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Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

MEXICO

FROM 20 TO 30 NOVEMBER 2012

IN ORDER TO EVALUATE THE CONTROL SYSTEMS IN PLACE GOVERNING THE PRODUCTION OF FISHERY PRODUCTS INTENDED FOR EXPORT TO THE EUROPEAN UNION

Executive Summary

This report describes the outcome of a Food and Veterinary Office audit in Mexico carried out from 20 to 30 November 2012, 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 authorities can guarantee that the conditions of production of fishery products in Mexico 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 2007 audit visit covering the same subject.

The report concludes, other than as regards primary production, that with the current organisation of Mexico's competent authorities and control systems in place it should be possible to offer sufficient guarantees concerning the sanitary conditions of fishery products to be imported into the European Union.

However, at present, the competent authority cannot fully ensure that all fishery products exported to the European Union respect the requirements defined in the "health certificate for imports of fishery products intended for human consumption" due to the deficiencies noted during the audit with regard to the implementation of the approval system for establishments, the follow-up of deficiencies, the export certification and official analyses and also due to the absence of official controls of primary production fishing vessels.

The report also concludes that the overall follow-up of the previous FVO audit report made by the competent authority can be considered as mostly satisfactory. However, recommendation No 2 on official controls over fishing vessels is still to be addressed and recommendations No 4 and 6 were only partially addressed.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
CA	Competent Authority
CCA	Central Competent Authority
CCAYAC	Commission of Analytical Control
COFEPRIS	Federal Commission for the Protection from Sanitary Risks
COS	Commission of Sanitary Operations
DG SANCO	Health and Consumers Directorate General of the European Commission
EC	European Community
EU	European Union
EU listed	Facility approved by the CA for EU fishery products export and listed on the internet site of DG SANCO
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
NOM	Mexican Norm
OJ	Official Journal of the European Union
PCBs	Polychlorinated Biphenyls
RASFF	Rapid Alert System for Food and Feed
SENASICA	National Service of Animal Health, Food Safety and Food Quality

1 Introduction

The audit took place in the United Mexican States (hereinafter Mexico) from 20 to 30 November 2012 and was undertaken as part of the Food and Veterinary Office's (FVO) audit programme. The FVO audit team (hereinafter the FVO team) comprised two inspectors from the FVO. An opening meeting was held in Mexico City on 20 November 2012 with the competent authorities (CAs): the Federal Commission for the Protection from Sanitary Risks (COFEPRIS) of the Health Secretariat ("*SALUD*") which is the Mexican central competent authority (CCA) for EU exports of fishery products) and; the National Service of Animal Health, Food Safety and Food Quality ("SENASICA") of the Agriculture, Livestock, Rural Development, Fisheries and Food Secretariat ("*SAGARPA*") which also acts as a CA for the sector. At this meeting the objectives of, and itinerary for the audit were confirmed, and the FVO team requested additional information required for its satisfactory completion.

2 Objectives and scope of the audit

The objectives of the audit were:-

- to evaluate whether the official controls put in place by the CAs can guarantee that the conditions of production of fishery products in Mexico 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 action submitted to the Commission services in response to the recommendations of the previous FVO audit report of 2007 (ref. DG(SANCO)/2007-7294 – MR – FINAL, 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. Full references to EU legal acts quoted in this report are provided in that Annex and refer, where applicable, to the last amended version.

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

COMPETENT AUTHORITY		
Federal level	1	
State level	2	
LABORATORY VISITS		
National Reference Laboratory	1	
Laboratory for Official Controls of fishery product, water and ice	3	
PRIMARY PRODUCTION		

Aquaculture farms	1	
Fishing vessels	5	
FACILITIES HANDLING FISHERY PRODUCTS		
Freezer vessels	4	
Processing Plants	7	
Cold stores	2	
Ice factories	1	

Representatives from COFEPRIS and SENASICA (where applicable) accompanied the FVO 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.

4 Background

4.1 General background

Mexico 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.

Mexico is also listed in the Annex to Commission Decision 2011/163/EU as having an approved residues monitoring plan for aquaculture products and therefore can export those fishery products to the EU.

The most recent audit took place in 2007 (ref. DG(SANCO)/2007-7294)[1] the report of which highlighted deficiencies in relation to the Mexican legislation (limits for environmental contaminants), the official control over primary production fishing vessels, landing sites and freezer vessels, the reliability of the establishments approval procedures, the control over ice production, the monitoring of environmental contaminants and the maintenance of the cold chain in establishments. The report – published on the Health and Consumers Directorate-General (SANCO) Internet site at http://ec.europa.eu/food/fvo/ir_search_en.cfm – made a number of recommendations in respect of the action required of the CA. Written guarantees were received from the CA in relation to the implementation of actions aimed at addressing those recommendations which were found satisfactory. The follow-up of these recommendations are reported under the relevant parts of this report.

1 Which was a follow-up of two earlier audits both carried out in 2004 (ref. DG(SANCO)/2004-7301 and DG(SANCO)/2004-7371).

4.2 Production and trade information

According to the list established by the CCA, imports of fishery products from Mexico into the EU are authorised from a total of 41 establishments (these include 10 establishments processing only or partially materials derived from aquaculture, two cold stores and 26 freezer vessels. This list, published on 31/10/2012 and valid as of 13/11/2012, is available on the SANCO website at the following address:

http://ec.europa.eu/food/food/biosafety/establishments/third_country/ index_en.htm.

According to information provided by the CCA, fishery products exports to the EU amounted to approximately 32,000 tonnes in 2011 (mainly frozen). Of this total, tuna species contributed with approximately 17,800 tonnes, cephalopods with approximately 13,400 tonnes (mainly *Octopus spp.*), and shrimp with approximately 700 tonnes (mainly *Litopenaeus vannamei*). These fishery products are exported to the EU by container reefer vessels to Spain (65% of EU imports), Italy, Portugal, The Netherlands, Greece and France.

According to the information provided by the CCA there were no imports into Mexico of raw material to be processed and later on exported to the EU.

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

Since the last FVO audit six RASFF notifications were issued on fishery products of Mexican origin. One was due to the presence of carbon monoxide, one due to improper health certificate and four due to rupture of the cold chain. Details on how these notifications were handled will be presented in Section 5 of the report (Findings and Conclusions).

5 Findings And Conclusions

5.1 Legislation

Legal requirements

Article 46(1)(a) of Regulation (EC) No 882/2004 states that Commission experts may carry out official controls in third countries in order to verify the compliance or equivalence of third countries legislation with the relevant EU legislation.

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

Findings

The main legal legislative acts that are relevant for the official controls of fishery products to be exported to the EU are the ones indicated in the audit report ref. DG(SANCO)/7301-2004 – the Mexican Constitution, the Organic Law of the Federal Public Administration, the General Health Law, Health Secretariat Internal Regulations, COFEPRIS Regulation, General Health Law Regulation for the Sanitary Control of Products and Services, Federal Law for Metrology and Standardization and Specific Agreements with the Federal States. Since 2004 these legal texts have been updated and amended where necessary.

The above mentioned legal texts confer on COFEPRIS the responsibility to implement, together with the federal states (through “Specific Agreements”) a control system covering fishery products for EU export and their production chain. This control system is further detailed in the written procedures drafted by COFEPRIS and their state representatives.

In addition to this legal framework there is also the General Fisheries Law that confers on SENASICA the responsibility of ensuring food safety requirements of fishery products until they leave the primary production establishment (without any prejudice to the mandates of other competent authorities). In order to apply this law a regulation has already been drafted by SENASICA, however, there is no time line for its adoption and publication.

Supplementing all the above legislation, Mexico has several norms (Mexican Norms - NOM) that establish the requirements applicable to, amongst others, fishery products, water, fishing vessels (including freezer and factory vessels), processing establishments, process hygiene, Hazard Analysis of Critical Control Points (HACCP), microbiological criteria and limits for contaminants. Although some of these norms present standards different from the EU ones, COFEPRIS adopted a procedure (COS-DEDS-P-05-PI-03) that ensures that all the applicable EU requirements are the ones to be followed in in relation to fishery products for EU export and their production chain.

Conclusions

From the limited review of Mexican legislation and standards applied to EU exports the FVO team concludes that they are largely in line with EU rules and provide an adequate basis for the competent authorities to implement an official control system aimed at providing the necessary guarantees with regard to EU requirements.

Recommendation No 7 of the 2007 FVO audit report on the limits for the contaminants listed in the Annex of Regulation (EC) No 1881/2006 has been satisfactorily 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.

Findings

Structure and organisation

Mexico has two administrative levels involved in official controls of fishery products. A federal and a state level. At federal level the two CAs in charge of the controls are COFEPRIS and SENASICA.

COFEPRIS services directly involved in official controls are the Commissions of Sanitary Approval (CAS), of Sanitary Operations (COS), of Evidence and Risk Management (CEMAR), of Analytical Control (CCAYAC) and the General Coordination of the Federal Sanitary System. Other services of COFEPRIS also contribute indirectly to the official control system.

COFEPRIS covers fishery products for EU export and part of their production chain (primary production is excluded) and acts as the CCA. At state level official duties are attributed to the State Health Services or to a State Commission for the Protection from Sanitary Risks (COESPRIS), which mirrors the organisation of COFEPRIS at state level.

COFEPRIS as CCA is directly in charge of, amongst others, the inspection of large fishing vessels (more than six metres), inspection and approval of facilities for EU export (including freezer vessels) and their listing, audits for approval (which include sampling), control over approved laboratories for official control analyses (through COS and CCAYAC) and health export certification. At state level COFEPRIS representatives are in charge of routine tasks such as inspections of approved facilities and sampling of water/ice and fishery products for microbiological testing. COFEPRIS state representatives may also carry out inspections of the large

fishing vessels on behalf of COFEPRIS.

SENASICA is responsible for covering the primary production chain of fishery products for EU export, which include small fishing vessels (six metres or less) and aquaculture farms. The SENASICA services directly involved in official controls covering primary production are the General Directorates of Fishery and Aquaculture Food Safety and of Animal Health. SENASICA is also in charge of the Residue Monitoring Programme and animal health issues. At state level official tasks may be carried out by the Aquaculture Animal Health State Committees under the supervision of SENASICA.

Powers, Independence and Supervision

The powers of the different CAs are defined in the various pieces of legislation mentioned in section 5.1 and they include amongst others, the power to enter and carry out inspections/audits in premises, to take samples of or from fishery products, water and ice, to seize products, to suspend an establishment's activities, to withdraw an establishment's approval and to examine relevant documentary material.

During the audit the CCA provided the FVO team with written evidence of action taken (temporary suspension of activities) as regards an establishment that was considered as not in line with EU requirements at the time of the FVO visit (see Section 5.3 and 5.4 (*Facilities, including vessels, handling fishery products*)). Also during the audit, the CCA provided to the FVO team a letter summoning an operator for an unannounced visit and the outcome of that visit. This unannounced visit took place due to the fact that the initially scheduled visit to this establishment had not taken place as the establishment was closed at the time of the FVO team's arrival there.

The duties of official staff are defined in the legislation mentioned in section 5.1 and other Mexican legislation applicable to civil servants which includes provisions to ensure the independence of staff, absence of conflict of interest and professional confidentiality.

In order to ensure that official tasks are conducted adequately by their state representatives, the CCA made available their procedures and also carried out audits of the states. The FVO team saw reports of those audits and verified that the audits assessed the performance of official inspections, the procedures and forms used for the inspections, the frequency of the inspections and the existence of programmes for the inspections. Apart from this audit mechanism the state level must provide the federal level with establishment inspection reports in cases where, during a visit, a critical non-compliance is detected.

Training

The CAs provided the FVO team with information regarding the training attended by staff performing official control tasks. Those training sessions included relevant subjects related to, amongst others, auditing and inspection, EU food and feed law, HACCP (including its evaluation) and export certification systems.

In general, staff, belonging to the different CAs at federal and state level, interviewed by the FVO team showed an adequate level of knowledge concerning the applicable EU legal requirements.

Resources available to the CA

During the audit the FVO team noted that official staff had access to appropriate facilities, documents and equipment to perform their tasks.

The FVO team also noted that official staff had access to a network of state authorised laboratories for the performance of the official controls of fishery products, water and ice.

Documented Control Procedures

COFEPRIS and SENASICA have developed and adopted several documented procedures, such as

standard procedures, guidance documents, forms and checklists covering the whole range of official control activities (including inspection of facilities, official sampling, inspection reporting, approval of establishments and certification). These documented procedures were made available to the FVO team and they can be deemed as fit for purpose. Those documented procedures have been adopted or replicated at state level.

The FVO team noted that the documented procedures were available to official staff who followed them on their official control activities. However, in some cases the frequencies set in the procedures were not followed at state level.

The FVO team also noted that although the procedures aimed at controlling primary production exist, the implementation of official controls is dependent on the willingness of the operator to be submitted to them (i.e. official controls over primary production are carried out on a voluntary basis). In order to ensure that fishery products to be exported to the EU comply with and were produced in accordance with the EU requirements, COFEPRIS requested of the EU listed establishments a list of suppliers of raw materials to assess if they were under SENASICA's voluntary official control system, which was provided.

Conclusions

The CAs designated for the official controls of fishery products present a structure, organisation and legal powers that allow for an adequate official control and enforcement across the full production chain of fishery products for EU export.

The control system, based on written procedures, provides an appropriate basis for the CAs to guarantee the implementation of adequate and consistent official controls of the fishery products EU export sector. Moreover, the supervision system as implemented allows the CCA to ensure that the official control tasks are carried out at state level in a uniform and consistent way.

The resources made available to the CAs allow for the satisfactory execution of official tasks and official staff presented adequate knowledge of the relevant EU rules and requirements.

5.3 National Provisions and Procedures for Listing Establishments exporting to the EU

Legal requirements

Article 12(1) and (2) of Regulation (EC) No 854/2004.

Part I.11. of the model health certificate for imports of fishery products intended for human consumption established in Appendix IV to Annex VI to Regulation (EC) No 2074/2005.

Findings

The CCA has in place a procedure to approve facilities for EU exports.

Following this procedure an inspection visit must be carried out prior to approval and listing. During that inspection visit structural conditions, layout, hygiene conditions of production, HACCP plans and other relevant conditions are all checked by CCA officials. Also during that visit final products are sampled to check for compliance with the applicable requirements and to check the hygiene conditions of production. Each item is then scored in accordance with the compliance degree (compliant (2), partially compliant (1) or non-compliant(0)).

An establishment is approved if the score is higher than 85% and does not have any deficiency that could pose a risk of unacceptable contamination of the final product. The remaining deficiencies should be corrected in accordance with a corrective action plan submitted by the operator and the verification of correction of those deficiencies may be made through photographs taken by the

operator showing those corrections.

This approval is valid for 12 months from the day of the official notification sent by the CCA to the operator communicating that the facility is EU listed (which occurs after the publication of the EU list of approved establishments in the DG SANCO's web page).

The FVO team was informed by the CCA that the EU listed establishments are allowed to export to the EU fishery products that were produced immediately following the day of the inspection visit even if the formal decision to approve the establishment is taken at a later date.

With regard to facilities (fishing vessels, aquaculture farms and collection centres[2])) supplying raw materials to the EU listed establishments the CCA provided the FVO team with a letter sent to the establishments concerned stating that their list of suppliers should be made available to the CAs. Additionally the CCA informed that it would only allow EU listed establishments to be supplied by officially controlled aquaculture farms, fishing vessels and collection centres.

The FVO team noted that:-

- The procedure was correctly applied by official staff in cases of first approval and renewal.
- The described procedure allows the approval of an establishment that is not fully compliant with structural and equipment requirements – this is not equivalent to the requirements set out in Article 12 of Regulation (EC) No 854/2004. The Mexican procedure also allows the follow-up of the correction of deficiencies through means other that an inspection visit.
- For one, recently approved EU listed establishment, the procedure in place was not followed. An inspection visit took place and a mock production exercise was performed to assess the production operations but samples of final products were not taken because the whole process was not completely performed (i.e. the exercise was done using frozen instead of fresh raw material). The evaluation of the visit came to a decision that the establishment should not be approved, but after an appeal by the food business operator this decision was overruled, ignoring the fact that the set procedures had not been correctly followed.
- Moreover, the FVO team visited this establishment and noted that:-
    - The reception and production areas presented structural non-compliances.
    - Other parts of the establishments were under repair.
        - At the end of the FVO audit the CCA presented to the FVO team a report of a new inspection visit to this establishment together with a decision to temporarily suspend activities.
- The list of suppliers shown to the FVO team by the various food business operators was not up-to-date and no modifications had been sent to the CCA.
- In one state, the majority of the establishments visited by the FVO team were being supplied by facilities which were not officially controlled or for which there was no written evidence of such controls.

Conclusions

The current procedure for approving and listing of facilities for EU exports does not give the guarantees required in Article 12 point 2 of Regulation (EC) No 854/2004 concerning EU listed establishments and raw material suppliers.

2 *Centros de acopio* - facilities that are used to collect fishery products from fishing vessels and where sorting and weighting of fishery products can also take place

With the current procedures in place recommendation No 3 of the previous FVO audit report on the approval and listing of establishments cannot be considered has adequately addressed. However, the findings on which this recommendation was made are no longer applicable.

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 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.

Article 11(4) of Regulation (EC) No 854/2004 establishes that EU controls carried out in the context of drawing up or updating lists of third countries from which imports of products of animal origin are permitted, shall take particular account of the extent and operation of official controls on imports of animals and their products (Article 46(1)(g) (h) of Regulation (EC) No 882/2004).

Article 11(4) (j) of Regulation (EC) No 854/2004 establishes that EU controls carried out in the context of drawing up or updating lists of third countries from which imports of products of animal origin are permitted, shall have regard to any experience of marketing of the product from the third countries and the results of any import control carried out and the assurances, which the third countries can give regarding equivalence to EU requirements.

Findings

Official control system in place

The official control system in place is shared by COFEPRIS federal level, COFEPRIS state representatives and SENASICA. The attributions and competences of these have been described in Section 5.2 above.

Aquaculture farms are approved by SENASICA for a period of two years (prior to 2012, approval was valid for one year) following an official visit to check the level of compliance with SENASICA's Good Practices Guide. In the past, approved aquaculture farms were inspected by SENASICA annually. Recently that frequency has been reduced to an annual visit of no less than 20% of approved farms. At state level, the Aquaculture Animal Health Committees participate in the inspections made by SENASICA and are in charge of monthly routine inspections to the approved aquaculture farms. The sampling for the Residues Monitoring Programme is carried out by authorised third parties under SENASICA supervision. Small fishing vessels can also be inspected and approved against the SENASICA Good Fishing Practices Manual.

The CCA performs the annual approval inspections. During these inspection visits, samples of fishery products and water/ice are taken for official control analyses. The CCA informed the FVO team that, at the same time as these inspections, the landing sites adjacent to the establishments and the large fishing vessels belonging to the establishment owner may also be checked.

Approval inspections are made using a form ("*Acta de Verificacion*"), which having been filled out is evaluated and a decision is issued. In general the follow-up of the corrections of the deficiencies noted is made through documentary evidence provided by the operator to the CCA. At the time of the issuance of the inspection decision a deadline of 15 days is set for the operator to correct the deficiencies or to submit a corrective action plan.

COFEPRIS state representatives are in charge of the regular inspections that are scheduled to take place six months after the approval inspection (surveillance inspection) and to collect fishery

products, water/ice for microbiological testing. The CCA informed the FVO team that the official visits to large fishing vessels are to be carried out by their state representatives with an annual frequency. The regular inspections are carried out also using a similar "*Acta de Verificacion*" and the procedures to be followed are the ones described above for approval inspections.

COFEPRIS state representatives are also in charge of the inspections of ice factories and collection centres. They also carry out visits to EU listed establishments at the time of export and sometimes to freezer vessels when they berth in Mexican ports.

Primary production

With regard to aquaculture farms involved in the production chain of fishery products for EU export the FVO team noted that:-

- SENASICA has a list of farms that were approved as being in compliance with the Aquaculture Good Practices Guide and the list is available to the CCA and to the interested stakeholders. A copy of the list was provided to the FVO team.
- The aquaculture farms were inspected by SENASICA federal level and state Committees following the procedures and using the forms, checklist and report templates mentioned in section 5.2. The defined frequencies were in general respected and the requirements checked were found equivalent to the EU ones.
- The collection of samples for the Residues Monitoring Programme made by staff of an authorised third party followed the procedure adequately, however, the sample collected is not tamper-proof, which is not in line with the requirements of Commission Decision 98/179/EC.
- The aquaculture farm visited by the FVO team can be considered as in line with EU requirements.

With regard to the fishing vessels (small and large) the FVO team noted that:-

- Small fishing vessels are not visited by SENASICA with a view to evaluate them regarding the requirements equivalent to the EU ones set for in Regulation (EC) No 853/2004.
- Inspections to large fishing vessels, when performed, are not documented. Moreover, the FVO team visited five large fishing vessels which had never been inspected by the CCA or its state representatives.
- The list of fishing vessels supplying EU listed establishments is kept by the CCA and sub-sets thereof are kept at the establishments (as lists of suppliers). The lists were made available to the FVO team and were found not to be up-to-date. The FVO team noted that fishing vessels not mentioned on the supplier's list had provided fishery products that were exported to the EU.
- The large fishing vessels visited by the FVO were considered as broadly in line with the applicable EU requirements.

Landing and first sale

The landing sites used in the production chain of fishery products for EU export can be adjacent to an establishment or independent.

With regard to landing sites the FVO team noted that:-

- The landing sites adjacent to the establishments are evaluated at the time of the establishment's visit.

- The ones visited by the FVO team were considered as broadly in line with the applicable EU requirements.
- The FVO team was not provided with any evidence of inspections carried out to independent landing sites or to the landing operations that take place there.

Facilities, including vessels, handling fishery products

With regard to the collection centres and ice factories the FVO team noted that inspection visits are infrequent and they do not cover all the identified facilities. The FVO team visited an ice factory that cannot be considered as meeting EU equivalent requirements (in particular with regard to surfaces in contact with ice and to dispatch operations).

The FVO team noted that, in general, freezer vessels (brine freezer – not more than -9°C) were approved by the CCA in accordance with the established procedures and frequencies. Of the four vessels visited by the FVO team only two have been inspected by COFEPRIS state representatives during 2012. All freezer vessels visited by the FVO team can be considered as largely in line with EU requirements. The FVO team also observed landing operations and concluded that those operations sometimes do not occur rapidly and that there was a delay before the fishery products are placed in a protected environment at the appropriate temperature.

Concerning the establishments visited the FVO team noted that:-

- Approval inspections are carried out by COFEPRIS federal level in accordance with the defined procedures and frequencies. For every approval inspection a form is filled in and evaluated. The form is signed by the team of inspectors and also by the operator. A copy of the form is left with the operator.
- A decision is issued after the evaluation and depends on the receipt of the analyses results (which can take up to two weeks). The FVO team observed that the issuance of a decision by the CCA can take from three weeks to three months. This has a direct impact on the correction of the deficiencies identified because the operator is required to provide the corrective action plan after having received the inspection decision. However, the FVO team saw in some cases that the operators had provided the CCA with corrective action plans before the issuance of the decision.
- The inspections carried out by COFEPRIS state representatives (surveillance inspections) are also made using a similar form but the set frequencies are not respected (none of the establishments visited by the FVO team were inspected within six months of approval as described in the procedures). In some cases the time lag between the approval and surveillance inspections was less than two months. Similar findings with regard to the issuance of the decisions were observed but the delay was shorter than that for the CCA.
- All establishments visited by the FVO team, except tw,o can be considered as broadly in line with EU requirements while presenting minor deficiencies with regard to hygiene practices (pouring and pooling of water), structures and equipment (rusted equipment, rusted surfaces, ceilings not cleaned and not easy to clean) and HACCP (incorrect hazard identification, poor risk analysis, critical limits not in line with EU requirements and the absence of an adequate logical process to decide on critical control point - decision tree). The establishments have in place own-checks analyses to verify if water/ice and fishery products comply with standards equivalent to the EU ones on microbiology and histamine.
- One of the establishments visited presented several deficiencies, concerning structures and equipment (e.g. absence of temperature recording device), unhygienic practices (water used for washing the products was not clean, poor cleaning of containers) and HACCP, that can represent a minor risk for the food safety of the products. Nevertheless, these deficiencies

can de easily and rapidly corrected.

- Another establishment (the one mentioned in point 5.3), that was not in operation at the time of the FVO visit, presented important deficiencies with regard to structures, general maintenance and temperature of the products. COFEPRIS presented at the closing meeting actions taken to prevent exports from this establishment.

Import controls of fishery products

The CCA informed the FVO team that no imports of raw material for processing and later export to the EU occur.

However, the FVO team noted that in one establishment imports of raw materials from another EU approved third country were received in 2008, processed and exported to the EU. At the time of the imports no attestation with regard to EU eligibility accompanied the consignment. This case had not been detected by the CAs. According to the food business operator this was a one-off occurrence.

Follow-up of RASFF notifications

The CCA has in place a procedure to deal with RASFF notifications. The CCA provided the FVO team with evidence of the investigations made on RASFF notifications, issued for EU imports from Mexico, which were found adequate. From their investigations Mexico concluded that the cases concerning the rupture of the cold chain occurred after the consignments had left Mexico and another two RASFF notifications were not related to Mexican exports (improper health certificate – product not produced in Mexico; and carbon monoxide – product of Mexican origin but further processed (filleted) in a EU member state).

Conclusions

Official controls of aquaculture farms provide adequate guarantees as regard EU rules. However, SENASICA cannot ensure the legal and analytical integrity of samples taken in the framework of the Residues Monitoring Programme, which undermines the reliability of the analytical results.

Official controls of fishing vessels are not carried out in accordance with the requirements set down in Regulation (EC) No 854/2004 and as such the CCA cannot provide guarantees that those fishing vessels comply with requisites at least equivalent to EU rules.

Official control over EU listed facilities is well implemented and follows the CCA procedures. However, shortcomings in their implementation, in particular with regard to the frequency of control and the follow-up of deficiencies noted during the inspections, do not allow the CAs to guarantee that those establishments comply fully with requirements at least equivalent to EU rules.

As regards official controls of ice factories, collection centres and landing sites (not EU listed), these present weaknesses that do not allow the CAs to provide guarantees that these facilities comply with requirements at least equivalent to the EU ones.

The procedures applied to imported raw material that could be processed prior to export to the EU do not ensure that such raw materials are EU eligible.

Recommendation No 1 and No 5 of the previous FVO report audit on the official controls over freezer vessels and water/ice have been satisfactorily addressed.

Recommendation No 6 of the previous FVO audit report on the maintenance of the temperature of fishery products has been partially addressed.

Recommendation No 2 of the previous FVO audit report on the official controls over fishing vessels has not been adequately addressed.

5.5 Official controls of fishery products

Legal requirements

Point II.1 of the model health certificate for imports of fishery products intended for human consumption established in Appendix IV to Annex VI to Regulation (EC) No 2074/2005, in particular official controls laid down in Annex III, Chapter II of Reg. (EC) No 854/2004.

Findings

The majority of official controls of fishery products are performed by the CCA and fishery products are sampled at the time of the approval inspections. In this regard the FVO team noted that:-

- Organoleptic checks are performed by both COFEPRIS levels. The CCA evaluates fishery products at the time of the inspection approval and the state level does the same during their official visits (inspections or export certifications).
- Testing for histamine is performed on fishery products using the Thin Layer Chromatography (TLC) method and on a sample made of nine sub-units. The tested batch is considered not to be EU compliant if any of the nine sub-units presents a result above 100 mg/kg of histamine.
- The CCA and its state representatives check consignments of fishery products at the time of export to ensure that no poisonous fishery products are exported to the EU.
- Parasite checks are performed on fishery products at the time of the official visits.
- Fishery products are tested for environmental contaminants (heavy metals) in laboratories authorised by the CCA. The FVO team noted one case of products that were exported with a level of lead above the EU limits (0,32 mg/kg – limit 0,30 mg/kg). No action in this regard was taken by the different CAs. It could not be excluded that those products were exported to the EU.
- Fishery products are not tested for other environmental contaminants, i.e. dioxins and PCBs (Polychlorinated Biphenyls).

Conclusions

Official controls over fishery products for EU export are performed adequately and they cover the majority of EU requirements. However, there are no official controls for dioxins or PCBs. Moreover, the reliability of the official results for histamine testing is compromised due to the fact that the method used is not the EU reference one or a method validated against it.

Recommendation No 4 of the previous FVO audit report on the monitoring of contaminants in fishery products has been partially addressed.

6 Official Certification

Legal requirements

Article 14 of Regulation (EC) No 854/2004.

Article 6 of Regulation (EC) No 2074/2005, in particular the model health certificate for imports of fishery products intended for human consumption established in its Appendix IV to Annex VI.

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

Findings

The CCA has in place a procedure for the issuance of export health certificates that include documentary evaluation of the consignment to be exported and also a physical and identity check. Export health certificates are only issued for EU listed establishments with a valid approval. The certificate is issued in TRACES (signed and stamped by official staff) and the information in Mexico is managed via a software system called SIIPRIS. The procedures as defined can be considered as largely in line with the applicable EU rules. However, the FVO team noted several failures in its implementation:-

- From the files reviewed in five establishments the FVO team noted in three of them that the information regarding traceability was not consistent between the catch certificate (issued in accordance to Regulation (EC) No 1005/2008) and the remaining documents (e.g. fishery products caught by one vessel attributed to a different one, fishery products from a large number of vessels declared as having originated from only a few of them).
- Some of the exported products came from non-EU eligible sources (Mexican fishing vessels or collection centres not on the list of authorised suppliers and not controlled by the CAs).
- Certification for EU exports of products produced with EU non-eligible raw material (e.g. raw material imported from another EU authorised third country without an attestation stating that EU requirements had been met).
- Box I.11 and I.28 of the export health certificates with the incorrect information (e.g. - freezer vessels indicated as dispatch location and cold store as production facility).
- Export of brine frozen tuna loins (initial freezing at no more than -9°C and destined to canning) without any mention of their use and stored at a temperature of -18°C. In this regard the operator showed to the FVO team a contract agreement from their EU client that the product was meant to be further processed into preserved food (an internet search made by the FVO team revealed that the client company produces salted and dried tuna).

Conclusions

In principle the system designed for export health certification can provide adequate guarantees with regard to EU compliance of the fishery products exported to the EU. However, the failures noted in the implementation of that system undermines the capacity of the CCA to fully ensure that all fishery products exported to the EU comply with EU equivalent requirements and were produced in accordance with EU equivalent rules.

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 National Reference Laboratory, CCAYAC, is accredited to ISO 17025 as a testing laboratory but does not participate in the testing of official samples.

CCAYAC is in charge of approving the laboratories that test official samples. This approval following in general the lines of ISO 17025, has a two year validity. However, CCAYAC is not an accreditation body. The laboratories performing official tests are obliged to provide CCAYAC with a regular summary of analyses results but without a set frequency for such reports. In two laboratories the FVO team noted six monthly summary reports.

The FVO team visited three approved laboratories and noted that two had also been accredited to ISO 17025 by the Mexican Accreditation Body (EMA). In one of the laboratories the limits of detection (LOD) and the limits of quantification (LOQ) of the methods used for heavy metals were updated recently (new validation studies) and were in line with EU requirements.

However, the analyses reports found in one establishment had different LOQ and LOD values that were not in line with EU requirements. In this establishment it was noted that there was a result for lead above the EU limits and that no action had been taken either by the laboratory who carried out the testing, or by the CAs or the food business operator.

All three laboratories were approved by CCAYAC and performed analyses on microbiology of water and ice, heavy metals and histamine. Although some of the laboratories had the capacity to perform histamine testing using the EU reference method, all official samples are tested through TLC method (the one that is mentioned in the NOM). All analytical results observed by the FVO team at the laboratories were in line with EU rules.

All methods used for testing official samples are based on NOM which do not correspond to any internationally recognised standard. CCAYAC informed the FVO team that they are currently working on the development of a NOM to perform histamine analysis using the HPLC (high performance liquid chromatography) method.

The laboratories visited had also been inspected by COFEPRIS COS within one year of their approval. This inspection is intended to verify that the approval conditions are still being met by the laboratories.

Conclusions

The laboratory capacity available to the CAs can, in principle, be considered adequate. However, the CAs cannot ensure the full reliability of the official analyses results mainly due to the analytical methods used, the performance criteria of some of those methods and the non-inclusion in the scope of the accreditation to ISO 17025 of the methods used by the laboratories.

8 Overall Conclusion

With the current organisation of Mexico's competent authorities and control systems in place it should be possible for the CCA to offer sufficient guarantees concerning the sanitary conditions of fishery products to be imported into the European Union, other than as regards primary production.

However, at present, the competent authority cannot fully ensure that all fishery products exported to the European Union respect the requirements defined in the “health certificate for imports of fishery products intended for human consumption” due to the deficiencies noted during the audit with regard to the implementation of the approval system for establishments, the follow-up of deficiencies, the export certification and official analyses and also due to the absence of official controls of primary production fishing vessels.

The overall follow-up of the previous FVO audit report made by the competent authority can be considered as mostly satisfactory. However, recommendation No 2 on official controls over fishing vessels is still to be addressed and recommendations No 4 and 6 were only partially addressed.

9 Closing meeting

During the closing meeting held in Mexico City on 30 November 2012, the FVO team presented the main findings and preliminary conclusions of the audit to all CAs.

During this meeting, all CAs present acknowledged the findings and preliminary conclusions presented by the FVO team and provided written commitments with set deadlines to correct the deficiencies. The CCA also presented written evidence of the actions taken with regard to the establishment that the FVO team considered as not in compliance with the EU requirements (export suspension).

10 Recommendations

The CAs should provide Commission services with an action plan, including a timetable for its completion, within one month of receipt of the report, in order to address the following recommendations for fishery products exported to the EU.

N°.	Recommendation
1.	The CAs should ensure that only establishments for which they can provide the guarantees set for in Article 12 point 2(a) of Regulation (EC) No 854/2004 are approved for EU exports and proposed to be EU listed. In addition, the CAs must ensure that all suppliers of raw materials to those EU listed establishments also comply with that same requirements.
2.	The CAs should ensure that official controls on the production of fishery products include regular checks on the hygiene conditions of landing as per Chapter I point 1 (a) of Annex III to Regulation (EC) No 854/2004.
3.	The CAs should ensure that official controls include inspections at regular intervals of vessels to verify whether the fishery products are handled correctly, the cleanliness of vessels and their equipment, staff hygiene and to check for compliance with the applicable hygiene and temperature requirements as per Chapter I point 1 (b) of Annex III to Regulation (EC) No 854/2004.
4.	Considering Chapter I point 1 (b) of Annex III to Regulation (EC) No 854/2004 the CAs should ensure that adequate follow-up of deficiencies takes place in order to provide guarantees that the establishments regularly inspected comply with requirements at least equivalent to EU ones with regard to approval, handling of fishery products, hygiene, temperature, staff hygiene and cleanliness of facilities.
5.	The CAs must ensure that only fishery products that comply with the requirements set for in part II.1 of the model of health certificate of Regulation (EC) No 2074/2005 are exported to the EU, in particular that any imported raw materials or products used to produce fishery products for EU exports are EU eligible.

N°.	Recommendation
6.	The CA should ensure that official samples taken in the framework of the Residues Monitoring Programme are sealed in accordance with the requirements of Commission Decision 98/179/EC in order to ensure their legal and analytical integrity.
7.	The CAs should ensure that only fishery products that comply with the health standards laid down in section VIII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down in Regulation (EC) No 2073/2005 and have satisfactorily undergone the official controls laid down in Annex III to Regulation (EC) No 854/2004 are exported to the EU, in particular with regard to the histamine and contaminants (heavy metals, dioxins and PCBs) (Regulations (EC) Nos 2073/2005 and 1881/2006 as regards their applicable limits).
8.	The CAs should ensure the reliability of the health certification of fishery products to be exported to the EU, taking into account the requirements of Directive 96/93/EC and Regulations (EC) Nos 854/2004 and 2074/2005, in particular, that the information provided in the certificates is accurate, when filling boxes I.11 and I.28 and that health certificates are only issued for products when all the public health attestations mentioned in part II.1 of the model of health certificate of Regulation (EC) No 2074/2005, in particular with regard to their origin, are fulfilled.
9.	The CAs must provide guarantees that whole fishery products frozen in brine at no more than -9ºC and intended for canning bear that indication when exported to the EU in order to ensure that those products are used with the purpose defined in Chapter I, Point II.7, of Section VIII, of Annex III to Regulation (EC) No 853/2004.
10.	The CAs should ensure that laboratories performing official control analyses use EU reference methods (or alternative methods validated to the EU reference ones), have performance criteria for the methods used in line with the EU rules, are assessed and that adequate quality controls are in place to provide for the reliability of test results (Codex Alimentarius, CAC/GL 26-1997).

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=2012-6550

Annex 1 - Legal References

Legal Reference	Official Journal	Title
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
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
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
Dec. 2006/766/EC	OJ L 320, 18.11.2006, p. 53-57	2006/766/EC: Commission Decision of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted
Reg. 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. 1005/2008	OJ L 286, 29.10.2008, p. 1-32	Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) No 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999
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
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

Legal Reference	Official Journal	Title
Reg. 252/2012	OJ L 84, 23.3.2012, p. 1-22	Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006