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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

KENYA

FROM 27 MAY TO 07 JUNE 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 Kenya carried out from 27 May to 7 June 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 Kenya destined 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 2006 audit covering the same subject.

The report concludes that there is an official control system in place for the production of fishery products for export to the EU. In principle the current organisation of the Kenyan CA and the control system implemented by them, can offer sufficient guarantees concerning the sanitary conditions of fishery products for EU export.

However, some deficiencies remain (particularly in relation to histamine testing methodology and instances of poor temperature control) which require correction 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 2006 have been noted and most recommendations in the previous report from 2006 have been adequately addressed.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
BTSF	Better Training for Safer Food
CA	Competent Authority
CCA	Central Competent Authority
DG SANCO	Health and Consumers Directorate General of the European Commission
EC	European Community
EN	European Norm
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
KEBS	Kenya Bureau of Standards
KEPHIS	Kenya Plant Health Inspectorate Service
MSOP	Manual of Standard Operating Procedures
PCBs	Polychlorinated Biphenyls
RASFF	Rapid Alert System for Food and Feed
TRACES	EU's TRAde Control and Expert System

1 Introduction

The audit took place in Kenya from 27 May to 7 June 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 Kenya 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 Commission Services in response to the recommendations of the previous FVO audit report DG(SANCO) 2006-8163 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 Nairobi on 27 May 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		
Central level	1	Directorate of Fish Quality Assurance and Marketing
Provincial level	2	Kisumu, Mombasa
LABORATORY VISITS		
	4	Kenya Bureau of Standards, Nairobi and Kisumu Kenya Plant Health Inspectorate Service, Nairobi SGS, Mombasa
PRIMARY PRODUCTION		
Hatcheries	1	Attached to one farm visited
Feed mill	1	Attached to one farm visited
Aquaculture farms	2	
Vessels	2	Transport vessels in Lake Victoria
LANDING AND FIRST SALE		

Landing sites	2	
FACILITIES HANDLING FISHERY PRODUCTS		
Processing Plants	8	

Representatives from the central CA (CCA) 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

Kenya 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 audit took place in 2006 (ref. DG(SANCO)/2006/8163), the report of which highlighted deficiencies in relation to inspection and standards of vessels and landing sites, official control procedures, imported raw material from approved vessels, listed establishments meeting EU requirements, monitoring of contaminants and standard of and methods used in laboratories participating in official controls. The report which is published on the Health and Consumers Directorate-General (SANCO) Internet site at http://ec.europa.eu/food/fvo/ir_search_en.cfm made a number of recommendations in respect of the action required by the CA. Written guarantees were received from the CCA in relation to the implementation of actions aimed at addressing those recommendations. Annual progress reports were asked for and have been submitted. 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 Eurostat (see table below), the main fishery products exported to the EU are chilled and frozen Nile perch, cooked tuna, cuttlefish and octopus. The main importing member states are by decreasing volume of imports: Italy, Netherlands, Spain, Portugal and Germany.

The audit team was informed by the CCA that all tuna exported to the EU derives from imported raw material.

According to the list set up by the CCA and available on the DG SANCO website (list valid as of 01/11/2012), imports of fishery products from Kenya into the EU are authorised from a total of 12

establishments. One of these has been suspended recently due to it ceasing production. See also Chapter 5.3.

This list is available on the SANCO website at the following address: http://ec.europa.eu/food/food/biosafety/establishments/third_country/index_en.htm

Table 1 summarises the exports from Kenya of fishery products to the EU.

Table 1 - Exports of fishery products from Kenya to the EU (tonnes) (source Eurostat)

Commodity	2012
Fish, chilled and frozen (0302, 0303)	837
Fillets and other fish meat (0304)	3,054
Crustaceans (0306)	6
Cephalopods (0307)	736
Prepared or preserved fish (1604)	4,350
Total	**8,983**

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

In 2011 there were in total three notifications, one for findings of Salmonella in chilled Nile perch, one for altered organoleptic characteristics of chilled Nile perch and one for poor temperature control of frozen octopus. In 2012 there was one notification concerning high counts of *Pseudomonas* and aerobic plate count in Nile perch. All notifications resulted in an on-the-spot visit by the CA and a request for an investigation by the producer including a written statement on how to solve the problem.

In one establishment visited, which had been the subject of a RASFF, the CA explained the procedures followed and provided evidence of the actions taken to resolve the issue.

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

Legislation is drafted by the Fisheries Department within the Ministry of Agriculture, Livestock and Fisheries and has to be passed by Parliament for enactment into law.

The audit team noted that the main pieces of legislation covering the fishery products production chain are the following:

- Fisheries Act, Chapter 378 of the Laws of Kenya, Revised edition 2012 (1991).
- Fisheries (Safety of Fish, Fishery Products and Fish Feed) Regulations, 2007 is included in the above mentioned Act.

The Fisheries Act empowers both the Cabinet Secretary and the Director of Fisheries Department to publish regulations aimed at providing for the development and management of the fisheries sector without passing through the Parliament.

As a complement to the Fisheries Act, there is a comprehensive Manual of Standard Operating Procedures (MSOP).

The MSOP set out the objectives and scope of activities for the management and responsibilities of the CA. It sets the qualification requirements for official fish inspectors. It also includes sanitary requirements for aquaculture and for capture fisheries and procedures for inspections, recall, sampling and laboratory analysis of water and fishery products for organoleptic, chemical, microbiological and environmental contaminants and export/import licencing and certification.

The MSOP also contains checklists for structural and hygiene requirements for different stages of the fishery products chain for all types of vessels, landing sites, transport, as well as the various types of processing and storage facilities.

Health standards, organoleptic checks, freshness indicators, histamine and parasites are covered by the Fisheries Act.

Conclusions

From the limited review of the national laws and the standards applied to fishery products and their production chain, Kenyan legislation can be considered as in line with the relevant EU requirements.

Recommendation No 5.1 of the 2006 report concerning an update of Kenyan food standards has been addressed.

5.2 Competent Authority

Legal requirements

Article 46 of Regulation (EC) No 882/2004 stipulates that EU controls in third countries shall verify compliance or equivalence of third countries' systems with EU food law. These controls shall have particular regard to points b) to (e), (g) and (h) of the aforementioned article. Points g) and h) are covered in Sections 5.4 of this report.

Findings

Structure and organisation

There has recently been a ministerial reorganisation in Kenya and the Ministry of Fisheries Development has, from the spring 2013, become a part of the Ministry of Agriculture, Livestock and Fisheries. Within the Ministry there is a State Department of Fisheries responsible for the implementation of legislation and the official control system for fishery products at all stages of production via the Directorate of Fish Quality Assurance and Marketing which is the CCA.

The Directorate has representation at regional and local levels.

- At regional level there are Provincial Offices where fish inspectors run monitoring programmes, do sampling, supervise local inspectors and also can be assigned as inspectors of local establishments.

- At local level, Provinces have District Offices and Divisions. District offices are staffed by fish inspectors who are assigned to establishments and other control functions. All fish inspectors may sign health certificates. District Offices also register and inspect aquaculture farms. Divisions are staffed by fish assistants who supervise landing sites, vessels and unloading procedures.

The Department of Fisheries has three other directorates:-

- Directorate of Inland and Riverine Fisheries responsible for the management of inland fisheries.
- Directorate of Marine and Coastal Fisheries responsible for management of Marine and Coastal Fisheries.
- Directorate of Aquaculture responsible for promoting aquaculture development and production.

These directorates are not directly involved in the EU export chain of fishery products.

The Ministry of Public Health and Sanitation is in charge of potable water and municipalities are responsible for checking water quality. However, the CA takes random samples at processing establishments.

Inspectors at CCA level supervise the implementation at regional and local level by performing annual inspections for renewal of approvals and by unannounced on-the-spot visits. The CCA also checks the inspection reports sent in from regional and local level.

Sampling for a national residue monitoring plan for aquaculture farms is conducted by the CCA in Nairobi.

Powers, Independence and Supervision

CA powers, enforcement actions and sanctions are regulated in the Fisheries Act.

It has the power to register, approve or suspend vessels and establishments and to take actions due to non-conformities.

All public officers are subject to Kenyan ethics and anti-corruption legislation to prevent conflicts of interest.

Inspectors at CCA level supervise the implementation at regional and local level by performing annual inspections for renewal of approvals of facilities and by unannounced on-the-spot visits. Reports of these inspections are distributed to both provincial and district offices and serve as guidance to control staff.

The Provincial and District Offices must send every inspection report to the CCA informing them of the outcome of inspections.

The CCA communicates with regional and local level by e-mail, information letters and SMS.

Training

Fisheries Officers (fish inspectors) are required to have university degrees (minimum BSc in food science, chemistry or similar). Additional training is provided depending on the scope of tasks assigned. In recent years staff attended among others, courses and workshops on Traces, ISO standards, fish quality, official controls, residue control of aquaculture as well as management and leadership training.

The CCA keeps a record of training carried out and makes an inventory of the needs for training of the inspectors. Some inspectors and Fisheries Assistants have participated in BTSF courses. Besides training, inspectors are also invited to workshops on topics relevant to the fishery sector and official

controls.

There are currently 49 inspectors in the CA. However it is estimated that a further 45 inspectors will be required to enhance control and to cater for planned expansion of the aquaculture sector. To cover this growth additional training, notably in aquaculture farm controls, will be required.

Documented Control Procedures

The MSOP is comprehensive and includes instructions for various types of inspections, sampling and checklists.

There are written procedures concerning:-

- The management and functions of the CA.
- Functions of fish inspectors.
- Types and procedures for inspection.
- Procedure for inspecting fish processing establishments, fishing vessels, landing sites, transport vehicles/boats, ice plants, cold stores, markets and shops.
- Procedure for inspecting whole fish at landing sites.
- Procedure for identification of suspected poisoned fish and handling of poisoned fish.
- Procedure for checking for parasites in fish.
- Programme for monitoring pesticide residues and heavy metals in fish, water and sediments.
- Procedure for collecting water samples for laboratory analysis.
- Procedure for collecting ice samples for laboratory analysis.
- Procedure for collecting fish samples for microbiological analysis.
- Procedure for collecting fish samples for the analysis of sodium metabisulphite.
- Procedure for taking swabs for laboratory analysis.
- Procedure for sampling fish for histamine analysis.
- Fish and Fishery products export documentation procedures.
- Procedure for checking traceability.
- Procedures for addressing RASFF alerts.
- Product recall procedures.

Conclusions

The CA responsible for official controls on fishery products is clearly designated and has an organisation at central, regional and local level with sufficient numbers of competent staff, with adequate powers to perform official controls.

Recommendations No 5.2(2) concerning training of staff and No 5.3(1) concerning documented official control procedures, of the 2006 report, have been 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

An establishment must apply for approval to produce fishery products from the CA. A "pre-inspection visit" (before approval inspection) to the premises is done and a report is written. Should it be necessary, an establishment must provide the CA with an action plan to address non-conformities and when the requirements are met, a fish processing licence is issued to allow production to commence. The licence is only valid for the remainder of the calendar year. A new establishment has also to have a certificate from the municipality proving that it is allowed to conduct business within the jurisdiction of that municipality.

Once an establishment is issued with a fish processing license and inspected by the CCA for compliance with requirements, the establishment is issued with a Certificate of Compliance which is necessary for export to the EU. The certificate is issued by the CCA and an approval number is given.

Decisions on approvals (new and renewals) for issuance of fish processing licences and certificates of compliance are taken after assessment of findings and recommendations made regarding the establishments by the Departmental Licencing Committee that consists of the Director of Fish Quality Assurance and Marketing, the Director of Marine and Coastal Fisheries, the Director of Aquaculture Development, the Director of Inland and Riverine Fisheries and Heads of the Provincial Offices.

Establishments are re-approved every year. The CCA performs an annual audit and verification (national inspection) to each establishment and based on the results of this inspection and results of an evaluation by the Provincial CA, the Departmental Licencing Committee decides on the continuation or suspension of approval. Fish processing licences and certificates of compliance are issued annually.

Establishments must also have a fish traders' licence issued by the CA and a licence from the municipal public health department that shows fulfilment of the requirement for medical examination of staff twice a year.

The audit team noted that:-

- There are at present twelve establishments listed for EU export. One of them has recently been suspended because it had ceased production. Two of them have not exported to the EU during the last two years, but according to the CA are subject to the same official control as exporting ones. This was confirmed by the audit team by checking the file of one such establishment at the Provincial Office.
- All establishments visited had their licences available.
- In the national inspection reports references are made to Regulation (EC) Nos 852, 853 and 854 of 2004.

Conclusions

There is an adequate system for approval and listing of establishments authorised to export to the EU in line with EU requirements.

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

Findings

5.4.1 Official control system in place

Aquaculture farms are registered and inspected by District Offices. The CCA is responsible for the sampling programme for the residue monitoring plan.

The hygiene conditions of landing sites are checked by staff from the District Offices and Fisheries Assistants are present full time at landing sites for inspection during unloading. Vessels must be registered in order to be allowed to land their catch.

Establishments are under the control of the CA and inspected once a month and yearly by the CCA to verify compliance.

There is a national requirement for medical checks of staff every six months which is monitored by the Municipalities and the CA.

5.4.2 Primary production

Fishing vessels are inspected by fish inspectors at landing sites when unloading. A yearly inspection of vessels is required and there is a checklist for this purpose.

District Offices register fishing vessels and provide identification numbers and also issue fishing licences.

Each landing site management keeps a register of boats licensed to land fish at each site. They also keep a logbook of the fish landed by each vessel. The register is used by the CA to register vessels and issue fishing licences.

The audit team saw two transport vessels in Lake Victoria. These vessels have a box with ice on board where the fish is stored after collection from various fishermen and transported to landing sites. One was unloading fish at the time of the visit and the audit team noted that the amount of ice was sufficient and the fish was handled in a hygienic manner.

In order to be listed for the export of farmed fishery products to the EU, Kenya has sent an

application to the Commission services for approval of its residue monitoring plan for aquaculture. The audit team visited two aquaculture farms in Nyanza and Western provinces to have an initial overview of the systems in place for control and the keeping of records on the use of medicinal products. Inspection reports were not available as no formal official control system is yet in place. However, an official control system for aquaculture products has been included in the MSOP and a National Residue Monitoring Plan has been prepared and submitted to the EU for consideration.

One farm was a cooperative of 21 local farmers with in total 27 small ponds (300 m² each) producing approximately 300 kg of tilapia per pond over a six to eight month rearing period to bring the fish to an approximate average weight of 400 grams. The farm had started in 2009 and has so far not needed any medical treatments. Each farmer is responsible for his/her pond/s records of feeding, source of fingerlings, stocking date etc. Monthly checks are performed to see how much fish there are and to estimate the growth rate. Ponds are harvested, left empty for two weeks after which mud is removed. Following this it is disinfected with lime and refilled with water, fertilised and re-stocked.

The second farm visited was within a rice producing farm. This enterprise produces tilapia and catfish and had their own hatchery and feed mill. One section of the farm was for breeding purposes of their own brood stock and spawning ponds for tilapia. Fingerlings are then transferred to rearing ponds at the other end of the farm. Fingerlings are also sold to other farms.

Each pond is one hectare and can produce 10 tonnes per pond within a six months rearing period following stocking with five gram fingerlings. The final weight for tilapia is 400 – 500 grams. The production of fish started five years ago and according to the farm so far no medication has been needed. The mortality rate is approximately 10%. Around eight tonnes of tilapia and 500 kg of catfish are produced monthly.

This farm has its own feed mill which can produce eight tonnes per day. They also sell feed outside their own farm. The mill can produce medicated feed batches if required.

There is a collecting pond for water upstream of the fish farm to protect from pesticides used for spraying the rice fields and some tilapia is kept in it as sentinel fish.

On-site water samples are tested for oxygen, pH and turbidity. Microbiological analyses are performed at an external laboratory.

5.4.3 Landing and first sale

At landing sites there are Fisheries Assistants permanently present to supervise all landings. They do daily checks on overall hygiene (staff, equipment and premises), freshness, temperature and grade of icing of the fish and the transport trucks. Records of these checks are kept at each site.

Fish inspectors from the District Office perform a routine inspection of the landing site every second month using a checklist which also covers trucks and vessels. If severe non-compliances are found, an immediate follow-up will be done. Other more minor irregularities are checked and documented at the next routine inspection.

Once a year both Provincial Office and the CCA visit each landing site and send their report to the District office. The local inspectors use this report to ensure harmonised implementation and interpretation of the legislation.

A transport document is issued at the landing site to accompany the fish to the receiving establishment.

There are also medical certificates for all handlers.

The audit team visited one landing site at Lake Victoria where Nile perch is landed from collecting boats. The landing site is run by the Beach Management Unit and the fishermen's cooperative society that have an office at the site. All fishermen using the landing site have to be members of the cooperative. A logbook of the landings is kept by the site's management and agents buying fish use that for traceability checks of the fish. Records of daily cleaning of where fish is handled are kept and so are records of non-daily cleaning of other parts of the premises. These records are checked and signed by inspectors from the District Office.

This landing site has a concrete jetty, a covered concrete platform where weighing and sorting of fish takes place and where buyers' agents may inspect the catch. There are stainless steel tables with wash basins with tap water. Most fish is taken directly to the transport trucks. Trucks bring ice with them from the buying establishment.

When necessary, fish is placed in the chilling room. There is a room also for changing clothes and there are toilets. There is also an ice producing unit to supply collecting boats and to sell to local residents.

The audit team also visited a landing site on the coast where octopus intended for EU export is landed. At this landing site there are only fishing vessels, no transport vessels. Boats are at sea for a day only and fish is iced when landed. Fin-fish for the local market is also landed here. This landing site belongs to the Department of Fisheries and the CA has a District office on-site. The CA registers all vessels, issues identification numbers and licences. A register is kept of all landings by vessel and the volume of fish is noted.

This coastal site has a reception hall with tiled benches and stainless steel tables with washbasins and tap water. Two cold rooms are available for storage when needed in the high fishing season. Toilets were available. The landing site has a satisfactory structure and is maintained in good condition. Tap water from the public network is available and used for cleaning of fishery products, equipment and will be used for ice production which is expected to commence shortly. Chlorinated water from a bore hole is used for cleaning floors.

5.4.4 Facilities, including vessels, handling fishery products

There are currently no Kenyan freezer or factory vessels.

The audit team visited eight establishments that were kept in good order and state of repair with easy to clean surfaces of walls and floors, hand washing facilities, water was ducted away, ice was used during production and staff worked in a hygienic manner. All establishments have ice production units for their own production needs and for transport of fish from landing sites.

There is a well-documented system of official controls of establishments. The "national inspection" is carried out annually by the CCA and monthly "routine inspections" are done by the Provincial CA or District Inspectors. Unannounced "spot check inspections" may also take place which can be done both by the CCA and Provincial or District level.

The audit team saw reports showing that the CA generally follows the stipulated frequency and the reports were available in all premises visited. However, reports were not available in one district for January 2013 as no controls had been performed that month due to training of inspectors taking place.

Deficiencies are reported and food business operators are required to produce an action plan for the correction of deficiencies. The CA follows-up the action plan either by checking at the next routine inspection or by an extra follow-up inspection where the deficiencies are more serious.

All establishments visited have a comprehensive own-check programme covering pre-requisite

issues such as maintenance, pest control and water quality. HACCP plans cover microbiological risks in fishery products. Heavy metals and pesticides are not considered a risk in the Lake Victoria region (except in one establishment), but are routinely included in the coastal region. A tuna producing establishment also included histamine in its plan. HACCP plans are checked by the CA and signed on every page.

In all but one establishments visited the temperature limit of incoming raw material was set in the HACCP plans to be below +5ºC or +7ºC. The temperatures recorded at reception checks were in general well below those limits. There is a Kenyan national standard for chilled fish to be kept at the temperature of melting ice.

Organoleptic checks are performed by food business operators at reception and records are kept. The CA checks the records of this control.

In a tuna producing establishment histamine testing was performed on each batch of raw material in an internal laboratory using a fluorometric method. All results shown were satisfactory.

In three coastal establishments visited, own-check heavy metal analyses are performed on all types of products. A fourth establishment relies on the CA analyses of heavy metals in official samples.

Own-checks of microbiological parameters are performed of fishery products, swabs and water/ice in internal laboratories or sent to external laboratories. In general total plate count, *E.coli, Coagulase positive Staphylococcus,* Coliforms*, Salmonella, Vibrio cholerae* or *parahaemolyticus* are analysed for. Water/ice analyses cover *total plate count* at *22ºC and 37ºC, E. coli,* Coliforms*,* Faecal *Streptococcus, Clostridium perfringens* including spores, *Salmonella* and *Vibrio cholerae*.

Water is supplied via a public network. Incoming water is filtered and treated with chlorine and UV light in all plants visited and free residual chlorine is measured and records kept. Cleaning of water tanks is also documented. Food business operators test the water other than in one establishment, where they consider the quarterly testing by the CA as adequate.

Cold stores have continuous temperature recording devices. Manual readings every hour of displays outside the chambers is also done and recorded. In general the temperature is kept at -18ºC or below. However, in one cold store the cartons were soft and the product had been packed and frozen in plate freezers the day before. The content in one box opened was nevertheless well frozen and no temperature measurement of the product was made. However, in the manual temperature records, temperatures above -18ºC were noted several times (-14 to -16ºC) and signed by the staff as "OK". In another establishment records of cold stores showed them not keeping to -18ºC. One example from 26/5 2013 showed -13ºC at 1100h and -18ºC was not reach until 0600h the following morning (27/5).

5.4.5 Import controls of fishery products

An application for an import permit must be sent to the CA.

Foreign vessels or food business operators must notify the District Office three days before landing so the inspectors can do the necessary background checks. Inspectors are present when the vessels unload and fill out a foreign inspection form with name of vessel, country of origin, type of product, temperature of product, amount, etc. The vessel is inspected for fish safety and issued with a foreign vessel inspection certificate.

Freezer vessels flying the flag of other countries landing their catch in Kenya need a catch certificate from the country of origin.

Reefer vessels are required to have a health certificate from the country of origin and a catch

certificate.

The audit team saw documents showing a reefer vessel from Thailand with frozen tuna in bulk storage that was not found on the published list of Thailand. There was a list of freezer vessels which had supplied the tuna that were all on EU approved lists.[1]

5.4.6 Follow-up of RASFF notifications

The food business operator is asked for an investigation to find the source of the problem and an action plan with corrective measures to prevent re-occurrence. The CA intensifies the inspection frequency and additional samples can be analysed to check the status. From a review of one case the audit team concluded that the set procedures had been followed and the issue satisfactorily resolved.

Conclusions

There is an official control system in place covering the production chain for fishery products, which also covers imported raw materials.

Fish intended for EU listed establishments is landed in sites under official control that were found adequate for the type of activity carried out. The CA inspects the handling of the fish on board before and during unloading of catches and records of these controls are kept.

Official controls on placing on the market are carried out following documented procedures.

In general, the establishments visited met with EU equivalent requirements and Recommendation No 5.2 (3) of the 2006 report concerning export approved establishments meeting EU requirements can be considered as addressed. However, some deficiencies were noted in cold stores where products were not always kept at -18ºC or below and in the HACCP programme implementation concerning the temperature of raw material on arrival.

Recommendation No 5.2 (1) of the 2006 report concerning standards of landing sites as well as Recommendation No 5.3 (2) concerning regular inspections of landing sites, vessels and establishments have been addressed.

Recommendation No 5.3 (3) concerning imported fishery products intended for re-export to the EU has been addressed in general. However, there was one example of a freezer vessel transporting frozen tuna in bulk that was not on a list of approved vessels.

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

The audit team noted the following:

- Organoleptic examinations are performed at landing sites by fish assistants and fish inspectors from the CA.

1 In response to the draft report the CA note that further investigations by them revealed that the reefer vessel from Thailand with frozen tuna in bulk storage had transshipped at port Victoria, Seychelles and not at sea and health certificates where issued. The tuna originated from EU listed vessels and was landed in Kenya by the reefer vessel.

- Histamine testing is performed twice a year in Italy in two samples each time. Only single results are reported and the method used is not noted on the result sheets.
- Mercury, Lead and Cadmium are analysed for in samples taken once or twice per year in line with the CA control programme. The results available to the audit team were satisfactory.
- Polychlorinated Biphenyls (PCBs) are analysed for in quarterly samples of fish (16), water (8) and sediment (8) from Lake Victoria with satisfactory results. The audit team was informed by the laboratory that pesticides are used in horticulture and the land around the Lake Victoria region is not used for that type of production.
- Dioxins are not analysed for.
- Microbiological analyses are in general performed four times a year on samples of fishery products and water/ice taken during the inspections of the establishments by the CA. Fishery products are analysed for total plate count*, E. coli, Salmonella, Staphylococcus aureus,* Coliforms and for *Vibrio parahaemolyticus* or *Vibrio cholera* with satisfactory results. In one establishment microbiological results from fishery product samples showed high levels of *E.coli* and coliforms. The CA called the food business operator to a meeting in the CA office to discuss the finding and requested an investigation following which an action plan was submitted to the CA. This resulted in a plan for cleaning of water tanks.
- Water and ice are analysed microbiologically for total plate count at *22ºC* and *37ºC, E. coli,* Coliforms*, Faecal Streptococcus, Clostridium perfringens* including spores*, Salmonella* and *Vibrio cholerae*. Chemical analyses are done by the CA once per year including heavy metals and PCBs. In one establishment four out of five fishery product sample results from one sampling occasion showed total plate count close to or above the set limit. At the time of the FVO visit, the food business operator had no documentation available on the event covering actions taken - neither own records nor documents from the CA. However, the CA later showed the team the documentation sent to the food business operator asking for an investigation and an action plan. No clear cause could be established, but hygiene training of staff took place.
- Parasites are checked for by the food business operators and the CA reviews the documentation of these checks.
- There are no species of poisonous fish handled and supplied to processing establishments in Kenya.
- Additives: There are requirements in the Kenyan legislation for checks of metabisulphites when used in shrimp production. However, at present there is no shrimp production going on.

Conclusions

There is a system in place for official controls on fishery products that covers most EU requirements. However, there are no results of dioxin testing and the number of samples for histamine testing is not in line with EU rules. The method used for histamine analysis in the foreign laboratory used for such tests is not known to the CA.

Corrective measures were taken when unsatisfactory results of fishery products and water analyses were found.

Recommendation No 5.3 (4) of the 2006 FVO report concerning monitoring of contaminants has not been fully addressed.

Recommendation No 5.3 (5) concerning water testing can be considered as addressed.

Recommendation No 6 ii) and No 6 iii) concerning the methodology for histamine testing have not been addressed.

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

The audit team noted that the food business operators must apply for a health certificate when they intend to export. The CA inspects the consignment on-the-spot and verifies the information from the food business operator concerning identity, labelling and traceability. The health certificate can then be signed. The EU model health certificate is used and the examples seen by the audit team were correctly filled out.

The audit team checked several certificates and noted that the CA follows the prescribed procedures and has knowledge of what they are signing.

Traceability checks can be done from export health certificates to records of incoming raw material batch numbers via a pre-export inspection report (or field inspection) that is performed prior to exports to verify the information given by the exporter about the consignment. In Mombasa the Traces system is used for sending information.

Catch certificates are issued by the Mombasa district office as all exporting establishments on the coast are within that district.

Conclusions

There is an adequate system in place for the issuance of EU export certificates for fishery products in line with EU requirements.

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 audit team visited four laboratories performing official controls on fishery products. All laboratories designated to participate in official controls are accredited. There is a governmental policy that all official laboratories must be accredited.

- Kenyan Bureau of Standards (KEBS) in Nairobi performs chemical and microbiological analyses of fishery products and water. The laboratory has previously done heavy metal analyses in fishery products. At present they are done in another laboratory due to technical problems with the equipment. The laboratory has modern facilities and is well equipped. The laboratory has participated in proficiency testing for *Salmonella* in fishery products once per year the last three years with satisfactory results and for *Salmonella* and other bacteria in water in November 2012, also with satisfactory results.

- KEBS in Kisumu does microbiological analyses of fishery products and water. The laboratory participates monthly in proficiency tests for various parameters and commodities with satisfactory results. Proficiency testing were performed for total plate count, coliforms and *E.coli* in fish in February and April 2012. There is an adequate document system applied but the premises are not fit for purpose (cooking of media, sample preparation, water filtration, spreading, cultivating all in one small room, a small steriliser in another room). However, it is scheduled to be relocated. Both the above laboratories had well trained and knowledgeable staff.

- SGS in Mombasa is accredited and has a wide variety of methods included in its scope. The rooms and equipment are of good standard and has competent staff.

For fishery products, analyses of official and food business operators' samples for microbiological parameters are done. Also water samples are analysed and heavy metals for both official and private purposes. Proficiency testing is done regularly for water and food for microbiological parameters with satisfactory results. However, no proficiency test is undertaken for heavy metals.

- Kenya Plant Health Inspectorate Service (KEPHIS) laboratory has been accredited until September 2012 when they voluntarily suspended it due to moving the laboratory to another building on the site. There has since been an audit 27-28 May 2013 to reinstate the accreditation.

This laboratory performs analyses for PCBs and heavy metals on official samples sent from the Lake Victoria region. For PCBs a validation is performed, but proficiency testing is not done yet. It is planned to be performed as part of the accreditation of the method.

Proficiency testing for heavy metals has not been done last year due to the move. This testing had been performed earlier (water and human milk) with satisfactory results. Certified reference material is used for each run of samples for heavy metals.

The laboratory is well equipped and has competent staff.

Conclusions

Official controls are only performed in accredited laboratories in accordance with the Kenyan governmental policy. However, proficiency testing for heavy metals have not been performed.

Recommendation No 6 i) of the 2006 report concerning laboratories is addressed.

6 Overall Conclusion

There is an official control system in place for the production of fishery products for export to the EU. The current organisation of the Kenyan CA and the control system implemented can offer adequate guarantees concerning the sanitary conditions of fishery products for EU export. Improvements in the implementation of official controls since the previous FVO audit in 2006 have been noted.

However, some deficiencies remain (particularly in relation to histamine testing methodology and instances of poor temperature control) which require correction to ensure that all fishery products for export fully respect the requirements set out in EU health certificate model in Regulation (EC) No 2074/2005.

7 Closing meeting

During the closing meeting held in Nairobi on 7 June 2013, the audit team presented the main findings and preliminary conclusions of the audit to the CA.

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

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.

N°.	Recommendation
1.	To ensure that fishery products intended for export to the EU have been handled in establishments, in particular in transport vessels from other third countries carrying frozen fishery products in bulk landed in Kenya, appear on lists in accordance with Article 12 of Regulation (EC) No 854/2004.
2.	To ensure that fishery products have been handled and stored, as established in Part II.1 of the health certificate, in compliance with Section VIII, Chapter I, point 3 and Chapter III, part B of Annex III to Regulation (EC) No 853/2004.
3.	To ensure that, as established in Part II.1 of the health certificate, fishery products exported to the EU have satisfactory undergone official controls laid down in Annex III to Regulation (EC) No 854/2004, in particular dioxins and that histamine testing is in line with Regulation (EC) No 2073/2005.
4.	To ensure, as established in Part II.1 of the health certificate, that fishery products exported to the EU have been handled in establishments implementing a programme based on HACCP principles taking into account temperature requirements in accordance with Article 5 of Regulation (EC) No 852/2004.
5.	To ensure that, as established in Part II.1 of the health certificate, that fishery products exported to the EU have satisfactory undergone the official controls laid down in Annex III to Regulation (EC) No 854/2004, in particular concerning dioxins.
6.	To ensure that laboratories performing official control analyses apply the principles of

N°.	Recommendation
	internationally recognised quality assurance techniques, including proficiency testing, and are evaluated and/or accredited under officially recognised quality management and assurance programmes equivalent to international standards, such as ISO/IEC 17025, to ensure the reliability of analytical results.

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=2013-6704

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. 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