



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Food and Veterinary Office

DG(SANTE) 2015-7469 - MR

FINAL REPORT OF AN AUDIT
CARRIED OUT IN
BANGLADESH
FROM 20 APRIL 2015 TO 30 APRIL 2015
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.

Executive Summary

This report describes the outcome of a Food and Veterinary Office audit in Bangladesh carried out from 20 to 30 April 2015, as part of its programme of audits in third countries.

The objectives of the audit were to evaluate whether the official controls put in place by the competent authority can guarantee that conditions of production of fishery products in Bangladesh destined for export to the EU are in line with the requirements laid down in EU legislation and in particular with health attestations contained in the certificate and to verify the extent to which the guarantees and corrective actions submitted to the Commission services in response to the recommendations of the previous Food and Veterinary Office fishery products report of 2010 have been implemented and enforced by the competent authority.

The report concludes that improvements have been made since the last audit and in principle, the current organisation of the competent authority and its documented operational procedures provide for an acceptable official control system for fishery products which is implemented in a satisfactory way.

However, certain deficiencies in their implementation (i.e. temperature controls, structural standards of freezer vessels; lack of histamine, dioxin/PCBs and additives testing; maximum limits for cadmium) do not offer the necessary guarantees that fishery products intended for EU export fully respect the requirements defined in the health certificate for imports of fishery products intended for human consumption as set out in the model defined in Regulation (EC) No 2074/2005.

The report addresses to the Bangladesh 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
CA	Competent Authority
DG(SANTE)	The Directorate-General for Health and Food Safety, formerly known as DG(SANCO) The Directorate-General for Health and Consumers
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 the European Commission
FVO	Food and Veterinary Office of the European Commission
HACCP	Hazard Analysis Critical Control Points
ISO	International Organisation for Standardisation
OJ	Official Journal of the EU
PCBs	Polychlorinated Biphenyls
RASFF	Rapid Alert System for Food and Feed

1 INTRODUCTION

The audit took place in Bangladesh from 20 to 30 April 2015 and was undertaken as part of the Food and Veterinary Office's (FVO) audit programme.

The audit team comprised three inspectors from the FVO. This was a joint audit covering both fishery products and residues for which a separate report (DG SANTE 2015/7517) will be published.

An opening meeting was held in Dhaka 20 April 2015 with the competent authority (CA), the Department of Fisheries under the Ministry of Fisheries and Livestock. 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.

2 OBJECTIVES AND SCOPE

The objectives of the audit covered by this report were:

- To evaluate whether the official controls put in place by the CA can guarantee that conditions of production of fishery products in Bangladesh destined for export to the EU are in line with the requirements laid down in EU legislation and in particular with health attestations contained in the certificate.
- To verify the extent to which the guarantees and corrective actions submitted to the Commission services in response to the recommendations of the previous FVO fishery products report of 2010 have been implemented and enforced by the CA.

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

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

COMPETENT AUTHORITY		
Central level	1	Department of Fisheries
Regional level	2	Chittagong and Khulna
Local level	3	Cox's Bazar, Khulna, Manikgong
	1	Marine Fisheries Office, (Department of Fisheries)
LABORATORY VISITS		
Chemical	3	Chittagong, Khulna, Dhaka
Microbiology	3	Chittagong, Khulna, Dhaka
PRIMARY PRODUCTION		
Feed mill	1	
Aquaculture farms	4	
LANDING AND FIRST SALE		
Landing sites	1	

Auction depot	1	
FACILITIES HANDLING FISHERY PRODUCTS		
Freezer vessels	2	
Processing Plants	3	
OTHERS		
Veterinary medicines	2	1 pharmacy, 1 outlet

3 LEGAL BASIS

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

Bangladesh 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.

Bangladesh is also listed for aquaculture in the Annex to Commission Decision 2011/163/EU and therefore can export aquaculture fishery products to the EU.

Article 11(4)(k) of Regulation (EC) No 854/2004 establishes that EU controls carried out in the context of drawing up or updating lists of third countries from which imports of products of animal origin are permitted, shall have regard to the results of EU controls carried out in the third country, in particular the results of the assessment of the CAs, and the actions they have taken in the light of the recommendations addressed to them following an EU control. As a consequence, the FVO team made an assessment of the assurances provided by the CA following the last fishery products audit to Bangladesh that took place in 2010. The report (ref. DG(SANCO)/2010-8434) is published on the Health and Food Safety Directorate-General (SANTE) website at http://ec.europa.eu/food/fvo/ir_search_en.cfm.

The 2010 audit highlighted deficiencies in relation to registration of farms, monitoring of hatcheries and farms and maximum limits for heavy metals, and the report made a number of recommendations in respect of the action required by the CA. Written guarantees were received from the CA in relation to the implementation of actions aimed at addressing those recommendations.

4.2 PRODUCTION AND TRADE INFORMATION

According to information provided by Eurostat (see table below), the main fishery products exported to the EU are aquaculture shrimp (*Penaeus monodon*, *Machrobracium rosenbergii*, *Metapenaeus monocerus*) and some wild caught fish. From inland waters it can be catfish,

striped snakehead, mourala fish, eel and others. Sea water trawlers catch amongst other species mackerel (*Scombridae*) and sardines (*Clupeidae*). Aquaculture fish is not exported to the EU at present. The main importing Member States are by decreasing order: Belgium, UK, the Netherlands, Germany and France.

The CA stated that no fishery products are allowed to be imported into Bangladesh as raw material and later on exported to the EU.

The CA also informed the audit team that the total production of shrimp in Bangladesh during 2013-2014 was just over 120,000 tonnes of which around 58% was *Penaeus monodon*, 34 % *Macrobrachium rosenbergii* and the rest included *Metapenaeus monoceros* and other shrimp species.

According to the list established by the CA and available on the DG SANTE website (list valid as of 27/11/2014), imports of fishery products from Bangladesh into the EU are authorised from a total of 74 establishments, all of these establishments process materials derived from aquaculture. Some also process wild caught species. There are no stand-alone cold stores approved and freezer vessels are not listed for export to the EU.

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

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

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

Commodity	2014
Fish, chilled and frozen (0303)	2,638
Crustaceans (0306)	34,192
Crustaceans (1605)	1,756
Total export to the EU	38,586

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

During the last three years there have been three RASFF notifications. Two occurred in 2012, one concerned *Vibrio cholerae* in frozen cooked black tiger prawns and one finding of oxytetracycline residues in frozen shrimps. The third notification happened in 2014 and concerned the finding of prohibited substances (nitrofurans) in shrimps in 2014.

5 FINDINGS AND CONCLUSIONS

5.1 LEGISLATION

Legal requirements

Article 46(1)(a) of Regulation (EC) No 882/2004.

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

Findings

1. The audit team noted that the main pieces of legislation covering the production chain of fishery products intended for export to the EU fisheries have been amended since the

previous fishery products audit. Since then, new rules have been adopted and guidelines have been developed. The most important pieces of legislation currently in force are:-

- Fish and Fish Products (Inspection and Quality Control) Ordinance, 1983 includes legal powers for the CA related to infringement procedures in relation to fishery products.
 - Marine Fisheries Ordinance 1983 includes legal powers for the CA related to infringement procedures in relation to fishery products.
 - Fish and Fish product (Inspection and Quality Control) Rules, 1997 (amended 2008 and 2014) gives powers and enforcement rights to the CA and also contains structural requirements for vessels, transports, landing sites, vending centres, ice plants, cold stores, packing centres, hatcheries, nurseries and processing establishments; standards for potable water; maximum limits for heavy metals; requirements for buying agents and proof of source of origin of fishery products; food additives; prohibited use of certain substances; veterinary medicinal products allowed to be used.
 - Fish Feed Acts 2010 and Fish Feed Rules 2011- fishery products are also included in these acts, e.g. maximum limits for mercury, lead and cadmium.
 - Fish Hatchery Acts 2010 and Fish Hatchery Rules 2011 including e.g. polychlorinated biphenyls (PCBs).
 - Public Servants Conduct Rules, 1979 includes requirements for official staff concerning conflict-of-interest.
 - Fish and Fishery Products Official Controls Protocol summarises the legal framework for the CA; contains e.g. detailed requirements for risk based official controls and rating of establishments and gives guidance to staff on how to perform sampling, audits and approvals. A number of detailed checklists developed for different types of control objects are included.
 - National Residue Control Plan (NRCP) Policy Guideline 2011 (revision 2012) gives advice on substances to monitor; sampling strategy and planning; collection and handling of samples; result reporting and investigation procedures.
 - Guidelines for the Control of Aquaculture Medicinal Products – AMPs (2015) gives advice to the distribution chain of veterinary medicinal products and for the CA's field monitoring of use.
2. The maximum limit (0.25mg/kg) allowed in the Fish and Fish Product (Inspection and Quality Control) Rules, 1997 amendment 2014 for cadmium in marine species, including sardines, mackerel and eel, which are species exported to the EU, is higher than the EU limit (0.10 mg/kg) in Regulation (EC) No 333/2007.
 3. In addition to legislation, the CA of Bangladesh is working together with industry organisations to develop codes of conduct for different parts of the production chain (farms, hatcheries, feed mills, collection centres, ice plants, vessels, transport vehicles and processing plants) which include detailed requirements for the different parts.

Conclusions on legislation

4. From the limited review of the national legislation and standards applied to fishery products and their production chain, the rules in force can be considered as broadly in line with relevant EU requirements other than concerning the maximum limit for cadmium in products of marine fish species.

5.2 COMPETENT AUTHORITY

Legal requirements

Article 46 of Regulation (EC) No 882/2004, in particular points b) to (e), (g) and (h) of the aforementioned Article. Points g) and h) are covered in Section 5.4 of this report.

Findings

5.2.1 Structure and organisation

- The CA for fishery products is the Department of Fisheries of the Ministry of Fisheries and Livestock. The CA is responsible for the implementation of legislation and the official control system of fishery products at all stages of production including the national residue monitoring plan and sampling.
 - The Department of Drug Administration within the Ministry of Health and Family Welfare is responsible for registration of drugs and the Department of Livestock Services under the Ministry of Fisheries and Livestock are also involved in the official control of veterinary medicinal products.
 - The Marine Fisheries Office, under the CA, is responsible for issuing annual fishing licences, performing controls on landing, vessel inspections and issuing catch certificates.
 - The Marine Mercantile Department of the Ministry of Shipping is responsible for registration of vessels which is obligatory to obtain a fishing licence.
 - The Coast Guard and the Bangladeshi Navy check at sea for legal aspects on fishing (species, periods of ban) and to prevent illegal fishing.
5. The central office of the CA is situated in Dhaka and it has three regional and seven local CA offices. The local CAs can also have sub-districts and inspectors placed in rural areas. At the time of the audit there were a total of 1,272 staff according to the CA. For EU exports, the regional CA inspectors are required to inspect EU listed establishments, including sampling for the national residue monitoring plan, sampling for pre-export testing and inspection of consignments as well as supervising local inspectors. Inspectors are assigned to certain EU export establishments for supervision during a certain period after which they are moved elsewhere. The local CA is responsible for registration of aquaculture farms.

5.2.2 Powers, Independence and Supervision

6. According to the Fish and Fish Products (Inspection and Quality Control) Ordinance, 1983 and Fish and Fish product (Inspection and Quality Control) Rules, 1997 (amended 2008), the Department of Fisheries has been empowered as the central CA for performing official control on primary production and on the production chain of fishery products including the marketing and use of fish feed. The regional and local CAs are empowered by the central CA to implement rules and perform official control.
7. The CA has the power to enter and inspect premises and vessels to check hygiene conditions and relevant documentation, collect samples for analysis, suspend activities or approvals, seize or dispose of products and launch sanctions including fines for non-compliances against food business operators. The audit team saw an example of communication with food business operators concerning enforcement and fines issued for non-compliances.

8. To ensure that staff is free from conflict of interest, the Public Servants Conduct Rules, 1979 contain e.g. requirements forbidding business relations between CA staff and food business operators; restrictions concerning gifts, etc.; only appointed staff to perform inspections; rules for separation between inspection staff and laboratory work including coding of samples to maintain anonymity.
9. Only laboratories designated by the central CA may participate in official controls.
10. The central CA supervises regional and local staff by monthly coordination meetings in Dhaka with regional CA representatives present where activities are reported and discussed. Regional CAs collect information from local CAs and monthly reports are sent to the central level. Staff from the central level also monitor regional and local CA activities by on-the-spot visits (minimum once a year) when annual assessments are performed for renewal of establishments' approval (See Chapter 5.3). Regional CAs supervise local CAs by on-the-spot visits, participation in investigations of non-compliances found and meetings and training. To ensure harmonisation of approach, all inspection reports are reviewed and signed by the head of the regional CA.

5.2.3 Training

11. There are records of personnel available in a centralised computer system. Each person's education, work experience, position and training attended are documented. The audit team was also provided with summaries of training activities carried out at the regional CAs.
12. The CA has been working together with United Nations Industrial Development Organisation (UNIDO) since 2010 in a project called Better Work & Standards Programme – Better Fisheries Quality (BEST-BFQ) co-funded by the EU and the Norwegian Agency for Development Cooperation (NORAD). This project is a follow-up programme to consolidate an earlier initiative implemented over the period 2005-2010 and co-funded by the same sponsors. Under the combined 10 year initiative legislation has been revised, a large scale education effort for both CA staff and stakeholders has been undertaken as well as guidelines developed and disseminated. Quality assurance and traceability related training have been performed for CA staff at all levels in which food business operators participated. Good Aquaculture Practices training has been given to a large number of CA and hatchery staff, farmers and feed mill personnel. There has also been participation in international training, workshops and studies by official staff.
13. A comprehensive information package has been distributed to CA staff and stakeholders covering guidelines for feed production, shrimp hatcheries, waste management in fish and fishery industry, Good Aquaculture Practice guide for farmers, farm record books and Compliance Guidelines for Shrimp Hatchery as well as Compliance Guidelines for Fish Feed Production, Import and Marketing.
14. Since 2010 training for laboratory staff have taken place in nine sessions on Quality Management, accreditation preparation, various methods and calibration of instruments.

5.2.4 Documented Control Procedures

15. To ensure a harmonised approach and compliance with legislation, the CA has compiled a comprehensive compendium entitled *The Fish and Fishery Products Official Controls*

Protocol that is distributed to all levels of the organisation. It contains requirements and instructions for risk based official controls and rating of establishments for routine inspections, listing/approval of establishments, verification of compliance of food business operators, reporting and corrective action requests, procedures for health certification, guidance to staff on how to perform sampling, audit and inspection procedures, quality control and performance evaluation within official controls, reporting and organisation of official controls, approval of laboratories, hygiene requirement verification and report templates. A number of detailed checklists have been developed for different elements of the production chain, e.g. hatcheries, farms, vessels, ice plants and establishments.

Conclusions on the competent authority

16. The CA is clearly designated and has an organisation at regional and local level. The CA has been given appropriate enforcement powers and adequate resources (facilities, equipment, competent staffs) to perform official controls and has put in place written procedures for the performance of their role.

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

17. There are approval procedures set out in the Fish and Fish Products (Inspection and Quality Control) Rules, 1997. Approvals/licences are issued by the regional CA to establishments and auction depots. The licence states that the establishment may produce fishery products and that they can export to the EU. The approval includes pre-requisite requirements, e.g. Good Manufacturing Practices, cleaning and sanitising procedures and HACCP plans.
18. An application for approval must be sent to the central CA and contain blueprints, pre-requisites, flow charts, HACCP plans, etc. If the application documents are deemed satisfactory, the central CA forwards the application to the regional CA with a *no objection certificate*. The regional CA performs an on-the-spot inspection to check if facilities and operational conditions are satisfactory. If so, the regional CA issues approval or demands corrective actions where deemed necessary. Unique identification numbers for establishments are allocated by the central CA.
19. To be listed for export to the EU, in addition, an assessment by members of a central committee takes place using a comprehensive checklist. This checklist is also used for the annual renewal of the licence. Licences are valid for one year and establishments are

reassessed on an annual basis. All establishments visited had their up-to-date licences available.

20. The list of EU export establishments is forwarded to the EU Commission and kept up-to-date. In case of serious shortcomings establishments can be suspended from exports to the EU and de-listed if corrective actions are not taken.
21. Freezer vessels are approved in the same way as land-based establishments with the difference that vessels are approved by a regional CA committee in consultation with the central CA. A list of 46 trawlers approved for export was available. There are no exports of fishery products directly from freezer vessels to the EU. Establishments buying raw material from freezer vessels do further processing and re-pack the final products.

Conclusions on provisions and procedures for listing establishments

22. There are provisions and procedures for listing establishments approved for export to the EU that can be considered as adequate.

5.4 OFFICIAL CONTROLS

5.4.1 Official controls of production and placing on the market

Legal requirements

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

Requirements contained in point II.1 (and point II.2 in case of aquaculture products) 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 I of Regulation (EC) No 854/2004.

Article 11(4) of Regulation (EC) No 854/2004 establishes that EU controls shall take particular account of the extent and operation of official controls on imports of animals and their products and the assurances which the third countries can give regarding equivalence to EU requirements (Article 46(1)(g) (h) of Regulation (EC) No 882/2004).

Findings

5.4.1.1 Official control system in place

23. The official control system covers the entire fishery products production chain. Official controls on the production and placing on the market of fishery products are foreseen to include aquaculture farms, landing centres, auction depots, processing establishments and transport. Specific checklists have been developed for each step of the production chain. Inspections and audits are in general unannounced.
 - Aquaculture farms are inspected, a minimum twice per year, during the growing season in one region, once a month in another region and whenever necessary for investigations and follow-up visits.
 - On-board inspections of freezer vessels are carried out on a quarterly basis.
 - Landing sites, auction depots are inspected once a quarter also.

- Establishments are inspected once a month. A checklist is used. Non-compliances are noted and the report is signed by the inspector and the food business operator. Food business operators are required to take action to correct deficiencies within a deadline set by the CA. In addition, establishments are inspected and evaluated once a year by a central commission using a comprehensive checklist that includes e.g. infrastructure, operational procedures, the quality management system and the own-check system in place for the renewal of approval. (See also Chapter 5.3 above)
 - Storage conditions and land transport are checked a minimum of twice per year up to once a month.
 - Water, ice and swab samples from processing establishments are done under a separate control programme.
24. Fishery products intended to be exported to the EU are subject to a mandatory pre-export inspection which includes:
- Randomly collected samples for chemical and microbiological checks;
 - Organoleptic examinations;
 - Verification of records and documents relating to the raw material and processing of products including traceability.

5.4.1.2 *Primary production*

25. Fishing vessels are inspected by the CA when landing each catch and organoleptic checks and sampling for microbiological tests are performed on the catch. A standardised checklist is used for these inspections. Vessels are also checked by the Marine Fisheries Office at landing and before departure to check compliance with technical rules (net mesh sizes, fishing zones, ban of fishing specific species etc.). The Marine Fisheries Office issues yearly fishing licences provided that the vessels are registered.
26. The audit team visited two shrimp farms (black tiger) and two fin fish farms (carp, pangasius, tilapia). There is one production cycle each year for shrimp – stocking in May and harvesting during November – February. Most of the production is classified as extensive and dependent on natural feed available for the shrimp. Feed including probiotics, vitamins and enzymes can be used, but medicated feed is not allowed in final rearing. Veterinary medicinal products may be used in hatcheries and nurseries. Feed is produced in feed mills in Bangladesh from local and imported ingredients or imported bagged and ready-to-use.
27. The local CA registers farms and performs regular unannounced official visits. At the time of the audit a total of over 1,860,000 farms had been registered. Farm record books have been developed and distributed by the CA since 2009. Farmers are obliged to note production data (amounts of produce, harvest, disinfection, feed and additives used) and inspectors make notes of each visit in the book with a summary of what has been found/discussed. A farm checklist is used and if non-compliances are found they are noted in the record book and reports are also written. Regional CA inspectors visit farms for sampling under the national residue monitoring plan.

28. There is a *Good Aquaculture Practice Guide* for farmers developed by the CA and the BEST—BFQ project that has been distributed to all farmers in conjunction with training given.

5.4.1.3 *Landing sites and first sale*

29. The audit team visited one landing site/jetty where only landing of frozen, packed fishery products took place.
30. The audit team visited an auction depot where local farmers bring their live harvested catch for sale. Information of the production including the farm registration number is given by the farmer when shrimp are delivered to auction depots to make traceability possible. Auction staff fill out a form with these details that the farmer has to sign. After being auctioned, the products are placed under ice in crates. The ice is provided on the site either by the auction buying it from an ice factory or by processing establishments purchasing raw material.

5.4.1.4 *Facilities, including vessels, handling fishery products*

31. The audit team visited two freezer vessels. One of them packed whole fish on deck in plastic bags and froze the catch without further handling. The second vessel caught shrimp that was rinsed in potable water brought with the vessel, de-headed, packed and frozen. The handling took place on deck covered by a tarpaulin. Neither vessel had HACCP plans nor temperature recording devices in the cold stores.
32. Three land-based establishments were visited by the audit team. All three can be considered as in line with EU equivalent requirements as regards general structure, maintenance and the flow of products. Reports and other documentation were available. They had been visited with the stipulated frequency, checklists had been used and reports were available. Findings were noted and follow-up of deficiencies was carried out which also was noted either in the next routine inspection report or separately if an extra follow-up inspection was performed. In one region a log book in each establishment was used where all visits were noted together with a short summary of issues discussed.
33. The establishments visited had only recently installed and taken into use automatic temperature recording devices in their cold stores. Records from those devices were therefore not available to the audit team. Manual records were kept by reading the displays outside the chambers. However, in one of the establishments visited, the temperature in one cold store chamber did not reach -18°C. A carton packed in December 2014 was brought out to the ante-room to check the temperature of the product. Three measurements were made and all showed temperatures around -14°C. Actions were taken by the CA on-the-spot by writing instructions to monitor and correct the deficiency in the log book.
34. All establishments have ice production facilities for their own production and for the transport of fish and shrimp from landing sites, farms and auctions. The official

temperature limit of incoming raw material is that of melting ice and during production not more than +5°C.

35. Transport vehicles are included in the approval of each establishment and are inspected once a month.
36. All establishments visited had a comprehensive own-check programme covering pre-requisites such as staff training, cleanliness, cleaning and sanitation, pest control and water quality. Hygiene records are compiled daily. Own-checks of microbiological parameters are performed of fishery products and water/ice in internal laboratories or in external.
37. HACCP plans cover physical, chemical and microbiological risks. However, histamine for mackerel and sardines in fishery products were not considered. Chemical contaminants including veterinary medicinal products for shrimp are considered for incoming raw materials. HACCP plans are checked by the CA as part of the official checklist used.
38. Food business operators are obliged to follow a residue control plan which includes monitoring of veterinary medicinal products, dyes, mycotoxins, heavy metals and pesticides in both products and water. Random visits of farms are also done by the food business operators to whom they supply product.
39. There is a national requirement for medical checks of staff.

5.4.1.5 *Checks on the EU eligibility of imported raw materials*

40. The CA stated that no fishery products are permitted to be imported as raw material for further export to the EU.

Conclusions on official controls of production and placing on the market

41. The official control system in place covers the entire production chain and it can be considered as providing, in general, necessary guarantees with regard to the applicable EU requirements. However, these guarantees are undermined by shortcomings noted with regard to not reaching -18°C in fishery products during storage, freezer vessels not meeting all EU equivalent structural standards or having HACCP plans assessed and the fact that not all relevant hazards are covered in HACCP plans.

5.4.2 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

42. Official controls of fishery products cover organoleptic checks, microbiology, heavy metals, parasites and poisonous fish. Besides performing organoleptic and parasite checks at landing, inspectors control the documentation of food business operator's own-checks at the establishments.
43. Monitoring for lead, mercury and cadmium is included in the national residue monitoring plan and the food business operator's obligatory sampling plan for veterinary medicinal products, dyes, mycotoxins and pesticides. Results from both sampling programmes were available to the audit team in the establishments visited and showed results below EU limits.
44. Histamine is not analysed for in fish belonging to species associated with high amount of histidine (*Scombridae*, *Clupeidae*).
45. Dioxins/PCBs analyses are not performed.
46. Microbiological analyses are done on samples taken for the compulsory pre-export testing for aerobic plate count, *E.coli*, *Salmonella*, *Vibrio cholera* and *Vibrio parahaemolyticus*.
47. Phosphates are used in shrimp production in the form of disodium diphosphate, labelled as E450 (i). Food business operators must perform checks on the contents and inspectors check the results of these own-checks, but there is no official sampling.
48. Water and ice samples are taken by the CA twice per year. Analyses for *aerobic plate count* 22°C and 30°C, *total coliforms* 37°C, *E.coli* and *Salmonella* are performed. In addition, food business operators sample water and ice weekly or every second week. Incoming water is treated with UV-light and filtered but not chlorinated.
49. Inspectors and fishermen are trained to look for poisonous fish.

Conclusions on official controls of fishery products

50. The CA implements official controls on fishery products exported to the EU that adequately cover most EU requirements (organoleptic checks, parasites, microbiology, heavy metals). However, there is no official control of histamine in relevant fish species, dioxins/PCBs or additives when used.

5.5 FOLLOW UP OF RASFF NOTIFICATIONS

Legal requirements

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 amongst other factors: any experience of marketing of the product from the third country and the results of any import control carried out.

Findings

51. RASFF notifications are received at the central CA. They are distributed to the regional CA for investigation and follow-up. The regional CA contacts the food business operator and local CA for investigations and corrective actions.

52. The audit team reviewed one case from 2012 concerning residues of oxytetracycline in shrimp and was shown letters sent out to the establishments with instructions for investigations and corrective actions to be taken. The local CA was also informed and inspectors were instructed to perform controls and investigations on farms providing raw material. Samples were taken at the farms of both shrimp and feed in an attempt to identify the source of contamination. Actions were taken at the local feed mill and the farmers were given training. The collected information was evaluated and the result sent to the central CA.

Conclusions on follow up of RASFF notifications

53. The measures taken by the CA following RASFF notifications were adequate and led to a higher awareness amongst the farmers regarding the use of medicines.

5.6 LABORATORIES

Legal requirements

Article 46(1)(d) and (c) of Regulation (EC) No 882/2004.

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

Regulations (EC) No 333/2007 and Regulation (EU) No 589/2014.

Findings

54. The audit team visited three chemical and three microbiological laboratories designated to participate in official controls of fishery products and water/ice.
55. Two of the three microbiology laboratories were accredited to the ISO 17025 standard. The process of accreditation had started in the third one which had a quality management system in place. All laboratories had participated in proficiency testing with satisfactory results.
56. The laboratories were visited by the audit team in parallel. The chemical laboratories are described in detail in the report covering residues (DG SANTE 2015/7517).
57. All three microbiological laboratories only analyse official samples. Samples are taken by local inspectors and brought to the regional CA office where they are coded by an assigned person, to make the samples anonymous to the laboratory staff.
58. Every batch of samples was run with blanks and positive controls. Work books were kept where, each day, all samples received were noted and the starting date for analyses and result reading dates for different parameters were noted. Results were sent to the CA which de-coded the samples and distributed the results to the office/inspector and food business operator involved.
59. The laboratories had adequate equipment and operated in air-conditioned facilities. A documented quality management system was in place including written work instructions (e.g. instruction for reception, cross-contamination of samples). An external entity calibrates equipment at different intervals according to a plan and equipment was labelled accordingly. Temperature controls of incubators and refrigerators were documented.
60. Staff were found to be knowledgeable and specialised and had a work system of back-up to ensure that competencies were covered. Lists of trainings were kept.

Conclusions on laboratories

61. Given the laboratories' accreditation to ISO 17025, their overall satisfactory results in regular proficiency testing and their internal quality controls, the laboratories designated by the CA for official analyses of fishery products can ensure the reliability of the results of the analyses.

5.7 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.

Findings

62. The CA has procedures for certification in place that include on-the-spot checks. When a consignment is assembled, the CA is notified and an inspection of it is performed. All consignments must pass a pre-export test. Random samples are taken by the inspector for chemical and microbiological analyses. All export health certificates are signed at the regional CA. The most recent model of the health certificate, in line with Regulation (EC) No 2074/2005, as amended is used. They were found correctly filled out and relevant languages were used.
63. Trace-back checks were done by the audit team in shrimp processing establishments from export health certificates to raw material suppliers. They showed that a production lot can be a whole day's production with shrimp originating from a large number of farms, which complicates investigation procedures should they be needed.

Conclusions on certification

64. There is a certification procedure fit for purpose. The system in place ensures that products are eligible for export and provides sufficient guarantees on traceability from production to export to the EU.

5.8 FOLLOW-UP OF PREVIOUS AUDIT 2010-8434

This section only covers recommendations, covering aquaculture products, from the 2010 report.

<i>No</i>	<i>Recommendation</i>	<i>Assessment</i>
10	Ensure that all aquaculture farms producing fin fish or shrimp for the EU market are registered under a system allowing adequate traceability in line with Article 6 (2) of Regulation (EC) No 852/2004.	Addressed - Aquaculture farms are registered and included in a system of official inspection See findings No 23 and No 27.

11	Ensure that national public health legislation is up to date and contains the appropriate maximum limits for certain contaminants, i.e. heavy metals as described in Commission Regulation (EC) No 629/2008 ¹ .	Largely addressed, except in relation to the maximum limits for some fish species which are not equivalent to EU thresholds See finding No 2. See recommendation No 4.
12	Ensure that the official monitoring of hatcheries and aquaculture farms, producing for the establishments approved for export to the EU, is carried out according to provisions at least equivalent to those mentioned in Annex I of Regulation (EC) No 852/2004.	Addressed - Aquaculture farms are registered and included in a system of official inspection See findings No 23 and No 27.

6 OVERALL CONCLUSIONS

Improvements have been made since the last audit and in principle, the current organisation of the competent authority and its documented operational procedures provide for an acceptable official control system for fishery products which is implemented in a satisfactory way.

However, certain deficiencies in their implementation (i.e. temperature controls, structural standards of freezer vessels; lack of histamine, dioxin/PCBs and additives testing; maximum limits for cadmium) do not offer the necessary guarantees that fishery products intended for EU export fully respect the requirements defined in the health certificate for imports of fishery products intended for human consumption as set out in the model defined in Regulation (EC) No 2074/2005.

7 CLOSING MEETING

During the closing meeting held in Dhaka on 30 April 2015, the audit team presented the main findings and preliminary conclusions of the audit to the CA. The CA acknowledged the findings and preliminary conclusions and provided commitment to correct the deficiencies.

8 RECOMMENDATIONS

No.	Recommendation
1.	The CA should ensure that freezer vessels providing fishery products to EU listed establishments meet standards at least equivalent to the requirements laid down in Chapter I of Annex II to Regulation (EC) No 852/2004 and in Section VIII, Chapter I of Annex III to Regulation (EC) No 853/2004 and that

¹ See Regulation (EC) No 1881/2006 as amended

No.	Recommendation
	<p>EU listed establishments in particular meet storage temperature requirements.</p> <p>Recommendation based on conclusion No 41.</p> <p>Associated findings No 31 and No 33.</p>
2.	<p>The CA should ensure, as established in Part II.1 of the health certificate defined in Regulation (EC) No 2074/2005, that fishery products exported to the EU have been caught and handled on board freezer vessels implementing a programme based on HACCP principles in accordance with Article 5 of Regulation (EC) No 852/2004.</p> <p>Recommendation based on conclusion No 41.</p> <p>Associated finding No 31.</p>
3.	<p>The CA should ensure that, as established in Part II.1 of the health certificate defined in Regulation (EC) No 2074/2005, that fishery products exported to the EU have satisfactorily undergone the official controls laid down in Annex III to Regulation (EC) No 854/2004, in particular concerning dioxins/PCBs.</p> <p>Recommendation based on conclusion No 50.</p> <p>Associated finding No 45.</p>
4.	<p>The CA should ensure that, as established in Part II.1 of the health certificate defined in Regulation (EC) No 2074/2005, fishery products exported to the EU have satisfactorily undergone the official controls laid down in Annex III to Regulation (EC) No 854/2004, in particular that histamine testing is in line with Regulation (EC) No 2073/2005 and that maximum limits applied for cadmium meet are in line with Regulation (EC) No 1881/2006.</p> <p>Recommendation based on conclusion No 4 and No 50.</p> <p>Associated findings No 2, No 44 and No 47.</p>

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dec. 2006/766/EC	OJ L 320, 18.11.2006, p. 53-57	2006/766/EC: Commission Decision of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted
Dec. 2011/163/EU	OJ L 70, 17.3.2011, p. 40-46	2011/163/EU: Commission Decision of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

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. 589/2014	OJ L 164, 3.6.2014, p. 18-40	Commission Regulation (EU) No 589/2014 of 2 June 2014 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012