

AUDIT
REPORT

Audit on the Follow-up and
Close-out of Non-compliances
- Sea-Fisheries Protection
Authority

AUGUST 2016



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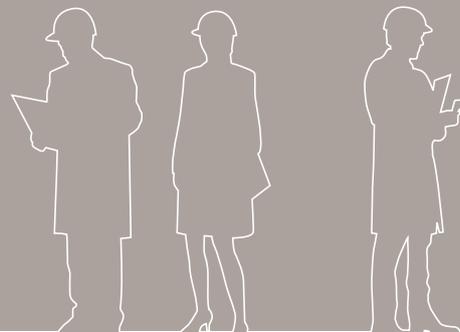


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GLOSSARY

FSAI	Food Safety Authority of Ireland
OAPI	Official Agencies Premises and Inspections Database (food safety database)
SFPA	Sea-Fisheries Protection Authority

1. EXECUTIVE SUMMARY

The Food Safety Authority of Ireland (FSAI) is responsible for the enforcement of all food legislation in Ireland, which is carried out through service contracts with official agencies. The Sea-Fisheries Protection Authority (SFPA) is responsible for official controls in relation to the production and placing on the market of fish, shellfish and fisheries products along the seafood chain up to but excluding the retail stage. This includes official controls on fishing vessels, in shellfish production areas as well as in establishments handling preparing and processing seafood.

As part of its legal mandate, the FSAI is required to verify that the system of official controls is working effectively. For the purposes of assessing the delivery of official controls by the SFPA, it was decided to audit the follow-up and close-out of non-compliances against the requirements of food law identified during official control inspections. Compliance by the SFPA with regard to relevant food legislation, adherence to the terms and requirements of the FSAI service contract as well as conformance with relevant documented procedures, were assessed. Audits were carried out in the Food Safety Unit and three port offices (Clonakilty, Dingle and Killybegs) of the SFPA, and on-site verification took place in six food businesses.

A structured approach for the organisation of staff for the performance of official controls was in place within each of the port offices audited. There had been a reduction in resources in two of the port offices. The lack of resources, coupled with the seasonality of pelagic landings, can pose difficulties for the management of official controls in port offices. Resource issues have also been highlighted in previous FSAI audits.

A risk assessment is required for each land-based approved establishment in order to determine the appropriate inspection frequency; and must be reviewed on an annual basis. While risk assessments had been carried out for each of the establishment files examined, only 40% had their risk assessments reviewed annually in 2014 and 2015. Of the 60% of establishments that did not have annual risk assessment reviews, 53% were subject to review in either 2014 or 2015, but not both.

In terms of planning and coordination of official controls, the audit team confirmed that there was a structured and well organised approach for the coordination and planning of official controls. However, the planned activity does not always take place. Thirty-three establishment files were assessed during the audits in the three port offices with regard to meeting the minimum inspection frequency required in accordance with their assigned risk category. There are nine possible inspection types but only five inspection types count towards achieving the assigned minimum inspection frequency as determined by the risk categorisation for the establishment. These are approval, full hygiene or any routine/follow-up/complaint inspection that encompassed three or more sections of the approved establishment checklist. From the 33 files reviewed during the audit, only 42% met the minimum inspection frequency designated in accordance with their risk categorisation in 2014; and 58% met the minimum inspection frequency in 2015.

The SFPA has documented a suite of procedures to guide sea-fisheries protection officers during official controls. These include the food safety control plan, standard operating procedures (SOPs), codes of practice, report templates and guidance documents on the use of the Official Agency Premises and Inspection (OAPI) database. The audit team found that the SFPA procedures were for the most part, sufficiently detailed to provide guidance for sea-fisheries protection officers during the course of their work. However, further enhancement of the procedures and guidance for staff are required in relation to recording inspection outcomes and the recording of the official controls associated with health certificates.

During the examination of the establishment files, the audit team reviewed the food safety inspection reports and correspondence to food business operators. The records of such inspections were detailed and each non-compliance was addressed individually in the report and correspondence to the food business operator. In many cases, advice and guidance were also provided to the food business operator in relation to the corrective action required by them to ensure compliance with food law. Where non-compliances were identified by the sea-fisheries protection officers as being of a serious nature, follow-up inspections took place. These follow-up inspections were timely and there was significant evidence of the work undertaken by the sea-fisheries protection officer in following up on non-compliances. Additionally, the sea-fisheries protection officers made good use of photographs to illustrate non-compliances to the food business operators, and these were included in the reports to the food business operators. Photographs were also used to demonstrate compliance when non-compliances were closed out. During the on-site verification activity, the audit team assessed the status of between two and fifteen non-compliances, with an average of eight non-compliances being assessed in each of the six establishments. In the six establishments audited, the percentages for outstanding or recurring non-compliances varied from 17% to 50%. In five of the six establishments, there were non-compliances which had been partially addressed, and these varied between 13% and 67%. Non-compliances which had been closed out varied across the six establishments from 33% to 60%. The audit team found that on average, across the six food business establishments, 30% of the non-compliances were outstanding or had recurred at the time of this audit. Thirty percent of non-compliances had been partially addressed by the food business operator, but required further corrective action to achieve compliance with food law. Forty percent of non-compliances had been satisfactorily addressed by the food business operator to comply with the requirements of food law.

The FSAI, in conjunction with the SFPA, developed OAPI, a web-based database system for recording establishment and official controls related to food safety. It provides the SFPA with a system for electronically recording details of the establishments under their supervision. It includes provisions for recording establishment approvals and registrations, as well as recording food safety official control activities in these establishments. The classification of official control checks (such as official controls associated with health certs, testing for histamine, parasite controls on fish, etc.) as a sub-type of inspections could lead to over-reporting of numbers of inspections carried out. In one establishment, 126 inspections were recorded as having taken place in 2014 and 2015. Analysis of the data showed that two routine inspections had taken place in 2014 and one full inspection had taken place in 2015. The remaining 123 official controls over the two-year period related mainly to the issuing of health certs and checks associated with health certs. This establishment was used as an example as the differences were particularly noticeable, due to the very high numbers of health certs being issued in respect of this establishment. In light of the classification of the official control checks as a sub-type of inspections, as in the above establishment, it is noted that there is potential for over-reporting of inspections carried out. The recording of health cert related information on OAPI was not consistent across all of the port offices.

At the time of this audit, OAPI had only two possible outcomes for inspections; "satisfactory" or "unsatisfactory". As a result, sea-fisheries protection officers routinely record the inspection outcome as "satisfactory" even though non-compliances have been identified. In such instances, they have no other option as the non-compliances identified during the inspection are not deemed serious enough to merit an "unsatisfactory" outcome. The FSAI and SFPA are considering amending the documented procedures and OAPI to allow for additional categories to reflect more accurately inspection outcomes.

The current system of recording of official controls associated with health certs on OAPI does not accurately reflect the actual number of official controls undertaken or their outcomes. As official control checks solely associated with health certs are classified as a sub-type of inspections and therefore, require the sea-fisheries protection officer to assign an inspection outcome; which will be satisfactory, if a health cert is issued. This, as a result, will significantly inflate the overall number of official controls classified as satisfactory. The differences in the percentage of inspections being recorded as having a satisfactory outcome when **all** inspection types are included as compared to the percentage satisfactory outcome across those inspection types which count towards the minimum inspection frequency.

The difference is most obvious in the Killybegs Port Office due to the high number of health certs issued and the manner in which they are recorded at that port office, with an average percentage of 77% for satisfactory outcome inspections. When the outcomes are calculated for only those inspections counting towards the minimum inspection frequency; the percentage of satisfactory outcome inspections drops to 16%.

The results of food safety official controls are being recorded in OAPI; however, it is not possible to use the system as a management tool at either central or port office level. Additional training to ensure correct and consistent recording of information and enhancements of the system is required to facilitate its use as a tool for management and allow oversight of official control information both at port office and central level.

The SFPA has established an internal auditing system to review and verify the application of official controls related to food safety. In the initial stages of establishing an internal audit system, the SFPA has contracted a company to conduct a number of internal audits on their behalf. In 2015, two internal audits were carried out. Two further audits are planned for 2016. At the time of the audit, systems to verify the effectiveness of official controls were in place in each of the port offices. Systems in place to monitor progress and highlight any establishments falling behind the designated minimum inspection frequency were in place in each of the port offices, but were not effective. A Key Performance Indicator (KPI) tool, which has been recently developed to assist senior port officers with reviewing progress on official controls being undertaken, was not being implemented in the port offices audited at the time of this audit.

A structured approach for the organisation of staff for the performance of official controls was in place within each of the port offices audited. However, the planned activity does not always take place, with only 58% of the establishments for which inspection frequency was assessed meeting their designated minimum frequency in 2015.

2. INTRODUCTION

The FSAI is responsible for the enforcement of food legislation in Ireland. The FSAI carries out this enforcement function through service contracts with official agencies. These service contracts outline an agreed level and standard of food safety activity that the official agencies perform as agents of the FSAI. The SFPA is one of the agencies that has entered into a service contract with the FSAI and is responsible for enforcing national and EU legislation as it applies to establishments under their supervision. It is a requirement of the service contract and food legislation that the SFPA ensures official controls are carried out regularly, on a risk basis, and with the appropriate frequency.

The SFPA is responsible for official controls in relation to the production and placing on the market of fish, shellfish and fisheries products along the seafood chain up to but excluding the retail stage. This includes official controls on fishing vessels, in shellfish production areas as well as in establishments handling preparing and processing seafood.

As part of its legal mandate, and in accordance with schedule 5 of the service contract, the FSAI is required to verify that the system of official controls is working effectively. For the purposes of assessing the delivery of official controls by the SFPA, it was decided to audit the follow-up and close-out of non-compliances against the requirements of food law identified during official control inspections. Compliance by the SFPA with regard to relevant food legislation, adherence to the terms and requirements of the FSAI service contract as well as conformance with relevant documented procedures were assessed.

This audit with the SFPA was carried out to assess the follow up and close out of non-compliances by the SFPA in land-based approved establishments, under their supervision. This report describes the audit objective, scope, methodology and the findings from the three port offices audited.

2.1. Audit Objective

The objective of this audit was to assess the follow up actions taken by the SFPA in relation to closing out non-compliances identified during official control activities in land-based approved establishments under their supervision.

2.2. Audit Scope

FSAI audits of official controls involve verifying compliance by official agencies regarding the requirements of the FSAI Service Contract, Regulation (EC) No 882/2004 and the Multi-Annual National Control Plan. The scope of the audit was the follow-up and close-out of non-compliances with food law by the SFPA in land-based approved establishments.

Audits were carried out in the Food Safety Unit and three port offices of the SFPA, and on-site verification took place in six establishments.

2.3. Audit Criteria and Reference Documents

- [Food Safety Authority of Ireland Act, 1998](#) (S.I. No. 29 of 1998), as amended.
- [Service Contract between the FSAI & the SFPA](#)
- [The Multi-Annual National Control Plan for Ireland 2012-2016](#)
- [Regulation \(EC\) No 178/2002](#) laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended
- [Regulation \(EC\) No 852/2004](#) on the hygiene of foodstuffs, as amended
- [Regulation \(EC\) No 853/2004](#) laying down specific hygiene rules for food of animal origin, as amended
- [Regulation \(EC\) No 854/2004](#) laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, as amended
- [Regulation \(EC\) No 882/2004](#) on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules, as amended
- [Regulation \(EC\) No 2073/2005](#) on microbiological criteria for foodstuffs, as amended
- [S.I. No. 432/2009: European Communities \(Food and Feed Hygiene\) Regulations, 2009](#)
- Guidance Notes/Codes of Practice and other relevant legislation detailed in the FSAI Service Contract with the SFPA
- SFPA Documented Procedures
- SFPA Food Safety Control Plans

2.4. Audit Methodology

This audit of official controls was undertaken using documented procedures which are included in the FSAI Quality Management System, namely the FSAI Audit Procedure and Charter. These procedures implement the FSAI audit obligations, defined in schedule 5 of the service contract between the FSAI and the SFPA, and are in accordance with the requirements of Regulation (EC) No 882/2004 (including Article 6.1 of Commission Decision 2006/677/EC) and the FSAI Act.

A pre-audit questionnaire was forwarded to the SFPA; the purpose of which was to collate and confirm information regarding official controls and documented procedures within the SFPA, which related to the scope of the audit. An evaluation plan was then developed, which provided a detailed overview of the audit; including audit scope, objectives, criteria and team. The evaluation plan also included a proposed itinerary for on-site activity. The on-site activity in the three port offices; Clonakilty, Dingle and Killybegs, took place during December, 2015 and January, 2016.

The first part of the audit in each port office was spent on desktop activities; commencing with an opening meeting to explain the objective of the audit, the audit methodology and how the audit findings would be reported. The desktop element involved a review of the information provided as part of the pre-audit questionnaire. It also included an audit of paperwork associated with official controls; with an emphasis on follow-up and close-out of non-compliances. Actions taken, arising from non-compliances identified during the course of official control inspections, from January 2014 to the time of this audit, were assessed. This evaluation included assessment of compliance with the requirements of the:

- Legislation
- Service contract between the FSAI and the SFPA, including Guidance Notes and Codes of Practice and
- SFPA documented procedures

Establishment files were used to provide evidence of activity relevant to follow-up and close-out of non-compliances, as appropriate. The files examined by the audit team included establishments in which enforcement action had been taken under the European Communities (Food & Feed Hygiene) Regulations, 2009 (S.I. No. 432 of 2009) or the Food Safety Authority of Ireland Act, 1998 (S.I. No. 29 of 1998).

Evidence of activity relevant to the follow-up and close-out of non-compliances included:

- Reports of official control inspections and audits
- Letters issued to food business operators in cases where non-compliances were identified during official controls,
- Records of enforcement actions taken, for example, copies of Compliance Notices issued under the European Communities (Food & Feed Hygiene) Regulations, 2009 (S.I. No. 432 of 2009) and Improvement Notices and Prohibitions Orders issued under the Food Safety Authority of Ireland Act, 1998 (S.I. No. 29 of 1998) and
- Paperwork associated with the issuing of these notices, including contemporaneous notes and records of consultations between sea-fisheries protection officers and senior port officers

The second part of the audit involved on-site verification in two food business establishments per port office, i.e. a total of six establishments. The on-site verification work included an assessment of the status of the non-compliances which had been identified during official control inspections.

A closing meeting was held at the end of the audit in each of the three port offices; the purpose of which was to outline the main findings from that port office. The findings were discussed and the SFPA staff present were provided with an opportunity to provide clarification and/or additional information, as well as providing feedback on the audit.

Following the three port office audits, an overall closing meeting was held with the SFPA at central level, to outline the findings from the audits. The findings were discussed and the SFPA was provided with an opportunity to provide clarification and/or additional information.

3. AUDIT FINDINGS

3.1. Official Controls performed in accordance with Regulation (EC) No 882/2004

4.1.1. Organisation and Structure of Official Controls

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for the purposes of the official controls set out in the Regulation. It also lays down operational criteria for the competent authorities.

The SFPA has a service contract with the FSAI which outlines the agreed level and standard of seafood safety activity that the SFPA performs as a competent authority. The SFPA has responsibility for the implementation and enforcement of national and EU legislation, which deals with health conditions for the production and placing on the market of fish, shellfish and fisheries products. The SFPA carries out official controls of seafood at all stages of production, processing and distribution with the exclusion of retail establishments. The SFPA has a dedicated Food Safety Unit, the primary function of which is to support and co-ordinate the food safety regulatory activities of the SFPA.

The SFPA has port offices which are managed by senior port officers who are supported by sea-fisheries protection officers and clerical staff. This audit involved audits with the food safety unit and the port offices in Clonakilty, Dingle and Killybegs.

A structured approach for the organisation of staff for the performance of official controls was in place within each of the port offices audited. The sea-fisheries protection officers dedicate approximately 50% of their time for official controls related to food safety. Staffing levels had reduced in Clonakilty by one in 2014, and are due to reduce by another one in 2016. The staffing levels were reduced by three people at the time of this audit in the Killybegs office. Resource issues have also been highlighted in previous FSAI audits. The lack of resources, coupled with the seasonality of pelagic landings, can pose difficulties for the management of official controls in port offices.

4.1.2. Coordination and Planning

Article 4(3) of Regulation (EC) No 882/2004 states when a Member State confers the competence to carry out official controls on an authority or authorities other than a central competent authority, in particular those at regional or local level, efficient and effective coordination shall be ensured between all the competent authorities involved, including where appropriate in the field of environmental and health protection. Article 4(5) of the Regulation requires that, when, within a competent authority more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Responsibility for official controls related to food safety is organised by the senior port officer and sea-fisheries protection officers who have been designated as food safety coordinators. Food safety control inspections are planned at the start of the year and where possible, are focussed between March and September to take account of the work associated with pelagic fish landings during the winter. The Food Safety Unit had in late 2015, introduced a food safety KPI tool, to assist senior port officers with reviewing progress on official controls being undertaken. It was noted that the recently introduced KPI tool was not being implemented in the three port offices.

In terms of planning and coordination of official controls, the audit team confirmed that there was a structured and well organised approach for the coordination and planning of official controls. However, the planned activity does

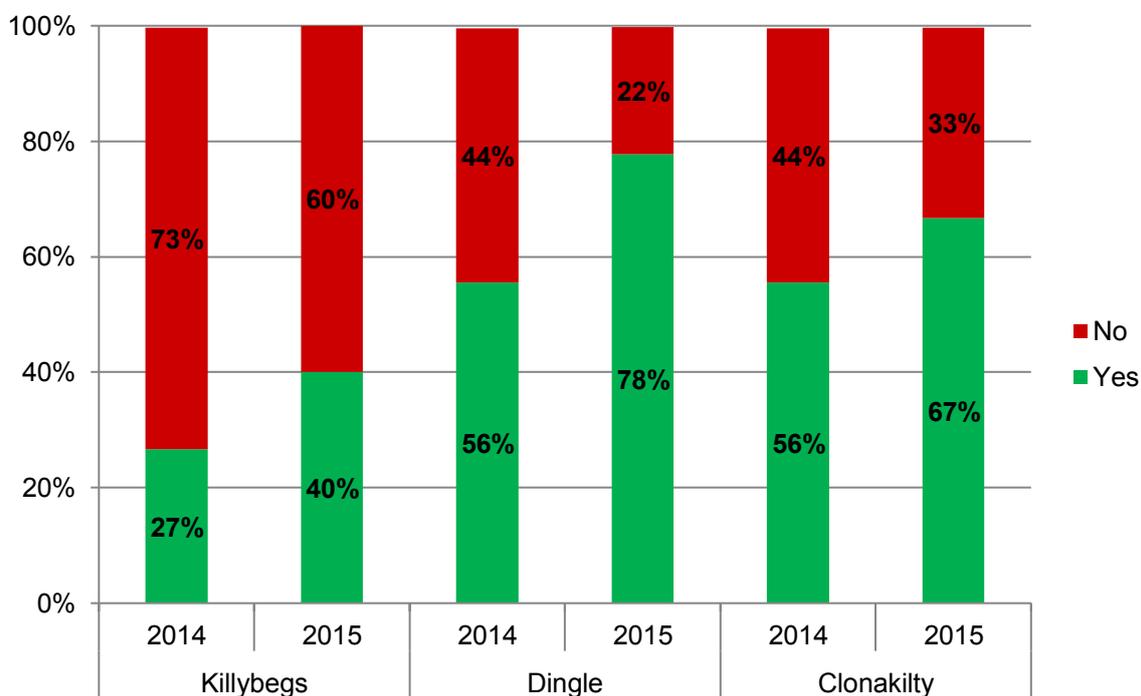
not always take place. Thirty-three establishment files were assessed during the audits in the three port offices with regards to meeting the minimum inspection frequency required in accordance with their assigned risk category. Only 42% of the reviewed files met the minimum inspection frequency designated in accordance with their risk categorisation in 2014; and 58% met the minimum inspection frequency in 2015.

In each of the three port offices audited, there were a number of seasonal establishments, with very restricted operating seasons. The determination of the minimum inspection frequency for these establishments does not take into account the seasonality of the business. However, this seasonality did not account for all of the establishments in which the designated minimum inspection frequency was not met.

The progress of inspections being carried out was being monitored throughout the year by the use of excel spreadsheets and whiteboards by the food safety coordinators and the senior port officers. The results of food safety official controls are being recorded into the SFPA OAPI database, which was developed by the FSAI.

Minimum inspection frequency was assessed across 33 establishment files, 15 in Killybegs and nine each in Dingle and Clonakilty. The percentages in Figure 1 relate to the % of those establishments in which minimum inspection frequency was achieved (or not), based on the establishment's risk categorisation.

Figure 1: Minimum Inspection Frequency



4.1.3. Prioritisation of Official Controls and Risk Categorisation

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. In doing so, account must be taken of identified risks that may influence food safety, past records of food business operator compliance, the reliability of own checks and any additional information on non-compliance. Controls shall in general, be carried out without prior warning.

The SFPA documents annually, a food safety control plan which provides a baseline framework for the official controls carried out by the SFPA's staff. The control plan outlines the food safety controls to be carried out in establishments which are under the supervision of the SFPA and includes detailed descriptions of the official controls and associated tasks that are undertaken in the various establishment types. A risk assessment is required for each land-based approved establishment in order to determine the appropriate inspection frequency; and must be reviewed on an annual basis.

File review conducted during the audit included assessment of the information relating to the risk assessment for 30 land-based approved establishments in the three port offices. Risk assessments had been carried out for each of the establishment files examined and the completed forms were retained in the establishment files. The revised risk assessment review form (introduced in January, 2015) was used and was retained in each of the establishment files for which reviews had been undertaken in 2015. However, only 40% of the 30 establishments had had their risk assessments reviewed annually, as is required by the food safety control plan. Of the 60% of establishments that did not have annual risk assessment reviews, 53% were subject to review in either 2014 or 2015, but not both. In two cases, while the risk assessment had been reviewed and documented in 2015, the previous record of the review of risk assessment was from 2010 in the first case, and 2012, in the second. During the audit, errors were identified in the recording of the risk category for four establishments, all of which were corrected at the time of the audit.

4.1.4. Documented Procedures

Article 8 of Regulation (EC) No 882/2004 requires that competent authorities carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

The SFPA has documented a suite of procedures to guide sea-fisheries protection officers during official controls. These include the food safety control plan, standard operating procedures (SOPs), codes of practice, report templates and guidance documents on the use of OAPI. These documents are available to staff via the SFPA intranet and were noted to be used during the audit.

The audit team found that the SFPA procedures were for the most part, sufficiently detailed to provide guidance for sea-fisheries protection officers during the course of their work. However, following assessment of the classification of audit outcomes as designated by sea-fisheries protection officers, and recorded in OAPI, it became clear that some additional considerations are required in relation to the manner in which the outcome of inspections are recorded. During the review of inspection reports, the audit team noted that there were many inspections which had a recorded outcome of "satisfactory", yet non-compliances had been identified by the sea-fisheries protection officer. The audit team noted in OAPI, that the possible outcomes for inspections are limited to either "satisfactory" or "unsatisfactory". For this reason sea-fisheries protection officers reported that they had determined the outcome to be "satisfactory", as the non-compliances identified during the inspection were not serious enough to merit an outcome of "unsatisfactory". In discussions with the audit team, sea-fisheries protection officers indicated the need for expansion of the number and categorisation of inspection outcomes.

The audit team noted the inspection checklist was used as required and comprehensive contemporaneous notes were available to support non-compliances identified during food safety inspections. The risk assessment review form was used for recording the more recent review of risk categorisations, carried out in 2015 and 2016. However, an incorrect version of the inspection report form had been used for an inspection in one of the food business operators which was selected for on-site verification activities.

Some significant inconsistencies were noted between port offices in relation to the manner in which health certs and the official controls associated with health certs are recorded on the OAPI system. This is further discussed in section 4.1.6. Additional detail in the user manual for OAPI would provide more guidance for staff recording these duties.

4.1.5. Identification, Follow-up and Close-out of Non-compliances

Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies non-compliance, it shall ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance.

Article 8.3 (b) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to ensure that corrective action is taken when needed

During the examination of the establishment files, the audit team reviewed the food safety inspection reports and correspondence to food business operators. Where non-compliances with food law were identified, the audit team reviewed work completed by the food business operator and how this was recorded on subsequent inspections as well as the actions taken by the sea-fisheries protection officer in following them up. The records of such inspections were detailed and each non-compliance was addressed individually in the report and correspondence to the food business operator. In many cases, advice and guidance was also provided to the food business operator in relation to the corrective action required by them to ensure compliance with food law.

Where non-compliances were identified by the sea-fisheries protection officers as being of a serious nature, follow-up inspections took place. These follow-up inspections were timely and there was significant evidence of the work undertaken by the sea-fisheries protection officer in following up on non-compliances. It was noted that in all cases, the food business operator was made aware of the outstanding or recurring non-compliances through the issuing of inspection reports and letters. These outlined clearly and in a detailed manner, the specific non-compliances and the fact that they remained outstanding from previous inspections.

Additionally, the sea-fisheries protection officers made good use of photographs to illustrate non-compliances to the food business operators, and these were included in the reports to the food business operators. Photographs were also used to demonstrate compliance when non-compliances were closed out.

During the audit, the records maintained for a number of enforcement actions taken by sea-fisheries protection officers were reviewed. It was noted that detailed contemporaneous notes are taken by the sea-fisheries protection officer, as well as in some cases, documented statements made by the inspector which outlined all the pertinent issues. Records of consultations between the sea-fisheries protection officer and the senior port officer were also maintained for enforcements taken under the FSAI Act.

Three of the enforcements that had been assigned to the Clonakilty Port Office related to establishments which are not within the port office functional area and had been issued by the Food Safety Unit. One of the enforcements that had been assigned to the Dingle Port Office was relating to an establishment supervised by the Castletownbere Port Office as there is some movement of inspectors between the two offices when the need arises. An Improvement Notice was recorded on an establishment file in OAPI as being issued to a food business operator. Following consultation between the sea-fisheries protection officer and the senior port officer, it was not

issued and a letter was sent to the food business operator. The record of the enforcement notice on OAPI was not amended at the time of the issue but was amended after this audit.

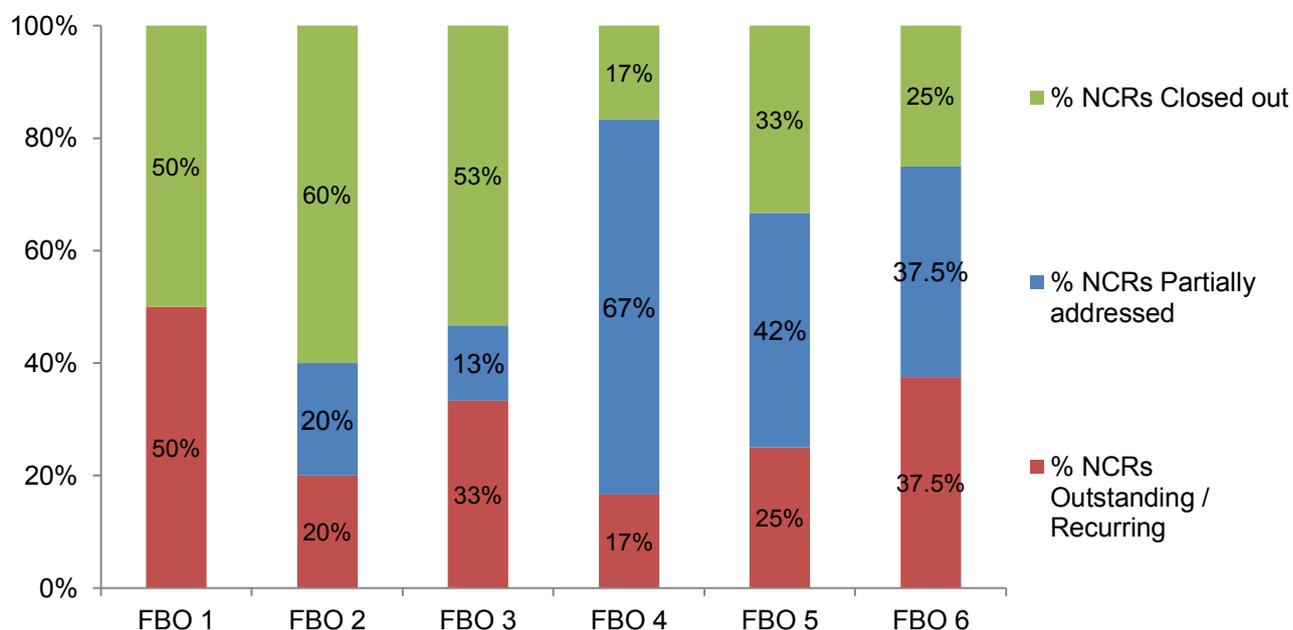
Six establishments were selected for on-site verification. To maximise this aspect of the audit, establishments in which there were a number of non-compliances identified were selected for the on-site verification activity. In each case, official control reports and related paperwork were evaluated and the non-compliances identified were reviewed by the audit team to assess corrective action taken by the food business operator and the follow-up action taken by the SFPA.

The audit team was accompanied by the sea-fisheries protection officer with responsibility for the establishment during the on-site verification audits. Although the focus was on the assessment of non-compliances raised during previous official controls, the audit was not restricted to these findings alone and recorded any additional non-compliances identified on the day. A number of non-compliances which had been previously identified during official controls by the sea-fisheries protection officers were assessed in each of the six establishments.

The audit team calculated the percentage of non-compliances in each of three following categories:

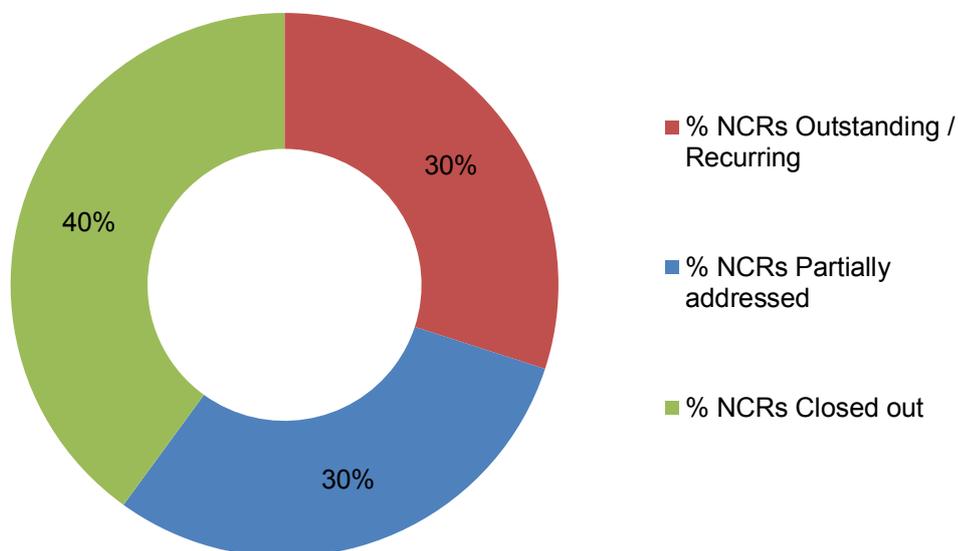
- Closed out – that is, corrective action had been taken by the food business operator to comply with food law
- Outstanding/recurring – that is, corrective action had not been taken by the food business operator to comply with food law or corrective action had been taken, but the non-compliance had recurred
- Partially addressed – that is, corrective action had been taken by the food business operator, but it was insufficient or did not adequately address the non-compliance, and so further corrective action was required to comply with food law

Figure 2: Close-out of Non-compliances by Food Business Establishment



During the on-site verification activity, the audit team assessed the status of between two and fifteen non-compliances, with an average of eight non-compliances being assessed, in each of the six establishments. In the six establishments audited, the percentages for outstanding or recurring non-compliances varied from 17% to 50%. In five of the six establishments, there were non-compliances which had been partially addressed, and these varied between 13% and 67%. Non-compliances which had been closed out, varied across the six establishments from 33% to 60%.

Figure 3: Close-out of Non-compliances ~ Average for the Six Establishments



The audit team found that on average across the six food business establishments, 30% of the non-compliances were outstanding or had recurred at the time of this audit. Thirty percent of non-compliances had been partially addressed by the food business operator but required further corrective action to achieve compliance with food law. Forty percent of non-compliances had been satisfactorily addressed by the food business operator to comply with the requirements of food law.

During the on-site verification work in the fourth establishment, it was found that while corrective action was taken by the food business operator, it did not fully address the non-compliance and therefore, 67% were categorised as being partially addressed. All six of the establishments had non-compliances which the audit team categorised as recurring/outstanding. These related mainly to operational hygiene and structural issues.

Some additional non-compliances were identified by the audit team during the on-site verification work. These were notified to the food business operator at the time and the audit team advised that the sea-fisheries protection officers would follow-up regarding corrective action.

4.1.6. Recording of Official Controls

The FSAI, in conjunction with the SFPA, developed OAPI, a web-based database system for recording establishment and official controls related to food safety. It provides the SFPA with a system for electronically recording details of the establishments under their supervision. It includes provisions for recording establishment approvals and registrations, as well as recording official control activities in these establishments. Records of official control activities related to food safety recorded in OAPI include establishment and food business operator information, inspections, samples and health certificates as well as other official control checks. OAPI was available to and being used by the sea-fisheries protection officers in each of the port offices audited.

In each of the three port offices, there were errors in the information recorded on OAPI relating to registered establishments. These errors related to incorrect addresses recorded for twelve registered establishments, an establishment which had been transferred to another port office in 2015 and had not been re-assigned within OAPI, to the new port office. In addition, two registered establishments in two different port offices were not subjected to official controls. All of the issues identified were rectified immediately by port office staff during or immediately following this audit.

During the review of establishment files, the audit team assessed the information recorded on OAPI relating to inspections and other activities undertaken in establishments. On reviewing the information recorded in OAPI, it became apparent that the classification of official control checks (such as testing for histamine, parasite controls on fish, etc.) as a sub-type of inspections could lead to over-reporting of numbers of inspections carried out. In one establishment, 126 inspections were recorded as having taken place in 2014 and 2015. On analysis of the data for this particular establishment, it was ascertained that two routine inspections had taken place in 2014 and one full inspection had taken place in 2015. The remaining 123 official controls over the two-year period related mainly to the issuing of health certs and the associated checks. This establishment is used as an example as the differences are particularly noticeable due to the very high numbers of health certs being issued in respect of this establishment. In light of the classification of the official control checks as a sub-type of inspections, as in the above establishment, it is noted that there is potential for over-reporting of inspections carried out. The recording of health cert related information on OAPI is not consistent across all of the port offices.

There are nine possible inspection types for sea-fisheries protection officers to select when entering an inspection into OAPI. These are: complaint, follow-up, full hygiene, approval, routine, official control checks, vessel hygiene checks, fish quality and vehicle hygiene. The following types of inspections count towards achieving the assigned minimum inspection frequency as determined by the risk categorisation for the establishment:

- Approval inspection
- Full hygiene inspection, or
- Any routine/follow-up/complaint inspection that encompassed three or more sections of the approved establishment checklist

The inspections carried out in 2014 and 2015 and recorded into OAPI, were in the following proportions:

Table 1: Proportion of each Inspection Type for 2014 & 2015

	Proportion of total Inspections
Official control checks	65%
Routine	14%
Full hygiene	9%
Approval	4%
Follow-up	3%
Vehicle hygiene	2%
Fish quality	2%
Vessel hygiene checks	1%
Complaint	1%

At the time of this audit, OAPI has only two possible outcomes for inspections; “satisfactory” or “unsatisfactory”. As a result, sea-fisheries protection officers routinely record the inspection outcome as “satisfactory” even though non-compliances have been identified. In such instances, they have no other option as the non-compliances identified during the inspection are not deemed serious enough to merit an “unsatisfactory” outcome. In other official agencies, there are up to five possible inspection outcomes one of which, for example, is “satisfactory with minor non-compliances”. The FSAI and the SFPA are considering amending the documented procedures and OAPI to allow for additional categories to reflect more accurately inspection outcomes.

The current system of recording of official controls associated with health certs on OAPI does not accurately reflect the actual number of official controls undertaken or their outcomes. As official control checks solely associated with health certs are classified as a sub-type of inspections and therefore require the sea-fisheries protection officer to assign an inspection outcome; which will be satisfactory, if a health cert is issued. As a result, this will significantly inflate the overall number of official controls classified as satisfactory.

Following the on-site work in the port offices, the audit team calculated the effect of this using the data in OAPI for 2014 and 2015.

Table 2: Satisfactory Inspection Outcome 2014 and 2015

	Clonakilty	Dingle	Killybegs
% Satisfactory outcome across ALL inspection types	84%	76%	77%
% Satisfactory outcome across the inspection types which count towards minimum inspection frequency (Approval, Full, Routine, Complaint and Follow-up)	95%	91%	16%

Table 1 demonstrates the differences in the percentage of inspections being recorded as having a satisfactory outcome when **all** inspection types are included as compared to the percentage satisfactory outcome across those inspection types which count towards the minimum inspection frequency. Once again, the difference is most obvious in the Killybegs Port Office due to the high number of health certs issued at that port office, with an average percentage of 77% for satisfactory outcome inspections. When the outcomes are calculated for only those inspections counting towards the minimum inspection frequency; the percentage of satisfactory outcome inspections drops to 16%.

The results of food safety official controls are being recorded in OAPI. However, it is not possible to use the system as a management tool at either central or port office level. Additional training to ensure correct and consistent recording of information and enhancements of the system are required to facilitate its use as a tool for management and allow oversight of official control information both at port office and central level.¹

4.1.7. Reports to Food Business Operators

Article 9 of Regulation (EC) No 882/2004 requires that competent authorities draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned. The competent authority shall provide the food business operator with a copy of the report on official controls carried out, at least in case of non-compliance.

Article 3 (2) of Regulation (EC) No 882/2004 requires official controls to be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an ad-hoc basis.

It was noted during the file review and on-site verification activities that detailed reports are sent to the food business operator(s) following on-site inspections. These reports specified the aspects of official controls assessed during the inspection, the non-compliances identified, the required corrective action and in some cases, the timeframe for such corrective action to be undertaken. In one of the establishments selected for on-site verification, the sea-fisheries protection officer had also outlined upcoming amendments to legislation, which would have an impact on the food business operator’s testing regime. Additionally, the sea-fisheries protection officers made good use of photographs to illustrate non-compliances identified to the food business operators, and these were included in the reports to the food business operators.

¹ At the time of publication, the SFPA and the FSAI have made enhancements to the OAPI system to take account of the audit findings from this audit.

4.1.8. Verification and Review of Official Controls

Article 4(4) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls.

Article 4(6) of the Regulation requires the competent authorities to carry out internal audits or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Article 8(3) states that the competent authorities must have procedures in place to verify the effectiveness of official controls and to ensure corrective action is taken when needed and to update documentation as appropriate.

The SFPA has established an internal auditing system to review and verify the application of official controls related to food safety. The internal auditing activities are based on a five year audit plan, which is risk-based and examines a cross section of departments throughout the SFPA. The SFPA has set up a specific unit, the Trade Compliance and Internal Auditing Unit, which has been tasked with carrying out internal audits. In the initial stages of establishing an internal audit system, the SFPA has contracted a company to conduct a number of internal audits on its behalf. In 2015, two internal audits were carried out. Two further audits are planned for 2016.

At the time of the audit, systems to verify the effectiveness of official controls were in place in each of the port offices. Depending on the port, the food safety coordinators and the senior port officers plan out the required inspections in accordance with risk categorisation for approved establishments at the start of the year. Planned inspections are reviewed by the food safety coordinator and senior port officer to monitor progress and highlight any establishments falling behind the designated minimum inspection frequency. There were different systems in each of the port offices for managing this, including a traffic light system, a white board system and an excel based system. While these systems review the planned arrangements, there are still some establishments which are not meeting the set inspection frequency corresponding to their risk categorisation. The KPI tool, which has been recently developed for use by all port offices, was not in use in the port offices audited.

Joint inspections, where two sea-fisheries protection officers undertake the relevant official control activity, routinely take place in land-based approved establishments.

4.1.9. Staff Performing Official Controls

Article 4 (2) of Regulation (EC) No 882/2004 requires the competent authority to ensure staff performing official controls are suitably qualified and experienced staff, that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Article 6 of Regulation (EC) No. 882/2004 requires the competent authorities to ensure that staff receive appropriate training and are kept up-to-date in their competencies.

Training for staff is organised centrally, through the Food Safety Unit and details of training undertaken by SFPA staff in 2014 and 2015 were provided to the audit team. The audit team found the staff in the three port offices audited to be very knowledgeable regarding both national and EU legislative requirements. It was clear during the on-site verification visits to the food businesses that good working relationships have been established between the food business operators and the sea-fisheries protection officers. Additionally, the sea-fisheries protection officers have a good knowledge of the food business activities being carried out and the management structures in the establishments visited.

Staff meetings are held throughout the year; at least quarterly, though sometimes more frequently; where food safety is discussed. Additionally, there are informal staff meetings and discussions related to food safety and official control activities as the need arises.

4.2. Food Business Operator Findings

The audit team provided a report to each port office, detailing the findings of the on-site verification work in each of the six establishments.

4.3. Audit Findings ~ Clonakilty Port Office

4.3.1. Organisation and Structure of Official Controls

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for the purposes of the official controls set out in the Regulation. It also lays down operational criteria for the competent authorities.

A structured approach for the organisation of staff for the performance of official controls was in place within the port office. The office is responsible for carrying out official controls in 19 approved establishments. There are five sea fisheries protection officers in the Clonakilty Port Office, with an approximate 50% whole time equivalent for food control. The senior port officer noted that staffing levels reduced by one in 2014 and are due to reduce by another one in 2016. The senior port officer noted that he has a national role in addition to his senior port officer role and so there is a 0.5 whole time equivalent available for port office work.

4.3.2. Coordination and Planning

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities.

Article 4(5) of the Regulation requires that, when, within a competent authority more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Responsibility for official controls related to food safety is organised by the senior port officer and inspections are planned at the start of the year. The Food Safety Unit had, in late 2015, introduced a food safety KPI tool to assist senior port officers with reviewing progress on official controls being undertaken. However, it was noted that the recently introduced KPI tool was not being implemented at port office level. There is an excel spreadsheet that is used to plan and monitor inspections carried out throughout the year. In terms of planning and coordination of official controls, the audit team confirmed that there was a structured and well organised approach for the coordination and planning of official controls at port office level. However, the planned activity does not always take place. There are a number of seasonal establishments the Clonakilty Port Office functional area, which can mean that the minimum inspection frequencies in these food business operators are not always met. Of the nine files reviewed during the audit, 44% of the establishments did not meet the minimum inspection frequency in 2014 and 33% did not meet the minimum inspection frequency required in 2015.

4.3.3. Prioritisation of Official Controls and Risk Categorisation

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. In doing so, account must be taken of identified risks that may influence food safety, past records of food business operators, the reliability of own checks and any additional information on non-compliance.

File review by the audit team included an assessment of the information relating to the risk assessment for seven of the establishments in the Clonakilty Port Office. It was noted that the annual review of establishment risk assessments had been carried out for five of the seven establishment files reviewed and the completed forms were retained in the establishment files. However, in the other two establishments, while there was a review of risk assessment for 2015, the reviews previous to that were from 2010 and 2012. The revised risk assessment

review form (introduced in January 2015) was used and was retained in each of the establishment files. There was one error in the recording of the risk categorisation on OAPI, which was followed up immediately by one of the sea-fisheries protection officers.

4.3.4. Documented Procedures

Article 8 of Regulation (EC) No 882/2004 requires that competent authorities carry out their official controls in accordance with documented procedures containing information and instructions for staff and must keep these procedures up-to-date.

Article 8(3) states that the competent authorities must have procedures in place to verify the effectiveness of official controls and to ensure corrective action is taken when needed and to update documentation as appropriate.

The audit team noted the inspection checklist was used as required and comprehensive contemporaneous notes were available to support non-compliances identified. The risk assessment review form was used for recording the more recent review of risk categorisations.

4.3.5. Identification, Follow-up and Close-out of Non-compliances

Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies non-compliance, it shall ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance.

Article 8.3 (b) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to ensure that corrective action is taken when needed

The review of the establishment files confirmed that when non-compliances with food law are identified during official control inspections, the food business operator is notified of the non-compliances and follow-up action is taken by the inspector, if appropriate. In addition, they are assessed for close-out by the inspector on subsequent inspections. In the two plants visited as part of the on-site verification, it was evident that when non-compliance occurs during official control inspections that there is prompt communication of the breaches of food law and follow-up with the food business operators. Additionally, the sea-fisheries protection officers made good use of photographs to illustrate non-compliances to the food business operators, and these were included in the reports to the food business operators. Additional photographs were also used to demonstrate compliance when a non-compliance was closed out.

During the audit, the records maintained for a number of enforcement actions recorded as being taken by sea-fisheries protection officers from Clonakilty Port Office were reviewed. Three of the enforcements that had been assigned to the Clonakilty Port Office related to establishments which are not within the port office functional area and had been issued by the Food Safety Unit.

4.3.6. Reports to Food Business Operators

Article 9 of Regulation (EC) No 882/2004 requires that competent authorities draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned. The competent authority shall provide the food business operator with a copy of the report on official controls carried out, at least in case of non-compliance.

It was noted during the file review and on-site verification activities that detailed reports are sent to the food business operators following on-site inspections. These reports specified the aspects of official controls assessed during the inspection, the non-compliances identified, the required corrective action and in some cases the timeframe for such corrective action to be undertaken. Additionally, the sea-fisheries protection officers made

good use of photographs to illustrate non-compliances to the food business operators, and these were included in the reports to the food business operators.

4.3.7. Verification and Review of Official Controls and Procedures

Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls

Article 4(4) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls.

Article 4(6) of the Regulation requires the competent authorities to carry out internal audits or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

At the time of the audit, systems to verify the effectiveness of official controls were in place in the Clonakilty Port Office. The food safety inspections are planned in accordance with risk categorisation for approved establishments at the start of the year. Planned inspections are reviewed by the team, to monitor progress and highlight any establishments falling behind the designated minimum inspection frequency. Of the nine files reviewed during the audit, 44% of the establishments did not meet the minimum inspection frequency in 2014, and 33% did not meet the minimum inspection frequency required in 2015.

The KPI tool, which has been recently developed for use by all port offices, was not in use in the Clonakilty Port Office.

Joint inspections where two sea-fisheries protection officers undertake the relevant official control activity, routinely take place in land-based approved establishments.

4.3.8. Staff Performing Official Controls

Article 4 (2) of Regulation (EC) No 882/2004 requires the competent authority to ensure staff performing official controls are suitably qualified and experienced staff, that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Article 6 of Regulation (EC) No 882/2004 requires the competent authorities to ensure that staff receive appropriate training and are kept up-to-date in their competencies.

The audit team found the staff in the Clonakilty Port Office to be very knowledgeable regarding both national and EU legislative requirements and they participated and co-operated fully with the audit. It was clear during the on-site verification visits to the food businesses that good working relationships have been established between the food business operators and the sea-fisheries protection officers. Additionally, the sea-fisheries protection officers have a good knowledge of the food business activities being carried out and the management structures in the establishments visited.

Training for staff is organised centrally, through the Food Safety Unit. Staff meetings are held throughout the year; generally monthly or every two months, where food safety is discussed.

4.3.9. Registration and Approval

Article 31 of Regulation (EC) No 882/2004 requires competent authorities to establish procedures for food business operators to follow when applying for the registration of their establishments in accordance with Regulation. In addition, it requires competent authorities to draw up and keep up-to-date a list of food business operators which have been registered.

Article 3 of regulation 854/ 2004 requires competent authorities to approve establishments in accordance with

Article 31 of Regulation 882. In addition, Article 3(3) states that a competent authority shall give an approval number to establishments manufacturing food of animal origin.

At the time of the audit, there were 19 approved land-based establishments in the Clonakilty Port Office functional area.

4.3.10. Recording of Official Controls

Outcome of inspections

Currently the only inspection outcome choices available on OAPI are limited to “satisfactory” and “unsatisfactory”. This necessitates the need to include inspections which have minor non-compliances as satisfactory as they are not considered serious enough to merit an unsatisfactory outcome.

Official control checks are a sub-type of inspection; therefore they must get an inspection outcome. This impacts on the satisfactory outcome inspection figures, though in the Clonakilty Port Office the difference is slight (84% for all inspections, i.e. including the official control checks, etc. in 2014 and 2015 and 95% satisfactory outcome for full, routine, approval, follow-up and complaint inspections in 2014 and 2015).

4.4. Audit Findings ~ Dingle Port Office

4.4.1. Organisation and Structure of Official Controls

Article 4 of Regulation (EC) No. 882/2004 requires Member States to designate the competent authorities responsible for the purposes of the official controls set out in the Regulation. It also lays down operational criteria for the competent authorities.

A structured approach for the organisation of staff for the performance of official controls was in place within the port office. The office was responsible for carrying out official controls in 11 approved establishments at the time of this audit, one establishment had recently closed. There are four sea-fisheries protection officers in the Dingle Port Office, with an approximate 50% whole time equivalent for food control.

4.4.2. Coordination and Planning

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities.

Article 4(5) of the Regulation requires that, when, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Responsibility for official controls related to food safety is organised by the senior port officer and one sea-fisheries protection officer who is designated as a food safety coordinator. Food safety control inspections are planned at the start of the year, but are focussed between March and September to take account of the work associated with pelagic fish landings during the winter. The Food Safety Unit had, in late 2015, introduced a food safety KPI tool, to assist senior port officers with reviewing progress on official controls being undertaken. It was noted that the recently introduced KPI tool was not being implemented in the Dingle Port Office. The food safety coordinator regularly reviews the inspections carried out to ensure targets are being met. In terms of planning and coordination of official controls, the audit team confirmed that there was a structured and well organised approach for the coordination and planning of official controls in the Dingle Port Office. However, the planned activity does not always take place. There are a number of seasonal establishments, with very restricted operating periods within the Dingle Port Office functional area. This may result in the minimum inspection frequencies in these food business operators not always being met. Of the nine files reviewed during the audit, 44% of the establishments

(four establishments) did not meet the minimum inspection frequency in 2014, and 22% (two establishments) did not meet the minimum inspection frequency required in 2015.

4.4.3. Prioritisation of Official Controls and Risk Categorisation

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. In doing so, account must be taken of identified risks that may influence food safety, past records of food business operators, the reliability of own checks and any additional information on non-compliance.

File review included an assessment of the information relating to the risk assessment of the establishments. It was noted that a review of establishment risk assessments had been carried out for each establishment file reviewed in August 2013 and the completed forms were retained in the establishment files. However, there were no records of the review of risk assessment for 2014. Risk categorisation had been reviewed in August, 2015 for each establishment file examined during the audit. The revised risk assessment review form (introduced in January, 2015) was used and was retained in each of the establishment files.

4.4.4. Documented Procedures

Article 8 of Regulation (EC) No 882/2004 requires that competent authorities carry out their official controls in accordance with documented procedures containing information and instructions for staff and must keep these procedures up-to-date.

Article 8(3) of the Regulation states that the competent authorities must have procedures in place to verify the effectiveness of official controls and to ensure corrective action is taken when needed and to update documentation as appropriate.

The audit team noted the inspection checklist was used as required and comprehensive contemporaneous notes were available to support non-compliances identified. The risk assessment review form was used for recording the more recent review of risk categorisations. However, an incorrect version of the inspection report form had been used for inspection of one of the establishments selected for on-site verification in November, 2015 (Version 5, instead of Version 7).

4.4.5. Identification, Follow-up and Close-out of Non-compliances

Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies non-compliance, it shall ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance.

Article 8.3 (b) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to ensure that corrective action is taken when needed

The review of the establishment files confirmed that when non-compliances with food law are identified during official control inspections the food business operator is notified of the non-compliances and follow-up action is taken by the inspector if appropriate. In addition, they are assessed for close-out by the inspector on subsequent inspections. In the two plants visited as part of the on-site verification, it could be seen that when non-compliance occurs during official control inspections that there is prompt communication of the breaches of food law and follow-up with the food business operators. Additionally, the sea-fisheries protection officers made good use of photographs to illustrate non-compliances to the food business operators, and these were included in the reports to the food business operators.

During the audit, the records maintained for a number of enforcement actions taken by sea-fisheries protection officers were reviewed. One of the enforcements that had been assigned to the Dingle Port Office was relating to an establishment supervised by the Castletownbere Port Office, as there is some movement of inspectors

between the two offices when the need arises. An Improvement Notice was recorded on an establishment file in OAPI as being issued, but following consultation between the sea-fisheries protection officer and the senior port officer, it was not issued and a letter was sent to the food business operator. During the review of risk categorisation undertaken in August 2015, the risk category for this establishment was amended in light of the recent compliance history.

4.4.6. Reports to Food Business Operators

Article 9 of Regulation (EC) No 882/2004 requires that competent authorities draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned. The competent authority shall provide the food business operator with a copy of the report on official controls carried out, at least in case of non-compliance.

It was noted during the file review and on-site verification activities that detailed reports are sent to the food business operators following on-site inspections. These reports specified the aspects of official controls assessed during the inspection, the non-compliances identified, the required corrective action and in some cases, the timeframe for such corrective action to be undertaken. Additionally, the sea-fisheries protection officers made good use of photographs to illustrate non-compliances to the food business operators, and these were included in the reports to the food business operators.

4.4.7. Verification and Review of Official Controls and Procedures

Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls

Article 4(4) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls.

At the time of the audit, systems to verify the effectiveness of official controls were in place in the Dingle Port Office. The food safety coordinator plans out the inspections required in accordance with risk categorisation for approved establishments at the start of the year. Food safety inspections are focussed between March and September to take account of the work associated with pelagic fish landings during the winter. Planned inspections are reviewed by the food safety coordinator to monitor progress and highlight any establishments falling behind the designated minimum inspection frequency. Of the nine files reviewed during the audit, 44% of the establishments (four establishments) did not meet the minimum inspection frequency in 2014, and 22% (two establishments) did not meet the minimum inspection frequency required in 2015.

The KPI tool which has been recently developed for use by all port offices was not in use in the Dingle Port Office.

Joint inspections where two sea-fisheries protection officers undertake the relevant official control activity, routinely take place in land-based approved establishments.

4.4.8. Staff Performing Official Controls

Article 4 (2) of Regulation (EC) No 882/2004 requires the competent authority to ensure staff performing official controls are suitably qualified and experienced, that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Article 6 of Regulation (EC) No 882/2004 requires the competent authorities to ensure that staff receive appropriate training and are kept up-to-date in their competencies.

The audit team found the staff in the Dingle Port Office to be very knowledgeable regarding both national and EU legislative requirements and they participated and co-operated fully with the audit. It was clear during the on-site

verification visits to the food businesses that good working relationships have been established between the food business operators and the sea-fisheries protection officers. Additionally, the sea-fisheries protection officers have a good knowledge of the food business activities being carried out and the management structures in the establishments visited.

Training for staff is organised centrally through the Food Safety Unit. Staff meetings are held throughout the year; (July, November and December in 2015), where food safety is discussed. Additionally, the senior port officer is in the Dingle Port Office on a regular basis and any issues that sea-fisheries protection officers are dealing with regarding inspections, food safety, etc. can be discussed either then or communicated via e-mail.

4.4.9. Registration and Approval

Article 31 of Regulation (EC) No 882/2004 requires competent authorities to establish procedures for food business operators to follow when applying for the registration of their establishments in accordance with the Regulation. In addition, it requires competent authorities to draw up and keep up-to-date a list of registered food business operators.

Article 3 of Regulation (EC) No 854/2004 requires competent authorities to approve establishments in accordance with Article 31 of Regulation (EC) No 882/2004. In addition, Article 3(3) of Regulation (EC) No 854/2004 states that a competent authority shall give an approval number to establishments manufacturing food of animal origin.

At the time of the audit, there were 11 approved land-based establishments; there had previously been 12, but one had recently closed.

There was one registered food business on the list of businesses within the Dingle Port Office, but this was not being actively supervised by the SFPA. The sea-fisheries protection officers followed up on this establishment immediately after the audit and provided the FSAI with an update regarding its status. The food business operator had initially been set up as a distribution depot and applied to the SFPA for registration. The sea-fisheries protection officers contacted the applicant and established that the operation had relocated to Dublin. Furthermore, the food business operator confirmed that fishery products had not been held or distributed from the facility. The establishment will be removed as a registered establishment and OAPI will be amended to remove the establishment from the list of active food business operators in the Dingle Port Office.

4.4.10. Recording of Official Controls

Outcome of inspections

Currently the only inspection outcome choices available on OAPI are limited to “satisfactory” and “unsatisfactory”. This necessitates the need to include inspections which have minor non compliances as satisfactory as they are not considered serious enough to merit an unsatisfactory outcome. The provision of additional outcome categories as well as guidance on outcome classification would be welcomed by the sea-fisheries protection officers in the Dingle office.

Official control checks are a sub-type of inspection; therefore they must get an inspection outcome. This impacts on the satisfactory outcome inspection figures (76% for all inspections, i.e. including the official control checks, etc., in 2014 and 2015 and 91% satisfactory outcome for full, routine, approval, follow-up and complaint inspections in 2014 and 2015).

4.5. Audit Findings ~ Killybegs Port Office

4.5.1. Organisation and Structure of Official Controls

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for the purposes of the official controls set out in the Regulation. It also lays down operational criteria for the competent authorities.

A structured approach for the organisation of staff for the performance of official controls was in place within the port office. The office is responsible for carrying out official controls in 43 approved establishments. There are 11 sea-fisheries protection officers in the Killybegs Port Office, with an approximate 50% whole time equivalent for food control. The senior port officer noted that staffing levels were reduced by three people at the time of this audit.

4.5.2. Coordination and Planning

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities.

Article 4(5) of the Regulation requires that, when, within a competent authority more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Responsibility for official controls related to food safety is organised by the senior port officer and two sea-fisheries protection officers who are designated as food safety coordinators. Food safety control inspections are planned at the start of the year and are monitored on a quarterly basis by one of the food safety coordinators. The Food Safety Unit had, in late 2015, introduced a food safety KPI tool, to assist senior port officers with reviewing progress on official controls being undertaken. The KPI tool, which had been recently developed, was not being implemented in this port office. In the Killybegs Port Office, there is a colour coded system to highlight establishments which have not received the number of planned inspections for each quarter and this is what is used to monitor inspection frequency. In terms of planning and coordination of official controls, the audit team confirmed that there was a structured and well organised approach for the coordination and planning of official controls in Killybegs. However, the planned activity does not always take place. Of the 15 files reviewed during the audit, 73% of the establishments did not meet the minimum inspection frequency in 2014, and 60% did not meet the minimum inspection frequency required in 2015.

4.5.3. Prioritisation of Official Controls and Risk Categorisation

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk-basis and with appropriate frequency. In doing so, an account must be taken of identified risks that may influence food safety, past records of food business operators, the reliability of own checks and any additional information on non-compliance.

File review included an assessment of the information relating to the risk assessment of the establishments. It was noted that full risk assessments had been carried out for each establishment file reviewed and the completed forms were retained in the establishment files. There was an inconsistent approach with regards to the review of the risk for approved establishments, with risk categorisation not being carried out annually, as required by the Food Safety Control Plan, in six of the files reviewed. The risk assessment review form (introduced in January, 2015) was used for recording the more recent review of risk categorisations and was retained on all of the files. There were three errors in the recording of the risk categorisation on OAPI.

4.5.4. Documented Procedures

Article 8 of Regulation (EC) No 882/2004 requires that competent authorities carry out their official controls in accordance with documented procedures containing information and instructions for staff and must keep these procedures up-to-date.

Article 8(3) of the Regulation states that the competent authorities must have procedures in place to verify the effectiveness of official controls and to ensure corrective action is taken when needed and to update documentation as appropriate.

The audit team noted the inspection checklist was used as required and comprehensive contemporaneous notes were available to support non-compliances identified. The risk assessment review form was used for recording the more recent review of risk categorisations.

4.5.5. Identification, Follow-up and Close-out of Non-compliances

Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies non-compliance, it shall ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and the operator's past record with regard to non-compliance.

Article 8.3 (b) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to ensure that corrective action is taken when needed

The review of the establishment files confirmed that when non-compliances with food law are identified during official control inspections the food business operator is notified of the non-compliance and follow-up action is taken by the inspector if appropriate. In addition, they are assessed for close-out by the inspector on subsequent inspections. In the two plants visited as part of the on-site verification, it could be seen that when non-compliance occurs during official control inspections that there is prompt communication of the breaches of food law and follow up with the food business operators.

During the audit, the records maintained for a number of enforcement actions taken by sea-fisheries protection officers were reviewed. It was noted that detailed contemporaneous notes are taken by the sea-fisheries protection officer, as well as in some cases, documented statements made by the inspector which outlined all the pertinent issues. Records of consultations with the senior port officer were also maintained for enforcements taken under the FSAI Act.

4.5.6. Reports to Food Business Operators

Article 9 of Regulation (EC) No 882/2004 requires that competent authorities draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the food business operator concerned. The competent authority shall provide the food business operator with a copy of the report on official controls carried out, at least in case of non-compliance.

It was noted during the file review and on-site verification activities that detailed reports are sent to the food business operator(s) following on-site inspections. These reports specified the aspects of official controls assessed during the inspection, the non-compliances identified, the required corrective action and in some cases, the timeframe for such corrective action to be undertaken. In one of the establishments, the most recent inspection report had outlined that a testing for polycyclic aromatic hydrocarbon (PAHs) would be required in the future, due to new legislation entering into force. The food business operator confirmed that the inspector had advised that this test be included in the annual testing plan for 2016, in order to have a baseline result in advance of the new testing requirement.

4.5.7. Verification and Review of Official Controls and Procedures

Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls

Article 4(4) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls.

At the time of the audit, systems to verify the effectiveness of official controls were in place in the Killybegs Port Office. The food safety coordinators map out the inspections required in accordance with risk categorisation for approved establishments at the start of the year on white boards. This is reviewed quarterly by the food safety coordinator to determine whether inspections are on target and a traffic light system is being used to highlight establishments which have fallen behind on inspection frequency. While some of the establishments have very frequent visits from the sea-fisheries protection officers for the purpose of providing health certificates for export of products, the minimum inspection frequency is not always met. Of the 15 files reviewed during the audit, 73% of the establishments did not meet the minimum inspection frequency in 2014, and 60% did not meet the minimum inspection frequency required in 2015.

The KPI tool, which has been recently developed for use by all port offices, was not in use in Killybegs.

Joint inspections where two sea-fisheries protection officers undertake the relevant official control activity routinely take place in land-based approved establishments.

4.5.8. Staff Performing Official Controls

Article 4 (2) of Regulation (EC) No 882/2004 requires the competent authority to ensure staff performing official controls are suitably qualified and experienced that appropriate and properly maintained facilities and equipment are available; and that staff performing official controls are free of any conflict of interest.

Article 6 of Regulation (EC) No 882/2004 requires the competent authorities to ensure that staff receive appropriate training and are kept up-to-date in their competencies.

The audit team found the staff in the Killybegs Port Office to be very knowledgeable regarding both national and EU legislative requirements and they participated and cooperated fully with the audit. It was clear during the on-site verification visits to the food businesses that good working relationships have been established between the food business operators and the sea-fisheries protection officers. Additionally, the sea-fisheries protection officers have a good knowledge of the food business activities being carried out and the management structures in the establishments visited.

Training for staff is organised centrally, through the Food Safety Unit. Staff meetings are held throughout the year; April and September in 2015; where food safety is discussed. Additionally, in Killybegs, informal discussions take place where any issues that sea-fisheries protection officers are dealing with regarding inspections, food safety, etc. are discussed as they arise and all staff can contribute.

4.5.9. Registration and Approval

Article 31 of Regulation (EC) No 882/2004 requires competent authorities to establish procedures for food business operators to follow when applying for the registration of their establishments in accordance with the Regulation. In addition, it requires competent authorities to draw up and keep up to date a list of registered food business operators.

Article 3 of Regulation (EC) No 854/ 2004 requires competent authorities to approve establishments in accordance with Article 31 of Regulation (EC) No 882/2004. In addition, Article 3(3) of Regulation (EC) No 882/2004 states that a competent authority shall give an approval number to establishments manufacturing food of animal origin.

At the time of the audit, there were 43 approved land-based establishments; there had previously been 44, but one had recently closed.

There was one registered food business on the list of businesses within the Killybegs port office, but this was not being actively supervised by the SFPA. The sea-fisheries protection officer within whose area this business fell (a fish stall), was to follow up with the Health Service Executive and the business to discuss supervision.

4.5.10. Recording of Official Controls

Number of inspections reported

Information from OAPI is counting official control checks as inspections, thereby leading to over-reporting of inspection numbers.

Due to the nature of the businesses supervised by the Killybegs Port Office, there are some food businesses which require numerous health certs to be issued. This results in totals for inspections carried out in these premises being over-reported. For example; 126 inspections recorded in one premises over a two year period. The review by the audit team of those inspection types which count towards achieving the assigned minimum inspection frequency (full, routine, approval, complaint and follow-up) carried out in this premises for 2015 found that it did not meet the minimum inspection frequency for its risk categorisation, i.e. two inspections for a medium non ready-to-eat establishment.

Outcome of inspections

Currently, the only inspection outcome choices available on OAPI are limited to “satisfactory” and “unsatisfactory”

Official control checks are a sub-type of inspection; therefore, they must get an inspection outcome. The current options available are giving a very high % satisfactory outcome inspection figure (77% for all inspections, i.e. including the official control checks, etc., in 2014 and 2015 and 16% satisfactory outcome for approval, full, routine, follow-up and complaint inspections in 2014 and 2015.

Incorrect establishment information recorded on OAPI

There were some anomalies in the establishment information recorded on OAPI for Killybegs Port. During the preparatory work for the audit, 12 establishments supervised by the port had a County Wexford address. These were corrected during the audit.

5. CONCLUSIONS

A structured approach for the organisation of staff for the performance of official controls was in place within each of the port offices audited. However, the planned activity does not always take place, with only 58% of the establishments for which inspection frequency was assessed, meeting their designated minimum frequency in 2015.

The results of food safety official controls are being recorded in OAPI; however, issues were identified with regard to the recording of the information. It is not possible to use the system as a management tool at either central or port office level. Additional training to ensure correct and consistent recording of information and enhancements of the system are required to facilitate its use as a tool for management and allow oversight of official control information both at port office and central level.

6. AUDIT FINDINGS REQUIRING CORRECTIVE ACTION

Audit findings requiring corrective action are listed in the corrective action plan. The audit team provided a report to each port office, detailing the findings of the on-site verification work in each of the six establishments, following the audit. The findings identified during this audit should be disseminated nationally to ensure that corrective actions and opportunities for improvement identified are implemented across all regions.

Link to Corrective Action Plan



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