EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Food and Veterinary Office

DG(SANTE) 2014-7127 - MR

FINAL REPORT OF AN AUDIT
CARRIED OUT IN
GREECE
FROM 14 OCTOBER 2014 TO 24 OCTOBER 2014
IN ORDER TO
EVALUATE THE CONTROL SYSTEMS IN PLACE GOVERNING THE PRODUCTION AND PLACING ON THE MARKET OF LIVE BIVALVE MOLLUSCS

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of a Food and Veterinary Office audit in Greece carried out from 14 to 24 October 2014, as part of its programme of audits for 2014.

The primary objectives of the audit were to assess whether the official controls of bivalve molluscs, echinoderms, tunicates and marine gastropods are organised and carried out in accordance with the relevant provisions 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 and whether the control system in place for the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods is in compliance with European Union requirements.

The audit also verified the implementation of the recommendations of the previous 2011 Food and Veterinary Office audit visit covering the same subject.

The current report concludes that considerable improvements have been made since the previous audit, however, the official control system in place covering live bivalve molluscs cannot yet be considered as fully in compliance with all European Union requirements. Important shortcomings are still present, notably related to the definition of sampling points for the collection of water for phytoplankton testing and live bivalve molluscs for biotoxins testing, the frequency of monitoring/testing of live bivalve molluscs for one group of toxins (Paralytic Shellfish Poison) and the absence of demonstration of the efficiency of the purification systems.

Of the twenty recommendations of the 2011 audit, ten can be considered as addressed, three partially addressed, six not addressed (monitoring of biotoxins (for Paralytic Shellfish Poison); decisions taken after monitoring; additional monitoring requirements; purification centres; analytical and legal validity of samples; coordination between Competent Authorities) and one is no longer applicable.

The report makes recommendations to the Competent Authorities aimed at addressing areas in which further improvements are required.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ASP	Amnesic Shellfish Poison
CA/s	Competent authority/ies
CCA	Central Competent Authority
EFET	Hellenic Food Authority
EU	European Union
EURL	EU Reference Laboratory
FBO	Food Business Operator
FVO	Food and Veterinary Office
HACCP	Hazard Analysis of Critical Control Points
LBM	Live bivalve molluscs
LC-MS/MS	Liquid chromatography–mass spectrometry
MRDF	Ministry of Rural Development & Food
NRL	National Reference Laboratory
PSP	Paralytic Shellfish Poison
RASFF	Rapid Alert System for Food and Feed Notifications
SANCO	General Directorate for Health and Consumers

1 INTRODUCTION

This audit took place in Greece from 14 to 24 October 2014 and was undertaken as part of the Food and Veterinary Office's (FVO) planned audit programme. The audit team (hereinafter the FVO team) comprised three auditors from the FVO and two national experts from European Union (EU) Member States.

An opening meeting was held in Athens on 14 October 2014 with the Directorate of Veterinary Public health of the Directorate General of Veterinary Services within the Ministry of Rural Development & Food (MRDF) which is the Central Competent Authority (CCA) 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. Representatives from the CCA and of different Competent Authorities (CAs) accompanied the FVO team during the whole audit.

2 OBJECTIVES AND SCOPE

The objectives of the audit were to assess:

- Whether the official controls of bivalve molluscs, echinoderms, tunicates and marine gastropods are organised and carried out in accordance with the relevant provisions 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.

- Whether the control system in place for the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods is in compliance with EU requirements.

- Verify the extent to which the guarantees and the corrective actions submitted to the Commission services in response to the recommendations of the previous FVO audit report on this subject (ref. DG(SANCO)/2011-8883) have been implemented and enforced by the Greek authorities.

In terms of scope, the audit focused on the organisation and performance of the CCA and CAs, the official control system in place covering the classification and monitoring of live bivalve molluscs (LBM) production areas, and the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods. Accordingly, certain aspects of the legislation referred to in Annex 1 were used as technical basis for the audit. Full legal references to EU legal acts quoted in this report are provided in that Annex and refer, where applicable, to the last amended version.

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

Competent Authorities Visits/Meetings		
CCA	1	Directorate General of Veterinary Services
Regional CAs	3	
Coast Guard	1	At regional level
Laboratory Visits		
Official testing of LBM for microbiology	3	Includes the National Reference Laboratory (NRL).
Official testing of LBM for biotoxins	1	
Official testing of water for phytoplankton	1	
Primary Production Facilities		
Production areas	1	Including a mock sampling exercise.
Dispatch centres	1	Also authorised to perform shelling of LBM.
Purification centres (also approved as dispatch centres)	4	Three of them also authorised to perform shelling of LBM.

3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation and, in particular, Article 45 of Regulation (EC) No 882/2004.

4 BACKGROUND

4.1 PREVIOUS FVO REPORTS

The most recent FVO audit to Greece on this subject was carried out from 11 to 21 October 2011 (ref. DG(SANCO)/2011-8883) (hereinafter 2011 FVO audit). The report of this audit is available on the Health and Consumers Directorate General (SANCO) website at: http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2912.

That report highlighted that the official control system in place presented significant deficiencies and that important deviations from EU legislation existed all along the production chain of bivalve molluscs and concluded that the system in place did not offer the necessary guarantees that bivalve molluscs placed on the market for human consumption comply with EU public health standards.

Recommendations were made with regard to:

- Coordination and cooperation between CAs (Recommendation No 1).

- Internal audits (Recommendation No 2).

- Classified production areas (e.g. boundaries, performance of sanitary surveys and classification – Recommendations Nos 3 to 7).

- Monitoring of classified production areas (e.g. to check malpractices, geographical distribution of sampling points, frequency of sampling and parameters to be monitored in LBM - Recommendations Nos 8 to 12).

- Validity of the official control samples (Recommendation No 13).

- Decisions after monitoring (Recommendation No 14).

- Additional monitoring requirements (Recommendations Nos 15 to 16).

- Exchange of information (Recommendation No 17).

- Official controls covering *Pectinidae* and marine gastropods not filter feeders harvested outside classified production areas (Recommendation No 18).

- Performance of tasks defined in Regulation (EC) No 882/2004 by the National Reference Laboratory (Recommendation No 19).

- Approval of facilities handling LBM e.g. purification centres (Recommendation No 20).

The FVO received written guarantees in relation to the recommendations listed above which were found satisfactory for eight of them.

4.2 PRODUCTION AND TRADE INFORMATION IN TONNES

In 2013, according to the CCA, approximately 13.800 tonnes LBM were produced, of which 95% were mussels, *Mytillus galloprovincialis*, and 2% were bearded mussels, *Modiolus barbatus*. Other LBM species were also produced in smaller quantities (e.g. clams, *Venus verrucosa* and *Callista chione*).

According to EUROSTAT figures for the same year Greece traded with other EU Member States approximately 11,600 tonnes of LBM mainly to Italy (70.2%), France (21.9%) and Spain (6.5%).

Presently the production chain of LBM in Greece comprises forty classified production areas (fifteen Class A, twenty four Class B and one with seasonal classification), thirty dispatch centres, thirteen purification centres and forty five shelling facilities. This information is made available by the CCA in its website at: http://www.minagric.gr/index.php/en/farmer-menu-2/establishments-menu/foodestab-menu/1443-egatastaseisalievmaton-2.

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

Since October 2011, ten RASFF notifications related to LBM were issued. These notifications refer to the presence of lipophilic toxins in mussels (two – one of them notified by Greece), presence of lead above the regulatory limits in bearded mussels (one) and microbiological contamination with *E. coli* above 230 MPN/100g in mussels (two) and clams (five). To highlight that: from those ten RASFF notifications three of them refer to products traded with Italy directly from classified production areas; and, two Greek operators are implicated in respectively three and five of those RASFF notifications.

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES

Legal Requirements

Articles 3 to 10, 54 and 55 of Regulation (EC) No 882/2004.

Findings

No changes, since the 2011 FVO audit, have occurred as regards the designation of the CCA and CAs (the Regions and Regional Units) for the official controls of LBM and their production chain.

Detailed information on these authorities, including their designation process, organisation, responsibilities, competences, powers, co-operation, staffing provisions (conflict of interest, qualification and training) and access to adequate facilities, equipment and laboratories can be found in the country profile at http://ec.europa.eu/food/fvo/controlsystems_en.cfm?co_id=GR. The country profile also includes general information with regard to: organisation of the official controls covering amongst others the establishments risk assessment and categorisation with a view to define the frequency for the official control visits; transparency and confidentiality; verification and review of official controls and procedures; control activities, methods and techniques; and, national enforcement measures.

The CCA informed the FVO team that their responsibilities have not changed since the last FVO audit with the exception of the decision on the classification of LBM production areas. Currently the CCA has the power to overrule the decision on classification taken by the regional services when the assessment of relevant documents demonstrates that the initial decision is not in line with the applicable EU regulations.

The CCA and the CAs stated to the FVO team on several occasions during the audit that there is a shortage of staff, financial resources and equipment for the implementation of the official controls of LBM and their production chain which, according to them, have a direct impact on the performance and implementation of official controls.

Specific training is coordinated by the CCA to provide official staff with adequate knowledge for the performance of official controls of LBM and their production chain.

Since the 2011 FVO audit the CCA has updated several guidelines, circulars and written procedures (in cooperation with the NRLs) covering the classification and monitoring of production areas, sampling and decisions to be taken after monitoring and including risk categorisation with a view of establishment frequencies for official control visits. Furthermore, the CAs have drafted additional documents (procedures, check-lists, report templates, etc.) to assist and guide official staff in the performance of their duties.

The CCA has an internal audit service that performs audits to veterinary services over a five-year cycle. Due to the outcome of the 2011 FVO audit the CCA decided to include the LBM sector in the 2012-2016 cycle. Several audit have already been carried out, their reports have been drafted and sent to the relevant services and actions to address the non-compliances detected have been forwarded to the CCA. An assessment of those actions has been made and a follow-up review with a view to the correction of remaining deficiencies is underway.

The CCA and CAs informed the FVO team that, apart from the internal audits and information flows on the LBM monitoring programme (decision on boundaries, location of sampling points, classification and closures), there are no other mechanisms in place to monitor the effectiveness of the official controls that they carry out.

Also, as described in the previous FVO audit report, the Department of Fisheries of the Regional Units and the services of the Coast Guard participate in the official controls of LBM. The former authority is responsible for licensing aquaculture farms and fishing/harvesting vessels (which was not covered during this audit) and the latter is responsible for patrolling production areas to check for malpractices and illegal harvesting (areas not classified or closed classified production areas).

The FVO team noted that:-

- Official staff performing official controls on LBM and their production chain carry out similar tasks for several other domains (e.g. animal health, other products of animal origin, etc.). Staff met by the FVO team presented variable degrees of knowledge with regard to the LBM subject (ranging from very good to weak). Staff that attended specific training on LBM show good level of knowledge on that topic.
- In some cases there was a discrepancy between the CCA guidelines and the written procedures developed at Regional Unit level (e.g. sampling procedures). It is to be noted that the CCA guidelines followed correctly EU regulations while the written procedures did not.
- Although official control task were carried out at all stages of the LBM production chain (with announced and unannounced visits) these controls were not planned and their results were not communicated which prevents the CCA and the CAs from ensuring that the controls are effective. The frequencies defined for the official controls (inspection visits) and based on a risk categorisation were not respected. Moreover, those controls were not able to detect a number of deficiencies found by the FVO team in the establishments visited (see sections 5.2 and 5.5).
- Enforcement actions and sanctions have been applied to some food business operator's (FBOs) visited due to the detection of severe non-compliances with EU food law.
- The CCA has available on its website detailed information with regard to classified LBM production areas, such as, delimitation of the area, location of sampling points,

current classification and sanitary decisions taken based on test results for biotoxins, microbiology and phytoplankton.

- The CCA informed that they are establishing a way to make available up-to-date maps of production areas as well as having a central database with the test results of the LBM samples taken during the monitoring of production areas.
- After the 2011 FVO audit and during 2012 and 2013 the CCA (internal audits service) carried out one internal audit of the CCA service responsible for the LBM sector and five audits of Regional Units. The CCA provided copies of those audit reports to the FVO which were found to be thorough and which pointed out many of the weakness identified in the previous and the current FVO audit. It is to be noted that since the 2011 FVO audit there were some aspects where progress and improvements have been made.

Conclusions

Competent authorities have been adequately designated for the official control of LBM and their production chain. Those authorities have a structure, organisation and legal powers that should, in principle, allow for an adequate official control.

However, shortcomings were found linked to Regulation (EC) No 882/2004, which had also been identified by the CCA in internal audit reports, as regards: knowledge of staff (Article 6); written procedures (including those to verify the effectiveness of the official controls) (Article 8); implementation of controls (Article 3); which do not allow the authorities to ensure that the official control system implemented is effective and appropriate as required under Article 4 (2.(a)) of Chapter II of Regulation (EC) No 882/2004.

As regards the previous audit report it can be concluded that:-

- Recommendation No 1, with regard to efficient and effective coordination, is still considered as not fully addressed.
- Recommendation No 2, with regard to internal audit, is considered as addressed.

5.2 REGISTRATION/APPROVAL OF ESTABLISHMENTS

Legal Requirements

Article 6 of Regulation (EC) No 852/2004, Article 4 of Regulation (EC) No 853/2004, Article 3 of Regulation (EC) No 854/2004 and Article 31 of Regulation (EC) No 882/2004

Findings

In accordance with the information provided by the CCA and the CAs the only facilities in Greece involved in the production of LBM and products derived therefrom are harvesting vessels (performing the cleaning and wrapping of LBM for further transport to dispatch or purification centres), dispatch centres, purification centres and shelling centres (the latter facilities shuck LBM manually and produce fresh products).

Article 6 of Greek Presidential Decree 79 of 2007 defines the administrative procedure to licence and approve establishments requiring approval in line with Regulation (EC) No 853/2004. This covers all the facilities mentioned above with the exception of harvesting vessels. Harvesting vessels are registered by the Department for Fisheries.

This procedure includes steps carried out by the regional services of the Region with possible cooperation between Regional Units' staff (licensing (to establish and to operate)) that include at least one on-the-spot visit to check for the conditions required for the approval (namely the requirements of Regulations (EC) Nos 852/2004 and 853/2004). CA staff informed the FVO team, that when all the applicable requirements are met and verified on-the-spot, the services of the Region submit to the CCA a request for attribution of an approval number. This number is granted by the CCA and communicated to the region which then communicates it to the FBO concerned.

During the licensing process there are steps that involve documentary checks and others that include on-the-spot checks. The presence of an HACCP plan is checked during the documentary checks and its assessment (including its implementation) should be part of the official control visits to be performed once the approval has been granted.

With regard to registered facilities the FVO team noted that:-

- As indicated above the authorities responsible for fisheries matters are the ones registering the harvesting vessels.
- The CCA and Regional Units involved in the official controls of LBM do not have a list of those facilities as required by Article 31 (1.(b)) of Regulation (EC) No 882/2004.

With regard to approved facilities the FVO team noted that:-

- The procedure for approval in place, described in Presidential Decree 79 of 2007, encompasses broadly the steps defined in Article 31 (2) of Regulation (EC) No 882/2004, i.e. submission of applications and on-the-spot visits.
- These on-the-spot visit are carried out with a view to assess the applicable requirements and to propose a license to operate if there is a positive outcome.
- During the FVO visits to approved premises it was noted that HACCP plans were not assessed until after the approval had been granted and that the assessments done during the following official control visits were restricted to a verification of the existence of the records defined in the HACCP plan.
- In one case, regarding the approval of a purification centre, the HACCP plan had never been assessed by any CA and eighteen months had already elapsed since the date of approval of the centre. Over the eighteen months no official visit that would allow for an assessment of the HACCP implementation had occurred.
- In all purification centres visited the information and documents provided by the FBOs concerned and the assessment made by the CAs of those documents could not demonstrate that the purification process would comply with the requirements of point A.3, Chapter IV, Section VII of Annex III to Regulation (EC) No 853/2004. Despite the noted shortcoming, these purification centres maintained their approval and additional purification centres had been approved.

- With the current implementation of their procedures the CAs cannot ensure that Article 31 (2(c)) of Regulation (EC) No 882/2004 is correctly applied when granting an approval. Moreover, the CAs are not implementating adequately the provisions of Article 31 (2(e)) of Regulation (EC) No 882/2004.
- Lists of approved establishments have been drawn-up by the CCA and they have been made available on the CCA website.

Conclusions

The current implementation of the procedures for registration and approval of facilities handling live bivalve molluscs is not carried out in accordance with Article 31 of Regulation (EC) No 882/2004.

Recommendation No 20 of the previous audit report, with regard to approval of establishments, is considered as not satisfactorily addressed.

5.3 OFFICIAL CONTROLS ON LIVE BIVALVE MOLLUSCS FROM CLASSIFIED PRODUCTION AND RELAYING AREAS

Legal Requirements

Article 6 of Regulation (EC) No 854/2004 and Chapter II of Annex II to Regulation (EC) No 854/2004.

According to the information provided by the CCA in response to the pre-audit questionnaire and the information available on its website, Greece has forty classified production areas distributed across fifteen Regional Units of six Regions. Of those forty classified production areas, fifteen are classified as A class, twenty four as B class and one has a seasonal classification (A and B). Within these areas there are two with seasonal production. Greece does not have relaying areas and one new production area has been defined and classified since the 2011 FVO audit.

Classification of production and relaying areas

Findings

The CCA informed the FVO team that all production areas have been identified by defining their boundaries and that sanitary surveys have been conducted. The CCA also stated that as a consequence of those actions the classification of production areas has been updated.

The CCA and CAs made available to the FVO team several data sets confirming the above mentioned statements.

From the site visits and documents provided the FVO team noted that:-

- In accordance with point A.1., Chapter II of Annex II to Regulation (EC) No

854/2004, decisions fixing the boundaries of classified production areas have been issued by the CAs and are available on the CCA website for all classified production areas.

- Sanitary surveys have been conducted in accordance with point A.6., Chapter II of Annex II to Regulation (EC) No 854/2004 for almost all production areas (as a group of areas or individually). These sanitary surveys were made with a view to confirm or redefine the boundaries and the set-up of microbiological sampling points representative for the area concerned. Sanitary surveys have not been carried out only for one production area in the Region of North Aegean (Lesvos – natural sea bed) and for two production areas in the Region of Epirus (Thesprotia – one farm; Preveza – one farm).
- The three sanitary surveys assessed showed different degrees of detail and it was not demonstrated in two of them that a shoreline survey has been carried out to provide all the relevant information required by point A.6.(a), Chapter II, of Annex II to Regulation (EC) No 854/2004.
- In the sanitary surveys no recommendation was made as regards the required sampling programmes nor had the responsible CAs established them, as required by point A.6.(d), Chapter II, of Annex II to Regulation (EC) No 854/2004. Nevertheless, the guidance documents issued by the CCA stipulates that the sampling of LBM for microbiological testing should be at least monthly.
- The sanitary surveys recommended, where applicable, the use of mussels as the sentinel species for future monitoring of production areas, however, formal presentation of historical and/or scientific data was not presented to the FVO team to support such recommendations. This practise was established without taking into consideration the relevant information provided in the "Microbiological Monitoring of Bivalve Mollusc Harvesting Areas – Guide to Good Practice: Technical Application", publish by the EU Reference Laboratory in their website (hereinafter the "EURL Technical Application Guide").
- The sanitary surveys, which contained in almost all cases a bacteriological survey of the production areas concerned is an important improvement when compared with the practice noted during the 2011 FVO audit. Although they do not fully follow the requirements of point A.6., Chapter II, of Annex II to Regulation (EC) No 854/2004, the current sanitary surveys provide in most cases a good indication with regard to the selection of sampling points for microbiological monitoring of production areas and their classification.
- Based on the Sanitary Surveys and in some cases the available historical data the CAs published decisions defining sampling points and identifying them with geographical coordinates. These decisions were made based on the microbiological assessment included in the sanitary surveys. However, valuable information also collected for the monitoring of biotoxins, phytoplankton toxic species and environmental contaminants was not assessed and/or used for the definition of the relevant sampling points.
- Updated decisions concerning the classification of all production areas were also issued by the CAs and published on the CCA website after validation by the CCA. The CCA and CAs only authorise harvesting from areas which have a classification decision issued and published.
- The update of the classification of the production areas was made based on the analytical results of LBM samples collected during the monitoring performed after the

last FVO audit and in line the requirements of points A.2., A.3., A4. and A.5., Chapter II of Annex II to Regulation (EC) No 854/2004. Samples were taken fortnightly during a period of intense monitoring in order to build up enough results for a preliminary classification and all of them were tested in accredited official laboratories with the EU reference method.

Although not formally indicated in Regulation (EC) No 854/2004, Greece, as other EU Member States, has classified production areas with seasonal production and production areas with seasonal classification.

With regard to the areas with seasonal production and seasonal classification the FVO team noted that:-

- In general the classification of these types of areas provide the guarantees required by Regulation (EC) No 854/2004 for the classification of production areas and the classification was made following the "Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Molluscs Production and Relaying Areas with regard to Regulation 854/2004" available in the DG SANCO website (hereinafter the "Community Guide").

Conclusions

Although the shortcomings identified during the current audit with regard to the classification of production areas and/or their update/maintenance, in particular the absence of shoreline surveys and drafted sampling plans, the situation observed presents notable improvements when compared with the results of the previous FVO audit.

As regards the previous audit report it can be concluded that:-

- Recommendation No 3, with regard to sanitary surveys to newly classified production areas, is considered as addressed.
- Recommendation No 4, with regard to establishment of boundaries for classified production areas, is considered as addressed.
- Recommendation No 5, with regard to classification of production areas, is considered as partially addressed (due to the shortcomings noted in relation with the shoreline surveys).
- Recommendation No 6, with regard to the authorisation of LBM harvesting only from classified production areas, is considered as addressed.
- Recommendation No 7, with regard to classification of production areas with seasonal production, is considered as addressed.

Monitoring of classified production and relaying areas

Findings

To allow a correct monitoring of classified production areas the CCA drafted guidance documents to be used by the CAs in charge of that monitoring. In those documents minimum frequencies for the sampling of LBM for microbiological, biotoxins and chemical testing and for the sampling of water for phytoplankton testing were established, as follows:-

- Microbiological quality of LBM – once a month (includes *E. coli* and *Salmonella* testing).
- Presence of biotoxins on LBM – weekly for all biotoxins (lipophilic toxins, amnesic shellfish poison (ASP) and paralytic shellfish poison (PSP)).
- Presence of toxin producing phytoplankton in water – weekly.
- Chemical contaminants in LBM – twice per year.

However, the CCA guidance documents also indicate that the NRL for biotoxins may decide which toxins are to be tested for in LBM weekly, based on the weekly results of phytoplankton testing and the past history of the production area as well as on a risk assessment for the area concerned. This process can be considered, in principle, as in line with the requirements of Regulation (EC) No 854/2004.

The CCA informed the FVO team that monitoring of production areas to check that there is no malpractice with regard to the origin, provenance and destination of LBM was strengthened by the modification of the LBM registration document, the routine tasks of Regional Units staff and the close cooperation with the services of the Coast Guard.

The FVO team noted that:

- Although sampling frequencies have been defined at central level in the CCA guidelines, the CAs have not drafted sampling plans to ensure that samples are taken at regular intervals and that the geographical distribution of sampling points and sampling frequency are as representative as possible for the area considered. This is not in line with point B.2., Chapter II of Annex II to Regulation (EC) No 854/2004.
- For the parameters to be monitored in production areas, with the exception of the microbiological quality of LBM, the sampling points have not been defined in order to ensure that the samples taken are as representative as possible for the area considered. This is not line with point B.2., Chapter II of Annex II to Regulation (EC) No 854/2004.
- In some production areas a single bivalve mollusc species is used as an indicator for all the other species harvested from the same area. This strategy is used for both microbiological and biotoxin monitoring of LBM and it was supported either solely by historical data or derives from specie availability at the time of sampling - no formal data assessment and/or scientific data was used to support those decisions. Point B.6., Chapter II of Annex II to Regulation (EC) No 854/2004 was not correctly applied and no adequate consideration was given to the "Community Guide" and the "EURL Technical Application Guide" on these matters.
- Monitoring of production areas to check for malpractice was planned and executed by the Coast Guard and the control of the issuance of the LBM registration documents is performed by the CAs during the official control tasks.

Microbiological monitoring

- The defined frequency for the sampling is in line with the requirements of Regulation (EC) No 854/2004 and was, in general, correctly followed by the CAs.

Biotoxins monitoring

- In all production areas LBM were sampled weekly and the frequencies for testing were applied as indicated below. However, in one Regional Unit samples were taken fortnightly until July 2014. This non-conformity was highlighted in the internal audits of the CCA to the Region concerned and the CCA informed the FVO team that at that time the Regional Unit had a different interpretation of the EU requirements and of the CCA guidance. This breach to the Regulation (EC) No 854/2004 was finally corrected and a weekly sampling of LBM was implemented as of July 2014.
- The frequencies defined and implemented for the testing of samples are in line with the requirements of Regulation (EC) No 854/2004 for lipophilic toxins (once a week) and for ASP (based on a risk assessment and supplemented with weekly sampling of water for relevant toxin-producing phytoplankton).
- As a general rule, and by decision of the NRL, LBM are tested for PSP fortnightly. The testing frequency for PSP is increased to weekly if the test carried out for lipophilic toxins (currently the mouse bioassay) shows signs of interference, if there is presence of relevant species of toxin-producing phytoplankton, or if previous test results reveal the presence of PSP toxin in LBM. This approach is not in line with the requirements of point B.5., Chapter II of Annex II to Regulation (EC) No 854/2004.

Phytoplankton monitoring

- The defined frequency for the sampling of water for testing for toxin-producing phytoplankton (qualitative and quantitative testing) is in line with the requirements of Regulation (EC) No 854/2004 and was, in general, correctly followed by the CAs. The sample procedures developed and implemented ensure that the sample is representative of the water column.
- In their guidance documents the CCA defined thresholds for alert (increased water sampling for phytoplankton) and for action (closure of production areas) for certain phytoplankton species. These thresholds can be considered generally adequate for all phytoplankton species with the exception of the maximum levels for certain species of dinophysis that may be responsible for the presence of lipophilic toxins in LBM. Although those specific levels may be high from a public health point of view, their impact is greatly reduced due to the weekly monitoring of LBM for lipophilic toxins.
- The actions taken when the phytoplankton alert levels are reached, i.e. increasing of water sampling for phytoplankton during the same week, is not in line with the requirements of point B.7., Chapter II of Annex II to Regulation (EC) No 854/2004.

Chemical contaminants monitoring

- The defined frequency for this sampling was established in order to detect any overshooting of the levels laid down in Regulation (EC) No 1881/2006 for the chemical contaminants, which is in line with the requirements of Regulation (EC) No 854/2004 and was, in general, adequately followed by the CAs. Although improvements have been made, compared to the situation found during the 2011 FVO audit, not all chemical parameters are included in that monitoring – dioxins are still absent.

Conclusions

Although the monitoring of production areas for microbiology and phytoplankton provides sufficient guarantees it cannot yet be considered as fully compliant with the requirements of

Regulation (EC) No 854/2004, in particular its points B.2 (sampling plans and sampling points (the latter for phytoplankton only) and B.7 (phytoplankton only) Chapter II of annex II to that Regulation.

The monitoring of production areas for biotoxins is still not in compliance with Regulation (EC) No 854/2004 in particular regarding the testing frequency of LBM for PSP (point B.5., Chapter II of Annex II to Regulation (EC) No 854/2004), the definition of sampling points (point B.2., Chapter II of Annex II to Regulation (EC) No 854/2004) and the LBM species tested (point B.6., Chapter II of Annex II to Regulation (EC) No 854/2004). The monitoring of production areas for chemical contaminants is still not in compliance with Regulation (EC) No 854/2004 in particular with regard to the parameters tested and the definition of sampling points.

As regards the previous audit report it can be concluded that:-

- Recommendation No 8, with regard to monitoring to check absence of malpractice, is considered as addressed.
- Recommendation No 9, with regard to the monitoring of microbiological quality of LBM, is considered as addressed.
- Recommendation No 10, with regard to monitoring of production areas for phytoplankton, is considered as partially addressed (due to the shortcomings noted in relation to the geographical distribution of the sampling points).
- Recommendation No 11, with regard to monitoring of production areas for biotoxins, is considered as not adequately addressed.
- Recommendation No 12, with regard to monitoring of production areas for chemical contaminants, is considered as partially addressed.

Decision after monitoring

Findings

The decisions to be implemented by the CAs when it is detected that the health standards for LBM are exceeded, or where there may be otherwise a risk to human health, are described in the CCA guidance documents.

The FVO team noted that:-

- The actions described in the guidance documents were adequately applied by the CAs. However, those actions are not in fully accordance with the requirements of Regulation (EC) No 854/2004, namely those of Annex II, Chapter II, point C., for the following situations:-
  - When in production areas classified as A areas the test results of monitoring show that the *E. coli* levels surpass the regulatory limits the CAs do not close the areas as required by Regulation (EC) No 854/2004 but instead apply a restricted harvesting regime and allow the harvesting of LBM which must then be sent to a purification centre. While this measure may be applied in Greece, the CAs cannot guarantee that the same is done when LBM are exported to another MS. Furthermore the CA of the receiving MS is also put in a delicate position because the classification of the production area involved remains as class A and they are

unaware of the conditions imposed at harvesting.

- When, as a preventive measure, a production area is closed due to the presence above certain level (action level) of toxin-producing phytoplankton the reopening of that area is not carried out in accordance with the requirements of Regulation (EC) No 854/2004. Instead the CAs may re-open the production areas either following one single test result of a sample of LBM and water, or, based only on the results of phytoplankton testing.

- In the case of detection of biotoxins in LBM the actions taken are in line with the requirements of Regulation (EC) No 854/2004.

Conclusions

Currently the decisions after monitoring concerning the presence of phytoplankton and the results for *E. coli* testing above the regulatory limits are not in compliance with Regulation (EC) No 854/2004. The decisions after monitoring concerning the results of biotoxins testing above the regulatory limits are in compliance with Regulation (EC) No 854/2004.

Recommendation No 14 of the previous audit report, with regard to decisions after monitoring, is considered as not adequately addressed.

Additional monitoring requirements

Findings

The CAs and the Coast Guard are responsible for monitoring production areas for which the CAs have forbidden the harvesting of LBM.

In this regard the FVO team noted that:-

- In order to enforce the closure of such areas the, CAs issue a decision concerning sanitary measures to be taken for production areas which are published on the CCA's website. The CAs also routinely check that harvesting has not occurred during the periods of prohibition of harvesting by checking the new registration documents.

- In the meeting held with the Coast Guard several documents were presented showing that the service plans its surveillance taking into account the CAs closure decisions and the results of their own control operations where LBM, harvested during closure periods, had been seized.

The CCA indicates in their guidance documents that samples are to be taken at the FBOs, i.e. dispatch and purification centres, to verify compliance of the LBM with the applicable limits for biotoxins and contaminants and with the relevant microbiological quality.

In this regard the FVO team noted that:-

- During their official control activities CAs staff sample LBM for testing only for their microbiological quality. The current arrangements for additional monitoring of LBM comprising laboratory tests of LBM do not cover biotoxins and contaminants which is a requirement of Regulation (EC) No 854/2004.

Conclusions

The arrangements in place to monitor closed production areas follow the requirements of point D.1., Chapter II, of Annex II to Regulation (EC) No 854/2004.

The system established by the CAs comprising laboratory testing to verify compliance of end product requirements does not follow adequately point D.2., Chapter II, of Annex II to Regulation (EC) No 854/2004, in particular concerning biotoxins and contaminants.

As regards the previous audit report it can be concluded that:-

- Recommendation No 15, with regard to additional monitoring of closed production areas, is considered as addressed.
- Recommendation No 16, with regard to additional monitoring of LBM from classified production areas, is considered as not adequately addressed.

Recording and exchange of information

Findings

Since the 2011 FVO audit the CCA has developed its website in order to make available all relevant information related to the classification and delimitation of production areas as well as measures taken following the monitoring of those production areas. On the website one can find an updated list of production areas indicating their boundaries and current classification.

The FVO team noted that:-

- All information generated by the official laboratories responsible for LBM testing and the information generated by the CCA and CAs is promptly communicated between them.
- The relevant information is passed to the Coast Guard and other interested stakeholders.
- However, the method of presentation of this data does not allow CAs staff to perform all the necessary controls at establishment level due to the high volume of information and the absence of data on the overall current and historical situation for the Greek production areas.
- In this regard the CCA informed the FVO team that a procurement procedure for the purchase of a database (or informatics system) has been launched in order to overcome the above problem.

Conclusions

Despite the weakness noted above the information exchange system in place broadly meets the requirements of Regulation (EC) No 854/2004.

Recommendation No 17 of the previous audit report, with regard to recording and exchange of information, is considered as addressed.

Food Business Operators' own-checks

The CCA stated in its responses to the pre-audit questionnaire, and confirmed during the

audit, that it does not apply the provisions of point F., Chapter II of Annex II to Regulation (EC) No 854/2004 when classifying production areas.

5.4 OFFICIAL CONTROLS ON *PECTINIDAE* AND LIVE MARINE GASTROPODS NOT FILTER FEEDERS HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Legal Requirements

Article 6 of Regulation (EC) No 854/2004 and Chapter III of Annex II to Regulation (EC) No 854/2004, having particular regard to the CA's official controls to verify FBOs' compliance with Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004; Council Decision 2002/226/EC.

The CCA stated in its responses to the pre-audit questionnaire and confirmed during the audit that Greece does not produce and place on the market *Pectinidae* or non-filter feeding live marine gastropods which are harvested outside classified production areas.

Recommendation No 18 of the previous audit report, with regard to this official control, is considered as no longer applicable.

5.5 OFFICIAL CONTROLS TO VERIFY FOOD BUSINESS OPERATORS' COMPLIANCE WITH THE REQUIREMENTS FOR THE PRODUCTION AND PLACING ON THE MARKET OF BIVALVE MOLLUSCS, ECHINODERMS, TUNICATES AND MARINE GASTROPODS

Legal Requirements

Article 4 of Regulation (EC) No 854/2004, having particular regard to the CA's official controls to verify FBOs' compliance with Regulation (EC) No 852/2004, Regulation (EC) No 853/2004 (section VII and VIII of Annex III) and the microbiological criteria laid down in Regulation (EC) No 2073/2005 .

Requirements for placing on the market

Findings

In order to improve the situation observed during the last FVO audit with regard to the official controls covering the placing on the market of LBM, and in particular the deficiencies noted regarding the handling of the registration document, the CCA drafted a new model of registration document which has recently been implemented.

The FVO team noted that in general the CAs verify the implementation of the requirements of Chapter I, Section VII, of Annex III to Regulation (EC) No 853/2004. Nevertheless, during the current audit the FVO detected minor shortcomings with regard to the completeness and correct filling of the registration documents (mainly in the old model of registration document).

During the official controls exercised by the CAs checks are performed with regard to the requirements of Section VII, of Annex III to Regulation (EC) No 853/2004, for production areas (Chapter II), for the wrapping and packaging of live bivalve molluscs (Chapter VI), for the identification marking and labelling (Chapter VII) and for other requirements (Chapter

VIII).

In relation to the above the FVO team noted that:-

- The control performed by CAs staff encompasses the elements identified above and when deficiencies are noted corrective actions are requested.
- Several shortcomings were identified in different situations which either reveal a weak control or a deficient knowledge of the requirements of Regulation (EC) No 853/2004 by the operators and the official staff. These shortcomings were:-
  - The packaging of LBM destined for direct retail sale does not ensure that the packages will remain closed until they are presented for sale to the final consumer.
  - The use of more than one identification mark on the same label without an explicit indication as to which identification mark the product is primarily linked.
  - The absence of identification of Greece as the producing country in the identification mark.

Conclusions

In general the official control system provides guarantees that FBOs placing LBM on the market comply with the requirements of Regulation (EC) No 853/2004, namely its Annex III, Section VII, Chapters I, II, VI, VII and VIII. However, gaps still exist with regard to the requirements of Chapters VI and VII of that Section, which may undermine the guarantees provided.

Health standards

Findings

During official control activities CAs staff verify if FBOs perform checks on LBM to guarantee that those LBM comply with the health standards defined in Chapter V, Section VII, of Annex III to Regulation (EC) No 853/2004.

The FVO team noted that CA staff carries out the verification mentioned above, however, the checks performed by the operators do not include biotoxin testing of LBM. This fact had not been recorded by the CAs as a non-compliance.

Conclusions

The current official system in place does not guarantee that FBOs ensure that LBM placed on the market meet the health standards laid down in Regulation (EC) No 853/2004, in particular its Chapter V, Section VII, of Annex III.

Dispatch and purification centres

Findings

The CCA has established a risk assessment guideline to categorise approved establishments according to associated risks and from there to establish a frequency for official control visits. After applying the risk assessment the CCA and CAs concluded that dispatch and purification centres should be evaluated twice per year. The CCA drafted a checklist to assess compliance

of dispatch and purification centres with the requirements of Regulation (EC) No 853/2004. Lists of approved dispatch and purification centres are available on the CCA website.

The FVO team noted that:-

- For all approved facilities visited that handle LBM a risk assessment had been carried out defining a risk category resulting in twice yearly inspection based on a specific checklist.
- The checklist in use represent a challenge to the CAs staff with regard to the interpretation of several point mentioned therein. This was commented on in the dialogues with different CAs.
- In all facilities visited during the audit the frequency set for inspection visits had not been followed.
- None of the four purification centres visited can be considered as fully compliant with the requirements of Regulation (EC) No 853/2004, in particular with regard to:-
  - The inability to demonstrate that the purification period is sufficient to achieve compliance with the microbiological criteria (all cases) as per the requirements of point A.3., Chapter IV, Section VII, of Annex III to Regulation (EC) No 853/2004.
  - The possibility to mix different species in the same tank (not observed but described as possible and not prevented), which is not in line with the requirements of point A.4., Chapter IV, Section VII, of Annex III to Regulation (EC) No 853/2004.
  - The observed depth of layers of shellfish present in the purification tanks which prevents the opening of shells during purification. This is not in line with the requirements of point A.5., Chapter IV, Section VII, of Annex III to Regulation (EC) No 853/2004.
- As described in section 5.2. of this report HACCP systems in place had not been evaluated by the CAs responsible for the approval and the ones checked by the FVO team presented several shortcomings.
- The dispatch centres visited during the audit could be considered as compliant with the structural and hygiene requirements of Regulation (EC) No 853/2004.

Conclusions

Currently the control system in place cannot provide guarantees that FBOs (in particular purifications centres) comply with all the applicable requirements laid down in Regulation (EC) No 853/2004, in particular its Chapter IV, Section VII, of Annex III.

Recommendation No 20 of the previous audit report, with regard to purification centres, is considered as not addressed.

Processing establishments

The CCA stated in its response to the pre-audit questionnaire and reiterated during the audit that Greece does not have any establishment processing LBM. At the end of the audit the CCA presented to the FVO team the EFET (Hellenic Food Authority) reply to the CCA

question on this issue. In that response EFET states that Greece does not have any establishment applying heat treatments to LBM harvested in Greek classified production areas. However, there are establishments in Greece that may apply such type of treatments to LBM imported from third countries or originating from production areas located in other Member States. Considering the timing of receipt of this information no establishment was visited by the FVO team and no additional information was collected.

RASFF notifications

Findings

The CCA stated in its responses to the pre-audit questionnaire and confirmed during the audit that in Greece the RASFF contact point is EFET. The CCA is required to coordinate investigations carried out by the CAs and related to RASFFs concerning LBM.

The FVO team assessed the follow-up of seven of the eleven RASFF notifications issued on LBM since the 2011 FVIO audit and found that the investigations have been adequately conducted. In two of these cases legal action was taken by the public prosecutor.

Conclusions

RASFF notifications are adequately followed up by the CCA and CAs involved.

5.6 LABORATORIES

Legal Requirements

Articles 11, 12 and 33 of Regulation (EC) No 882/2004, and Article 3 of Regulation (EC) No 2074/2005.

Findings

Currently the CCA and CAs uses five MRDF laboratories to perform LBM microbiological testing as part of official controls one of which is the NRL for microbiology. Official LBM biotoxins testing is carried out by one of those laboratories which is also NRL for biotoxins. A university laboratory is used for official tests for phytoplankton in water.

Guidance documents were issued by the CCA for the sampling of official control samples and those documents were made available to the CAs in charge of sampling (or controlling the sampling).

As regards LBM sampling (microbiology and biotoxins) and water (phytoplankton) the FVO team noted:-

- All samples are collected by authorised staff that are identified in CAs lists. Those authorised staff include official staff and also FBO employees (mainly LBM gatherers). It was not demonstrated that a conflict of interest is precluded in the case of FBO authorised samplers.

- Training on sampling was provided to samplers but only concerning water sampling for phytoplankton testing.
- The guidance documents issued can be considered adequate for water sampling and LBM sampling for microbiology. The guidance documents covering LBM sampling for biotoxins provide incomplete guidance to authorised samplers.
- In one instance it was seen that the sampling instructions drafted by the official staff in charge of sampling were different from the guidance documents. Although the instructions could be considered in line with EU requirements concerning the microbiological testing, their application would not allow the laboratory in charge of biotoxins testing to adequately perform those tests.

With regard to the laboratories the FVO team noted that:-

- All laboratories have been accredited against ISO 17025 for the relevant methods by the Greek accreditation body (ESYD).
- In general the turnover periods between taking of samples and the communication of test results allows the CCA and/or the CAs to take timely actions.
- The laboratories participate regularly in proficiency tests with, in general, acceptable results.

Microbiology

- Since the 2011 FVO audit the NRL for microbiology has included in its quality manual a document describing the tasks of a NRL as set out in Article 33 of Regulation (EC) No 882/2004. Evidence of the execution of all these tasks was not provided with the exception of the meetings held in October 2014 with two official control laboratories. Also in this regard the FVO team noted that the NRL follow-up of poor results of proficiency tests was limited to the receipt of the justifications provided by the laboratory concerned.
- As regards staff, structures and equipment all laboratories performing official control testing were fit for purpose. However, the NRL presented weaknesses with regard to space available to provide training to official control laboratories (few work stations), space available to guarantee good laboratory practices ("*no way back" layout principle*) and equipment used for the testing of samples.
- The frequency of participation in proficiency testing and their type is insufficient to fully demonstrate competence on the performance of those microbiological tests – once in two years with LBM matrix and once a year with dry lenticules.
- The analytical methods used are the ones indicated in EU regulations.

Biotoxins

- The analytical methods used for routine testing are:
  - Mouse bioassay based on the standard method of Yasumoto *et* al (1978) for lipophilic toxins.
  - Mouse bioassay based on the AOAC official method 959.08 for PSP.
  - HPLC-UV-DAD (High performance Liquid Chromatography with Ultraviolet detection and Diode Array Detector) for ASP.

- These methods are in accordance with Regulation (EC) No 2074/2005.
  - In addition LBM are also tested for lipophilic biotoxins with the LC-MS/MS (Liquid chromatography–mass spectrometry) method [1] when:
  - The mouse bioassay gives positive results.
  - The mouse bioassay shows severe clinical symptoms.
  - Phytoplankton water testing shows presence of species responsible for this toxin
  - Results from previous week demonstrate toxin accumulation.
  - Samples come from Thermaikos Gulf (during 2014).
  - Decisions are required on a previously closed area for the presence of this toxin in LBM.
  - Samples with interesting profile with regard to emerging toxins are found.
- The LC-MS-MS method is not yet accredited against ISO 17025 and the laboratory is undertaking all efforts to achieve accreditation by the end of 2014.
- The laboratory informed the FVO team that they have only one LC-MS/MS and that a maintenance service contract is not yet in place. This, associated with the fact that this is the only laboratory in Greece that performs biotoxins testing of LBM, raises strong reservations that monitoring of production areas for biotoxins cannot be guaranteed as required by Regulation (EC) No 854/2004 and that the laboratory results will be provided to the CCA and CAs allowing them to take timely decisions.
- The sample quantity arriving at the laboratory originated from certain production areas is insufficient for the laboratory to perform all relevant analytical tests for biotoxins.
- The quality controls implemented to ensure the reliability of the test results for PSP is weak taking into account the guides of good laboratory practices.

Conclusions

In general it can be concluded that currently Greece has adequate laboratory capacity to perform official control testing of samples in the framework of the official controls of LBM. However, gaps still exist with regard to the legal and analytical validity of the samples (FBOs samplers) and the performance by the NRL for microbiology of their tasks.

As regards the previous audit report it can be concluded that:-

- Recommendation No 13, with regard to the analytical validity of samples, is considered as not addressed.
- Recommendation No 19, with regard to laboratories, is considered as partially addressed.

1 As of 1st January 2015 this is the only reference method that can be used for testing LBM for lipophilic toxins.

6 OVERALL CONCLUSIONS

Considerable improvements have been made since the 2011 FVO audit, however, the official control system in place covering LBM cannot yet be considered as fully in compliance with all EU requirements. Important shortcomings are still present, notably related to the definition of sampling points for the collection of water for phytoplankton testing and LBM for biotoxins testing, the frequency of monitoring/testing of LBM for one group of toxins (PSP) and the absence of demonstration of the efficiency of the purification systems.

Of the twenty recommendations of the previous 2011 audit, ten can be considered as addressed, three partially addressed, six not addressed (monitoring of biotoxins (for PSP); decisions taken after monitoring; additional monitoring requirements; purification centres; analytical and legal validity of samples; coordination between CAs) and one is no longer applicable.

7 CLOSING MEETING

During the closing meeting held in Athens on 24 October 2014, the FVO team presented the findings and preliminary conclusions of the audit to the CCA.

During this meeting, the CCA acknowledged these findings and conclusions and provided a commitment to correct the deficiencies identified. At this meeting the CCA also stressed that Greece suffers from a severe lack of human resources (highlighted by the fact that the European Commission took legal action against Greece following the conclusion of the Infringement Process N0 2004/3093 on lack of staff for the performance of official controls). The CCA also recalled results of a study presented to SANCO showing that in June 2013 the CCA had a deficit of staff of 43 % and the CAs of 46%.

The CCA also highlighted the fact that current urgent issues, such as blue tongue and sheep pox, forced the different authorities involved to redeploy current available staff to these priorities to the detriment of routine official tasks in other areas (e.g. LBM).

With regard to supervision the CCA highlighted that meetings took place in 2013 and 2014 between the CCA and the CA of Thessaloniki with a view to improving the control system of LBM (copies of the letters provided at the closing meeting).

8 RECOMMENDATIONS

No.	Recommendation
1.	Greek authorities should ensure that official controls are carried out regularly as required by Article 3 (1) of Regulation (EC) No 882/2004.
2.	Greek authorities should ensure that staff performing official control tasks have adequate knowledge that enables them to perform their tasks competently as required by Article 6 of Regulation (EC) No 882/2004.
3.	Greek authorities should ensure that they have procedures in place to verify the effectiveness of the official controls that they carry out as required by Article 8 (3.(a)) of Regulation (EC) No 882/2004.
4.	Greek authorities should ensure that procedures for establishment approval are implemented in accordance with the requirements defined in Regulation (EC) No 882/2004, in particular its Article 31 (2.(c) and 2.(e)) and that the list of approved establishment only indicates establishments that are deemed as compliant with all EU applicable requirements, in particular those of Regulations (EC) Nos 852/2004 and 853/2004.
5.	Greek authorities should draft and make available lists of facilities involved in the production chain of bivalve molluscs, that should be registered under Regulation (EC) No 852/2004, as required by Article 31 (1.(b)) of Regulation (EC) No 882/2004.
6.	Greek authorities should ensure that sanitary surveys carried out with a view to classify production areas or to update their classification follow the requirements defined in Regulation (EC) No 854/2004, in particular its Annex II, Chapter II, point A.6.(a) on shoreline surveys.
7.	Greek authorities should ensure that during or at the end of the process of classification of a production area a sampling plan is established as required by Regulation (EC) No 854/2004, in particular its Annex II, Chapter II, point A.6.(d), indicating at least the number of samples, geographical distribution of the sampling point and sampling frequency. In addition consideration should be given to the "Community Guide" and the "EURL Technical Application Guide" in order to indicate and justify which LBM species are to be sampled.
8.	Greek authorities should draft sampling plans for the monitoring of production areas for microbiological contamination, presence of biotoxins and chemical contaminants of LBM and phytoplankton in water as required in Regulation (EC) No 854/2004, in particular its Annex II, Chapter II, point B.2.
9.	Greek authorities should ensure that the distribution of sampling points defined for the monitoring of production areas for biotoxins and chemical contaminants in LBM and phytoplankton in water are as representative as possible for the area under consideration as required in Regulation (EC) No

No.	Recommendation
	854/2004, in particular its Annex II, Chapter II, point B.2.
10.	Greek authorities should ensure that one LBM species is selected to be used as an indicator species only where the requirements of Regulation (EC) No 854/2004 are correctly applied, in particular its Annex II, Chapter II, point B.6.
11.	Greek authorities should ensure that the frequency of LBM testing for biotoxins, in particular PSP, is defined in accordance with the requirements of Regulation (EC) No 854/2004, in particular its Annex II, Chapter II, point B.5.
12.	Greek authorities should ensure that the actions that are taken when any changes in toxic populations that may lead to toxin accumulation are detected respect the requirements of Regulation (EC) No 854/2004, in particular those of Annex II, Chapter II, point B.7. with regard to LBM sampling frequency and testing.
13.	Greek authorities should ensure that for all classified production areas all chemical contaminants for which Regulation (EC) No 1881/2006 establishes limits are subject to monitoring as required by Regulation (EC) No 854/2004, in particular its Annex II, Chapter II, point B.8.
14.	Greek authorities should ensure that when, in a classified production area the health standards for LBM are exceeded or when there may otherwise be a risk to human health, appropriate decisions are taken as required by Regulation (EC) No 854/2004, in particular its Annex II, Chapter II, point C.
15.	Greek authorities should ensure that a system comprising laboratory testing to verify compliance of end product with the regulatory requirements is put in place and covers all relevant parameters as required by Regulation (EC) No 854/2004, in particular its Annex II, Chapter II, point D.2.
16.	Greek authorities should ensure that LBM placed on the market comply with the relevant requirements concerning the closure of packages for direct sale to final consumer and the identification mark defined in Chapters VI and VII, Section VII, of Annex III to Regulation (EC) No 853/2004.
17.	Greek authorities should ensure that FBOs demonstrate that LBM placed on the market comply with the standards laid down in Chapter V, Section VII, of Annex III to Regulation (EC) No 853/2004.
18.	Greek authorities should ensure that purification centres comply with the relevant requirements defined in Chapters IV, Section VII, of Annex III to Regulation (EC) No 853/2004, in particular its points A.3., A.4. and A.5.
19.	Greek authorities should ensure that samples are collected by official staff or staff under their control in order to ensure the legal and analytical validity of

No.	Recommendation
	the samples and that the quantity of sample arriving to the official laboratories is sufficient for the performance of the required testing.
20.	The NRL for microbiology should ensure that it performs adequately all applicable tasks defined in Article 33 of Regulation (EC) No 882/2004.
21.	Greek authorities and NRLs should ensure that laboratories performing official control testing participate regularly in relevant proficiency testing and that adequate quality controls are in place to guarantee the reliability of the test results.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2014-7127

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dec. 2002/226/EC	OJ L 75, 16.3.2002, p. 65-66	2002/226/EC: Commission Decision of 15 March 2002 establishing special health checks for the harvesting and processing of certain bivalve molluscs with a level of amnesic shellfish poison (ASP) exceeding the limit laid down by Council Directive 91/492/EEC
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