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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

ITALY

FROM 16 TO 26 OCTOBER 2012

IN ORDER TO EVALUATE THE CONTROL SYSTEMS IN PLACE GOVERNING THE PRODUCTION AND PLACING ON THE MARKET OF BIVALVE MOLLUSCS

Executive Summary

The audit was carried out as part of the Food and Veterinary Office audit programme for 2012.

The main purpose of the audit was to verify that the official controls of live bivalve molluscs, including echinoderms, tunicates and marine gastropods are implemented according to the requirements of EU rules and to evaluate 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.

The report concludes that the official controls of live bivalve molluscs echinoderms, tunicates and marine gastropods are organised and carried out at all stages of the production chain and are supported by an accredited laboratory network. Official control of live bivalve mollusc establishments is in general satisfactory. However, these controls present deficiencies which are in particular significant in relation to the classification and monitoring of live bivalve mollusc production areas. Furthermore the central Competent Authority cannot ensure that appropriate verification, at all levels, of the effectiveness, quality and consistency of official control is carried out.

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
ASL	Local Health Unit
ASP	Amnesic Shellfish Poison
CA	Competent Authority
EU	European Union
FVO	Food and Veterinary Office
HACCP	Hazard Analysis of Critical Control Points
ISO	International Organization for Standardization
IZS	*Istituto Zooprofilattico Sperimentale*
MH	Ministry of Health
NRL	National reference Laboratory
PSP	Paralytic Shellfish Poison
SANCO	General Directorate for Health and Consumers

1 Introduction

This audit took place in Italy from 16 to 26 October 2012 and was undertaken as part of the FVO (Food and Veterinary Office) planned audit programme. The audit team comprised two auditors from the FVO and two national experts from EU Member States. An opening meeting was held in Rome on 16 October with the Ministry of Health (MH) which is the central Competent Authority (CA) 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 central CA accompanied the FVO team during the whole audit.

2 Objectives and Scope

The objectives of the audit were to:

- Verify that 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.
- Evaluate 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.

In terms of scope the audit focused mainly on the organisation and performance of the CAs, the official control system in place covering the classification and monitoring of live bivalve mollusc production and relaying areas and the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods. Accordingly, certain aspect of the legislation referred in Annex 1 were used as technical basis for the audit.

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

MEETINGS / VISITS	no.	COMMENTS
Central Competent Authorities Regional Competent Authorities Local Competent Authorities	1	Rome
	2	Sardinia and Marche
	4	Cagliari, Oristano. Fano, Ancona
Laboratories	4	
Production areas	2	
Harvesting vessels	2	
Dispatch and purification centres	3	
Processing establishments	1	

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.

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

4 Background

4.1 Previous FVO reports

The previous FVO audit on this subject in Italy was carried out in 2004 (ref. DG(SANCO)/7026/2004). The report of this audit is available on the Health and Consumers Directorate General website at: http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=1299.

Recommendations relevant to the live bivalve molluscs area concerned the implementation of EU legislation, monitoring and classification of production areas, accreditation of laboratories and the report also stated that relevant toxin testing should cover all species affected.

A General Review Audit was carried out by the FVO in Italy in November 2011 to monitor progress in relation to the open recommendations (three in relation to the 2004 audit report). The report of this audit is available on the Health and Consumers Directorate General website at: http://ec.europa.eu/food/fvo/follow_up_en.cfm?co_id=IT.

The FVO assessment, following the General Review Audit was that actions are still required to address the recommendations concerning bivalve molluscs.

4.2 Production and trade information

According to information provided by EUROSTAT, in 2009, Italy placed on the market around 166,000 tonnes of bivalve molluscs and non-filter gastropods, of which mussels represented 46% and clams 53%.

The Italian central CA informed the audit team that in 2010 Italy placed on the market over 171,466 tonnes of bivalve molluscs and non filter gastropods, of which mussels represented 20% and clams 79%.

4.3 Rapid Alert System for Food and Feed Notifications

Since 2007, 38 alert notifications were issued. These notifications refer mainly to the presence of lipophilic toxins and microbiological contamination above 230 *E.coli*/100g in mussels.

The audit team reviewed the procedures in place for following up alert notifications and found them to be adequate.

5 Findings And Conclusions

5.1 Competent Authorities

Legal Requirements

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

Findings

Responsibility for official controls for live bivalve molluscs is assigned centrally but, in practice,

day to day responsibility for enforcement functions is divided between central, regional and local authorities. The central CA is the MH.

In particular, the Department of Veterinary Public Health, Food Safety and Collegial Bodies for Health Protection has the competencies in the area covered in this audit (see country profile at http://ec.europa.eu/food/fvo/act_getProfile.cfm?pdf_id=125). This Department comprises three Directorates, from which the Directorate General of Food Hygiene, Food Safety and Nutrition and, in particular Office III is dealing with the hygiene of products of animal origin.

The central CA retains responsibility for national coordination, guidance, monitoring, supervision and inspection.

The NAS is a special branch of the Carabinieri (national police force) which operates under the supervision and direction of the MH.

At regional level the responsibility for official control of bivalve molluscs is within the Regional Public Health Services. The regional CA have co-ordination functions while the implementation of controls is carried out at local level by inspectors employed in the Local Health Units (ASLs).

The internal organisation of the Regional Public Health Services differs between regions.

In Sardinia the Prevention Service of the Hygiene and Health Department and the Fisheries Service of the Agriculture Department are responsible for the official controls of bivalve molluscs.

The Fisheries Service of the Agriculture Department is responsible for the classification of the production areas in collaboration with the ASLs. The Prevention Service of the Hygiene and Health Department is responsible for the monitoring of the production areas as well as for the official control of food business operators (dispatch and purification centres and processing establishments).

In Marche the Prevention Service (Veterinary and Food Safety Functional Point) of the Regional Health Department is in charge of the official control of bivalve molluscs.

The coordination of the regional CAs and between the centre and the regions is established via the Standing Conference for Relations between the State, the Regions and Autonomous Provinces.

A bivalve molluscs working group within the Standing Conference has prepared and drafted a guideline for the official control of bivalve molluscs at national level. This working group meets once a month.

This guideline has been approved by the Standing Conference on the 8 July 2010.

The regions have then to transpose this guideline into a regional legal act in order to be able to implement it. The central CA informed the audit team that all the regions included these guidelines into regional acts. The audit team noted that these guidelines were formally adopted in the two regions visited.

In these guidelines it is specified that regions have to report to the central CA on activities carried out in the framework of the bivalve molluscs official controls. Every year by 21 of March every regional CA has to send to the central CA an annual report on the control activities carried out for bivalve molluscs.

This annual report covers mainly the current sanitary status of the live bivalve mollusc production areas, production capacity and reports of non-compliances. However, the current reporting system does not provide to the central CA the necessary data to ensure that the regions properly implement the live bivalve molluscs monitoring programmes in accordance with the national guidelines and with EU legislation.

The central CA informed the audit team that funds are available to establish a national computerised system for data collection in order to have a better reporting tool. The central CA stated that during

2013 the new system is expected to be ready.

As regards the coordination and collaboration of the different services involved in the bivalve molluscs sector in the regions visited the audit team noted:

- In Sardinia there is a division of responsibilities for classification of production areas that requires an effective communication between the two different services involved. This was not in place. For example the Fisheries Service informed the audit team that providing a complete list of monitoring results for the classified areas was complicated due to difficulties experienced accessing data from the relevant ASLs and also from the official laboratory.
- In the same way one ASL visited informed the audit team that a letter regarding the classification of production areas was sent to the Fisheries Service in April 2012 and no reply has yet been received.
- In Sardinia supervision of the bivalve molluscs monitoring programmes implemented by the ASLs is carried out by the Regional CA. ASLs have to send an annual report on activities carried out in the bivalve molluscs sector as specified in the regional CA plan for monitoring of bivalve molluscs. However, for the time being only two out of four annual reports were sent to the regional CA by the ASLs for 2011. These reports should have been received by January 2012.
- In Marche there is no procedure to ensure that the regional CA regularly receives information from the ASLs as regards the implementation of official controls on bivalve molluscs.

The central CA has an audit system in the framework of Regulation (EC) No 882/2004.

Audits can be systems audits of the overall management structure of the regional CA services and sectoral audits looking vertically at the implementation of controls.

In the bivalve molluscs sector two audits were conducted in Friuli and Sardinia in 2011. For 2012 three audits are planned, one already conducted in Sicily, with Campania and Lazio yet to start.

The audit team reviewed the Sardinian audit report where several deficiencies were detected by the central CA auditors in the system of official controls of bivalve molluscs. An action plan was produced by the Sardinian regional CA aimed at addressing the audit report's recommendations.

Most of the deficiencies detected by the FVO audit team during the visits had already been detected by the central CA auditors.

The audit team noted that the regional CA is still working on correcting all the deficiencies detected during the internal audit.

The central CA informed the audit team that at central level it is difficult to take action to ensure that deficiencies in the regions are corrected. The audit team was informed that only in cases where the regions present serious non-compliances can the central government take actions at a political level (economic sanctions).

At regional level, audits and inspections are also conducted by the regional CA to supervise the implementation of the official controls by the relevant ASLs. The audit team also noted that the regional services identified the same deficiencies as the FVO team when auditing ASLs.

In 2012 one audit and four inspections have been conducted in the bivalve molluscs sector in Sardinia. The outcome of the audit was very negative. Immediate recommendations were made for deficiencies noted as serious. Three out of the four inspections had also very negative results. Recommendations were also made to address deficiencies identified.

At the time of the FVO visit the relevant ASLs were working to correct deficiencies noted by the audit and inspections carried out by the regional CA.

During the visit to the regional CA office, the head of the Hygiene and Health Department stated that they have not enough staff to properly carry out all their assigned tasks.

In Marche no audits have been carried out for bivalve molluscs in the last years neither by the central CA nor by the regional CA. Audits on general issues were conducted from 2006 to 2008.

At central level four training sessions were planned on bivalve molluscs in 2012. Three have already been provided in Oristano, Chioggia and Napoli. During the visit to Sardinia the audit team saw evidence of the training session organised in Oristano (2,3 October 2012). The audit team was provided with the content of the course and a list of attendees. This training was organised by the *Istituto Zooprofilattico Sperimentale* (IZS) Umbria-Marche on monitoring of live bivalve molluscs production areas.

In Sardinia one training on live bivalve molluscs is also planned for December 2012 for 100 staff.

Training for auditors was provided in Sardinia for 54 veterinarians in six provinces in July 2012.

Training on Regulation (EC) No 882/2004 (Articles 4 and 6) was also provided in May 2011.

In Marche training was also provided by the regional CA to the officials controlling bivalve molluscs.

The national and regional guidelines provide provisions and instructions on how to carry out inspections of approved establishments. Premises are categorized based on risk assessment. The category given by the ASL to establishments will determine their inspection frequency.

The audit team verified in the ASLs visited that specific local control procedures were established related to live bivalve molluscs official controls which follow the national and regional guidelines for the sector.

Checklists, inspection reports and sampling submission forms are used across the ASLs visited.

Temporary closure notices and notification of classified live bivalve mollusc production and relaying areas were also issued by the regional CA when appropriate.

Conclusions

Competent authorities for the official control of activities within the scope of the FVO audit are designated as required in Article 4 of Regulation (EC) No 882/2004. However, the central CA is not currently in a position to give assurances that regions properly implement national/regional guidelines or EU legislation as the relevant official control data is not yet available to the central CA.

At regional level effective coordination and cooperation is not ensured.

An effective supervision of local CA official controls is not fully implemented.

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 Italy, harvesters/fishermen have to be licensed before they start harvesting live bivalve molluscs.

Purification and dispatch centres and bivalve molluscs processing establishments are approved by the regional CA.

The audit team verified that the procedures in place are followed and are compliant with EU regulations. The audit team checked the approval of one new establishment. In this case the audit team verified that the regional CA had approved this establishment following the prescribed procedure for approval and in accordance with EU requirements.

Approval documents were present in all the establishments visited.

The central CA maintains and updates a list of all approved establishments. In the regions visited an up-to-date list of the approved establishments was also available.

Conclusions

The procedures in place for registration and approval of food business operators are compliant with EU regulations.

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; Council Decision 2002/226/EC.

5.3.1 Classification of production and relaying areas

Findings

Two regions with a total of 120 classified production areas were visited.

Classification of live bivalve mollusc production areas is done using the three classes (A, B or C) and the *E.coli* criteria for those classes foreseen under EU regulations. An additional class is used, "Prohibited", when *E.coli* results/100gr of flesh and intravalvular liquid are above 46,000 *E.coli*/100gr.

All production areas newly classified are required to have a sanitary survey in accordance with national guidelines.

The necessary classification timeframe and minimum data required is set out in national guidelines and in regional plans. The specification (monitoring every two weeks for a minimum of six months) is considered appropriate for the purpose.

In Sardinia all the production areas were classified in the 1990s. In accordance with the regional monitoring plan all classified areas have to be reviewed every three years in order to check if a new classification is necessary.

In 2007 the Fisheries Service in collaboration with the ASLs visited all the existing areas. Boundaries were properly defined and geographical coordinates were given to the sampling points in each area.

In 2011 all the production areas in Sardinia were reclassified. All but five of them were downgraded from A to B class or from B to C class.

In Marche a review was conducted in 2009 where in accordance with the data available for the previous three years some areas were reclassified. The regional CA stated that the review planned

for 2012 was postponed in order to be able to take into account the EU Guide to the "Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Molluscs Production and Relaying Areas with Regard to Regulation (EC) No 854/2004" published in DG SANCO's website in June 2012. The regional CA informed the audit team that the postponed review of classification areas will start soon and will take into consideration the above guide. The Marche CA expects that all the areas will be fully reviewed and reclassified by 2015. To date, the regional CA has not requested the ASLs to conduct a sanitary survey for classification.

In the two regions visited new production areas have recently been classified.

The audit team noted:

- Sanitary surveys as established in Regulation (EC) No 854/2004 had not been conducted in classified production areas for reclassification or to change class category.
- Four new live bivalve mollusc production areas have been classified without conducting the sanitary surveys prescribed in Regulation (EC) No 854/2004.
- Sanitary surveys have not been adequately conducted in two newly classified areas. For these, there is no list of sources of pollutions, no examination of the quantity of organic pollutants which are released during the year, no determination of the characteristic of the circulation of pollutants and no definition of a programme with sampling points to ensure that results of analyses are representative of the areas considered.
- Boundaries of production areas were precisely defined by geographical coordinates and appropriately communicated to producers.
- In one region visited, and for both principal species harvested (clams and mussels), water and bivalve mollusc monitoring points were not precisely defined by geographical coordinates which undermines their representation for the area concerned. Instead monitoring points were located on the basis of a descriptive methodology – for example following the bathometric contour (clams) or at the harvesting point nearest the coast (mussels). The above mentioned EU guideline stipulates that monitoring points should be defined by geographical coordinates – if necessary (for example to ensure adequate access to natural products during sampling) with a geographical tolerance around the defined point. However, it was noted that the actual location of sampling (grid coordinates from GPS) was recorded on the sampling forms.
- In the other region visited sampling points were geographically defined.
- The regional CA classified the areas without having enough data for microbiological parameters as the monitoring time and frequency have not been respected as in the regional plan (Sardinia). The regional and local CA stated that sometimes it is very difficult to complete a monitoring programme in one area due to the lack of collaboration of food business operators. It is important to highlight that the CA need the collaboration of food business operators for monitoring of production areas as the CA does not have its own means to take samples. Also it is the food business operators who pay the monitoring for classification.
- Several production areas were not reclassified even where the monitoring data showed results above the mandatory limit for A, B and C class areas.
- Some production areas have not been monitored for a long time (possibly due to the absence of harvesting) but the given classification was maintained.
- In Sardinia the Fisheries Service is the regional CA that takes the final decision on production area classification. It was noted that this service classified the areas in

accordance with the advice of the relevant ASLs. However, the information provided by the ASLs is not assessed properly by the Fisheries Service to check if the monitoring was properly carried out and or that a sanitary survey had been properly carried out.

- Until 2011 in Sardinia some production areas have been classified or reclassified based on *E. coli* results using an analytical method that is not the EU reference one.

Conclusions

Live bivalve molluscs are harvested from production areas classified in one of three categories according to the level of faecal contamination (class A, B ,C). Boundaries of classified production areas are fixed as required in point A.1 of Chapter II of Annex II to Regulation (EC) No 854/2004.

However, requirements of point A.6 of Chapter II of Annex II to Regulation (EC) No 854/2004 regarding sanitary surveys and sampling programmes for newly classified production areas or reclassification of production areas are not met. Furthermore, in some cases reviews of classification of production areas in the light of the results obtained during monitoring of classified production areas for faecal contamination are not properly carried out. As a result, the requirements of EU legislation for classification of class A production areas regarding health standards for microbiological contamination established in point A.3 of Chapter II of Annex II of Regulation (EC) No 854/2004 are not respected.

5.3.2 Monitoring of classified production and relaying areas

Findings

In the two regions visited a regional sampling plan has been drawn up for the monitoring of the microbiological quality of live bivalve molluscs, of the possible presence of toxin-producing phytoplankton in production water, of the presence of biotoxins in live bivalve molluscs, and of the levels of chemical contaminants in live bivalve molluscs. The regional plans clearly state the frequency of monitoring and the sampling methods.

The regional sampling plans have been drafted in accordance with the national guidelines for the production of live bivalve molluscs.

Sampling for the monitoring of live bivalve molluscs production areas is undertaken by the local CA or by the food business operator.

In the regions visited there are two different systems for production of live bivalve molluscs, farmed mussels and mussels and clams from natural beds. Marine gastropods are also harvested in production areas. The monitoring programme for farmed mussels differs from the one for clams in natural beds. In Marche a special monitoring plan has also been drafted for production areas (more than three miles from the coast) where, amongst other species, marine gastropods are harvested.

Sampling of farmed mussels was observed in the Marche region. Sampling was performed either by officers of the ASLs or by food business operators according to an agreed written procedure. In the case of higher risk (for example previous positive samples or adverse environmental conditions) sampling was performed by the ASL. Samples were obtained using the normal commercial method of harvesting. Water samples for phytoplankton analysis were obtained using a phytoplankton net. Samples were appropriately taken and transported. Bivalve mollusc samples were transported in cool boxes with ice packs. The necessary details (including location grid reference) were recorded on sampling forms.

<u>Microbiological quality of live bivalve molluscs</u>

Regional CA guidelines for monitoring the microbiological quality of bivalve molluscs established

that, at a minimum, samples must be taken every two months in order to monitor the microbiological quality of live bivalve molluscs. Samples are analysed to determine *E.coli* and *Salmonella.*

The EU guidelines recommend, as best practice, a minimum monitoring frequency for non-remote areas of at least monthly. The audit team consider the monitoring frequency established in the CA guidelines as low, particularly for class A areas from where live bivalve molluscs can be directly marketed and in view of the number of results above the regulatory limits of the assigned classification status observed.

In Sardinia a regional working group is currently discussing the change of monitoring frequency to once a month in order to follow the recommended EU guidelines.

In Marche region, samples for mussels are collected in each production area from two sampling points nearest the coast where more contamination is likely to occur. The two samples are then mixed to produce a single sample for testing. In the production areas of natural beds for clams samples are taken by dredging an area of 500 metres parallel to the coast at three to six meters deep and six to nine metres deep. This implies two individual samples for testing per production area.

In Sardinia sampling points are defined by geographic coordinates. Samples are taken from the different designated sampling points within a production area and mixed to produce the final sample. This practice leads to results which may not be representative of the status of the production area concerned, which is not in line with EU requirements. Mixing samples from different locations may bias results, for example by diluting contamination levels of more contaminated locations.

The audit team verified data from monitoring of productions areas in the two regions visited and noted that:

- Frequencies set in the annual regional sampling plans were not respected in most of the ASLs visited.
- Some production areas have not been monitored for a long time (possible due to the absence of harvesting).
- When monitoring results are above regulatory limits, actions are not routinely taken as regards the classification of the production areas concerned. The classification of production areas is reviewed only every three years.
- The regional plans also foresee a weekly intensive monitoring when results are above regulatory limits. This was not confirmed in most of the production areas for which the audit team received monitoring data.
- The geographical distribution of the sampling points for monitoring of production areas is not clearly defined in one region visited.
- Samples from different sampling points are pooled to produce a single one. The sampling methods cannot ensure that the results of the analysis are representative of the areas concerned, which is not in line with EU legislation. Furthermore not all the defined sampling points in individual production areas are regularly monitored.
- Monitoring of production areas where marine gastropods are harvested does not include *E. coli* but S*almonella.*

There is a programme for the monitoring of viruses in Sardinia. It is not part of the official control. This programme detected presence of viruses quite often in production areas. When viruses are detected in a production area a letter is sent to the ASL and to the food business operator in order to intensify the purification process. No other actions are taken as it is neither considered to be a non-

compliance nor part of the official control.

Water from the classified production areas for phytoplankton monitoring

At the time of the audit, the regional CAs had a system in place to monitor the presence of toxin-producing phytoplankton in water. The sample should be representative of the water column. The sampling frequency varied in the two regions visited. Furthermore, in both regions, the information obtained from the monitoring of phytoplankton is only informative as there is no defined action plan to implement if algae values are high. Therefore it is not used to take further actions such as intensification of sampling.

In the region of Marche the frequency is once every two weeks for mussels and no frequency has been established for the production areas of natural beds for clams.

In Sardinia the frequency set is weekly however, for some areas the frequency of monitoring was monthly. In other areas neither of these two frequencies was respected. The regional CA stated that sometimes food business operators refuse to collaborate in sampling.

Presence of biotoxins in live bivalve molluscs

The two regions visited have a regional monitoring plan for biotoxins in live bivalve molluscs. The monitoring plans include all the toxins (amnesic shellfish poison (ASP), paralytic shellfish poison (PSP) and lipophilic toxins).

The monitoring of mussel production areas is carried out at regular intervals and covers all the toxins. In one region the monitoring of clam production areas for the presence of biotoxins is only carried out sporadically.

In Marche fortnightly samples for all toxin groups are taken when the areas are open for harvesting for farmed mussels and mussels in natural beds. For clams produced in natural beds sampling is carried out only if phytoplankton analyses show an increase in toxic algae.

Production areas where marine gastropods are harvested are monitored for the presence of biotoxins in molluscs every three months.

In Sardinia weekly samples for all toxin groups should be taken when the areas are open for harvesting for farmed mussels and mussels and clams in natural beds.

The audit team reviewed several examples of monitoring data for live bivalve mollusc production areas and found that:

- Sampling frequency for biotoxins analysis established in the regional plans is not respected in most of the ASLs visited.
- Sampling frequency for biotoxins analysis in most cases is not weekly. Sampling frequency has been reduced.
- The regional CA could not provide any documented risk assessment to justify a lower sampling frequency for biotoxins.
- In one region visited clams from natural beds are rarely monitored for the presence of biotoxins. The presence of biotoxins in clams is only monitored when toxic producing phytoplankton is detected in the production areas which is difficult to achieve as no monitoring frequency for phytoplankton has been established for these areas.
- The geographical distribution of the sampling points for monitoring of production areas is not clearly defined in one region visited.
- Samples from different sampling points are pooled to produce a single one. The sampling methods cannot ensure that the results of the analysis are representative of the areas

concerned, which is not in line with EU legislation. Furthermore not all the defined sampling points in one production area are regularly monitored.

- Biotoxins is not part of the monitoring programme for marine gastropods in one region visited.

Presence of chemical contaminants in live bivalve molluscs

The two regions visited have a regional monitoring plan for contaminants in live bivalve molluscs. The monitoring plans include heavy metals such as mercury, lead and cadmium. The stipulated sampling frequency is twice a year.

The audit team noted that the stipulated frequency was in most cases respected and samples are taken to monitor for the presence of heavy metals. Dioxins and Polycyclic Aromatic Hydrocarbons are not included in the monitoring plans.

Conclusions

The frequency of monitoring for the presence of toxin-producing phytoplankton in water and for biotoxins in live bivalve molluscs and marine gastropods as well as the frequency of monitoring of the microbiological quality of live bivalve molluscs and marine gastropods was in several cases not carried out according to the one established in the national/regional guidelines or in EU legislation (Point B.5. of Chapter II of annex II to Regulation (EC) No 854/2004). Therefore, sampling frequencies do not ensure that results of analyses are representative of the areas concerned, which is not in line with point B.2. of Chapter II of Annex II to Regulation (EC) No 854/2004. In particular, clams from natural beds are rarely monitored for the presence of biotoxins.

The geographical distribution of the sampling points and the sampling methods used for the monitoring for the presence of toxin-producing phytoplankton in water, for biotoxins in live bivalve molluscs as well as for the monitoring of microbiological quality of live bivalve molluscs cannot ensure that results of the analyses are representative of the areas concerned, which is not in line with Point B.2. of Chapter II of Annex II to Regulation (EC) No 854/2004.

The monitoring of contaminants does not include all the parameters as established in EU requirements.

5.3.3 Decisions after monitoring

Findings

In the two regions visited the regional CAs have procedures to take action when the results of sampling show that the health standards for molluscs are not met.

When the presence of *E. coli* in live bivalve molluscs shows a result above the EU limits in samples taken for monitoring of A or B classified production areas, live bivalve mollusc production areas are not closed for harvesting as a general rule until further microbiological contamination is confirmed. This means that areas with a certain classification (A or B) might remain open despite initial sample results being above the respective regulatory limit.

When microbiological results show *E. coli* above the regulatory limit an intensive sampling should be carried out on a weekly basis. The frequency of sampling in the production areas concerned has to be increased from bimonthly to weekly.

The different ASLs have nevertheless to take measures to ensure that food business operators only place on the market live bivalve molluscs that respect the health standards defined in EU regulations. In case of A class areas, live bivalve molluscs can be sent to a purification centre,

relaying area or processing establishment. In case of B class areas live bivalve molluscs can be sent to a relaying area or to a processing establishment. In both cases the production area is not closed as indicated above.

When the presence of *E. coli* in live bivalve molluscs shows a result above the EU limits in samples taken for monitoring of C classified production areas, live bivalve molluscs production areas are closed for harvesting.

When one or more of the three regulated families of biotoxins in live bivalve molluscs are detected above the regulatory limit, the regional CA closes the areas as soon as it gets the analytical results. The regional CA takes the decision to re-open an area in accordance with EU legislation; based on two negative results (i.e. biotoxins levels are below regulatory limits from two consecutive samples taken not less than 48 hours apart).

When heavy metals are detected above the regulatory limits production areas are also closed.

The audit team noted:

- Procedures for dealing with results outwith classification or above the regulatory limits for biotoxins are implemented by the ASLs. These procedures set out the actions to be taken and the information to be communicated to all the interested parties.
- Whenever regulatory limits are exceeded for biotoxins in live bivalve molluscs, ASLs are responsible for the enforcement of temporary closure notices in the production areas concerned. In Sardinia the municipal authorities are involved in the closure of areas. The audit team noted that production areas closed for harvesting were re-opened, after two consecutive samples (in 48 hours) showing results below the regulatory limits.
- The decisions taken by the regional CA ensure, in general, that live bivalve molluscs harvested from production areas showing results outwith classification are placed on the market by food business operators once they respect the health standards. Examples of actions taken were observed and were correctly implemented. However, in one case one area was not closed when a result was reported above the regulatory limit in a C class production area. The product was allowed to be sent to a relaying area.
- When the presence of *E. coli* in live bivalve molluscs shows a result above the EU limits in samples taken for monitoring of A or B classified production areas, live bivalves molluscs were sent to purification centres, relaying areas or processing establishments.

Regulation (EC) No 854/2004 states that where the analysis results of sampling show that live bivalve molluscs health standards are not respected, the CA must close the production area, and then may reclassify it. In both regions visited frequent examples of non-conformities with the classification requirements for microbiology were observed for class A clam areas. Instead of closure and reclassification, the food business operators were frequently given the option to send product for purification (in the case of non-conformities not exceeding class B levels), to relaying areas or to processing establishments. However, the central CA explained that even if they do not totally disagree with the FVO findings related to decisions after monitoring of production areas they have a different interpretation of the Annex of Regulation (EC) No 854/2004 on that point compared to that of the FVO team.

Conclusions

Decisions after monitoring are taken by the regional CAs when non-compliances are detected. When non-compliances were related to the presence of biotoxins, heavy metals or *E. coli* exceeding class C thresholds, production areas are closed in line with the requirements of Point C of Chapter II of Annex II to Regulation (EC) No 854/2004.

However, when non-compliances were related to the presence of *E. coli* exceeding class A or B thresholds production areas are not closed which is not in line with the requirements of Point C of Chapter II of Annex II to Regulation (EC) No 854/2004.

5.3.4 Additional monitoring requirements

Findings

The audit team verified that a control system comprising laboratory tests to verify food business operators' compliance with the requirements (biotoxins, contaminants and microbiological quality) for the end product at all stages of production, processing and distribution is in place in the visited regions.

The audit team saw evidence that official samples were taken by the regional CAs in the establishments visited. All the results reviewed did not exceed regulatory limits.

Conclusions

Laboratory tests to verify food business operators' compliance with EU requirements as required by Point D.2. of Chapter II of Annex II to Regulation (EC) No 854/2004 were carried out.

5.3.5 Recording and exchange of information

Findings

A list of approved production areas, with details of their location and boundaries, as well as the classification status of the areas has been established and is kept up-to-date by the different ASLs. These lists are regularly communicated to the interested parties, whenever changes in the location, boundaries, class or closures of production areas occur.

However, in one region visited the official laboratory (IZS Umbria-Marche) had a list of production areas that was out of date.

The audit team saw evidence that the regional CAs acted promptly when monitoring indicates that production areas must be closed.

Conclusions

Recording and exchange of information is largely performed as required under Point E. of Chapter II of Annex II to Regulation 854/2004.

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 food business operators' compliance with Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004; Council Decision 2002/226/EC.

Findings

There is no harvesting or production of *Pectinidae* in the two regions visited. The central CA informed the audit team that there is a small production of scallops in other regions but no data was

available on quantities or sites where scallops are harvested.

Marine gastropods are produced in the two regions visited. The regional CA informed the audit team that marine gastropods are only harvested inside production areas.

Conclusion

There is no harvesting of *Pectinidae* and marine gastropods outside production areas in the regions visited.

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 food business operator's 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.

5.5.1 Requirements for placing on the market

Findings

The audit team did not observe the harvesting and handling of live bivalve molluscs following harvest. However, two production areas were visited via harvesting vessels. The audit team accompanied the food business operators and regional CA to collect water and live bivalve molluscs samples from the production areas visited. Conditions observed on board were adequate.

Live bivalve mollusc harvesting associations in collaboration with the regional CA issue registration documents that must accompany every batch of live bivalve molluscs harvested. Information about species, amount, origin, destination and production area sanitary status are filled in and signed by the gatherer and the document accompanies the batch.

At the dispatch/purification centres visited, lists of suppliers of live bivalve molluscs were kept for each batch together with the accompanying document.

Conclusions

Live bivalve molluscs are placed on the market in line with requirements of Chapter I of Annex III to Regulation (EC) No 853/2004.

5.5.2 Official control of food business operators

Findings

The official controls of establishments are carried out by the relevant ASLs in the regions visited.

ASLs are in charge of the approval of purification and dispatch centres and bivalve mollusc processing establishments as well as for the official control inspections. Inspection visits are carried out in accordance with the risk associated with the establishments.

Since 2007, there is a national guideline for inspection, setting out how to establish an inspection frequency. A risk analysis should be carried out annually after which the establishment is

categorised and allocated an inspection frequency.

The ASL concerned must perform a risk assessment and establish a minimum inspection frequency in accordance with the particularities of the establishment.

In Sardinia the determination of the risk for an establishment is defined in the Regional Integrated Control Plan. Every year a risk assessment is conducted.

The audit team verified that the set frequency of inspections and verifications was respected by the regional CA. Checklists and official reports are used. Official samples are also taken when visiting the establishments for end product testing. Sampling forms were available and correctly filled in.

In Marche the determination of the establishment risk is defined in the regional guidelines. The regional CA carries out three types of official control; inspections, verifications and audits. Several reports of inspections and verifications were reviewed by the audit team. Verifications cover structural and hygiene conditions of premises and HACCP plans.

The audit team noted in the ASLs visited that the annual verification of the structural elements of establishments is carried out using a checklist, that only mentions the requirements of Regulation (EC) No 852/2004. The regional CA stated that a new checklist covering aspects of Regulations (EC) Nos 852/2004 and 853/2004 was sent to the ASLs.

In one establishment visited the ASL officials in charge of the establishment did not use the updated checklist sent by the regional CA.

The audit team also noted that in Marche the annual verification of HACCP plans in establishments had not been carried out in the last three years.

Inspection reports are available that identify deficiencies and specify deadlines for correction. Follow-up of the actions taken by the food business operators are carried out.

Conclusions

Live bivalve molluscs are placed on the market in accordance with EU requirements.

The official controls in food business operators are carried out based on risk and the frequency is in general respected by the relevant ASLs. Official controls include official testing of end product.

However, HACCP plan evaluation is not carried out in line with the frequency established by the regional CA.

5.5.3 Facilities handling bivalve molluscs

Findings

The audit team visited one dispatch centre, one processing establishment and two dispatch/purification centres.

One of the dispatch/purification centres for purification of live bivalve molluscs visited is one of the biggest in Italy. In accordance with the data provided more than six thousand tonnes of live bivalve molluscs were purified in 2011. This establishment also purifies live bivalve molluscs from other Member States (mainly from Spain, Greece and France).

All the purification and dispatch centres visited had structural and hygiene conditions that can be considered as compliant with EU legislation.

All establishments visited had an HACCP plan available which was mostly in line with EU requirements. However, the audit team noted that, in one case, some risks were not considered in the risk analysis carried out (i.e. biotoxins, viruses, and some chemical contaminants) and the

identification of the critical control points was not properly justified (no use of a decision tree). Also, the indication of a minimum time of depuration of 18 hours, used as a critical limit was not correctly monitored.

Two establishments conducting purification of products from class B areas were visited. The purification plant equipment was found to be modern and to a high specification. Processes for the treatment of recycling seawater were found to be comprehensive and satisfactory. Regarding purification plant operational parameters the Italian national guideline contains significant guidance and assistance. However, it does not contain any guidance or requirements on the necessary duration of purification. In both plants visited purification times were based exclusively on the time needed to reduce *E.coli* to below the legislative end product standard and did not consider any other microbiological risks.

In one case, the validation of the purification system by the food business operator was absent. The food business operator informed the audit that data from August 2004 until December 2007 was used to validate the system but no report was drafted and communicated to the local or regional CA.

At both establishments visited comprehensive own-check analyses were performed using both internal and external laboratories. At one establishment each batch was tested both before and following purification. The methods used were in accordance with EU reference methods and the results of analyses were satisfactory.

The audit team also visited one dispatch centre that had structural and hygiene conditions that can be considered as compliant with EU legislation. A HACCP plan was available and own-check were carried out regularly to check the main parameters in live bivalve molluscs such as *E. coli*, *Salmonella*, *Vibrio parahaemolyticus*, biotoxins and heavy metals. Official analyses were also carried out for end product testing.

The team visited a further establishment processing live bivalve molluscs and frozen molluscs. The live bivalve molluscs come only from Italy while the frozen bivalve molluscs originate from Members States (mainly Spain) and from third countries. This establishment also conducts sterilization for canned food. The sterilization process was not in operation at the time of the visit. The establishment had structural and hygiene conditions that can be considered in general as compliant with EU legislation. However, only one cold store was used for final product as well as frozen raw material and intermediary products. The risk of cross contamination cannot be ruled out due to the improper separation between the different products categories. Own-checks were carried out in accordance with the stipulated frequency.

Conclusions

The establishments visited are in general compliant with Regulations (EC) Nos 852/2004 and 853/2004. However, the implementation of all HACCP principles was not in line with EU requirements and compliance of food business operators with the requirements of Part A.2 and 3 of Chapter IV of Section VII of Annex II of Regulation (EC) No 853/2004 was not assured by the CAs.

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

Laboratories are designated by the central CA for participation in the official control of the bivalve mollusc sector.

The audit team visited the following four laboratories that participate in official controls of live bivalve molluscs in Italy. Two of them were designated as National Reference Laboratories (NRL) for biotoxins and microbiology:

- IZS Sardinia for biotoxins
- IZS Umbria-Marche for microbiology, also NRL
- Marine Research Centre for biotoxins also NRL
- Sassari University laboratory for phytoplankton

Three of the four laboratories visited have the Italian Accreditation service (ACCREDIA) accreditation to ISO 17025. The Sassari University laboratory for phytoplankton is not accredited. The laboratories mostly used accredited EU reference methods or validated alternative methods, when carrying out official analyses of live bivalve molluscs for biotoxins and microbiology. However, the PSP method used in the IZS of Sardinia is not accredited.

The phytoplankton method used is internationally recognised.

The audit team noted that all laboratories visited have a quality management system in place and participate regularly in proficiency testing with satisfactory results. Facilities and equipment are adequate and well maintained. Staff met during the visits is well trained, committed and very professional.

The NRL for live bivalve molluscs microbiology is the IZS Umbria-Marche. Evidence of its role as NRL was shown to the audit team and found to be in line with EU requirements.

The NRL for live bivalve molluscs biotoxins is the Marine Research Centre. Evidence of its role as NRL was shown to the audit team and found to be in line with EU requirements. This laboratory regularly participates in proficiency testing organised by the EU reference laboratory.

The audit team noted:

- PSP methods used in the IZS of Sardinia and IZS of Umbria-Marche are not performed in accordance with the EU reference method.
- The audit team was informed that the IZS of Sardinia uses the mouse bioassay for PSP. Only one mouse is injected and if it dies after one hour the sample is sent to the NRL for confirmation. However, in the visit to the biotoxins NRL the records kept showed that the laboratory has not received a PSP sample from the IZS of Sassari since 2010 despite the fact that the condition for sending samples to the NRL had been met.
- For the samples reviewed analysis reporting times were found to be satisfactory (four to five days from sampling) and the authorities were immediately notified of non-conformities.
- ACCREDIA did not regularly carry out audits of all analytical methods used for testing live bivalve molluscs. The audit team verified that at least in the last five years no audits on specific tests used in the live bivalve molluscs sector were conducted by the accreditation body.

Conclusions

Laboratories designated by the central CA to carry out official control are accredited to ISO 17025 and use the EU reference methods. However, the method for PSP is not accredited in one laboratory visited and was not properly performed in other two laboratories visited. Furthermore accredited methods are not regularly audited contrary to ISO requirements.

The NRLs visited carried out their duties as established in Article 33.2 (B), (C) of Regulation (EC) No 882/2004.

6 Overall Conclusions

The official controls of live bivalve molluscs echinoderms, tunicates and marine gastropods are organised and carried out at all stages of the production chain and are supported by an accredited laboratory network. Official control of live bivalve mollusc establishments is in general satisfactory. However, these controls present deficiencies which are in particular significant in relation to the classification and monitoring of live bivalve mollusc production areas. Furthermore the Central Competent Authority cannot ensure that appropriate verification, at all levels, of the effectiveness, quality and consistency of official control is carried out.

7 Closing Meeting

A closing meeting was held on 26 October 2012 with representatives of the CAs. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The CAs agreed with most of the findings. However, the central CA stated that, even if they did not totally disagree with the audit team findings related to decisions after monitoring of production areas, its interpretation of point D.1 of Chapter II of Annex II of Regulation (EC) No 854/2004 justifies the actions taken by the regional CA.

8 Recommendations

The Italian CA should provide the Commission services with an action plan, including a time table for its completion, within 25 working days of receipt of the report, in order to address the recommendations mentioned in the following table.

N°.	Recommendation
1.	The central CA should ensure that official controls of live bivalve molluscs are properly implemented by the regional CAs in all Italian regions. The central CA should also ensure efficient and effective coordination and cooperation between CAs as required under Article 4.5 of Regulation (EC) No 882/2004
2.	The CAs should ensure that the requirements regarding sanitary surveys of Point A.6. of Chapter II of Annex II to Regulation (EC) No 854/2004 are taken into account in newly classified areas and when necessary for reclassification of areas
3.	The CAs should ensure that, when classifying a production area, the geographical distribution of the sampling points ensures that the results of the analysis are as representative as possible for the area concerned in accordance with the requirements established in Point A.6. (d) of Chapter II of Annex II to Regulation (EC) No 854/2004
4.	The CAs should ensure that, when monitoring a production area, the geographical distribution of the sampling points and the sampling frequency ensures that the results of the analysis are as representative as possible for the area concerned in accordance with the requirements established in Point B.2 of Chapter II of Annex II to Regulation

N°.	Recommendation
	(EC) No 854/2004
5.	The CAs should ensure that, when monitoring classified production areas, the sampling plan to check for the presence of toxin-producing plankton in production water must take particular account of possible variations in the presence of plankton containing marine biotoxins and that when changes in the composition of plankton containing toxins suggest an accumulation of toxins in molluscan flesh, the sampling frequency of molluscs is to be increased, as established in Point B.4 and 7 of Chapter II of Annex II to Regulation (EC) No 854/2004
6.	The CAs should ensure that, the sampling frequency for biotoxins analyses in all species of molluscs and marine gastropods is in line with Point B.5 of Chapter II of Annex II to Regulation (EC) No 854/2004
7.	The CAs should ensure that the monitoring of chemical contaminants in live bivalve molluscs includes all the relevant substances, in particular those required in Point B.8 of Chapter II of Annex II to Regulation (EC) No 854/2004
8.	The CAs should ensure that, decisions in accordance with EU legislation are taken when live bivalve molluscs health standards for microbiological contamination are exceeded, as required in Point C.1 of Chapter II of Annex II to Regulation (EC) No 854/2004
9.	The CAs should ensure that the requirements established in Article 5 of Regulation (EC) No 852/2004 for HACCP based procedures are fulfilled by food business operators
10.	The CAs should ensure that the official control of food business operators are carried out in accordance with Article 4 of Regulation (EC) No 854/2004 and that food business operators carrying out purification comply with the requirements of Part A.2 and 3 of Chapter IV of Section VII of Annex II of Regulation (EC) No 853/2004
11.	The CAs should ensure that the EU reference method is used for detection of paralytic shellfish poison and that it is accredited according to Article 12.3 of Regulation (EC) No 882/2004
12.	The CAs should ensure that accredited laboratories operate and are assessed following ISO 17025 requirements as set out in Article 12.2 of Regulation (EC) No 882/2004 in order to guarantee that analytical methods within the scope of accreditation are fit for purpose

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6542

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

Legal Reference	Official Journal	Title
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004