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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

MALDIVES

FROM 22 TO 29 JANUARY 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 an audit in Maldives carried out by the Food and Veterinary Office from 22 to 29 January 2013, as part of its programme of inspections in Member States and 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 production of fishery products in Maldives destined for export to 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 inspection visit covering fishery products.

The report concluded that in principle the current organisation of the competent authority and the control system implemented can offer sufficient guarantees concerning the sanitary conditions of fishery products for European Union export. Improvements in the implementation of official control have been noted since the previous audit. However, the competent authority cannot fully ensure that all fishery products exported to the European Union respect the requirements mentioned in the model health certificate due to the deficiencies noted during the audit, in particular concerning the official control of fishery products and HACCP plans implementation.

The competent authority has addressed most of the recommendations of the previous audit report.

The report addresses to the Maldives 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
CA	Competent Authority
SANCO	Health and Consumers Directorate General of the European Commission
EC	European Community
EU	European Union
EU listed	Facility approved by the CA for EU fishery products export and listed on the internet site of DG SANCO
EUROSTAT	Statistical Services of the European Union
FVO	Food and Veterinary Office of the European Commission
HACCP	Hazard Analysis Critical Control Points
HPLC	High Performance Liquid Chromatography
ISO	International Organisation for Standardisation
MFDA	Maldives Food and Drug Authority
MoH	Ministry of Health
OJ	Official Journal of the European Union
RASFF	Rapid Alert System for Food and Feed
SOP	Standard Operating Procedure

1 Introduction

The audit took place in Maldives from 22 to 29 January 2013 and was undertaken as part of the Food and Veterinary Office's (FVO) audit programme.

The audit team comprised two auditors 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 Maldives 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 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 2006 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 a technical basis for the audit.

In pursuit of these objectives, the audit team proceeded as follows:

- an opening meeting was held in Malé on 22 January 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;
- the following sites were visited:

Competent authority		
CA - Central level	1	
Laboratory visits		
Official laboratories	1	
Primary production		
Fishing and transport vessels	7	
Landing and first sale		
Landing sites/ auction halls/ wholesale markets	2	
Facilities handling Fishery Products		
Factory vessels	1	
Processing plants	4	

Representatives from the CA 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 or equivalence 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

Maldives 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.

A previous FVO fishery products audit took place in 2006 (ref. DG(SANCO)/2006-8303) which highlighted deficiencies in relation to the official control of fishery products, establishments, fishing vessels and laboratories. 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 nine recommendations in respect of the action required by the CA. Written guarantees, which were considered adequate by the Commission, were received from the CA in relation to the implementation of actions aimed at addressing those recommendations.

4.2 Production and trade information

According to the information provided by the CA the main fishery product exported to the EU is fresh tuna. According to EUROSTAT the EU imported approximately 8,500 tonnes of fishery products in 2012. The main EU importing Member States were Germany, France, Italy, Spain and UK. Maldives also exported small quantities of reef fish to the EU.

According to the list established by the CA and available on the SANCO website (list valid as of 03/01/2013), imports of fishery products from Maldives into the EU are authorised from a total of nine establishments and one factory vessel.

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.

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

There have been fourteen RASFF notifications concerning fishery products since the 2006 audit. These notifications were related to histamine and bad hygiene state of chilled tuna.

The audit team had the opportunity to check the CA procedure following a RASFF. In the case reviewed by the audit team, it was noted that measures were taken to investigate the origin of the problem and to implement corrective actions as applicable. Having reviewed the circumstances the CA concluded that this problem had occurred outside the establishment. The CA informed the audit team that the probable cause was a rupture of the cold chain during the transport to the EU or at the

EU border post.

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.

Findings

The audit team noted that the main legislation in force in Maldives to control fishery products intended for EU export remains the one mentioned in the 2006 audit report.

The Ministry of Economic Development and Trade adopted the standards of EU directives and subsequent relevant legislation. The adoption was made by Regulation A-27/95 on 18 January 1995 for fish and fishery products exported to EU.

A new regulation to repeal Regulation A-27/95 has been prepared in order to align the Maldives legislation with the relevant current EU Regulations. This piece of legislation is still at a draft stage.

The CA informed the audit team that, in the interim, it was decided to apply directly EU legislation to fishery products for EU export. The audit team noted that EU requirements are applied to fishery products exported to the EU and to their production chain.

Conclusions

The CA applies EU requirements to fishery products exported to the EU. Therefore, the ad hoc standards applied by the Maldives CA provide, in general an adequate basis with regard to the guarantees to be provided for fishery product exports to the EU.

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. Points g) and h) are covered in Sections 5.4 of this report.

Findings

Structure and Organization

The structure and organisation of the CA has changed since the 2006 audit.

In 2006 Maldives Food and Drug Authority (MFDA) was established as a CA by Presidential Decree (Circular number 2006/19), by merging Food Safety Section of the Department of Public Health, Pharmaceutical Section, Public Health Laboratory (former CA) and Port Health. MFDA was placed under the Ministry of Health (MoH).

The CA has its headquarters in Malé and is responsible for the official control of fishery products in Maldives. There is no regional or district level of the CA.

However, Island Health Facilities located in each of the 20 atolls of Maldives and operating under the MoH were nominated in 2010 by the CA to carry out the registration and sanitary inspection of fishing vessels in islands remote from Malé. Although part of the MoH, the Community Health Officers from the Island Health Facilities are not directly under MFDA authority.

The Island Health Facilities received a circular from the CA communicating the tasks that they are assigned to carry out and containing also the relevant Standard Operation Procedures (SOPs) in relation to these tasks. Community Health Officers received instructions from the MFDA on how to carry out these inspections for which they are obliged to follow SOPs produced by the CA.

Island Health Facilities have also been given the competence to inspect fishery product consignments prior to leaving the establishments where establishments are located in remote islands (mainly for canned and frozen fish). The Community Health Officers use a checklist issued by the CA for this purpose.

Powers and independence; supervision and authority to enforce legislation

Circular 2006/19 above-mentioned confers competencies, power and independence on the CA to carry out their tasks.

The CA has the power to suspend health certification and also to withdraw establishments from the EU list.

Supervision of the Community Health Officers is carried out by the CA in order to ensure a harmonisation of the official control of fishing vessels in all the relevant atolls.

The CA informed the audit team that it is its intention to supervise the work carried out by the Community Health Officers on registration and approval of fishing vessels. Of the 20 atolls concerned five, to date, have been supervised by the CA.

Island Health Facilities have to report every six months to the CA on fishing vessel inspections providing information on the number of vessels inspected and details of the inspection findings. The audit team saw evidence of the above mentioned reports.

Training

Training has been provided to CA officials on EU legislation. One official attended a training session on fishery products in Ireland under SANCO's "Better Training for Safer Food" initiative.

Officials from the CA also received training on EU legislation and RASFF given by a Member State consultant. This training was also cascaded to all officials of the CA by the CA officials formerly trained.

The CA informed the audit team that training had been provided to CA officials on inspection techniques and Hazard Analysis and Critical Control Points (HACCP) evaluation, among others.

The CA informed the audit team that training was also provided by the CA to Community Health Officers in charge of inspection and registration of fishing vessels.

The CA has drawn up several SOPs where most of the EU applicable legislation is mentioned. However, the audit team noted that familiarity with current EU legislation can be called into question due to the references to repealed legislation in the SOPs (e. g. Commission Directive 2001/22/EC, Commission Regulation (EC) No 466/2001) and due to the lack of awareness of some pieces of EU legislation recently published or amended.

Documented control procedures

Documented control procedures were drafted by the CA and are in use. They include amongst others checklists (for auditing EU listed facilities, for fishing vessels), forms (approval form, hygiene certificate application form, fishing vessel registration form) and SOPs related to the

official control of fishery products intended for export to the EU.

The CA informed the audit team that the checklist for auditing of establishments is used as a reference but not filled out. The audit team noted that the checklists are based on EU requirements, in particular, Regulations (EC) No 852/2004 and (EC) No 853/2004.

The CA uses as a tool to carry out official control several SOPs, for approval and registration of establishments/fishing vessels, certification, EU listing, etc. However, the audit team noted that in some SOPs it is not clearly indicated what action should be taken by the CA in cases of non-compliance (e. g. no definition of major deficiencies in order to suspend establishments). It was also noted that applicable EU regulations concerning contaminants mentioned in some SOPs were not the most recent ones.

The CA informed the audit team that some of these SOPs are not yet implemented.

Conclusions

The current structure and organisation of the CA, including its powers and authority, are adequate to perform the official controls of the production chain of fishery products intended for EU export. Those official controls are based on EU legislation and associated SOPs that can be broadly considered to be in line with EU requirements. However, the absence of up-to-date SOPs, notably concerning contaminants, calls into question the ability of official services to give assurances that fishery products subject to official laboratory analysis comply with requirements equivalent to those set out in Regulations (EC) No 1881/2006 and (EC) No 333/2007.

The CA staff has had appropriate training and presents in general an acceptable level of knowledge of EU requirements applicable to fishery products.

Recommendations 2, 4 and 5 from the previous inspection report have been satisfactorily addressed.

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

Establishments/factory vessels have to be approved to export to the EU in line with requirements based on Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004.

A food business operator firstly applies to the CA for approval. The CA reviews documentation submitted by the food business operators prior to approval, which includes Good Manufacturing Practices (GMP) and HACCP plans. Layout approval should be also carried out before the construction of the premises. Once the CA has assessed all the required documents it carries out an on the-spot-visit. If the establishment is found to be in line with EU requirements an approval document is then issued. Establishments are approved for six months. The approval document is known as a “Certificate of Compliance”.

Evaluation and approval of HACCP plans are also carried out by the CA.

Fishing vessels are registered and approved after an inspection visit. For the approval/registration of fishing vessels CA officials check the hygiene and structure of the vessels using a checklist based on EU requirements. Vessel approval is valid for one year.

The audit team noted that an approval document was present in all the establishments/factory vessel visited. This document specifies the products for which the establishment has been approved and

states that it has been audited based on Regulations (EC) No 852/2004 and (EC) No 853/2004.

However, in one recently approved facility, the CA approved a factory vessel with a HACCP plan that did not follow adequately all the HACCP principles equivalent to EU requirements.

Registration and approval documents were also present in all the fishing vessels visited by the audit team.

Conclusions

The CA has drafted procedures, which meet EU requirements, for listing establishments/factory vessels exporting to the EU. The audit team found the procedures were followed in all but one factory vessel visited which was approved having a HACCP plan that was not in line with Article 5 of Regulation (EC) No 852/2004.

Recommendation No 1 of the previous audit report has been satisfactorily addressed.

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 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 46(1)(g) (h) of Regulation (EC) No 882/2004).

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.

Findings

5.4.1 Official control system in place

The CA has in place an official control system based on written procedures and EU legislation that covers the entire fishery products production chain (fishing vessels, landing sites, laboratories and processing establishments). This system includes approval of establishments/fishing vessels, inspection and reporting procedures and the use of the checklists referred to above.

Regular inspection visits to fishery product facilities are performed with a set frequency. EU listed establishments are visited in principle twice a year. Fishing vessels are inspected once a year.

Inspection forms are completed indicating the result of the evaluation and any deficiencies noted. A deadline of seven days is given by the CA to correct the deficiencies found or to provide a corrective action plan.

During the inspection visits fishery product samples are taken by the CA for official analysis of microbiological and chemical parameters in line with a sampling programme.

5.4.2 Primary production

The fish is caught mainly by local fishing vessels (dhonis) and sometimes transferred to collector

vessels with Refrigerated Sea Water tanks. Public landing sites and auctions/markets are not used for fish destined for export to the EU. Fish is transferred directly from the quay to the fish processing plants.

Only vessels inspected and found in compliance with established requirements are authorised to provide fishery products to EU listed establishments. The audit team also observed that the checklist used for these inspections covers EU requirements.

Transport/collector vessels owned by the establishments are not individually inspected by the CA. They are considered by the CA as part of the establishments and are included in the inspection visits to the establishments. However, the audit team found no documentary evidence of any inspections of these transport vessels.

The audit team visited two landing sites and six fishing vessels which were found to be acceptable. The landing sites were attached to two fishery product establishments. Both landing sites were found to be in line with EU requirements taking into account the operations that take place there.

During a visit to one establishment with its own landing site, the audit team found deficiencies in a transport vessel which included; separations in holds made from material not easy to clean and not impervious that contact directly with fishery products; and hold surfaces that were not in sound conditions.

5.4.3 Facilities, including vessels, handling fishery products

The audit team visited four establishments and one factory vessel listed for export to the EU. In all establishments visited the approval document for export to the EU was present.

Establishments have to be visited with a set frequency of six months. The audit team noted that CA officials perform inspections to those establishments to evaluate their hygiene and structural conditions as well as the implementation of the pre-requisite programmes and HACCP based procedures.

During these visits a checklist based on EU requirements is used as a guidance to verify that FBOs operate according to EU legislation. Visits are carried out using two official forms. One is the Audit Record Sheet where remarks/findings are recorded. The second form is used to record findings of organoleptic checks.

The audit team saw examples of non-compliance reports identifying structural and hygiene shortcomings and noted that CA officials had set deadlines for their correction (seven days). The audit team also noted that CA officials had performed a follow-up of the deficiencies identified during the inspections.

The audit team noted that EU listed establishments are visited with the stipulated frequency. During the visits samples of product for official control are taken by the CA.

The audit team reviewed several reports of inspections and verified that non-conformities are identified and follow-up is carried out. Reports presented also respected the frequency established. When deficiencies are identified a food business operator is required to present an action plan with corrective actions in seven days after receiving the report. The audit team noted that in one case an audit report was not received by the food business operator until two months after the audit. In this case the food business operator could only take remedial action after the report had been received and not immediately following the inspection visit.

Deficiencies identified by the audit team when visiting establishments had not always been identified by CA officials.

The audit team found the following range of deficiencies in the establishments visited:-

- Doors opening to the outside not sufficiently pest and dust proof.

- Cold store with frozen condensation in need of maintenance.
- Cold store for frozen tuna not equipped with a temperature recording-device.
- Processing/waste water not directly ducted to a drainage system, in particular from processing tables with pooling of water and condensation on ceilings.
- Hand operated taps.

Regarding HACCP plans, the audit team noted that only two of the four establishments visited implement and maintain permanent procedures based on HACCP principles in a satisfactory way. For the other two, the shortcomings of the HACCP procedures observed were related to lack of identification of hazards (i.e. parasites and heavy metals), incorrect risk assessment of the hazards identified, plans not in line with the actual activities performed, critical limits above EU requirements (temperature of fresh products) and identification of critical control points without the use of a logical approach (decision tree). Furthermore, the HACCP plan of the factory vessel visited by the FVO team could not be considered as in line to the EU requirements due to similar shortcomings noted by the FVO team.

Food business operator own-checks include testing of microbiological parameters in products (total viable count, *E coli, S Aureus, Salmonella*), water, ice and contact surfaces (total coliforms count, faecal coliforms count, total viable count).

Testing of chemical parameters like histamine and heavy metals are also carried out by food business operators.

Several checks for the presence of histamine are carried out in the establishments visited. Notably sampling is carried out at reception of raw material and in finished product. In most of the cases nine units are taken for histamine testing of finished products. A fluorometric method is used. However, in some cases sampling methods were not in line with EU requirements.

Testing for contaminants is carried out for mercury, lead and cadmium. The audit team noted different sampling frequencies between establishments for heavy metals testing, ranging from quarterly to yearly.

The audit team noted that analyses for heavy metals were conducted in foreign accredited laboratories against ISO standards 17025 located outside Maldives. However, the CA could not present evidence that the testing methods used were within the scope of the laboratories' accreditation and that the designated laboratories follow the performance criteria as established in EU Regulation (EC) No 333/2007.

The audit team also noted that microbiological testing of water and ice for faecal coliforms, coliforms and total viable count was performed monthly under the own-check programmes of the establishments. In one establishment visited the team noted that for four samples taken in 2012 the microbiological results indicated a problem in the quality of water. For only two of these samples was it possible to see corrective actions taken in an attempt to solve and prevent the deficiency. However due to the subsequent non-conformities found, the corrective measure taken (cleaning the tanks both times) was not sufficient to prevent a recurrence of the contamination. During the same period an official sample also detected the same shortcoming. The team also noted that the CA officials were not aware of three of the food business operators irregular results and that no corrective action had been taken for two of them.

From a general point of view the audit team noted that all establishments visited had a comprehensive sampling programme covering, with the exception of ciguatera, all the main risks and a well documented own-check records.

Conclusions

The CA has an official control system for the production of fishery products for EU export that covers the entire production chain.

Official control of fishing vessels is in line with EU requirements. However, official controls of transport vessels to guarantee that they meet the relevant requirements of Annex III to Regulation (EC) No 853/2004 are not carried out.

Regarding the official control system for establishments approved for export to the EU, the audit team considers it adequate. However, due to shortcomings in its implementation, in particular HACCP plans implementation, inadequate follow-up, verification of food business operator own-checks including performance criteria of methods used for heavy metals (Regulation (EC) No 333/2007), currently the CA cannot ensure that some establishments meet standards fully equivalent to EU requirements.

Recommendation No 3 of the previous audit regarding fishing vessels has been 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

With regard to the official controls of fishery products the audit team noted that:

- CA officials perform organoleptic checks on fishery products when visiting establishments, as set out in Chapter II of Annex II to Regulation (EC) No 854/2004. A form in line with EU requirements is filled in by the inspector to record these checks.
- CA officials take samples of tuna for the determination of levels of histamine. Samples for testing for histamine are taken twice a year and sent to the official laboratory where an accredited fluorometric test method is used. Nine units comprise the sample as required under EU legislation. However, the method used is not a High Performance Liquid Chromatography (HPLC) method which is the EU reference method for histamine testing.
- A monitoring programme to control the level of contaminants has not yet been set up by the CA. The CA informed the audit team that due to the fact that there are no facilities in Maldives to perform such tests the CA asked food business operators to carry out heavy metal tests in accredited laboratories at least once a year. As a result, the CA relies on the results of food business operators own-checks on this issue.
- Microbiological checks are carried out systematically by the CA when verifying food business operators' own-checks. Parameters tested for include among others, total viable count, total coliforms count, *E. Coli, Salmonella, Staphylococci, Vibrio cholera*.
- CA officials perform checks to monitor the quality of drinking water. Water and ice is tested for microbiological parameters such as total coliforms count, faecal coliforms count, and total viable count. Water is also tested for chemical parameters such as physical appearance, pH, turbidity, total dissolved solids and conductivity.
- CA officials do not perform checks during landing and before export of fishery products to ensure that no poisonous fish are present. It is indicated in the certification SOP that ciguatera testing should be carried out prior to export of reef fish. The audit team was informed by the CA that currently ciguatera is not in the sampling programme for fishery products (reef fish) exported to the EU. As result, the CA does not carry out any official

controls to ensure that reef fish species sensitive to ciguatera are not exported to the EU.

Conclusion

The official controls of fishery products implemented by the CA cover almost all the requirements mentioned in the model health certificate and in Chapter II of Annex III to Regulation (EC) No 854/2004. Nevertheless, these official controls do not allow the CA to ensure that fishery products exported to the EU comply with the EU limits for environmental contaminants and do not contain biotoxins such as ciguatera.

Recommendation No 7 of the previous inspection report regarding organoleptic checks has been addressed.

Recommendation No 8 of the previous inspection report regarding official control of fishery products has not been fully addressed.

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

The CA has a clear and comprehensive procedure for certification for EU export. A detailed procedure is described in the CA SOP on how to certify fishery products to be exported to the EU.

The model health certificate currently in use is the one in Regulation (EC) No 2074/2005.

The audit team visited the certification team in the airport cargo facilities. It was noted that the officials in charge of the certification follow the procedure in place. All the export health certificates reviewed were properly filled in and accompanied by the set of documents required by the CA such as the packaging list, declaration of food business operator quality manager on compliance with EU requirements, histamine testing reports.

Health certificates are signed by a designated CA official after a product check is performed by him or by another CA official. The checks performed include visual inspection and sampling if necessary.

A physical inspection of the consignment can be made by the CA to reconcile the product present with the health certificate.

Conclusions

The procedures designed by the CA offer guarantees at least equivalent to the requirements of Directive 96/93/EC.

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 (EU) No 252/2012 and (EC) No 333/2007,

Regulation (EC) No 1881/2006.

Findings

The audit team visited the only laboratory designated and approved by the CA to carry out analyses in the framework of the official control on fishery products in Maldives.

The laboratory is accredited, since 2008, to ISO standard 17025 by the Bureau of Laboratory Quality Standards (located in Thailand and affiliated to ILAC). The current accreditation was acquired in January 2011 and will be valid until January 2014 and includes in its scope microbiology tests for fishery products and water and histamine in fishery products. Additionally four other tests for drinking water have been accredited.

The laboratory participated in proficiency tests for histamine twice per year in 2010 and 2011 and once in 2012 with satisfactory results. The laboratory also participates in several proficiency test runs every year covering the analysis included in the scope of its accreditation and for different matrices. The majority of the results for the 2010 runs were not satisfactory and the laboratory took the necessary corrective measures. For 2012 runs the majority of the results were satisfactory.

Although the analytical method used for histamine (fluorometric method based on AOAC 997-2005) is included in the scope of the accreditation it is not the EU reference method prescribed in Chapter I of Annex I to Regulation (EC) No 2073/2005.

The laboratory performs fishery products and water/ice analyses in the framework of official controls but also for the operators own-checks. At reception the official samples delivered by the CA are not traceable to the establishment of origin of the sample.

The laboratory has adequate procedures and criteria for sample reception, sample handling, record keeping and issuance of test results. Nevertheless, the audit team noted shortcomings with regard to best before dates of some microbiological media and the identification of a standard solution used for equipment calibration.

The laboratory was satisfactorily equipped for the analysis performed, has in place an adequate maintenance and calibration plan for equipment and staff presented adequate knowledge.

The audit team reviewed several analysis reports and noted that the fishery products involved had met EU requirements and that the laboratory procedures with regard to sampling reception, records, analysis performance and issuance of test results were properly followed.

Conclusions

The CA has designated one accredited laboratory for official control considered in general fit for purpose. The laboratory was, overall, in good condition with capable staff. However, the analysis method used for histamine is not the EU reference method.

Recommendation No 6 regarding accreditation of the previous inspection report has been satisfactorily addressed.

Recommendation No 9 regarding testing and sampling methods of the previous inspection report

has not been satisfactorily addressed.

8 Overall Conclusion

In principle the current organisation of the CA and the control system implemented can offer sufficient guarantees concerning the sanitary conditions of fishery products for EU export. Improvements in the implementation of official control have been noted since the previous audit. However, the competent authority cannot fully ensure that all fishery products exported to the EU respect the requirements mentioned in the model health certificate due to the deficiencies noted during the audit, in particular concerning the official controls of fishery products and HACCP plans implementation.

9 Closing meeting

During the closing meeting held in Malé on 29 January 2013, the audit team presented the main findings and preliminary conclusions of the audit to the CA.

During this meeting, the CA acknowledged these findings and preliminary conclusions and provided a commitment to correct the deficiencies found.

10 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.

N°.	Recommendation
1.	The CA should ensure, for contaminants, that the standards applied to fishery products for EU export are in line with current EU requirements. In particular, the standards applied should be the up-to-date ones in line with the latest amended version of Regulations (EC) No 1881/2006 and (EC) No 333/2007.
2.	The CA should ensure that collector/transport vessels providing fishery products to EU listed establishments meet requirements equivalent to those established in Section VIII, Chapter I of Annex III to Regulation (EC) No 853/2004 as required in point II.1 of the model health certificate laid down in Appendix IV to Annex VI to Regulation (EC) No 2074/2005.
3.	The CA should ensure that fishery products exported to the EU are produced and dispatched from establishments/factory vessels listed in line with Article 12 of Regulation (EC) No 854/2004.
4.	The CA should ensure that establishments/factory vessels have in place, implement and maintain permanent procedures based on HACCP principles in accordance with Regulation (EC) No 852/2004, in particular Article 5, as required in point II.1 of the model health certificate laid down in Appendix IV to Annex VI to Regulation (EC) No 2074/2005.
5.	The CA should ensure that official controls verify food business operators' relevant own-check records and that a proper follow-up is carried out when non-conformities

N°.	Recommendation
	are identified in order to ensure that fishery products are hygienically obtained in line with Section VIII of Annex III to Regulation (EC) No 853/2004 as required in point II.1 of the model health certificate laid down in Appendix IV to Annex VI to Regulation (EC) No 2074/2005.
6.	The CA should provide guarantees that fishery products for export to the EU have satisfactorily undergone all the official controls laid down in Chapter II of Annex III to Regulation (EC) No 854/2004, in particular, concerning ciguatera and the monitoring of environmental contaminants.
7.	The CA should ensure that laboratories involved in official control take into account in particular, the analytical method for histamine and the performance criteria for heavy metals as is laid down in Regulation (EC) No 2073/2005 and Regulation (EC) No 333/2007 respectively.

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=2013-6712

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
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

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. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Reg. 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