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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

PERU

FROM 25 SEPTEMBER 2017 TO 05 OCTOBER 2017

IN ORDER TO

EVALUATE THE CONTROL SYSTEMS IN PLACE GOVERNING THE PRODUCTION OF BIVALVE MOLLUSCS INTENDED FOR EXPORT TO THE EUROPEAN UNION

Executive Summary

This report describes the outcome of a DG Health and Food Safety audit in Peru carried out from 25 September to 5 October, as part of its programme of audits in non-EU countries.

The objectives of the audit were to evaluate the corrective measures that the competent authority committed to put in place to respond to the emergency measures introduced by Commission Decision 2008/866/EC, which suspended the imports into the EU of certain bivalve molluscs from Peru; to evaluate whether the official controls in place for bivalve molluscs destined for the EU could guarantee that their production conditions were in line with the requirements laid down in EU legislation; to verify the extent to which the guarantees and corrective actions submitted to the Commission services in response to the recommendations of previous Commission reports were implemented and enforced; and to assess the measures taken following the El Niño climate event which occurred in the first months of 2017.

The report concludes that there is positive progress in relation to the implementation of the recommendations made in the previous report, and a clear improvement in the approach taken by the competent authority towards official control of bivalve molluscs. In particular, the report shows that the entire production chain is now under effective official control, as highlighted by the approach taken by the official services to the El Niño event. These improvements are relatively recent and more time is needed to consolidate them and to assess the full impact of the changes made. The controls involving sampling are reliable. But this reliability could be undermined if Peru decides to reinstate the use of private laboratories for the official monitoring programme (although these belong to the competent authority's supporting entities network) without introducing effective official supervision on them.

Exports of bivalve molluscs from Peru, which are currently limited to eviscerated aquaculture scallops based on Commission Decision 2008/866/EC and the decision of the Peruvian competent authority, can be considered as providing sufficient guarantees to the requirements of the EU health certificate. Sanitary surveys and classification of production areas are not optimal. Owing to the different physiology of other species, and the type of processing that they would be subject to, a resumption of export for these would necessitate an additional evaluation.

The report contains recommendations to the Peruvian competent authority to address the shortcomings identified.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
BM	Bivalve molluscs (they could be live bivalve molluscs (live BM) and fishery products derived from them (BM)
DG Health and Food Safety or DG SANTE	Directorate General Health and Food Safety of the European Commission
EU	European Union
EURL	European Union Reference Laboratory for monitoring bacteriological and viral contamination of BM
EURL guidance document	The guidance document of the EURL
INACAL	Peruvian accreditation body
IOC	Intergovernmental Oceanographic Commission
MNP	Most probable number
SANTE list	The list of classified production areas and facilities approved and listed by the competent authority for participation in the EU bivalve molluscs export chain, available on the SANTE's website (at https://ec.europa.eu/food/safety/international_affairs/trade/non-eu-countries_en)

1 INTRODUCTION

The audit took place in Peru from 25 September to 5 October 2017 and was undertaken as part of the DG Health and Food Safety's planned audit programme. The audit team comprised two auditors from DG Health and Food Safety and two national experts from two Member States.

An opening meeting was held in Lima on 25 September with the National Fisheries Health Service (*Organismo Nacional de Salud Pesquera*-SANIPES) which is the competent authority within the scope of this audit. At this meeting the team confirmed the objectives of, and the itinerary for the audit, and requested additional information regarding the specific elements of the control system in place and further clarification for some of the documents and information that was sent prior to the audit. Representatives from the competent authority accompanied the audit team during the whole audit.

2 OBJECTIVES AND SCOPE

The objectives of the audit were:

- To evaluate the corrective measures that the Peruvian authority committed to put in place to respond to the emergency measures introduced by Commission Decision 2008/866/EC.
- To evaluate whether the official controls for BM destined to the EU can guarantee that their production conditions are in line with the requirements laid down in EU legislation and in particular with the health attestations contained in the certificate of Appendix IV to Annex VI to Regulation (EC) No 2074/2005.
- To verify the extent to which the guarantees and corrective actions submitted to the Commission services in response to the recommendations of previous Commission reports have been implemented and enforced.
- To assess the measures taken by the authorities following the *El Niño* climate event which occurred in the first months of 2017.

In terms of scope, the audit covered the production of BM intended to be exported to the EU, in particular eviscerated aquaculture scallops. The audit focussed on the official control system in place, including the organisation and performance of the competent authority, and on the export certification procedure. The whole EU export chain was evaluated, in particular, production areas, landing sites, establishments handling BM[1] and laboratories.

Accordingly, relevant aspects of the EU legislation referred to in Annex 1 were used as technical basis for the audit.

[1] According to the information provided by the CA, stand-alone cold stores do not participate in the export of eviscerated aquaculture scallops in Peru.

In pursuit of these objectives, the following sites were visited:

COMPETENT AUTHORITY		
Central level	2	Opening and closing meetings
Regional level	2	Decentralised offices in Chimbote and Sechura
LABORATORY VISITS		
Bacteriology (for *E. Coli* and *Salmonella*)	4	The two official laboratories existing at the time of the audit (in Callao and Sechura) and two private laboratories from the laboratory supporting network (one of them temporarily suspended by the authority)
Virology (for hepatitis A virus)	3	The official laboratory existing at the time of the audit and two private laboratories from the laboratory supporting network (one of them temporarily self-withdrawn from the network)
Phytoplankton	3	The two official laboratories existing at the time of the audit (one of them not yet operational) and one private laboratory from the laboratory supporting network.
Biotoxins	4	The official laboratory existing at the time of the audit for the three biotoxin groups and three private laboratories from the laboratory supporting network (one of them temporarily self-withdrawn from the network): two of them for the three biotoxins and the other for amnesic shellfish poison and lipophilic toxin group.
CLASSIFIED PRODUCTION AREAS AND LANDING SITES		
Production areas	1	To observe sample collection of sea water for testing phytoplankton and of live BM for testing biotoxins
Landing site	1	Where live BM of the production area visited are landed
FACILITIES HANDLING BM		
Processing establishments	5	Three primary processing establishments and two processing establishments. Only one in operation at the time of the visit (but processing a different type of fishery product) the rest not in operation

3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation and, in particular, under 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 rules.

Full legal references are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the last amended version.

4 BACKGROUND

4.1 GENERAL BACKGROUND

At the time of the audit, Peru was listed in Annex I to Commission Decision 2006/766/EC as a country from which Member States could import live, chilled, frozen or processed BM, echinoderms, tunicates and marine gastropods for human consumption. However, Decision 2008/866/EC (latest amended by Decision (EU) 2015/2022) limited imports to eviscerated scallops of aquaculture origin and heat treated BM following an outbreak of hepatitis A related to the consumption of BM imported from Peru in a EU Member State.

A previous Commission audit took place in 2011 (ref. DG(SANCO)2011-8890) which had highlighted deficiencies in relation to the classification and monitoring of live BM production areas, and the report –published on the DG Health and Food Safety's Internet site at http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=2759 made a number of recommendations. Written guarantees were received from the Peruvian authorities in relation to the implementation of those recommendations. After a desk review of these written guarantees, all the recommendations were considered to be satisfactorily addressed.

4.2 PRODUCTION AND TRADE INFORMATION

According to the data provided by the competent authority in the answer to the pre-audit questionnaire, 98-99% of the BM exported from Peru to the EU in the last three years was eviscerated aquaculture scallops (*Argopecten purpuratus*). The rest (1-2%, depending on the year) was canned razor clams (*Ensis macha* and *Tangelus dombeii*). Export volumes were around 8,500 tonnes in 2014; 5,000 tonnes in 2015 and 3,500 tonnes in 2016 (export volumes decreased to due to an overall reduction in production). The importing Member States by decreased order (slightly varying between years) were: France, Belgium, Spain, the Netherlands, Germany, Italy, United Kingdom and Denmark.

According to the lists drawn up by SANIPES and available on the SANTE's website (at http://ec.europa.eu/food/food/biosafety/establishments/third_country/index_en.htm) (hereafter SANTE list) at the time of the audit there were ten classified production areas approved and listed by the authorities for participation in the EU BM export chain; and, 23 of the establishments approved and listed to export fishery products were processing and exporting BM.

4.3 *EL NIÑO* EVENT

In the first months of 2017, the *El Niño* event severely affected the production of scallops in Peru. *El Niño* is the warm phase of the "El Niño Southern Oscillation" and is associated with a band of warm ocean water that develops in the central and east-central equatorial Pacific, including off the Pacific coast of South America. "El Niño Southern Oscillation" refers to the cycle of warm and cold temperatures, as measured by sea surface temperature of the tropical central and eastern Pacific Ocean, and cause global changes of both temperatures and rainfall.

In the case of Peru, it produced high mortality of the resources (up to 85% in certain areas) and floods and discharges that affected the areas where scallops were produced.

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITY

Legal requirements

Article 46.1 of Regulation (EC) No 882/2004 stipulates that EU controls in non-EU countries shall verify compliance or equivalence of non-EU countries systems with EU food law. These controls shall have particular regard to points (b) to (e), (g) and (h) of the aforementioned Article.

Observations

1. SANIPES is the authority responsible for the control system of the entire BM production chain, including the export to the EU. In addition to the headquarters, it has thirteen decentralised branches in the country (only those with BM production are involved in the BM control programme).

2. A new team in charge for the official control system of BM (both at central level and in the decentralised branches) was recently appointed. This new team is reinforced by new hierarchy, also recently appointed.

3. SANIPES informed that as part of the measures to improve the system, it has decided to focus its resources and to limit the export of bivalve molluscs to eviscerated aquaculture scallops. In doing so, Peru will not -for the time being- export heat treated razor clams (which were until recently around 1-2% of the total volume of BM exported) or *Donax spp* (which were the origin of the export restrictions due to contamination with hepatitis A virus).

4. The authority stated that all scallops exported to the EU are produced in classified production areas, and that Peru does not import scallops from other countries for further export to the EU.

Findings

5. The audit team observed major positive changes in the official control system of BM since the last audit, most of which were implemented in the months preceding the audit. These changes are described in different parts of this report.

6. Since October 2016, the official monitoring programme of classified production areas is entirely carried out by the competent authority and its official laboratories (before, it was substantially implemented by stakeholders). Currently, samples are collected by official staff and are analysed in the competent authority's laboratories. The number of official inspectors increased from 50 to 110 in the last six months, and the authority has its own laboratories for the parameters included in the official monitoring programme. As

required in Article 46.1(d) of Regulation (EC) No 882/2004, there are adequate resources, including diagnostic facilities, available to the authorities. For testing lipophilic toxins, at the time of the audit there was only one machine to perform liquid chromatography-mass spectrometry/mass spectrometry in use; in case of breakdown or maintenance, it would not be sufficient to ensure ongoing monitoring. A backup equipment has been already sourced and official samples are sent to one of the supporting network laboratories until this new equipment is operational.

7. The reports of recent official inspections of establishments, showed a tangible improvement in the detection of non-compliances and in the enforcement of requirements, in line with Article 46.1(d) of Regulation (EC) No 882/2004.

Conclusions on competent authority

8. The authority in charge of BM has the necessary staff and equipment to carry out effective controls on BM that are exported to the EU. The fact that the official monitoring control programme has been completely transferred from stakeholders to the competent authority and its official laboratories has been extremely beneficial to bring the entire system under effective official control.

5.2 OFFICIAL CONTROLS ON BIVALVE MOLLUSCS

Legal requirements

Articles 12 and 13 of Regulation (EC) No 854/2004 and Part I.8 and 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 when referring to Regulations (EC) Nos 852/2004, 853/2004, 854/2004 and 2073/2005.

5.2.1 Classification of production areas

Observations

9. According to the SANTE list, at the time of the audit there were a total of ten classified production areas, all of them for scallops. The competent authority does not allow scallops harvested outside classified production areas to be exported to the EU market.

10. At the time of the audit, all production areas were classified as "A" based on the level of faecal contamination results. The authority confirmed that there are no relaying or conditioning areas in Peru.

Findings

11. The competent authority has fixed the location and boundaries of classified production areas, as required in Annex II, Chapter II, point A.1. to Regulation (EC) No 854/2004, and there are maps available for all of them.

12. There are sanitary surveys for all scallop production areas, also for those that were recently withdrawn from the SANTE list, as required in Annex II, Chapter II, point A.6. to Regulation (EC) No 854/2004. In certain cases these sanitary surveys group several areas that are located in the same zone or bay.

13. The competent authority has already re-evaluated a number of sanitary surveys. The periodicity of review or re-evaluation of sanitary surveys was not standardised, contrary to the guidance document from the European Union Reference Laboratory (EURL) for monitoring bacteriological and viral contamination of BM[2] (hereafter the EURL guidance document), which recommends an annual review to ensure that the environmental conditions have not changed and that the classifications are still valid, and a complete re-evaluation of pollution sources and the sampling plan every six years. In the cases verified by the audit team, re-evaluation was triggered by unusual *E. coli* results from the monitoring programme.

14. Sanitary survey reports contained the main elements recommended in the EURL guidance document. Potential sources of microbiological contamination were not comprehensively reflected in the reports and no investigative bacteriological surveys were evident in the reports the audit team examined.

15. Sampling points used to monitor microbiological contamination in classified production areas were fixed before sanitary surveys took place. The location of sampling points was not a defined outcome of the initial sanitary survey or re-evaluation. Sanitary surveys have been effectively used to verify the locations of existing points and support the status quo, with the result that the location of these points has not been modified following the outcome of the surveys. Thus, the geographical distribution of the sampling points used in the monitoring programme may not necessarily be representative of production areas contrary to the requirement of Annex II, Chapter II, point A.6(d) to Regulation (EC) No 854/2004. Following an initiative of the new team in the authorities, and in part due to the possible effects of floods and discharges in scallop production areas following *El Niño*, new sampling points are being monitored providing results similar to the already fixed sampling points.

16. Historically, stakeholders financed sanitary surveys. Recently, the competent authority started funding them instead of stakeholders, thus eliminating potential conflicts of interest.

17. Classification is awarded for ten years, based on the evaluation of the data from the previous twelve months. After that, the classification is reviewed annually. For the end of the year review the authority evaluates the dataset obtained during the year. This system for classification of production areas cannot be considered as equivalent to the best practice recommended by the EURL guidelines.

[2] Microbiological monitoring of BM harvesting areas, Guide to Good Practice: Technical Application Issue 6, January 2017.

18. Although this is not formalised in any official text, the authorities allowed, for "A" production areas, up to 25% of results to be between 230 most probable number (MPN) *E. coli* per 100g and 940 MPN *E. coli* per 100g. This is not in line with the requirement in Annex II, Chapter II, point A.3. of Regulation (EC) No 854/2004. In addition, review of data is not rolling which allows for potential between year exceedances. The audit team evaluated 3-year datasets with fortnightly monitoring frequency from all the production areas currently listed for export to the EU (with the exception of anomalous data following the impact of *El Niño*), and in all cases the classification awarded by the competent authority was in line with EU requirements for class "A" classification.

5.2.2 Monitoring of classified production areas

Observations

19. The monitoring programme sets the frequency of sampling. Water is sampled weekly to determine the potential toxin-producing plankton species as well as the total phytoplankton counts. Live BM are sampled weekly to determine the presence of biotoxins (lipophilic toxin group, amnesic shellfish poison and paralytic shellfish poison), fortnightly to determine their microbiological quality (*E. coli*, *Salmonella* and hepatitis A virus) and twice per year to determine the presence of heavy metals (lead, cadmium and mercury). Other contaminants (polycyclic aromatic hydrocarbons, dioxins and dioxin-like PCBs) may be tested but not as part of the monitoring programme.

20. The competent authority has defined the location of the sampling points of classified production areas with names and coordinates. Points' positions are included in the monitoring programme and are indicated in maps.

Findings

21. Following *El Niño*, the authority withdrew eight production areas (seven for scallops and one for razor clams) from the SANTE list. The reason for this was the impossibility to monitor these areas, either because there were no BM available for sampling or for logistical reasons (e.g. blocked roads). This measure is considered to be in line with Annex II, Chapter II, point B.1. to Regulation (EC) No 854/2004.

22. The competent authority monitor classified production areas according to its monitoring programme, which is in general line with Annex II, Chapter II, point B.1. to Regulation (EC) No 854/2004 as regards the parameters to be checked. As contamination with hepatitis A virus was at the origin of the export restrictions in 2008, it is worth to highlight that classified production areas are monitored fortnightly for presence of hepatitis A virus.

23. Sampling frequencies for microbiological contamination systematically observe the recommendation on the EURL guidance document, and for toxin-producing plankton are adequate to meet the aim of Annex II, Chapter II, point B.4. to Regulation (EC) No 854/2004. Sampling frequencies for biotoxins are in line with Annex II, Chapter II, point B.5. to Regulation (EC) No 854/2004.

24. The authorities had sample collection and transport protocols and used them[3]. Criteria for sample collection, sampling method, number of individuals and sample transport are appropriate and are consistent with the EURL guidance document, the ISO standards[4], and, in the case of phytoplankton, water samples that can be considered as representative of the water column, as required in Annex II, Chapter II, point B.7. to Regulation (EC) No 854/2004. The sampling procedure followed was adequate (e.g. the sample submission form contains all relevant information; samples are placed in clearly labelled bags and are accompanied by the sampling form). For phytoplankton, the protocol allows 36 hours for the sample to be delivered at the laboratory which it is quite a long time taking into account the fragility of the phytoplankton. For microbiological testing samples, submission instructions and training were under preparation. The audit team checked the temperature at reception of some samples at laboratories and it was within acceptance criteria (0 - 10°C).

25. Sampling points are defined in the monitoring programme and are exactly the same for microbiological quality, phytoplankton and biotoxins. Their selection has not been scientifically justified to demonstrate that their location is representative of the area being monitored as required in Annex II, Chapter II, point B.2. to Regulation (EC) No 854/2004.

26. In particular for toxin-producing plankton, monitoring results are not adequate to suggest an accumulation of toxins in mollusc flesh and therefore trigger an intensive live BM sampling as intended in Annex II, Chapter II, point B.4(a) to Regulation (EC) No 854/2004, because sampling points are located in the middle of production areas instead of outside, and the production areas observed had hydrodynamic, bathymetry characteristic that should be considered; and results for phytoplankton testing can take up to 36 hours according to the monitoring programme (another 36 hours are allowed for the transport of samples to the laboratory, see paragraph 24).

27. Following an initiative of the new team in the authority, and in part due to the possible effects of floods and discharges in scallop production areas following *El Niño*, they have started to monitor additional sampling points for phytoplankton and results will be compared.

5.2.3 Decisions after monitoring

Observations

28. After monitoring, the competent authority takes decisions using a formalised contingency plan. Where the results of sampling show that any of the monitored

[3] A new protocol was issued at the end of the audit. A copy was provided to the audit team, however it was not evaluated as it was not the protocol in force when the corresponding visit took place.

[4] E.g. ISO 6887-3:2017-02, Microbiology of the food chain — Preparation of test samples, initial suspension and decimal dilutions for microbiological examination —Part 3:Specific rules for the preparation of fish and fishery products.

parameters are exceeded, the authority closes the corresponding classified production area. To re-open closed areas, the authority waits until having two consecutive results within the concerned parameter limit with samples collected no less than 48 hours apart.

Findings

29. The official procedure to close classified production areas in case of exceedance of health standards limits is in line with Annex II, Chapter II, point C.1 to Regulation (EC) No 854/2004. Anomalous results for *E. coli* trigger investigative sampling and pollution event investigations as recommended in the EURL guidance document.

30. The authorities only issue harvest pre-authorisations and live BM registration documents when areas are open in order to prevent the unauthorised harvesting of live BM, which is in line with Annex II, Chapter II, point C.1 to Regulation (EC) No 854/2004.

31. Reopening criteria are adequate for closures due to presence of biotoxins, as foreseen in Annex II, Chapter II, point C.2 to Regulation (EC) No 854/2004. However, these criteria are not appropriate when closures due to microbiological contamination, as they do not take account the potential different behaviour of faecal indicator bacteria (*E. coli*) and hepatitis A virus in BM. Notwithstanding the above considerations, on the basis of the monitoring data for *E. coli, Salmonella* and hepatitis A virus, production areas for scallops for export to the EU are not characteristically impacted by significant amounts of microbiological contamination.

32. BM harvested between the date of sampling and the date of the laboratory result are handled according to the official contingency plan, i.e.

    - for biotoxins, if the sample exceeds the limit, the BM are destroyed, which the audit team considered adequate;

    - for microbiological contamination, BM are detained and re-tested. After the re-test, BM are released if results are below the limit, destroyed if results exceed the limit for *Salmonella* or hepatitis A or sent for heat treatment if results exceed the limit for *E. coli*. These measures are not representative of the microbiological status of the live BM of origin: results from *E. coli, Salmonella* and hepatitis A virus testing of eviscerated frozen final product are not directly related to harvesting area contamination, the main location of microbiological contamination (i.e. the hepatopancreas) has been excised and freezing further reduces bacteriological viability and culturability. Therefore, whilst testing may reveal contamination acquired through the production chain, the results of microbiological tests on finished product are considered to be of limited value.

5.2.4 Additional monitoring requirements

Findings

33. The competent authority informed that classified production areas from which the harvesting of BM has been forbidden are monitored as required in Annex II, Chapter II, point D.1 to Regulation (EC) No 854/2004.

34. The competent authority requires operators to test all consignment of products that are to be exported to the EU for *E. coli*, *Salmonella*, hepatitis A virus, biotoxins and heavy metals in laboratories belonging to the official supporting network (see paragraph 52), but it does not directly carry out laboratory tests to verify food business operators' compliance with the requirements for the end product (which is requested in Annex II, Chapter II, point D.2 to Regulation (EC) No 854/2004). Each consignment, which can include scallops produced on different dates (e.g. the audit team saw one which comprised more than five months of production), is sampled by staff from the laboratory supporting network. The competent authority designs the sampling plan on *ad-hoc* basis for each consignment. The laboratory staff take a subsample from each batch arriving from each classified production area per day (see paragraphs 36 and 37), to finally form the five samples that have to be analysed. This method of sampling impacts the representativeness of the sample result as any potential exceeding parameter in a daily lot would be diluted in the final sample. Therefore, this system does not provide the same guarantees required in Annex II, Chapter II, point D.2 to Regulation (EC) No 854/2004 for the verification of marine biotoxins, contaminants and microbiological quality of molluscs.

5.2.5 Recording and exchange of information

Findings

35. The authority's website has a list of approved production areas with details of their location and boundaries, as well as their classification. Information on the closure and re-opening of production areas is immediately sent to interested parties in the format of a rapid report by smart phone applications or by e-mail. A more detailed report is sent later to interested parties and is also published on the official website. This system of recording and exchange of information is in line with the requirements of Annex II, Chapter II, point E to Regulation (EC) No 854/2004.

5.2.6 Movement of live bivalve molluscs and registration document accompanying batches

Findings

36. According to the procedures, harvesters should request a pre-authorisation the day before harvesting. This document will describe the species, volume, production area, landing sited, etc. Officials are always present at the time of landing for checking the adequacy of the batch to the information contained in the harvest pre-authorisation and

to issue a registration document (*Documento de Extracción de Recurso*), that contains the information required in Annex III, Section VII, Chapter I, point 4 to Regulation (EC) No 853/2004. Prior to issuing the registration document, officials must check that production areas are open, based on the rapid report described in paragraph 35. The audit team, following a case where a registration document was issued for an open production area while the rapid report stated the area was closed, noted that the format of this report was recently improved to include more accurate information, in particular the factual dates when areas are closed.

37. The audit team noted that registration documents accompany batches whenever there is a movement on BM from landing site to establishments or between establishments, as required in Annex III, Section VII, Chapter I to Regulation (EC) No 853/2004.

5.2.7 Official control of establishments and facilities handling BM

Observations

38. The system of official control of approved establishments is developed by the corresponding Unit at central level, and it includes:

- Three to four unannounced inspections, that can include checks on traceability, water, etc.
- An annual audit, that is used for the full assessment of establishments (authorisations to operate have to be annually updated). The procedures include the use of official checklists for general requirements, HACCP and traceability during audits, and to issue a report. The follow-up of all previous shortcomings, which require resolution, is also carried out.

Findings

39. Only one of the establishments visited during the audit was in operation- and it was not processing scallops as there has been little harvesting due to the recent impact of *El Niño*.

40. There are a number of establishments that do not export directly to the EU but are involved in the processing of the exported products. They shuck and wash the scallops and the product is later sent to establishments for freezing. These establishments are subject to official controls, but currently they are not included on the SANTE list. Ten days before the start of this audit, the competent authority issued a communication requesting all these establishments to be listed before end of November this year.

41. The competent authority indicated that there are traders involved in the production chain of scallops. They do not handle the scallops, and have no premises, and thus the competent authority has very little information about them, and they have not been so far under official control. Ten days before the start of the audit, the competent authority issued a communication requesting all traders to register themselves before end of November this year. None of the establishments visited during the audit has used traders for buying or selling scallops.

Conclusions on official controls on BM

42. Sanitary surveys are not totally suitable for establishing the monitoring for microbiological contamination due to the fix location of sampling points. However, the fact that results of the additional sampling points provide similar results give further assurances on their validity.

43. The transference of the funding of sanitary surveys from stakeholders to the authority has eliminated the potential conflicts of interest providing additional confidence in the official control system.

44. The current classification of all production areas is consistent with the new EU class A classification requirements (applicable since 1 January 2017) notwithstanding the shortcomings in the system for classification.

45. The current monitoring programme covers most of the requirements of EU legislation but the fact that sampling points for phytoplankton and biotoxins may not be representative of the area monitored could undermine its value.

46. The criteria for reopening classified production areas which showed microbiological contamination and the actions taken for products under suspicion are not considered entirely appropriate. However, production areas for scallops for export to the EU are not characteristically impacted by significant amounts of microbiological contamination and there is a low risk of this shortcoming having a negative public health impact.

47. The sampling method for verification of food business operators' compliance with the requirements for the end product impacts the representativeness and the consequent results may therefore be of limited value.

48. Information made available by competent authority and prompt exchange of updated information to its decentralised branches and stakeholders helps the system to avoid mistakes due to delays.

49. Official controls over the movement of scallops for export to the EU can in principle guarantee their traceability.

50. Currently there are establishments involved in the export chain of scallops to the EU which are not listed (primary processing establishments) or registered (traders), which weaken the eligibility assurances of the scallops exported to the EU.

5.3 LABORATORIES

Legal requirements

Article 46.1(d) of Regulation (EC) No 882/2004; Chapter 1 of Annex I to Regulation (EC) No 2073/2005 and Article 3 and Annex III to Regulation (EC) No 2074/2005.

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.

Observations

51. At the time of the audit, testing of scallop production areas within the monitoring programme (for *E. Coli*, *Salmonella*, hepatitis A virus, phytoplankton, biotoxins and heavy metals) was exclusively carried out by competent authority's official laboratories.

52. Until October 2016, testing was carried out by the private laboratories, accredited by the Peruvian national accreditation body (INACAL), and annually audited by the authorities. The competent authority has available on its website the list of private laboratories belonging to this official supporting network.

53. The competent authority informed the audit team of its plan to give back to private laboratories of the official supporting network certain percentage of the samples of the monitoring programme in the near future.

Findings

54. The audit team visited all the competent authority's laboratories, and found them to be of high standard.

55. The audit team visited the majority of the private laboratories of the supporting network (including some that were temporarily delisted at own-initiative or temporarily suspended by the authorities). These private laboratories are accredited by INACAL, and are annually audited by the competent authority. Some of them presented a number of significant shortcomings, which indicates a lack of effective supervision on them. Currently, official supervision does not ensure the reliability of their results.

56. In the last months, there has been a considerable number of additions and deletions of private laboratories or individual methods to the network, which makes it difficult to have an overall reliable picture of the situation. For example, one of the private laboratories, authorised to test for *E. Coli*, *Salmonella*, hepatitis A virus, phytoplankton and the three biotoxins, requested its withdrawal from the network at the beginning of the audit for a period of two months.

57. In the case of testing for biotoxins, the competent authority tolerates that analyses contracted to private laboratories are subcontracted to other laboratories of the network if they do not have the required method in place.

5.3.1 Laboratories for microbiology

5.3.1.1 Bacteriology

Findings

58. Facilities and equipment are fit for purpose in all laboratories and staff knowledgeable and demonstrably technically competent. There is good confidence that the methods as described are applied appropriately and the quality of test results is high. There is no formal communication between laboratories mediated by the competent authority and the network of laboratories.

59. EU reference methods for enumeration of *E. coli* and detection of *Salmonella*, with minor inconstancies with current published ISO standards, are in use and are accredited by INACAL. Methods are in general well controlled in the laboratories and are consistent with EU requirements of Annex I, Chapter 1 to Regulation (EC) No 2073/2005. However, the frequency of proficiency testing, which is determined by INACAL, is considered as low bearing in mind the volume of testing undertaken and importance of decisions made on the basis of test results.

60. Standard operating procedures or desk instructions are not used across all the laboratories. This is not prescribed in ISO 17025 for methods where multiple ISOs are required for their application (such as *E. coli* determination), but it is considered good practice.

5.3.1.2 Virology

Findings

61. Facilities and equipment for molecular detection of hepatitis A virus are modern, fit for purpose and demonstrated significant investment in all laboratories. Staff are extremely knowledgeable and demonstrably technically competent.

62. ISO/TS 15216-2: Corrected version 2013-05-01 was cited as the reference method in all laboratories visited. This method is considered appropriate for qualitative detection of hepatitis A virus in BM and food surfaces. The ISO technical specification was supplemented with detailed desk instructions. The method is well controlled at each stage and is accredited by INACAL in all laboratories. Verification of practical limit of detection in specific matrix under test had been determined at each laboratory and results of proficiency testing are satisfactory, although the latter is undertaken at low frequency (once every 2 years, as required by INACAL). Despite the infrequency of positive results witnessed, there is good confidence that the quality of test results is high.

63. The method for food surfaces, with minor modifications, was applied to end product (i.e. eviscerated frozen scallops). As hepatitis A virus is known to concentrate in the hepatopancreas of BM, and it is removed through evisceration, the application of this method for food surfaces to end product may reveal surface contamination acquired

through the process chain but it is of limited value given the expected location of hepatitis A virus in BM.

5.3.2 Laboratories for toxin-producing plankton

Findings

64. All the laboratories have an internal quality system in place, and standard procedures and other laboratory documents are in use.

65. Laboratories carry out the determination of the potential toxin-producing plankton species as well as the total phytoplankton counts, with the internationally used Utermöhl method based on the norm EN 15204 for the quantitative analyses. Results of proficiency testing are satisfactory.

5.3.3 Laboratories for biotoxins

Findings

66. All the laboratories have an internal quality system in place, and standard operation procedures and other laboratory documents are in use.

67. All of them use EU reference methods[5] and they are accredited by INACAL.

68. Regarding competent authority's laboratories, analytical methods are validated and laboratories have participated in proficiency tests with satisfactory results. In particular for lipophilic toxins, the quantification of certain compounds is adequately done by using homologs (as certain reference materials are not commercially available).

69. Regarding private laboratories, although with the certain shortcomings, the paralytic shellfish poison and amnesic shellfish poison analyses are in principle adequate. For the analysis of lipophilic toxins (which has traditionally been the biotoxins most frequently found in the Peruvian waters), the method is in different implementing phases in different laboratories. Laboratories have either not participated or have participated with unsatisfactory results in proficiency tests for lipophilic toxins and reference materials (not only the ones not commercially available) for this toxin group are not always available in laboratories.

[5] For paralytic shellfish poison: mouse bioassay based on the AOAC official method 959.08, Edition 2007; for amnesic shellfish poison: high-performance liquid chromatography with ultraviolet detection method (Intergovernmental Oceanographic Commission (IOC) of UNESCO Manuals and Guides nº 33, chapter 7, Wrigth and Quilliam); and for lipophilic toxin group: by liquid chromatography-mass spectrometry/mass spectrometry).

Conclusions on laboratories

70. The performance of the laboratories currently carrying out testing of the entire official monitoring programme (*i.e.* competent authority's laboratories) allows the authorities to provide the required guarantees regarding the reliability of the testing results.

71. The lack of participation, low participation or non-satisfactory results in proficiency testing in private laboratories may raise doubts as regards the reliability of the results.

72. Although EU analytical reference methods to determine lipophilic toxins are used in private laboratories, the lack of reference materials and quantification of certain compounds could result in this biotoxin group to be underestimated.

5.4 OFFICIAL CERTIFICATION

Legal requirements

Article 14 and Annex VI to Regulation (EC) No 854/2004; Article 6 and Appendix IV to Annex VI to Regulation (EC) No 2074/2005; and, Article 6 of Directive 96/93/EC.

Observations

73. The EU Trade Control and Expert System (TRACES) is used for official certification in Peru.

74. A general special tool for trade management (*Ventanilla única de comercio exterior*-VUCE) is in place in Peru. It works as an integrated system that allows parties involved in trade and international transportation to manage, through electronic means, the procedures required by the various authorities, in accordance with current regulations or requested by these parties for goods' transit, entering or leaving the territory.

Findings

75. According to the official procedures, food business operators are responsible to include on-line all the relevant information of the consignment to be exported. This information is verified on-the-spot by staff from the official laboratory supporting network, when the sample described in paragraph 34 is taken (laboratories are ISO/IEC 17020: 2012 accredited for "Conformity assessment - Requirements for the operation of various types of bodies performing inspection"). Sampling process is sometimes verified by the competent authority, but this is not formalised. This procedure is in line with Article 3.4(a) of Council Directive 96/93/EC. The corresponding competent authority's Unit at the central level headquarters performs the evaluation of information and issues the health certificate.

Conclusions on official certification

76. The system in place for official certification of scallops provides enough guarantees to the requirements of the EU health certificate.

5.5 FOLLOW-UP OF PREVIOUS RECOMMENDATIONS

The table below summarises the follow-up to the recommendations made in report DG(SANCO)2011-8890:

No.	Recommendation	Findings
1	The competent authority should ensure that only production areas that are regularly monitored in line with Chapter II of Annex II to Regulation (EC) No 854/2004 are EU-listed.	Addressed. See findings 19 and 21-24.
2	The competent authority should adequately implement their Communication No 055-2011- SANIPES/ITP to ensure that samples are collected in all the designated production areas' sampling points in order to be able to either classify the area or to maintain the determined classification as established in points A and B of Chapter II of Annex II to Regulation (EC) No 854/2004.	Addressed. See findings 20 and 25.
3	The competent authority should adequately implement their Communication No 055-2011- SANIPES/ITP to ensure that samples are collected in all the designated sampling points for the regular monitoring for microbiology, toxin-producing phytoplankton and biotoxins even if harvesting is not taking place as established in points A and B of Chapter II of Annex II to Regulation (EC) No 854/2004.	Addressed. See finding 22.
4	The competent authority should ensure that bivalve molluscs intended for export into the EU comply with the health standards for live bivalve molluscs (considering the requirements of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 and Annex I to Commission Regulation (EC) No 2073/2005).	Addressed. See findings 20-34.
5	The competent authority should ensure that shortcomings identified in establishments visited are corrected, in order to ensure that all EU-listed establishments are in line with requirements set out in Regulations (EC) No 852/2004 and (EC) No 853/2004.	In principle, addressed. See findings 38-40.
6	The competent authority should ensure that deficiencies identified during the audit in the laboratories visited are corrected in order to guarantee the reliability of the results of the analysis performed.	Not addressed. See findings 51-69.

6 OVERALL CONCLUSIONS

There is positive progress in relation to the implementation of the recommendations made in the previous report, and a clear improvement in the approach taken by the competent authority towards official control of bivalve molluscs. In particular, the report shows that the

entire production chain is now under effective official control, as highlighted by the approach taken by the official services to the *El Niño* event. These improvements are relatively recent and more time is needed to consolidate them and to assess the full impact of the changes made. The controls involving sampling are reliable. But this reliability could be undermined if Peru decides to reinstate the use of private laboratories for the official monitoring programme (although these belong to the competent authority's supporting entities network) without introducing effective official supervision on them.

Exports of bivalve molluscs from Peru, which are currently limited to eviscerated aquaculture scallops based on Commission Decision 2008/866/EC and the decision of the Peruvian competent authority, can be considered as providing sufficient guarantees to the requirements of the EU health certificate. Sanitary surveys and classification of production areas are not optimal. Owing to the different physiology of other species, and the type of processing that they would be subject to, a resumption of export for these would necessitate an additional evaluation.

7 CLOSING MEETING

During the closing meeting held in Lima on 5 October 2017, the audit team presented the main findings and preliminary conclusions of the audit to the competent authority. During this meeting, the competent authority acknowledged these findings and preliminary conclusions presented by the audit team, and provided a commitment to resolve the points raised.

The competent authority remarked that, although its idea is to enhance the presence of competent authority's laboratories in all areas where BM are produced, and to carry out all monitoring with them, a laboratory supporting network is needed. The competent authority acknowledged that laboratories should then comply with the relevant requirements and added that the main problem is related to training of staff.

8 RECOMMENDATIONS

The Peruvian competent authority is invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within 25 working days of receipt of this audit report.

No.	Recommendation
1.	The competent authority should ensure that sanitary surveys comply with requirements at least equivalent to those required in Chapter II A.6 of Annex II to Regulation (EC) No 854/2004 and to those recommended by the EURL guidelines, in order to provide all guarantees required by the health certificate for EU imports of fishery products defined in Appendix IV of Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 42. Associated findings Nos 12-15.
2.	The competent authority should ensure that the classification of production areas complies with requirements at least equivalent to those required in Chapter II. A of Annex II to Regulation (EC) No 854/2004, in order to provide all guarantees required by the health certificate for imports of fishery products defined in Appendix IV of Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 44. Associated findings Nos 17 and 18.
3.	The competent authority should ensure that geographical distribution of the sampling points in production areas complies with requirements at least equivalent to those required in Point B.2 of Chapter II of Annex II to Regulation (EC) No 854/2004, in order to provide all guarantees required by the health certificate for imports of fishery products defined in Appendix IV of Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 45. Associated findings Nos 25 and 26.
4.	The competent authority should ensure that the reopening of production areas that are closed in line with Point C of Chapter II of Annex II to Regulation (EC) No 854/2004 due to microbiological contamination, is appropriate to providing all guarantees required by the health certificate for imports of fishery products defined in Appendix IV of Annex VI to Regulation (EC) No 2074/2005.

No.	Recommendation
	Recommendation based on conclusion No 46. Associated finding No 31.
5.	The competent authority should ensure that verification of food business operators' compliance with the requirements for the end product complies with requirements at least equivalent to those required in Point D.2 of Chapter II of Annex II to Regulation (EC) No 854/2004, in order to provide all guarantees required by the health certificate for imports of fishery products defined in Appendix IV of Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 47. Associated finding No 34.
6.	The competent authority should ensure that the SANTE list includes all those relevant establishments that participate in the export chain as required in Article 12 of Regulation (EC) No 854/2004, and that all food business operators are under official control in order to provide all guarantees required by the health certificate for imports of fishery products defined in Appendix IV of Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 50. Associated findings Nos 40 and 41.
7.	The competent authority should ensure that, if private laboratories are involved in official controls of BM, these laboratories must be under effective official supervision in order to ensure the reliability of analytical results. Recommendation based on conclusion No 70. Associated findings Nos 55-57.
8.	The competent authority should ensure that laboratories involved in official controls of BM can demonstrate their performance for specific tests in order to ensure the reliability of analytical results. Recommendation based on conclusion No 71. Associated findings Nos 59, 62 and 69.
9.	The competent authority should ensure that laboratories involved in the official monitoring for biotoxins carry out analyses of all compounds included in the biotoxins groups mentioned in Annex III, Section VII, Chapter V point 2 to Regulation (EC) No 853/2004, in order to provide all guarantees required

No.	Recommendation
	by the health certificate for EU imports of fishery products defined in Appendix IV of Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 72. Associated finding No 69.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2017-6156

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
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
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
Dir. 98/83/EC	OJ L 330, 5.12.1998, p. 32-54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
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. 2008/866/EC	OJ L 307, 18.11.2008, p. 9-10	2008/866/EC: Commission Decision of 12 November 2008 on emergency measures suspending imports from Peru of certain bivalve molluscs intended for human consumption