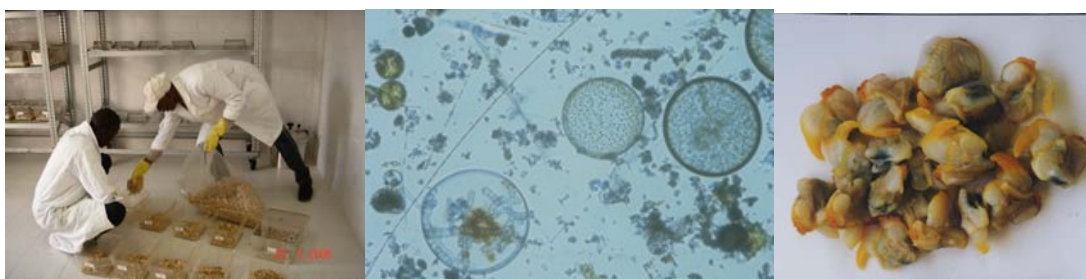


Pre-inspection Mauritania Bivalve Mollusks Food Safety April 20-24th 2008

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Report C049/08



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Summary

Mauritania is working on the completion of a Food Safety Program for Bivalve Mollusks, in order to be obtain an export approval by the Europe Union for the last 4 years (and before). For the second semester 2008 the FVO has programmed a veterinary inspection for the on bivalve mollusks. In order to prepare themselves for the veterinary inspection the competent authority of Mauritania (ONISPA) has requested Wageningen IMARES for a pre-inspection of the Mauritanian system. The pre-inspection was performed during the period of 20-24 April in Mauritania (Nouakchott and Nouadhibou).

The general conclusion is that at this moment of inspection the Mauritanian authorities will not be able to pass an FVO inspection. An extensive amount of work has to be done in order to be able to provide Mauritania with an accreditation for the export of bivalve Mollusks to the EU.

The official organization, which is responsible for the control of Bivalve Mollusks (ONISPA) could not present an organisational description nor a organogram. The organization should be formalized.

At this moment the main concerns consist of the lack of implementation (procedures) of official controls for Bivalve Mollusks, for inspection of vessels, establishments and monitoring. Since there are no fishing or production activities the implementation should be completed on paper.

Also there is a lack of the evaluation of the realized monitoring results for microbiology and chemical parameters and the generation of reports of syntheses. These reports need to be the basis for the assignment of production areas, and the classification of production zones. In relation to this the official assignment of production areas and zones is not officially realized, which is not in compliance to European and Mauritanian legislation.

The heavy metal content of the clams at off shore locations is found to be above the official threshold limits (Cadmium). The results are based on data obtained in 2006. However, no other data could be presented. Therefore it is highly recommended to analyse present samples (2006, 2007 and 2008) in order to have proper understanding in the fluctuation of the Cadmium over the years and throughout the year.

The personnel is shown to have correct knowledge on sanitary bivalve mollusk aspects, and there is awareness of the lacks within the control system. The quality should be translated to a proper laboratory Quality system, which provide procedures, and protocols for the entire laboratory operation (ISO procedures). At this moment the procedures are not officialized, and the traceability can be improved, which makes the laboratory work for official controls discutable.

The inspector is confident that the personnel is capable of performing the task, based on their knowledge. The amount of work which need to be completed is extensive, and therefore will be a bottleneck to perform before the FVO inspection (no calculation of probability can be made at this stage). Therefore it is advised that a proper plan of action should be prepared based on the recommendations written in this report. The plan of action should be completed with all personnel involved and not on an individual basis.

1. Introduction

During the last four years Mauritania has been working on the completion of a Food Safety Program of Bivalve Mollusks, in order to obtain an export approval by the Europe Union. During the preparations for an inspection by the FVO (Food and Veterinary Office) no fisheries or production activities for Bivalve Mollusks occurred in Mauritania. The only fisheries during this period was assisted by both IMARES (former RIVO), IFREMER (France) and for ISO purposes by Capital et Qualité (France). By the end of 2006 an inspection of the FVO was foreseen to inspect the fisheries and bivalve mollusk regulation, and enforcement system, but this never took place. During the period of 2007-2008 the Mauritanian inspection services and the authorities, were obliged to continue the development, implementation and performance of the bivalve mollusk monitoring system, and the incorporation of the required control and inspection systems.

For the second semester 2008 the FVO has programmed a veterinary inspection for the on bivalve mollusks. In order to prepare themselves for the veterinary inspection the competent authority of Mauritania (ONISPA) has requested IMARES for a pre-inspection of the Mauritanian system. The results of the pre-inspection, which was performed from 20-24 April in Mauritania is described in this report.

2. Aim

The aim of the mission was to perform a pre assessment on the status of the Bivalve Food Safety program in Mauritania. The pre-inspection was carried out in order to prepare Mauritania for the upcoming Food and Veterinary Office (FVO) inspection, planned for the second semester of 2008.

3. Methodology

In order to obtain adequate inspection results, the inspection was carried out in accordance to the inspection routine of FVO. Due to a lack of precise FVO procedures, the inspection was carried out based on the experience of the inspector (Marnix Poelman). The experience is based on the attendance of two FVO inspections in the Netherlands (2001 and 2005), in which the pre-inspector had involvement in the preparation and guidance the FVO inspection in the Netherlands . Also internal quality audits of IMARES were a basis of experience.

4. Program

The pre-inspection program was performed in the period of April 20th through April 24th. The program was set up as follows:

Sunday April 20th

Travel from Amsterdam to Nouakchott

21:00 – 22:45 Meeting with Mr. Ba (Director ONISPA) and Mr. Lekhal (SMAP)

Monday April 21th

6:30 – 11:00 Travel from Nouakchott to Noadhibou

11:30 – 12:00 Installation and tour ONISPA (Office National d'Inspection Sanitaire des Produits de la Pêche et de l'aquaculture).

13:00 - 14:00 Introduction of Mission and Explanation of structures

14:00 - 16:00 Documentation of structure, organization, laboratories, ministry

16:00 – 18:30 Documentation introduction Mollusk Bivalve Organisation

Tuesday April 22th

9:00 – 18:00 Documentation Mollusk Bivalve monitoring and control,
Organization Bivalve Mollusks,
mode of actions
Results of Monitoring data, microbiology, biotoxins, metals etc.

Wednesday April 23th

9:00 - 10:00 Remaining Questions

11:00 - 18:00 Traceability within laboratory

Methods of Analyses

18:00 – 22:00 Travel from Nouadhibou to Nouakchott

Thursday April 24th

9:00 – 14:00 Inspection Laboratory Nouakchott

14:00 – 20:00 Drawing up of report

20:00 Flight Nouakchott to Amsterdam

5. Inspection

Several ministries and organizations are concerned with Bivalve Food Safety . The ministry of fisheries is responsible for the implementation of official controls on bivalve mollusk (BM), and the licensing of production facilities. The official registration of the fishing vessels and production establishments is performed by the ministry (department DIPIS, Direction des Industries de Pêche et de l'inspection sanitaire). The regulations concerning fisheries, and food safety issues for fisheries are drawn up by the ministry and accorded by the Parliament.

ONISPA (Office National pour l' Inspection Sanitaire des Produits de Pêche et de l'Aquaculture) is the Competent Authority, assigned for the official inspections and control of Sanitary aspects (for both fisheries and Bivalve Mollusks, production areas and control of production) . ONISPA was installed in March 2007 via Decree 066-2007 (the Decree is currently under modification for implementation of bivalve mollusk demands, and laboratory transfers). ONISPA is installed under direct supervision of the ministry and has an normalized working relationship with DIPIS. ONISPA is under supervision of one director, and consists of two departments, one for the Inspection, and for laboratory department.

The ministry has assigned the former laboratories of IMROP (Institute Mauritanian de Recherché Oceanographic and des Peches) in Nouadhibou and Nouakchott as part of ONISPA in April 2008 (1 week prior to this inspection). Before this period, the laboratories were management under supervision of IMROP. The tasks and mission of ONISPA will therefore be redefine with inclusion of specific laboratory and mollusk bivalve aspects.

5.1 Structure of Official Organizations

The tasks and missions of ONISPA are defined in Decree 066-2007, this document includes the specification of tasks for the official inspections. The first modification of the legislation will include the transfer of the laboratories (personnel and equipment) of IMROP to ONISPA (currently in modification, including bivalve mollusk specifications and laboratory transfers).

No organogram for ONISPA could be presented at the time of inspection, the specific tasks of the management/personnel and the organization structure were not formalized in documentation.

A program of the year and a report on the past year could not be presented (for both Bivalve Mollusks and Fish products). Therefore the performed activities, progress and compliance of the performed tasks could not be verified.

The inspection service has developed a manual for inspections (Manuel de Procedures d'inspection et de control de la qualité des produits de la pêche de Mauritanie, which is in place for the inspection services. The inspection protocol is not up to date (still directed to the organization of IMROP), and does not address specific demands for the control of Bivalve Mollusks. The control and inspection of production of bivalve mollusk is therefore not defined, and no specific procedures, and protocols for bivalve mollusks exist. However, the line out of the official controls is thought through and contains many useful issues for implementation of bivalve mollusks.

The overall structure within ONISPA, including the laboratories seems to be based on an individual basis, meaning that personnel is working on a very independent and solitary in the organization. Interaction , collaboration, feed back routine, communication, and overall management (at inspection and laboratory level) need to be more organized. The management is in many occasions not stimulating the quality within the laboratory and there is no evaluation of the quality of the personnel.

The acquisition of the hired personnel is performed via official governmental rules, which were not inspected.

The monitoring of bivalve mollusks and the aspects on laboratories will be described in following chapters.

Recommendations

- Formalize the organization and description of the organization
- Monitor the organization via annual reports and program of the year. The organogram and description of the organization should be in place prior to the FVO inspection.
- Improve the overall management of ONSIPA, in order to be able to deliver the standards which are needed for bivalve mollusk aspects.
- Update the manual for official inspection for the ONISPA organization and implementation of Bivalve Mollusk specific aspects prior to the FVO inspection (including vessels, establishments).

5.2 Legislation and official controls on Bivalve mollusks

The legislation of the production, processing and the requirements for official controls are published in 2006. The legislation, which is related to bivalve mollusks is defined in:

- Arrêté conjoint n° 2859 MPEM /MCAT/MSAS/SEPME portant désignation du laboratoire de l'IMROP comme laboratoire national de référence de chimie et microbiologie.
- Arrêté conjoint n° 2862 MPEM /MCAT/MSAS/SEPME relatif aux critères microbiologiques, chimiques et biotoxines marines applicables aux mollusques bivalves vivants et aux produits de la pêche et les méthodes d'analyse à utiliser.
- Arrêté conjoint n° 2863 MPEM /MCAT/MSAS/SEPME relatif aux règles d'hygiène applicables aux mollusques bivalves vivants, aux produits de la pêche et aux exploitants du secteur alimentaire

The legislation is not updated for the creation of ONSIPA, and therefore needs (minor) revisions. The regulation for bivalve mollusks is copied from the EU legislation and therefore is complete for assignment of production areas, and bivalve mollusks food safety issues. The implementation of the legislation is not performed at this stage. No specific inspection controls are designed, and the required monitoring program for production zones is only performed on a project basis (2005-2006). There is a lack of decision schemes and implementation of direct actions for marine biotoxins and microbiology.

The missing aspects are defined to be worked out in the PSCMA TdR: Plan de Surveillance Contaminants Milieu Aquatique (Term of Reference), which is a document of the Mauritanian government which will demand for assistance on these topics. The performance of the tasks will however not be performed before October, and therefore does not seem to be a solution for the lacking aspect.

As stated in degree No 2862 the Bivalve mollusks should be tested for metals prior to marketing. There is no monitoring plan or risk assessment in place for end product testing. There is a lack of practice in bivalve mollusk production, however there is also a lack of procedures for the official controls. Production practice will not be able without proper implementation of the procedures for official controls. This issue can be addressed by monitoring the harvesting area and providing an occasional (random) end product testing for verification.

As stated in Degree No 2859 the assigned Reference Laboratory for Chemistry and microbiology is IMROP/ONISPA. The degree describes an obligation to prepare a report on the activities of the laboratory. The report could be presented and includes the tasks, and activities performed. Although the information is not extensive, the report is present.

Recommendations:

- Update Legislation in order to apply include the laboratorial change of ONISPA.
- Design inspection protocols based on the legislation of bivalve mollusks (for vessels, establishment, end product testing and monitoring actions).
- Implement the regulation for bivalve food safety issues, which is momentarily not properly arranged (see paragraph Bivalve Mollusks Manual). This needs to be fully performed before the arrival of the FVO.
- Design and implement official decision schemes in case of acute food safety risks (biotoxins).

5.3 Manual on Bivalve Mollusk

A manual of monitoring (Manuel du program de surveillance) is in use on a laboratory level in Nouadhibou. This document described the methods of sampling, frequencies, sample locations and descriptions of used method. The manual focuses on the monitoring of the potential production zones of microbiology (*E. coli*), marine biotoxins, phytoplankton and chemical components (heavy metals, hydrocarbons). The content of the Manual is recently revised, however there is no control of the editions, the manual is mainly used as a working document. There are references to used methods, however there are no references to official protocols on a laboratory level.

The manual included specific paragraphs, which describes the necessitation of reports of syntheses of the monitoring results. None of the reports (microbiology, phytoplankton, heavy metals and marine biotoxins) could be presented at the time. Based on both the European and Mauritanian legislation, the bivalve mollusk production areas should be assigned based on monitoring data as well as on a syntheses of the results. However, within ONISPA no evaluation of the results have taken place, and no production zones for Bivalve Mollusks have been identified. Therefore the justification, and basics of the regulation is not implemented, which should be officials by ONISPA. Specific attention should be given to the heavy metal results (see further).

Next to the assignment of production zones for bivalve mollusks, the regulations include the obligation for the classification of the production zones based on the microbiological results. No syntheses of the microbiological results could be presented, this included the lack of an official designation of the microbiological classification.

No procedures for the enforcement of the regulations during fisheries could be presented for phytoplankton, marine biotoxins or microbiological. The regulation states that monitoring should be in place for these parameters, the monitoring should be complemented by a plan of action when monitoring results exceed the threshold limits especially for marine biotoxins. Within this context plan of action, including procedures when monitoring results are not compliant to the regulation, official communication pathways, and control and enforcement (inspection) activities are missing.

Recommendations

- Update the Manual on Monitoring of Bivalve Mollusks for official controls
- Complete reports and syntheses of the monitoring results.
- Officially assigned production areas for bivalve mollusks based on the reports of syntheses (see figure 1 for a schematic procedural overview of a possible approach)
- Assign classification of the production zones based on the reports of syntheses (see figure 1 for a schematic procedural overview of a possible approach)
- Write action plans for situations in which monitoring results exceed the threshold limits. These should include official communication pathways, and control enforcement (inspection) activities. (see figure 2 and 3 for a possible action plan)
- Continue monitoring, and analyze stored samples

Figure 1. Schematic overview of a possible approach for the assignment of production areas, and classification of production zones.

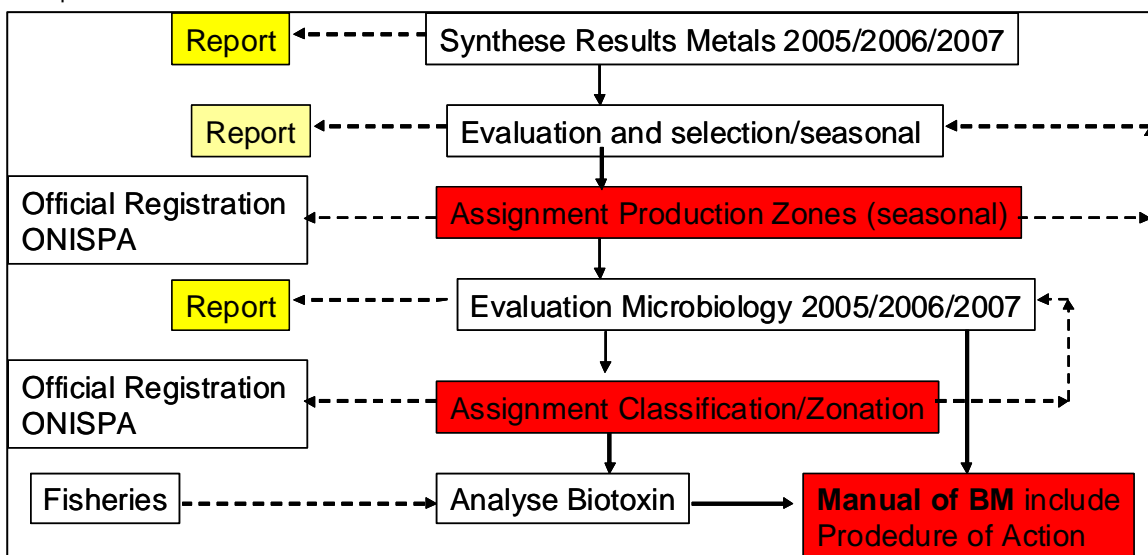


Figure 2. Overview possible action plan for marine biotoxin monitoring during fisheries activities.

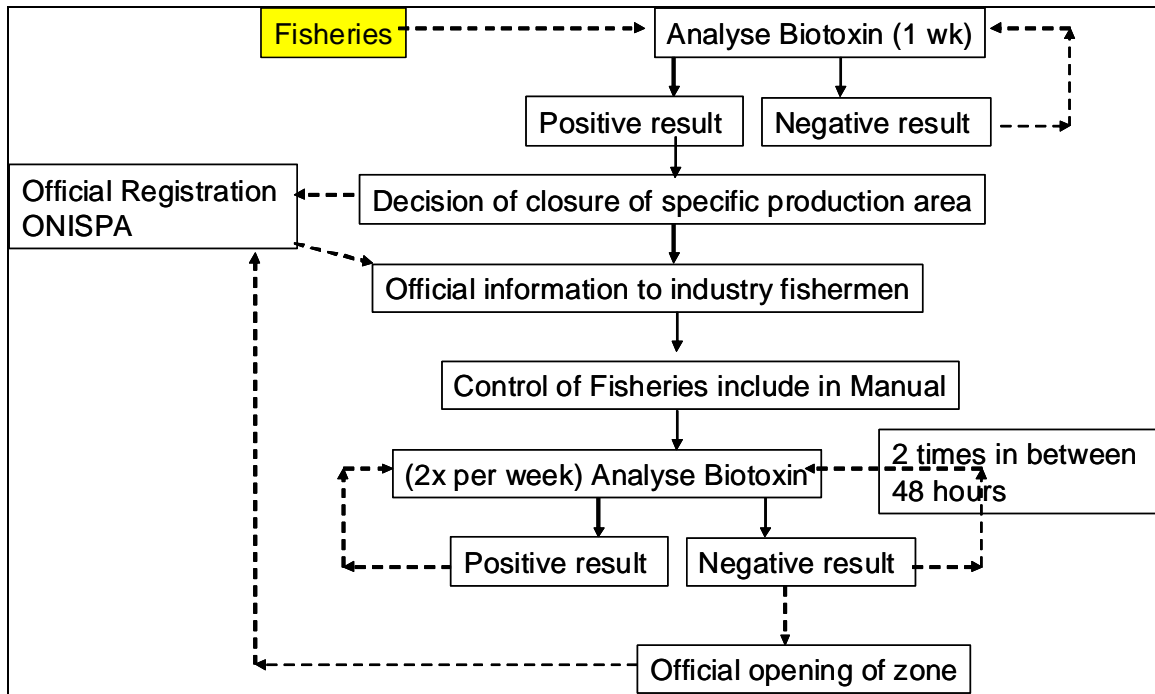
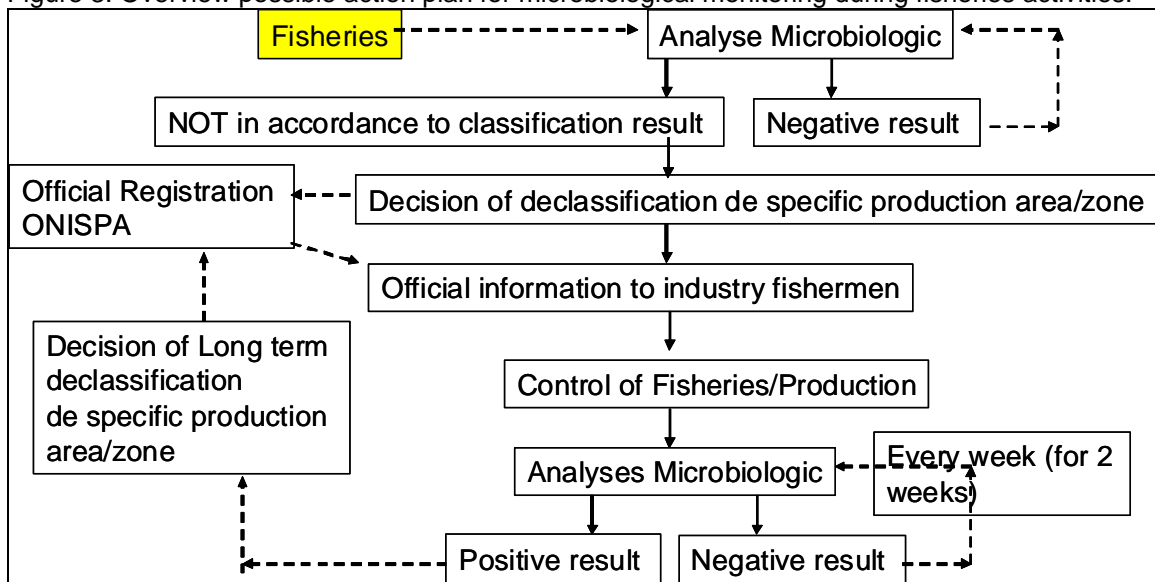


Figure 3. Overview possible action plan for microbiological monitoring during fisheries activities.



5.4 Microbiological monitoring

Microbiological monitoring for *E. coli* was performed during the period of 2005-2006, and from the beginning of 2008 till present. The presented results for the bivalve Mollusks (*Venus* sp) production zones illustrate that the microbiological status of the production zones complies with the demands set for Class A. However, a clear report containing the microbiological results could not be presented. The report should contain a description of the sources of pollution, description and explanation of the production zones (including coordinates) and an advise on classification of the production zones.

In addition to the lack of a synthesis report, also an official assignment and classification is not performed. The official classification is required (also by Mauritanian legislation). In addition the procedures for the classification should be written in the Bivalve Mollusk Manual.

The methods of analyses are properly in place, and intercalibration studies from 2007 show proper results. The intercalibration should however be performed on a more frequent basis, and interlaboratory studies between Nouakchott and Nouadhibou are not performed.

The method used is protocolised, However the analyses which are performed (2006) were performed according to older protocols, which could not be presented. Therefore the reliability of the quality of analyses is difficult to trace. The protocols of analyses are in place, however no official protocol (verified and numbered) could be presented.

Recommendations

- Continuation of the microbiological monitoring is strongly advised
- Perform Improvement of the analytical protocols
- Officially implement procedures of classification of the production zones , based on a report of synthesis (containing sources of pollution, description and explanation of the production zones)

5.5 Marine Biotxin monitoring

During the period of 2006 a monitoring for marine biotoxins has been performed. The samples were analysed by the end of 2006. No exceeding of the threshold for marine biotoxins were observed.

The methods used are compliant to the European legislation, and are also used by IFREMER (France). The laboratory procedures are only registered in unofficial (not numbered, and signed) protocols, besides the protocols need revision in order to implement the process in the protocols. The internal laboratory data is not archived or administrated properly, therefore traceability and quality verification is difficult.

The results of the marine biotoxins are not synthesized and a potential zones for monitoring and harvesting are not defined. No monitoring or action plan for monitoring and enforcement during fisheries was delivered.

Recommendations:

- Make a syntheses of the marine biotoxins, and set up a plan of action for monitoring during fisheries (including closure zones, and information to the industry (figure 2)).
- Improve and officialize the protocols for the analyses of marine biotoxins
- Improve the administration of the internal laboratory data.

5.6 Phytoplankton

Phytoplankton results could only be reported as total cell counts, the sort specific results are only available on a laboratory level, and have not been fully reported and made official. The results are therefore hard to interpret and only understandable after explanation. Therefore the data is not very well controllable or reproducible at this stage.

An official protocol for the analyses of phytoplankton cell counts could not be presented. However, an intercalibration study performed by IFREMER and IMROP showed that the cell counts performed by IMROP fulfill the demands set in the ring trial. The intercalibration study and the analyses were performed by a former researcher.

At this moment there is no technician available who is capable of performing the phytoplankton analyses. Plans for the training of a new technician are made (training by former technician and training in Maroc), however no running activities on training were presented.

Recommendations

- Training of new technician(s) for the analyses of phytoplankton on short notice.
- Prepare and officialize protocols for the analyses of phytoplankton.
- Elucidate and clarify results of analyses for phytoplankton

5.7 Heavy metals

Heavy metal analyses results were presented for near shore samples of mussels (2005-2006), these samples were analysed in 2007. The specification of the results was not available during the writing of this report. Next to the near shore samples, 16 samples of praires were analyzed (in the Netherlands) at the end of 2006. These samples included a quarterly sampling of 4 locations in 2006. These results illustrated high levels of Cadmium (2-6 mg/kg fresh weight, threshold value legislation is 1 mg/kg fresh weight), and therefore deserve special attention (the cause is found in upwelling). Next to the 16 samples of 2006, no further samples from offshore locations were analysed for heavy metals. However, samples from 2006 are present in lyophilized form, and samples of 2007 are available (not analysed) from April through August). Therefore the only available information is based on one year monitoring, and shows regulatory levels have been exceeded of the legislative levels. No information on interannual and seasonal variation could be elucidated further, and therefore the compliance with legislation.

The analyses of heavy metals is performed on a laboratory level in Nouadhibou and Nouakchott. During the inspection no analyses could be performed due to broken equipment (destruction oven, and gas compressor). The analyses for Cd and Pb have been examined in a quick scan. The protocols used are not formalized and need improvement in terms of calculation and use of reference materials, and standard solutions.

The analyses were performed on a laboratory level, however the archive (both electronical and paper) was hard to understand and only the technician was able to reproduce some results. The traceability on a laboratory level could be improved.

A report of the synthesis of the heavy metal results could not be presented. The syntheses of the results is included in the Manual for Bivalve Mollusks, and therefore should be performed. This is of importance for the assignment of production areas, since the production areas should be in compliance with the regulation in terms of product quality (this may include seasonal harvest allowance). The assignment of official production zones should be realized based on the report of synthesis.

Recommendations

- Improve and formalize protocols of analyses (including quality control)
- Analyse metals in bivalve mollusk samples of 2006 (lipophylized) and 2007 (Only April to August) as soon as possible.
The microwave oven can be fixed rapidly. There is a fine of 6keuro involved. After this 1 month, with a report of syntheses this will take maximum 2 months. This is recommended strongly.
- Prepare report of Synthesis for heavy metals
- Repair equipment in order to be able to run analyses

5.8 ISO and laboratory quality

During the inspection two laboratories (Nouadhibou and Nouakchott) were visited, at both locations the procedures for the laboratory work and organization were evaluated. Both laboratories serve under one head of department. At both locations two departments are available (chemistry and microbiology). There is one Quality manager who is responsible for both departments. The laboratory is recently transferred from the responsibility of IMROP to ONISPA, and performs official analyses on Fisheries and Bivalve Mollusks.

At the moment of inspection no updated organogram for the implementation of ONISPA nor documentation on the structure of the laboratories could be presented. The organization is at this moment mainly informally organized (no specific tasks have been described). There is a lack of implemented procedures for the general organization of the laboratory, however the preparation of the documents is currently in progress. Procedures for several aspects (organization, calibration/validation, registration etc) are in provision form, these will be accorded by the a weekly session in which the personnel is informed. This is recorded by a meeting report, which could be presented.

At this moment there is no internal quality control performed on the protocols. The analyses are primarily performed by the technicians, and often the protocols are not complete. The general missing aspects in the protocols are internal quality control, in house validation/calibration procedures, reporting schemes, laboratory registration forms (which are used) and data storage (electronic and paper). The laboratory analyses and results are at this moment mainly organized by the technicians, without cross checking procedures.

On a laboratory level the traceability was found not to be satisfactory. Random samples which were followed from result to registration and the other way around, should either difficulties to track on a registration level (wrong dates), or on laboratory level (lack of graphs or differences in results). There is a need for the improvement of the registration and traceability within the laboratory system, the different units are in place, however the integration and practical functioning of the laboratory system can not be proved.

During a tour around the laboratory the conclusion was made that no internal nor external control on the metrology was performed. In many cases balances were not verified on their performance, freezers were not controlled, and pH meters were not calibrated before use. There is a lack of external metrologists (throughout the whole of West Africa) and certified weights (for internal control), the latter should be solved on short notice, since this is of influence on the quality of the laboratory work.

In some cases (phytoplankton, microbiology) the results of Intercalibration studies could be reported. This is of great value for the analyses performance. For metals the laboratory has performed a QUASIMEME study, but no results were received (IMARES will contact QUASIMEME in order to check the availability of the results).

The archive of the analyses results is scattered around the laboratory. The technicians store the information on the computer, but the archive is not centralized. The data is not retrievable easily, and does require some searching. At the end most information is available. The archive of results and laboratory data needs improvement on short notice.

A report of Capital Quality of November 2008 was presented, this includes the description of an audit performed in 2008, and harbors many ISO parameters and recommendations. Two missions were performed by Capital et Qualite one for the internal audit and one for the formation of ISO. The advises which are present in the document should be followed for successful ISO implementation.

Recommendations

- Complete procedures for the laboratory work (and organization).
- Improve and officialize protocols for all analyses rapidly
- Perform verification/calibration of the laboratory equipment rapidly
- Improve the internal quality control on a laboratory levels
- Continue and start Quality Control schemes for intercalibration where necessary
- Follow the available protocols for the analyses at any time
- Improve archive for results and laboratory data.
- Revise, control and improve traceability of samples from registration to results, as much as possible

6. Conclusions

The general conclusion is that at this moment of inspection the Mauritanian authorities will not be able to pass an FVO inspection. An extensive amount of work has to be done in order to be able to provide Mauritania with an accreditation for the export of bivalve Mollusks to the EU.

In order to be able to comply with the European Regulations the recommendations as described in chapter 5 should be addressed. The minimal demands which need to be fulfilled are presented in the recommendations. In order to be capable to succeed an FVO-inspection successfully the recommendations on improvement, and implementation on a legislative level should be elaborated. Next to that the lack of analyses and the exceeded threshold limits for heavy metals should be addressed by intensive sampling and analyses. Also the quality on a laboratory level should be improved on short notice. On an organisatory level the organization of IONSIPA should be formalized, and inspection protocols should be present.

The inspector is confident that the personnel is capable of performing the task, based on their knowledge. The amount of work which need to be completed is extensive, and therefore will be a bottleneck to perform before the FVO inspection (no calculation of probability can be made at this stage). Therefore it is advised that a proper plan of action should be prepared based on the recommendations written in this report. The plan of action should be completed with all personnel involved and not on an individual basis. It is advised to adopt a steering committee for the follow up of the progress.

Justification

Report: C049/08
Project Number: 439.41049.01

The scientific quality of this report has been peer reviewed by the Scientific Team of Wageningen IMARES.

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Head of Department Aquaculture
For him: Dr. ir. T.P. Bult
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