EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2019-6617

FINAL REPORT OF AN AUDIT

CARRIED OUT IN

MAURITANIA

FROM 23 SEPTEMBER 2019 TO 27 SEPTEMBER 2019

IN ORDER TO

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

Executive summary

This report describes the outcome of a Directorate-General Health and Food Safety audit in Mauritania carried out from 23 to 26 September 2019, as part of its programme of audits in third countries.

Currently Mauritania is not authorised to export bivalve molluscs in any form for human consumption to the EU. This audit follows a request from the Mauritanian competent authorities to export live oysters to the EU and to therefore be included on the list of countries authorised to export bivalve molluscs to the EU (Annex I to Commission Decision No 2006/766/EC).

The objectives of the audit were to verify the compliance or equivalence of Mauritanian legislation and the official control system with EU legislation and to verify that the competent authority is in a position to reliably certify the statements included in the model of health certificate of Appendix V to Annex VI to Commission Regulation (EC) No 2074/2005, for imports into the EU of live bivalve molluscs intended for human consumption.

The report concludes that although most of the EU requirements have been directly incorporated into national legislation for the production and placing on the market of live bivalve molluscs, there are some of them that have not been implemented (even for national production). For those that are implemented, there are serious deficiencies, in particular regarding the classification and monitoring of production areas, which are the basis for an appropriate official control of live bivalve molluscs. There are also serious concerns about the reliability of laboratory results for some of the parameters monitored.

The official control system of live bivalve molluscs in Mauritania cannot be considered to give similar guarantees to the one required in the EU, and the Mauritanian competent authority is not in a position to reliably certify the health attestations of the certificate needed to export live bivalve molluscs intended for human consumption to the EU.

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

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ASP	Amnesic shellfish poison
DG	Directorate-General
EU	European Union
EURL	EU reference laboratory
LC-MS/MS	Liquid chromatography-mass spectrometry/ mass spectrometry
MPN	Most probable number
ONISPA	National Office for Sanitary Inspection of Fishery and Aquaculture Products-*Office National d'Inspection Sanitaire des Produits de la pêche et de l'Aquaculture*
PSP	Paralytic shellfish poison
TUNAC	Tunisian National Accreditation Council

1 INTRODUCTION

The audit took place in the Islamic Republic of Mauritania from 23 to 26 September 2019 and was undertaken as part of the Directorate-General (DG) Health and Food Safety's planned audit programme following a request from the Mauritanian Ministry for Fish and Maritime Economy to export live oysters. The audit team comprised one auditor from DG Health and Food Safety and two experts from two European Union (EU) Member States.

An opening meeting was held in Nouadhibou on 23 September with the National Office for Sanitary Inspection of Fishery and Aquaculture Products (*Office National d'Inspection Sanitaire des Produits de la pêche et de l'Aquaculture*-ONISPA) which is the technical competent authority within the scope of this audit, in charge of the organisation and implementation of control and inspections of fishery products and live bivalve molluscs. At this meeting the audit 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 ONISPA accompanied the audit team during the whole audit.

2 OBJECTIVES AND SCOPE

The objectives of the audit were[1]:

- To verify the compliance or equivalence of Mauritanian legislation and official control system with EU legislation.
- To verify that the competent authority is in a position to reliably certify the statements included in the model of health certificate of Appendix V to Annex VI to Commission Regulation (EC) No 2074/2005, for the imports into the EU of live bivalve molluscs intended for human consumption.

In terms of scope the audit focused on the organisation and performance of the competent authority, the official control system in place covering production and distribution chains applicable to live bivalve molluscs to be exported to the EU and, to the extent possible, the export certification procedure.

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

[1] Article 11 of Regulation (EC) No 178/2002 requires compliance or equivalence for imported products.

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

Competent Authority		
ONISPA	3	Opening and closing meeting, and an interim meeting at the end of the second day
Laboratory visits		
E. coli quantification	1	This laboratory carries out analyses of live bivalve molluscs in the framework of official monitoring of classified production areas for *E. coli.* It also carries out analyses of the final product in the framework of food business operators' own-checks
Salmonella detection		This laboratory only analyses *Salmonella* in the final product in the framework of food business operators' own-checks
Phytoplankton	1	
Biotoxins	3	For paralytic shellfish poison (PSP), amnesic shellfish poison (ASP) and the lipophilic toxin group
Heavy metals	2	For cadmium and lead in Nouadhibou. Although the laboratory analysing mercury was not visited as it is in Nouakchott, documents related to official controls were also provided by the competent authority and assessed by the audit expert
Classified production areas		
Production areas	1	The same production areas were visited twice, first during the high tide to observe sample collection of sea water for testing for phytoplankton/toxin-producing plankton and a second time during the low tide to observe sample collection of oysters for testing for *E. coli* and biotoxins
Facilities handling bivalve molluscs		
Dispatch centre	1	Not in operation at the time of the visit

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

Mauritania is not authorised to export bivalve molluscs in any form for human consumption to the EU as it not currently listed in Annex I to Commission Decision 2006/766/EC, list of

third countries and territories from which imports of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods.

The current audit follows a request from the Mauritanian Ministry for Fish and Maritime Economy to export live oysters from one (or two) production area(s), with an estimated volume of 30 to 300 tonnes per year. The competent authority has banned the harvesting in the other three production areas in the same region due to the high levels of heavy metals.

Although a DG SANTE audit on this topic took place in 2011 (ref. DG(SANCO)/2011-6203[2]), the audit team could not assess the system in its totality, as the authorities had only recently started to monitor the production areas. The report concluded that the official control system was not satisfactory and that there were significant deficiencies that compromised the reliability of the analyses carried out.

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITY

Legal requirements

Article 46(1)(b) to (e), (g) and (h) of Regulation (EC) No 882/2004

Findings

1. The structure and organisation of the competent authority remains as described in the last audit report. The Ministry for Fish and Maritime Economy is the central authority for live bivalve molluscs but it does not participate in official controls. The ONISPA is the technical competent authority within the scope of this audit, in charge of the organisation and implementation of control and inspections of live bivalve molluscs.

2. Within the ONISPA, the Department for Sanitary Inspection, with two Services (North and South), is in charge of inspections; and the Department of Chemistry - Microbiology and monitoring of aquatic environment is in charge of laboratory activities, including the execution of sanitary surveys.

3. The inspection system has been accredited to ISO/CEI 17020 by the Tunisian National Accreditation Council (TUNAC), who carries out annual surveillance audits.

Conclusions on competent authority

4. The competent authority designated for the official control of live bivalve molluscs has a structure and an organisation that would allow for an adequate official control along the full production chain for EU exports.

[2] Available at http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=2659

5.2 LEGISLATION

Legal requirements

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

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

Findings

5. The national legislation includes practically all EU requirements, but some of them are not implemented, even for oysters placed on the local market or sent to neighbouring countries. The audit team was not able to evaluate how these requirements can be officially controlled.

Conclusions on legislation

6. Although practically all EU requirements are in national legislation, the competent authority would need to include the ones still absent and would need to implement all of them in order to be in a position to certify the public heath attestations of the health export certificate.

5.3 NATIONAL PROVISIONS AND PROCEDURES FOR LISTING LIVE BIVALVE MOLLUSCS PRODUCTION AREAS AND ESTABLISHMENTS INTENDED TO EXPORT TO THE EU

Legal requirements

Article 12(1), (2) and (3) and Article 13 of Regulation (EC) No 854/2004; part I.8. I.11. and I.28. of part A of the model health certificate for imports of live bivalve molluscs intended for human consumption established in Appendix V to Annex VI to Regulation (EC) No 2074/2005.

Findings

7. The competent authority's intention is to use the already existing procedure for listing fishery product establishments for listing live bivalve molluscs production areas and establishments. That procedure could provide the guarantees required by Articles 12 and 13 of Regulation (EC) No 854/2004 if all requirements of EU legislation were met.

Conclusions on national provisions and procedures for listing live bivalve molluscs production areas and establishments intended to export to the EU

8. If implemented as planned, the procedure for listing live bivalve molluscs production areas and establishments would, in principle, allow the authorities to draw up of lists of approved production areas and dispatch centres and to provide the EU with the necessary guarantees in this regard.

5.4 OFFICIAL CONTROLS OF LIVE BIVALVE MOLLUSCS

Legal requirements

Articles 12 and 13 of Regulation (EC) No 854/2004.

Parts I.8 and II.1 of the model health certificate for imports of live bivalve molluscs intended for human consumption established in Appendix V to Annex VI to Regulation (EC) No 2074/2005, in particular when referring to Regulations (EC) Nos 178/2002, 852/2004, 853/2004, 854/2004 all of the European Parliament and of the Council and to Commission Regulation (EC) No 2073/2005.

Findings

5.4.1 Classification of production areas

9. As required in Chapter II, point A.1 of Annex II to Regulation (EC) No 854/2004, the competent authority established years ago the location and boundaries of the two classified production areas from where they intend to export and fixed them in national legislation. However, a document produced by the Mauritanian Oceanographic and Fisheries Research Institute, dated 2011-2012 and provided by the competent authority after the audit, proposes a delimitation for one of the production areas which is different from the boundaries established in national legislation. This raises certain uncertainty on the appropriateness of the boundaries selected by the competent authority.

10. The national legislation also includes the classification of each production area. The authorities established the classification of the two production areas from where Mauritania intends to export following a study made in 2008-2010. This study does not contain any of the elements required in Chapter II, point A.6.(a) to (c) of Annex II to Regulation (EC) No 854/2004, to note:

    a) an inventory of the sources of pollution of human or animal origin likely to be a source of contamination for the production area, such as the ones that the document mentioned in paragraph 9 points out (camel herds, wild birds, wastewater from vessels),

    b) an examination of the quantities of organic pollutants that which are released during the different periods of the year, according to the seasonal variations of both human and animal populations in the catchment area, rainfall readings, waste-water treatment, etc.,

    c) a determination of the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area.

11. For the classification of production areas, the study used sampling points which were determined beforehand and not based on the examination of the data mentioned in the previous paragraph, contrary to what is required in Chapter II, point A.6.(d) of Annex II to Regulation (EC) No 854/2004. Samples were taken by food business operators without supervision from the competent authority and without an agreed protocol. The

laboratory tested the samples using a different method than the one prescribed in EU legislation (*i.e.* EN/ISO 16649-3), and using faecal coliforms instead of *E. coli*. Those methods cannot be considered equivalent, making the results non reliable.

12. The two classified production areas from where the competent authority intends to export were classified as "A" in 2011. The competent authority has never reviewed this classification or has reclassified the production areas, contrary to Chapter II, point A.2 of Annex II to Regulation (EC) No 854/2004[3].

13. One of the two production areas remains as class "A" although the weekly results during four weeks in 2017 indicated higher contamination than the existing limit for class "A" (results were >16 000 most probable number (MPN) *E. coli* per 100g while the limit for class "A" was 230). The competent authority carried out an investigative bacteriological survey to determine the possible origin of this microbiological contamination episode but the result was inconclusive. Within this survey, the competent authority took samples from the two production areas and from the vicinity of one of them, and all of them had the same results (>16 000) during the same period of time. The competent authority did not request the official laboratory to carry out further dilution of the samples in order to know the exact value of contamination. This would have allowed them to determine if contamination levels exceeded the limit of 46 000 *E. coli* per 100g established in Chapter II, point A.5 of Annex II to Regulation (EC) No 854/2004 and the production areas should therefore have been prohibited.

14. The other production area also remains as class "A" although the competent authority has not monitored it for more than two years.

5.4.2 Monitoring of classified production areas

The competent authority has a monitoring programme that sets the following frequency of sampling: water is sampled monthly to determine the potential toxin-producing plankton species, and live bivalve molluscs are sampled fortnightly to determine the presence of biotoxins (PSP; ASP and the lipophilic toxin group), monthly to determine their microbiological quality (*i.e. E. coli*) and four times per year to determine the presence of heavy metals (lead, cadmium and mercury) and other contaminants (polycyclic aromatic hydrocarbons, dioxins and dioxin-like PCBs).

Authorised competent authority staff perform the sampling of water and live bivalve molluscs.

[3] Which establishes that the competent authority must define a review period for sampling data from each production area in order to determine compliance with the standards for each classification (in this case "A").

The audit team noted the following:

15. The competent authority has designated the location of the sampling points of classified production areas with codes, but there is no evidence that the sampling points for toxin-producing plankton, biotoxins and microbiological contamination are representative of the production areas, which make the results questionable.

    - In the production area visited, the location of the single sampling point designated for the monitoring of toxin-producing plankton and biotoxins could be representative of the entire area due to the characteristics of the bay, which allows a complete renewal of water almost on daily basis. However, if this is the case, an adequate frequency for these two parameters (toxin-producing plankton and biotoxins) would be of the utmost importance (see paragraphs 16 and 17).
    - According to the competent authority, for microbiological contamination, the results are valid for a radius of 100m from the sampling point, and the production of oysters beyond this 100m would immediately generate a new sampling point in order to confirm the health status of the production area. The existence of this practice raises doubts about the representativeness of the sampling point selected for each production area.

16. The monthly sampling frequencies for toxin-producing plankton do not meet the aim of Annex II, Chapter II, point B.4. to Regulation (EC) No 854/2004. In addition, the alert levels (decided at national level) that would trigger an intensive sampling of live bivalve molluscs to determine the presence of biotoxins is too high for a number of toxic species (*e.g.* for Dinophysis is 500 000 cells per litre) and different toxicity of different species within the same genus has not been considered. This makes this monitoring of very little value as an early warning for the increase of biotoxins levels.

17. The fortnightly sampling frequencies for biotoxins do not meet the requirements of Annex II, Chapter II, point B.5. to Regulation (EC) No 854/2004. The authorities have reduced the weekly sampling prescribed in EU legislation based exclusively on the previous years' results, instead of following a risk assessment that suggests a very low risk of toxic episodes, as required in Annex II, Chapter II, point B.5. to Regulation (EC) No 854/2004. This, together with the already mentioned limited value of the monitoring for toxin-producing plankton, poses a risk that the competent authority misses biotoxin episodes that can appear and disappear between two consecutive samplings.

18. Monthly sampling frequencies for microbiological contamination are adequate, as they observe the recommendation of the guidance document of the European Union Reference Laboratory (EURL) for monitoring bacteriological and viral contamination of bivalve molluscs[4].

[4] The guidance document of the EU Reference Laboratory for monitoring bacteriological and viral contamination of bivalve molluscs ("Good Practice Guide; issue 7", December 2018).

5.4.3 Decisions after monitoring

19. There were no results above the limits during the monitoring of production areas for biotoxins and toxin-producing plankton. Therefore, the audit team could not evaluate the decision-making process and the implementation of actions in those cases.

20. The competent authority does not close or reclassify production areas when they exceed the maximum microbiological limit required for class "A" production areas, which is not in line with Chapter II, point C.1 of Annex II to Regulation (EC) No 854/2004. According to the data provided by the competent authority, such a case only occurred in 2017 (one episode lasting four weeks, see paragraph 13). At that time, the authority prohibited the harvesting of oysters in the relevant production area. The production area was re-opened following two results for *E.coli* of <230 MPN per 100g separated by one week, regardless of the inconclusive results of the investigative bacteriological survey carried out to determine the possible origin of this microbiological contamination.

5.4.4 Additional monitoring requirements

21. The national legislation includes the requirements laid down in Chapter II, point D.2 of Annex II to Regulation (EC) No 854/2004 regarding laboratory tests to verify food business operators' compliance with the requirements for the end product to verify the levels of biotoxins and contaminants and the microbiological quality of the molluscs. However, they are not completely updated (*i.e*. microbiological criteria). Currently, the authorities do not implement these requirements.

5.4.5 Recording and exchange of information

22. When analysis results exceed any of the biotoxin EU regulatory limits or the microbiological quality parameters required for class "A" production areas, the corresponding laboratory section sends immediate information to all interested parties and the competent authority takes immediate action to prohibit the harvesting of live bivalve molluscs in the relevant production area. Reporting of exceedance of toxin-producing plankton with the nationally established levels is not in a written procedure, but the audit team noted that it takes place by phone. Interested parties are also informed without delay when harvesting can resume. In general, this is as at least equivalent to Chapter II, point E.(b) and (c) of Annex II to Regulation (EC) No 854/2004.

5.4.6 Food business operators' own-checks

23. The audit team has not seen evidence that the competent authorities use food business operators' own-checks to decide on the classification, opening or closing of production areas, as allowed in Chapter II, point F of Annex II to Regulation (EC) No 854/2004.

5.4.7 Movement of live bivalve molluscs and registration document accompanying batches

24. National legislation includes the requirements of Section VII, Chapter I.3 of Annex III to Regulation (EC) No 853/2004. These requirements are currently not implemented.

5.4.8 Official control of establishments handling bivalve molluscs

25. At the time of the audit there was just one dispatch centre that intended to export to the EU. In principle, the competent authority did not intend to approve any purification centre.

26. The competent authority decided to inspect this establishment once per year; however, this was not implemented.

27. The competent authority has a checklist for inspections, but it did not mention certain requirements (*e.g.* registration document for the movement of live bivalve molluscs, requirements for packing and labelling) although they are included in national legislation. The competent authority did not provide evidence that those requirements were under official control.

28. The inspectors produce reports and hand them over to food business operators. The reports did not require food business operators to correct non-compliances.

Conclusions on official controls on live bivalve molluscs

29. Although the competent authority has established the location and boundaries of classified production areas, the appropriateness of their demarcation is undermined by the fact that a different delimitation has been proposed for one of the areas concerned in a study made by another Mauritanian authority.

30. The sanitary survey used for the classification of production areas is not fit for purpose, as it did not include all required elements and it used a testing method which does not provide equivalent results to the EU reference method.

31. The classification of production areas cannot be considered as equivalent to the requirements of EU legislation, and the competent authority is therefore not in a position to certify the public heath attestations of the health export certificate.This is due to the use of sampling points which might not be representative and to the fact that the authority has not reviewed the classification of production areas since 2011, nor reclassified them following abnormally high results for class "A" production areas with inconclusive investigations.

32. The competent authority is not in a position to certify certain public heath attestations of the health export certificate as the monitoring of production areas is not adequate and the geographical distribution of the sampling points (for microbiological quality, toxin-producing plankton and biotoxins) and the sampling frequencies for biotoxins cannot ensure that analyses results are as representative as possible of the area under consideration.

33. The low frequency of sampling for the presence of toxin-producing plankton together with the inadequate distribution of sampling points, makes the monitoring inadequate as

an early warning system for the appearance of biotoxins.

34. The decisions taken following the monitoring results in classified production areas does not provide sufficient guarantees for the competent authority to certify the public heath attestations of the health export certificate.

35. The additional monitoring requirements incorporated into national legislations would allow the competent authority to certify the public heath attestations of the health export certificate, but currently they are neither fully updated nor implemented.

36. The system for recording and exchange of information would, in principle, allow the competent authority to certify the public heath attestations of the health export certificate.

37. The requirement for the control of movement of live bivalve molluscs and a registration document accompanying batches would allow the competent authority to certify the public heath attestations of the health export certificate, but as they are not fully implemented and under official control, they currently do not.

38. The current absence of adequate official control of establishments does not allow the competent authority to certify the public heath attestations of the health export certificate.

5.5 LABORATORIES

Legal requirements

Article 46(1)(d) of Regulation (EC) No 882/2004 in association with Article 11 of Regulation (EC) No 178/2002

Chapter II of Annex I to Regulation (EC) No 854/2004

Chapter 1 of Annex I to Regulation (EC) No 2073/2005

Article 3 and Annex III to Regulation (EC) No 2074/2005

Regulations (EC) Nos 1881/2006 and 333/2007; and Regulation (EU) No 2017/644

Points 41 and 42 of Guidelines of Codex Alimentarius competent authority C/GL 26-1997 on the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.

Findings

5.5.1 Laboratory for microbiology

39. The laboratory has adequate facilities and equipment metrologically verified, and its staff is trained and competent in their corresponding fields of expertise.

40. This laboratory tests official samples taken at production areas for *E.coli* and food business operators' samples taken at establishments for *E.coli* and *Salmonella*.

41. The laboratory has a procedure for sample handling, transport and reception. According to this procedure, the temperature criteria of 10ºC for sample acceptance at arrival can be exceeded since the time for transport from production areas to the laboratory is always less than four hours.

42. The laboratory has been accredited according to EN/ISO/IEC 17025 by TUNAC since 2013. The scope of accreditation includes the detection of *Salmonella* according to the EU reference method ISO 6579-1 and the enumeration of *E. coli* using a non-EU reference method (ISO 16649-2). At the time of the audit, the enumeration of *E. coli* was carried out using the EU reference method ISO 16649-3, which was not in the scope of accreditation.

43. The audit team noted the following, that affect the validity and/or reliability of results:

    - the laboratory lacked the precision criteria, required by ISO 16649-3 (2015) as internal quality control for *E. coli* quantification by MPN,
    - the laboratory did not control the production and performance of culture media according to ISO 11133 (2014). The laboratory did not use strains from international reference culture collection. The competent authority informed the audit team that the laboratory had recently bought Word Data Centre for Microorganisms- strains (in September 2019), but at the time of the audit they were not yet used. The performance assessment of diluent and solid culture media was done in each laboratory batch; however the performance assessment of liquid media used for *E. coli* was done occasionally,
    - the dehydrated liquid culture media was out of date. It was also highly hydrated (in block instead of in powder) which makes it impossible to weight it precisely The liquid culture media used for *E. coli* quantification presented pH value deviations much higher than those accepted by the manufacturer or established in ISO 16649-3 (2015). This could negatively influence the recovery and growth of *E. coli* strains, especially those from marine origin,
    - the laboratory did not present some of the results for *E. coli* according to ISO 7217 (2007), Amend1 (2013).

44. The laboratory participates twice a year in proficiency tests organized by the French Veterinary Public Health Association for the methods accredited (*i.e. Salmonella spp*. using ISO 6579-1 and *E. coli* using ISO 16649-2). The laboratory has not participated in any internationally organised proficiency tests for the method ISO 16649-3. In 2018, the laboratory participated in the inter-laboratory quality essay for this method organised by ONISPA.

5.5.2 Laboratory for toxin-producing plankton

45. The laboratory has adequate facilities and equipment and it has trained staff. They have adequate bibliography available.

46. The laboratory uses an international method based on the norm EN 15204[5] for the counting and identification of phytoplankton species.

47. Laboratory analysis requests require that results are given on genus, which does not take into account the different toxicity of certain species of the same genus (e.g. *Dinophysis acuta*, *acuminata* and *caudate*). The audit team noted that, although not included the laboratory procedures, staff were providing results on species.

48. Relevant species are not required to be identified (*e.g. Alexadrium minutum*).

5.5.3 Laboratory for biotoxins

Regarding the laboratory for PSP

49. The laboratory analyses PSP according to an EU recognised method established in Annex III to Regulation (EC) No 2074/2005 (*i.e*. mouse bioassay based on the AOAC official method 959.08, Edition 2007).

50. The audit team noted the following, that affect the validity and/or reliability of results:

- the laboratory rears its own mice for testing. The animals originate from a single batch of mice that was bought in Morocco in 2005. The use of these animals can create analytical interferences due to the high level of consanguinity,
- the method has not been internally validated (to check certain operational parameters). The only internal quality check that the laboratory carries out is the periodical check of the conversion factor (which expresses the weight of saxitoxin that is equivalent to one mouse unit),
- the laboratory does not perform positive controls, which is not in line with its own internal procedure. The competent authority explained that there is no natural contaminated material and the use of reference material using this type of method would be extremely costly,
- the method is not accredited.

51. This laboratory has not participated in internationally organised proficiency testing in order to demonstrate its performance.

Regarding the laboratory for ASP

52. The laboratory analyses ASP according to the EU reference method established in Annex III to Regulation (EC) No 2074/2005 (high-performance liquid chromatography

[5] EN 15204: Water quality - Guidance standard on the enumeration of phytoplankton using inverted microscopy (Utermöhl technique).

with ultraviolet detection method). This method has been internally validated and it is also accredited.

53. Every year since 2017 the laboratory has participated in proficiency tests for ASP organised by Quasimeme (three samples each year). Two out of the nine results were non-conforming, but the competent authority presented the corresponding assessment and the corrective actions they have taken.

Regarding the laboratory for the lipophilic toxin group

54. The laboratory is in the process to have the EU reference method for the analyses of the lipophilic toxin group established in Annex III to Regulation (EC) No 2074/2005 (liquid chromatography-mass spectrometry/ mass spectrometry-LC-MS/MS) ready. The method used is a laboratory internal version of the methods of the EURL for marine biotoxins and of the French Agency for Food, Environmental and Occupational Health and Safety. The method has not been internally validated.

55. The LC-MS/MS equipment is adequate. The staff have received training in official laboratories in EU Member States. The equipment has been experiencing technical difficulties since June this year and the competent authority is struggling to get it repaired. In parallel to the LC-MS/MS, the laboratory is analysing the lipophilic toxin group by mouse bioassay, which is not longer an EU-recognised method.

56. The method is not accredited.

57. Some reference materials (not only the ones not commercially available) for this toxin group are not available.

58. This laboratory has recently participated in an international proficiency testing organised by Quasimeme. Some of the compounds were not evaluated and there were non-conforming results with high deviations for a number of the evaluated ones. Staff attributed these results to the fact that the method is still not fully ready.

5.5.4 Laboratories for heavy metals

59. Lead, cadmium and mercury are analysed with methods which comply with the performance criteria of Commission Regulation (EC) No 333/2007.

60. The three methods are validated with adequate validation parameters, and uncertainties have been calculated. The three methods are also accredited.

61. This laboratory has participated in the last few years in proficiency tests organised by Quasimeme with an adequate frequency and with satisfactory results.

Conclusions on laboratories

62. Laboratories for microbiology, toxin-producing plankton, biotoxins and heavy metals are in general fit for purpose.

63. Although the testing is in general done with EU-recognised or reference methods, the fact that laboratories for microbiology and biotoxins use methods that are not subject to adequate internal quality controls or that are not internally validated and/or accredited reduces the reliability of those particular tests results.

64. The fact that laboratories for microbiology and biotoxins do not participate in proficiency testing for all methods and that they do not use the specific matrix in proficiency testing reduces the reliability of those particular tests results.

65. Although the EU analytical reference method to determine lipophilic toxins is used in the laboratory, the fact that the method is still in the process of being ready and the equipment is facing technical problems reduces the reliability of results. In addition, the lack of reference materials and quantification of certain compounds could result in this biotoxin group being underestimated.

5.6 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

Council Directive 96/93/EC

Findings

66. The competent authority indicated that for export of live bivalve molluscs to the EU they will use the same procedure as for fishery products (including the use of the Commission's Trade Control and Expert System). This certification procedure is, in principle, in line with the rules of certification of Directive 96/93/EC.

Conclusions on official certification

67. Although the certification procedure in place follows sound principles, the shortcomings detected during this audit in almost all the stages of the oyster production chain, impede the competent authority to have all necessary information to sign the public health attestations included in the certificate for exporting live bivalve molluscs to the EU.

6 OVERALL CONCLUSIONS

Although most of the EU requirements have been directly incorporated into national legislation for production of bivalve molluscs, there some of them that have not been implemented (even for national production). For those that are implemented, there are serious deficiencies in the way they are implemented, in particular regarding the classification and monitoring of production areas, which are the basis for any official control of bivalve molluscs. There are also serious concerns about the reliability of laboratory results for some of the parameters monitored.

Therefore, the official control system of live bivalve molluscs in Mauritania cannot be considered as at least equivalent to the EU one, and the Mauritanian competent authority is not in a position to reliably certify the health attestations of the model set out in Part A, Appendix V to Annex VI to Regulation (EC) No 2074/2005 for imports of live bivalve molluscs intended for human consumption.

7 CLOSING MEETING

During the closing meeting held in Nouadhibou on 26 September 2019, the audit team presented the main findings and preliminary conclusions of the audit to the competent authority. The competent authority made a few comments and informed the audit team that further documentation was going to be sent.

8 RECOMMENDATIONS

The competent authorities are invited to provide, within one month of receipt of the report, details of the actions taken and planned, including deadlines for their completion ("action plan"), aimed at addressing the recommendations set out below.

No.	Recommendation
1.	The competent authority should fix the boundaries of classified production areas in accordance with rules at least equivalent to point A.1 of Chapter II of Annex II to Regulation (EC) No 854/2004 in order to provide all the guarantees required by the health certificate for imports of live bivalve molluscs set out in the model of Part A, Appendix V to Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 29. Associated finding No 9.
2.	The competent authority should establish rules at least equivalent to point A.2 of Chapter II of Annex II to Regulation (EC) No 854/2004 (*i.e.* to define a review period for sampling data from each production area in order to determine compliance with the standards for production areas "A", "B" and "C") in order to provide all the guarantees required by the health certificate for imports of live bivalve molluscs set out in the model of Part A, Appendix V to Annex VI to Regulation (EC) No

No.	Recommendation
	2074/2005. Recommendation based on conclusion Nos 31. Associated findings No 12.
3.	The competent authority should maintain the classification of class "A" production areas using standards at least equivalent to the EU rules, in particular those related to the health standards and microbiological criteria defined in point A.3 of Chapter II of Annex II to Regulation (EC) No 854/2004, in order to provide all the guarantees required by the health certificate for imports of live bivalve molluscs set out in the model of Part A, Appendix V to Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 31. Associated findings Nos 13 and 14.
4.	When classifying production areas, the competent authority should ensure that data at least equivalent to those required in points A.6(a) to (c) of Chapter II of Annex II to Regulation (EC) No 854/2004 are available and that a sampling programme at least equivalent to point A.6(d) of the same reference is established ensuring a correct classification, in order to provide all the guarantees required by the health certificate for imports of live bivalve molluscs set out in the model of Part A, Appendix V to Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 30. Associated findings Nos 10 and 11.
5.	The competent authority should ensure that the geographical distribution of the sampling points 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 live bivalve molluscs defined in Appendix V of Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 32. Associated finding No 15.
6.	The competent authority should ensure that the sampling frequency for monitoring of biotoxins complies with requirements at least equivalent to those required in points B.2 and B.5 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 live bivalve molluscs defined in Appendix V of Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 32. Associated finding No 17.

No.	Recommendation
7.	The competent authority should ensure that the monitoring for plankton in production areas is carried out in line with points B.2, B.4 and B.7 of Chapter II of Annex II to Regulation (EC) No 854/2004, and provide reliable results that can be used to manage biotoxins risks, in order to provide all guarantees required by the health certificate for imports of live bivalve molluscs defined in Appendix V of Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 33. Associated findings Nos 16, 47 and 48.
8.	The competent authority should define adequately and implement the decisions after monitoring, in particular as regards the EU requirements of point C.1 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 live bivalve molluscs defined in Appendix V of Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 34. Associated finding No 20.
9.	The competent authority should update and implement the national legislation that requires a control system to be established, comprising laboratory tests to verify food business operators compliance with end product requirements using standards at least equivalent to the EU rules, in particular those defined 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 live bivalve molluscs defined in Appendix V of Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 35 Associated finding No 21.
10.	The competent authority should implement an official control system for the production and placing on the market of live bivalve molluscs that ensures compliance of food business operators with standards at least equivalent to those of Annex II to Regulation (EC) No 852/2004 and Section VII of Annex III to Regulation (EC) No 853/2004, in order to provide all guarantees required by the health certificate for imports of live bivalve molluscs defined in Appendix V of Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusions Nos 37 and 38. Associated findings Nos 24, 26, 27 and 28.
11.	The competent authority should ensure that official laboratories produce reliable analytical results.

No.	Recommendation
	Recommendation based on conclusion No 63. Associated findings Nos 42, 43, 50, 54, 55 and 56.
12.	The competent authority should ensure that laboratories involved in official controls of bivalve molluscs can demonstrate their performance for matrix specific tests or similar ones in order to ensure the reliability of analytical results. Recommendation based on conclusion No 64. Associated findings Nos 44, 51 and 58.
13.	The competent authority should ensure that official laboratories for biotoxins carry out analyses of all compounds included in the biotoxins groups mentioned in point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004, in order to provide all guarantees required by the health certificate for imports of live bivalve molluscs defined in Appendix V of Annex VI to Regulation (EC) No 2074/2005. Recommendation based on conclusion No 65. Associated finding No 57.

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=2019-6617

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dec. 2006/766/EC	OJ L 320, 18.11.2006, p. 53-57	2006/766/EC: Commission Decision of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted
Dir. 96/93/EC	OJ L 13, 16.1.1997, p. 28-30	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
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 - Article 46 (TC)	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 control of the levels of trace elements and processing contaminants in foodstuffs
Reg. 2017/644	OJ L 92, 6.4.2017, p. 9–34	Commission Regulation (EU) 2017/644 of 5 April 2017 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 589/2014