vessels and establishments for further processing,

- fish from Chinese vessels, and
- fishery products from aquaculture.

According to the CA, no fishery products from wholesale market or public landing sites may be used for export production. Imported fish arrives mainly in containers. Catches are directly transported from the vessel to the processing plants. Only legally compliant vessels which are approved by the Department of Fishery Administration and subjected to inspection are permitted to participate in the EU export chain. EU listed processing establishments must verify that fish they process has come from a vessel with a valid permit. The audit team visited two fishery vessels with valid permits which complied with EU requirements as regards storage conditions, temperature control, hygiene status of the crew and which had been inspected in line with the set frequency. The consignments of wild caught raw material assessed by the audit team were all covered by catch certificates.

The landing site visited presented satisfactory hygiene conditions.

The audit team visited an aquaculture farm producing Japanese eel (*Anguilla japonica*) mainly for export to Japan, Korea and the EU with a production area of 1,857 hectares. The farm was registered by the MoA for domestic production and in parallel by CIQ for exports. The ponds were concrete basins supplied with ground water from their own wells. The eels are reared in a rotation system and the annual production was around 100 tons. The team assessed the records and pond books. The books contained extensive data on feeding, health status, mortality, medical treatments and traceability. MoA and CIQ run own residue monitoring programmes. CIQ organises the compulsory analysis of each consignment prior to export certification to the EU in line with the requirements of Commission Decision 2002/994/EC.

#### 5.4.3 Facilities, including vessels, handling fishery products

The audit team visited six establishments listed for export to the EU and assessed the official controls of three freezer vessels. Establishments undergo a periodic inspection twice a year which are more comprehensive than the quarterly routine inspections. Within a year inspections must cover all issues relevant for export approval. During inspections a checklist based on export requirements including EU standards is used. Inspection reports in the establishments reviewed by the team were found compliant with the CA's current procedures. The establishments visited had been audited and inspected with the stipulated frequencies. Non-compliances had been noted and rectified in the establishments visited. One establishment visited was subject to a RASFF notification in 2011 because of mislabelling. It was downgraded by the CA from the lowest risk category “one” to category “three” which increased the inspection frequency. Deficiencies noted in the reports reviewed reports were found to be rectified. In one establishment the audit team noted the storage of raw material on a decaying walkway situated above the opening to the production unit with the possibility for debris falling into the production unit. The food business operator and the CIQ assured the audit team that this situation would immediately be rectified.

In all establishments and freezer vessels visited HACCP plans were in place and being implemented. The determination of Critical Control Points was not done by a decision tree as described in the Guidance Document for HACCP of the European Commission. Instead the appropriate questions were incorporated in a table with adequate results.

Concerning own-checks the audit team noted that all food business operators in establishments visited tested the microbiological parameters in products (total viable count, *E.coli*, *Staphylococcus Aureus*, *Salmonella*, *Listeria* (for ready to eat products)) and in water used for processing (e.g. total bacterial count, coliforms, Chlorine) and contact surfaces (faecal coliforms).

#### *5.4.4 Checks on the EU eligibility of imported raw materials*

CIQ is responsible for the import controls of fishery products. All imported consignments of fishery products must undergo an import check and an import certificate is issued by the CA. During the visits to establishments the audit team examined several imported consignments from third countries which were being processed for EU exports. The import certificate of CIQ was present in all cases reviewed by the audit team. Most consignments were produced on freezer vessels which were EU approved and on the DG SANCO list for the country concerned. Catch certificates were present for all imported consignments.

#### *5.4.5 Follow-up of RASFF notifications*

In 2012 there has been twenty-one RASFF notifications. CIQ has a procedure in place for the follow-up of RASFF notifications. In cases reviewed, the team noted that the root causes had been investigated and follow-up actions initiated. The follow-up actions comprised tracing back of consignments, investigations at the food business operators and corrective measures. The CA stated that in some cases the level of information provided by the RASFF system did not allow to trace back the consignments to the processing establishment. The audit team verified the follow-up of one RASFF (for mislabeling) dealt with by the CA. This notification resulted in an on-the-spot visit by the CA and an investigation with follow-up. After the inspection the omission was rectified and the establishment was given a higher risk category with a higher frequency of inspection.

### **Conclusions**

The CA has an official control system in place which is implemented by written procedures based on defined export standards. This system covers the production of fishery products and aquaculture destined for EU export. Official controls of EU listed establishments are in place and comply with EU equivalent standards.

Recommendations No 1,3,4,6,7,8,9 and 10 of the previous inspection report have been satisfactorily addressed.

## **5.5 OFFICIAL CONTROLS OF 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 Annex III, Chapter II of Regulation (EC) No 854/2004.

### **Findings**

Official controls are performed by the CA under a legal framework described in section 5.1 and in accordance with work instructions and monitoring programmes. The audit team noted that:

- The CAs perform organoleptic checks and checks for parasites on fishery products when visiting establishments, in line with Chapter II of Annex II to Regulation (EC) No 852/2004. Freshness indicators are checked in case of suspicion. The audit team found evidence of these checks in copies of the official inspection reports.
- Microbiological checks are carried out systematically according to a sampling plan and are

used to verify the operators' own-checks. Evidence for checks, on the following parameters was noted by the audit team, and were applied according to the risk profile for the product concerned: Salmonella, E. Coli, Staph. Aureus, Listeria, Total bacterial count.

- Contaminants are monitored for by the CA through an annual sampling plan which covers, lead, mercury, cadmium, dioxins, polychlorinated biphenyls (PCBs) and in smoked products polycyclic aromatic hydrocarbons (PAHs). Additives, in particular polyphosphates were checked for in final products.
- Residues are tested for according to an annual plan produced by the provincial CIA in cooperation with AQSIQ. They comprise nitrofurans, chloramphenicol, malachite green and crystal violet for shrimps, chloramphenicol and nitrofurans for other species.
- In processing plans handling histidine sensitive species, the level of histamine was determined by the operators as part of own-checks. The sampling frequency ranged between 50 and 100% of the batches. One establishment visited had its own laboratories which used fluorometric methods. The CA takes samples in establishments for confirmatory analysis in official laboratories using HPLC methods.
- In one province visited only five official samples had been taken for histamine analysis. The CA of this province stated that this practice is in place since 2006 to reduce the costs of sampling given that there were no positive results on histamine.
- The CA verifies the own-checks of operators on water and analyses on several microbiological and chemical parameters.
- There was no risk of the processing of poisonous fish at the premises visited. The CA stated that particular procedures for the detection of poisonous species are in place. Exercises on the detection of puffer fish (Tetraodontidae) were conducted by CIQ.

## **Conclusions**

The CA has implemented an effective control system on fishery products intended for export to the EU. It covers all relevant EU requirements. One deviation from EU standards was detected concerning the lower number of histamine samples which is not in line with the requirements of Regulation (EC) No 2073/2005.

### **5.6 OFFICIAL CERTIFICATION**

#### **Legal requirements**

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.

Article 6 of Directive 96/93/EC establishes that the Commission shall ensure that the rules and principles applied by third countries certifying officers offer guarantees at least equivalent to those laid down in this Directive.

#### **Findings**

To obtain an export certificate the operator must apply at the responsible CIQ office. The accompanying documents are checked by certifying officers. Based on perceived risk and a defined frequency a CIQ computer system determines the fishery product exports to be physically checked.

If a consignment is selected for a physical check a mandatory sampling applies. However, all consignments of products of aquaculture origin are physically checked and sampled. The export certificate is only issued when a favourable test result is available. The certification information can be reviewed at point of export by the Customs via its computer system. The audit team checked, in an establishment visited, copies of the most recent export certificates for consignments intended for the EU. They met EU requirements concerning the model used and the features are, *inter alia*, one single sheet, descriptions of produce, consignee and consignor, stamps and the correct deletion of non-applicable declarations.

## Conclusions

The export certification procedure can be considered as adequate to provide the guarantees required by the model health certificate of Regulation (EC) No 2074/2005.

Recommendation No 2 of the previous inspection report has been satisfactorily addressed.

### 5.7 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 to Regulation (EC) No 2074/2005,

Regulations (EC) Nos 1883/2006 and 333/2007.

#### Findings

The CIQ has a system of 35 provincial laboratories in place. They carry out official analyses for CIQ on fishery products. Besides the main provincial laboratories, there are 452 local laboratories carrying out more limited official analyses. All laboratories are accredited to ISO/IEC 17025. These official laboratories accept samples from food business operators. The audit team visited provincial laboratories in Fujian, Ningbo City and Shandong.

All visited laboratories were well equipped with qualified staff. SOPs were in place for the reception, handling, storage, sampling and reporting of analytical samples. The scope of analytical methods accredited covered all necessary subjects as required by EU legislation for fishery products including those from aquaculture:

- Microbiology e.g. Salmonella, E.coli, Staphylococcus aureus, Listeria monocytogenes.
- Freshness indicators: total volatile basic nitrogen, histamine.
- Chemical elements such as heavy metals, e.g. lead, cadmium, mercury, arsenic.
- Food additives such as sulphites and poly-phosphates.
- Residues and contaminants e.g. chloramphenicol, furazolidone, nitrofurazones, PAH, PCBs and dioxins.

The methods used meet EU standards: (HPLC method for histamines).

All laboratories participate in several national and international proficiency tests with, to-date, good results (z scores lower than 2). Every provincial laboratory has a speciality field where they play a leading role and therefore organise ring and proficiency tests for other official laboratories in their particular field.

The audit team reviewed several analysis reports and noted, that the laboratory protocols with regard to sampling reception, records, analysis performance and issuance of test results had been followed.

## **Conclusions**

The CA has designated a network of accredited laboratories for official controls which are considered fit for purpose. The laboratories visited complied with the requirements of the ISO/IEC 17025 accreditation and EU legislation.

Recommendation No 5 of the previous inspection report has been satisfactorily addressed.

## **6 OVERALL CONCLUSION**

There is an efficient official control system in place for the production of fishery products for export to the EU. The current organisation of the competent authorities and the control system implemented offer sufficient guarantees concerning the sanitary conditions of fishery products for EU export.

Only minor shortcomings were detected (e.g. number of histamine samples, listing data for one establishment) which should be corrected to ensure that all fishery products for export fully respect the requirements set out in the EU's model health certificate.

Improvements in the implementation of official controls since the previous FVO audit in 2009 has been noted and the recommendations of this report have been adequately addressed.

## **7 CLOSING MEETING**

During the closing meeting held in Beijing on 13 November 2013, the audit team presented the main findings and preliminary conclusions of the audit to the CA.

During this meeting, the CAs acknowledged the findings and preliminary conclusions presented by the audit team and provided a commitment to correct the deficiencies.

The CA pointed out that they have a different interpretation than the FVO concerning the number of official histamine samples to be taken.

## **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 fishery products exported to the EU.



<b>N°.</b>	<b>Recommendation</b>
1.	Ensure that nine official histamine samples are taken in line with the requirements set out in line with Regulation (EC) No 2073/2005.
2.	Ensure that the list of export establishments forwarded to the European Commission is up-to-date and reflects the actual situation in the processing establishments listed.

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=2013-6718](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6718)

## 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
Dec. 2011/163/EU	OJ L 70, 17.3.2011, p. 40-46	2011/163/EU: Commission Decision of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

<b>Legal Reference</b>	<b>Official Journal</b>	<b>Title</b>
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. 1883/2006	OJ L 364, 20.12.2006, p. 32-43	Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs