



Údarás Sábháilteachta Bia na hÉireann
Food Safety Authority of Ireland

AUDIT REPORT

Audit of the Effectiveness of Official
Controls by the Sea-Fisheries
Protection Authority at Ready-To-Eat
Fishery Products Establishments

February 2025



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1 Glossary

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| FSAI | Food Safety Authority of Ireland |
| FFSU | Food and Fisheries Support Unit |
| FBO | Food business operator |
| FSCP | Food Safety Control Plan |
| OAPI | Official Agency Premises Information system |
| OCR | Official Controls Regulation (Regulation (EU) No 2017/625 of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products) |
| RTE | Ready-to-eat |
| SFPA | Sea-Fisheries Protection Authority |
| SFPO | Sea fisheries protection officer |
| SPO | Senior port officer |
| TCIAU | Trade Compliance and Internal Auditing Unit |

2 Executive summary

The Food Safety Authority of Ireland (FSAI) is responsible for the enforcement of all food legislation in Ireland. This is carried out through service contracts with official agencies. The Sea-Fisheries Protection Authority (SFPA) has entered into a service contract with the FSAI that outlines the agreed level and standard of seafood safety activity (official controls) that the SFPA performs as an official agency and competent body.

As part of its legal mandate, the FSAI is required to verify that the system of official controls is working effectively. For the purpose of assessing the delivery of official controls in the official agencies, the FSAI conducts an annual risk-based programme of audits.

This audit of the Effectiveness of Official Controls by the SFPA in ready-to-eat (RTE) fishery products establishments, was undertaken as part of the FSAI's planned programme of audits in 2024. The audit covered the organisation, planning, implementation, and review of official controls within the SFPA at national and regional levels in relation to RTE fishery products establishments in order to confirm compliance with food law, service contract requirements and conformance with the SFPA's own documented procedures.

The audit commenced in the SFPA headquarters in Clonakilty, Cork, on 1 May 2024 and was followed by visits to three port offices. Sixteen food business establishments across five port regions were selected in order to verify the delivery and effectiveness of official controls carried out as well as the level of food business compliance with food law. The FSAI audit team was accompanied throughout the audit by a representative from the SFPA Food Safety Unit and at each food business by sea fisheries protection officers (SFPOs) from the relevant port office.

The audit team found that there is a structured and organised system of official controls in place within the SFPA to verify requirements of food law pertaining to food businesses under their supervision involved in the production of RTE fishery products. SFPOs are duly authorised to carry out official controls and other activities, and to ensure the necessary legislation is in place to support enforcement. Those involved in official controls are suitably qualified and trained to perform this work.

Procedures are in place for those who wish to apply to the SFPA for approval/registration of their food business. All approved RTE fishery products establishments have a unique identification number, a risk rating, a target number of inspections linked to their risk rating and all high-risk RTE fishery products establishments are allocated a supervising SFPO.

SFPO's dedicate their time between official controls related to food law and their responsibilities for the enforcement of fisheries conservation legislation. A baseline framework for official controls in food businesses is contained in the SFPA's Annual Food Safety Control Plan which also includes detailed descriptions of the official controls and associated tasks that are undertaken in the various establishment types. Documented procedures for carrying out official controls have been established in a series of guidance notes and codes of practice in areas such as approval procedures, inspections and sampling as well as templates for inspection reports and sample submissions. The audit team noted that SFPA procedures in general, provided sufficient detail to SFPOs for the performance of official controls.

The SFPA designs official controls based on risk, with a target number of inspections set for each food business operator (FBO) that is linked to the risk assessment rating. The SFPA's documented procedures require that as a minimum a risk assessment review must be carried out for all approved establishments annually and this review should be documented using the Record of Risk Assessment Review Form. However, this form was not completed for a number of files reviewed by the audit team and in some cases the records related to the review were not made available to the audit team either during or after the audit.

Each month, the SFPA Food and Fisheries Support Unit (FFSU) circulates a report detailing the number of inspections conducted at each port in relation to the target number of inspections. These reports include the number of inspections for the individual ports as well as a cumulative total of inspection for all ports. These reports focus primarily on quantitative data, and no formal qualitative analysis of the inspections is performed.

The majority (82% in 2022 and almost 75% in 2023) of SFPA food safety inspections in RTE fishery products establishments were carried out with prior notice, despite the requirement in Regulation (EU) 2017/625 that official controls should be performed without prior notice, except

where such notice is necessary and duly justified. This obligation is repeated in the SFPA food safety control plan. The audit team considers that such a high rate of prior notice inspections could negatively impact the effectiveness of official controls.

Sixteen food business establishments across five port regions were selected in order to verify the delivery and effectiveness of official controls being carried out as well as the level of food business compliance with food law. However, the team did not enter three of the businesses selected as they were not operating, and no personnel were present on-site on the day of the unannounced visit. Of the remaining 13 businesses, only 1 was producing RTE foods on the day of the visit. A compliance notice was issued by the SFPA in one premises visited due to a lack of traceability for some products stored on-site. No significant findings were identified during the audit visits to the remaining 12 premises, however almost all had minor non-compliances identified by the audit team which were outlined to the FBO verbally on the day and will be followed up by the SFPA during subsequent official controls.

3 Introduction

This audit was part of the planned programme of audits of official controls, undertaken by the Food Safety Authority of Ireland (FSAI) in 2024. The FSAI is responsible for the enforcement of all food legislation in Ireland and carries out this enforcement function through service contracts with official agencies.

The Sea-Fisheries Protection Authority (SFPA) has entered into a service contract with the FSAI that outlines the agreed level and standard of seafood safety activity that the SFPA, as a competent authority and official agency, is required to perform. Under the service contract agreement, it has responsibility for the implementation and enforcement of national and European Union (EU) food legislation as it applies to establishments under SFPA supervision.

3.1 Audit objective

The overall objective of the audit was to evaluate official controls carried out by the SFPA in RTE fishery products establishments. The primary objective of the audit was to evaluate the effectiveness of official controls carried out by the SFPA in establishments producing RTE fishery products. The

secondary objective was to assess the compliance of selected food business operators (FBOs) with food law which related to their food business operation.

3.2 Audit scope

The scope of the audit included the structure and organisation of official controls carried out by the SFPA relating to establishments producing RTE fishery products, with an emphasis on establishments producing RTE smoked fish and other RTE products such as pâté, prawn cocktail and cooked meat such as crabmeat. It also included an assessment of a selected number of FBOs' compliance with food law. It assessed whether SFPA authorised officers were complying with the audit criteria against which the audit was carried out. The audit commenced on 1 May 2024 and on-site visits were completed on 12 June 2024. Data used was downloaded from the Official Agency Premises Information system (OAPI) on 21 March 2024. Establishments solely engaged in processing live bi-valve molluscs or sushi were outside the scope of this audit.

The scope included:

- Legislation applicable to official controls
- Documented procedures to ensure that official controls are carried out uniformly, to a consistently high standard and in compliance with planned arrangements
- Inspections, sampling plans and reports of same
- Food business operators' food safety management systems and related records.

3.3 Audit criteria and reference documents

- [Food Safety Authority of Ireland Act, 1998](#) (S.I. No 29 of 1998), as amended.
- [Regulation \(EC\) No 178/2002](#) laying down the general principles and requirements of food law, establishing the European Food Safety Authority, as amended.
- [Regulation \(EU\) 2017/625](#) on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, as amended.
- [Regulation \(EC\) No 852/2004](#) on the hygiene of foodstuffs, as amended.
- [Regulation \(EC\) No 853/2004](#) of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.
- [Regulation \(EC\) No 2073/2005](#) of 15 November 2005 on microbiological criteria for foodstuffs.
- [Regulation \(EU\) No 1169/2011](#) of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers.

- [Regulation \(EU\) No 1379/2013](#) on the common organisation of the markets in fishery and aquaculture products.
- European Union (Food and Feed Hygiene) Regulations 2020 ([S.I. No. 22/2020](#)).
- Other relevant legislation detailed in the [FSAI Service Contract](#).
- Service contract between the FSAI and SFPA (Dated 14 December 2019).
- Relevant FSAI Guidance Notes.
- Ireland's Integrated Multiannual National Control Plan (MANCP) 2021 to 2025.
- Relevant EU Commission Notices, Guidance documents and Guidelines.

3.4 Audit methodology

This audit was undertaken using documented procedures which are included in the FSAI Business Management System, namely the FSAI Audit Procedure and [Audit Charter](#). These procedures implement the FSAI's audit obligations as set out in Section 48 (9) of the Food Safety Authority of Ireland Act, 1998, as amended. They are also in accordance with the requirements of the EU Commission guidance document on the implementation of the provisions for the conduct of audits under Article 6 of Regulation (EU) 2017/625 on official controls and other official activities (Official Controls Regulation (OCR)).

Information maintained within the FSAI was supplemented by that contained in the pre audit questionnaire completed by the SFPA. An evaluation plan describing the audit process including its scope, objectives, the audit team and a proposed draft itinerary was sent to the SFPA ahead of on-site activities.

The audit commenced in the SFPA headquarters in Clonakilty, and involved a high-level overview of SFPA structures and food safety control procedures applicable for the period 1 January 2022 to 23 March 2024. This was followed by visits to three port offices during which the audit team reviewed records of inspections carried out by sea fisheries protection officers (SFPOs) as well as other relevant or supporting information held within the port office regarding approval procedures, risk categorisation, FBO compliance, enforcement details, communications to/from the SFPA and the FBO. Follow-up activities were also evaluated in relation to the close-out of non-compliances identified during official control inspections.

Sixteen food businesses across five port office areas were selected for on-site verification of the delivery and effectiveness of SFPA official control activities, as well as assessment of the level of

FBO compliance with food law. On the day of the visit, the audit team verbally informed SFPA staff of any findings relating to the establishment. A closing meeting with the FBO then took place, during which the audit findings were verbally outlined to the FBO.

Throughout the audit, the FSAI audit team was accompanied by a representative from the SFPA Food Safety Unit and at each food business by SFPOs from the relevant port office.

Following completion of the on-site work, an online meeting was held with SFPA representatives, where a verbal summary of the audit findings was provided.

4 Audit findings

4.1 Official controls performed in accordance with Regulation (EU) No 625/2017

4.1.1 Organisation and structure of official controls

Article 4(1) of the OCR requires Member States to designate the competent authorities responsible for the purposes of the official controls set out in the Regulation. The FSAI is the central competent authority responsible for the enforcement of food legislation in Ireland. Section 48 of the FSAI Act 1998 makes provision for the FSAI to enter into a service contract with official agencies for the purposes of carrying out its functions. The service contract between the FSAI and the SFPA outlines the responsibilities and obligations as well as the agreed level and standard of seafood safety activity that the SFPA performs as a competent authority. For this audit the service contract dated 14 December 2019 between the FSAI and the SFPA was applicable.

The SFPA's headquarters is situated in Clonakilty, Co. Cork, and includes a specialised Food Safety Team within its Food and Fisheries Support Unit (FFSU). Led by the Director of Food & Fisheries Support, this unit facilitates and coordinates the SFPA's food safety regulatory activities. The SFPA has teams of SFPOs and administration staff based in the eight port offices geographically distributed around the Irish coast. Sea fisheries protection officers carry out both food safety and fisheries control duties and work on a roster basis with some ports organised on a 3-cycle shift to provide 24-hour cover and others operate on a 2-cycle shift basis. Each port office

is managed by a senior port officer (SPO). The Food Safety Unit coordinates SFPA activities nationally and collaborates directly with each of the eight port offices that form the regional structure of the organisation

Article 5(1)(e) of the OCR requires competent authorities to have access to a sufficient number of suitably qualified and experienced staff so that official controls and other official activities can be performed efficiently and effectively. Figure 1 below outlines the staffing provision at year end 2023 within the SFPA for the past 6 years and demonstrates an increase in the number of whole-time equivalent (WTE) staff with food safety responsibilities over the 6-year period albeit the increase in WTE posts filled in 2023 was slight.

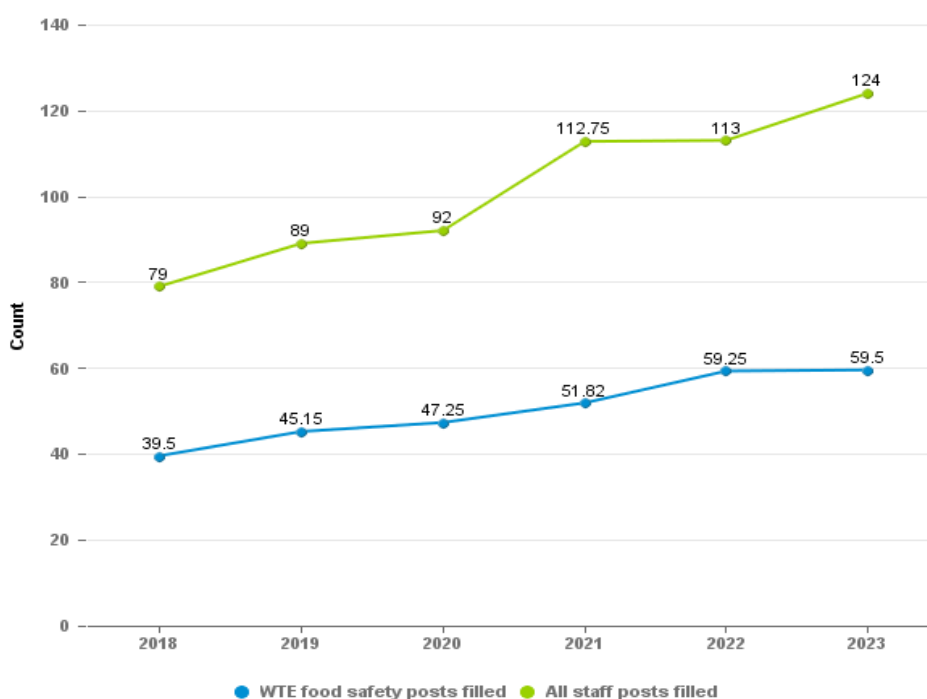


Figure 1: Comparison of all posts filled vs. whole-time equivalent (WTE) staff with food safety responsibilities (2018-2023)

The audit team confirmed that all FBO establishments producing RTE fishery products within the scope of this audit had a risk category recorded on OAPI and that each RTE establishment assessed as high-risk had been allocated a SFPO and in some cases two SFPOs were allocated to some high-risk FBOs.

Schedule 2, Section 4 of the service contract details how conformance with the requirements of the service contract is monitored. The records of the bilateral liaison meetings held in 2022 (3 meetings), 2023 (3 meetings) and the relevant period of 2024 (1 meeting) were reviewed by the audit team, and it was found that the minutes contained information on the discussions of areas of responsibility of all aspects of official controls within the service contract. The service contract requires that the SFPA prepares an Annual Control Plan each year and submits it to the FSAI in the last quarter of the year preceding the year to which it applies, if not submitted by end year, then it must be submitted no later than the end of the first quarter of the calendar year to which it relates. The Annual Control Plan for 2024 was submitted as part of the response to the pre-audit questionnaire and a copy of the Control Plan was submitted to the FSAI's Enforcement Policy team in May 2024. This is not in accordance with the requirement in Section 1.6 of the Service Contract.

4.1.2 General obligations concerning the competent authorities

Article 5 of the OCR requires competent authorities to have the legal powers to perform official controls and other official activities and to take the action provided for in the Regulation.

The legal powers to carry out official controls are conferred on SFPOs by the Food Safety Authority of Ireland Act 1998, the Sea-Fisheries and Maritime Jurisdiction Act 2006 and S.I. No. 22 of 2020 European Communities (Food and Feed Hygiene) Regulations 2020 which gives effect to the OCR. To complete the authorisation process, names of officers are published in Iris Oifigiúil in line with the obligations in the Sea-Fisheries and Maritime Jurisdiction Act 2006.

During the on-site component of the audit, the FSAI team verified that authorised officers performing official controls have been issued with warrants to enforce legal powers under the above legislation and all officers had their warrants in their possession on the day of the audit.

4.1.3 Disclosure of interests

Article 5(1)(c) of the OCR requires competent authorities to have procedures and/or arrangements in place to ensure that staff performing official controls and other official activities are free from any conflict of interest. In addition, Section 57 of the Sea Fisheries and Maritime Jurisdiction Act places an ongoing real time disclosure of interests' obligation on all SFPA staff or others engaged by the SFPA.

In order to facilitate these obligations, the SFPA issues an annual reminder to all relevant persons about their obligation to disclose interests. The reminder includes a statement that the non-disclosure of interests is taken by the SFPA as a declaration that the individual concerned does not have an interest to declare. The audit team was advised that the SFPA considers the issuance of this annual reminder to be sufficient in meeting the obligation to disclose interests.

4.1.4 Training

Article 5(4) of the OCR requires that staff receive appropriate training for their area of competence. Staff receive regular additional training as necessary and also receive training in the subject matters set out in Chapter I of Annex II to the OCR.

A Learning Needs Analysis was completed by the SFPA Human Resources Team in 2022, and was followed by the development of a draft Learning and Development Strategy for the organisation. In 2023, the SFPA introduced SFPA Engage, which is an internal platform that contains online/on-demand courses, information on upcoming courses as well as storing the training records for users. Food safety training records for SFPOs are maintained by FFSU and retained centrally by the Human Resources Team.

Newly recruited SFPOs undergo a 6-to-8-month training period that includes a food safety training programme. At the time of the audit this programme included 29 modules which are delivered in lecture format (face-to-face and online) with corresponding slides and support documents for each module available on SFPA Engage. New recruits also undergo practical training in official control tasks in establishments supervised by the SFPA. In addition to the modules, new SFPOs must complete 11 selected modules available on the FSAI Learning Portal. Before an SFPO is authorised and provided with their warrant, they must successfully complete a QQI level 6: Designing Food Safety Management Systems course.

For existing staff, each year the SFPO and SPO will identify training needs as part of the SFPA's Performance Management and Development System (PMDS). At the time of the audit a mandatory refresher training for SFPOs on Auditing Seafood Premises including Hazard Analysis and Critical Control Points (HACCP), Pre-requisite programmes and Report Writing was operating over a rolling 3.5-year period which began in 2022. An optional Food Standards Auditing Course at

QQI level 6 is available for experienced SFPOs. A total number of 30 SFPOs and 3 HQ staff had completed this optional training at the time of the audit. The FFSU also provide online training sessions, referred to as 'Fish Bites' on specific topics from time to time which are delivered by internal SFPA staff. These recordings, which are 60 to 90 minutes long, are made available on demand for all staff. Email updates of 'lessons learnt' are circulated to staff to raise awareness of application of legislation during specific events both nationally and internationally e.g. one email from December 2023 focused on lessons learnt from some of the Food incidents and Complaints the SFPA dealt with in 2023 while another outlined upcoming changes to legislation e.g. *Listeria*. Staff are also encouraged to attend the Better Training for Safer Food (BTSF) courses and for the period covered by the scope of this audit there were 39 SFPA participants on BTSF physical courses with a further 11 SFPA participants set to attend BTSF courses in the latter half of 2024.

According to the Food Safety Control plan for 2024, all SFPOs are required to complete SFPA arranged training on 'Ice and Water: Assessing Regulatory Requirements'. This training had been proposed for 2023 and moved to 2024 but had not commenced at the time of the audit.

In conclusion, staff encountered during the audit were skilled and knowledgeable of relevant food legislation and they participated and co-operated fully with the audit. It was also clear during the on-site element of the audit, that a good professional working relationship had been established between the SFPOs and the FBO. Additionally for the establishments visited the SFPOs demonstrated good knowledge of the businesses, its activities and management structure.

The induction training for new recruits is comprehensive and the mandatory refresher training for SFPOs on Auditing Seafood Premises including Hazard Analysis and Critical Control Points (HACCP), Pre-requisite programmes and Report Writing will enhance the competence of existing staff. Some training required to be completed during 2023 by SFPOs had not been undertaken and was yet to commence at the time of the audit.

4.1.5 Internal audits

Article 6 of the OCR requires the competent authorities to carry out internal audits or have audits carried out on themselves. It also requires the competent authorities to take appropriate measures considering the results of those audits. Such internal audits shall be subject to independent scrutiny and shall be carried out in a transparent manner.

The SFPA has an internal audit system in place for the assessment of official controls in the areas of seafood safety and sea fisheries control. The Trade Compliance and Internal Auditing Unit (TCIAU) plans the audit programme and coordinates the technical internal auditing system. The draft audit programme proposed by the TCIAU is reviewed by the Management Board and approved by the audit and risk committee. An external company is contracted to carry out the technical internal audit service. The TCIAU has overall responsibility for defining the audit objectives, scope and provides the liaison between the audit team and the SFPA.

During the period 1 January 2022 to March 2024, 2 internal audits were conducted under food safety legislation:

IA Food 2301 Purification and Dispatch Premises

IA Food 2302 Managing Food Incidents

An internal audit on Hygiene in Fish Processing Establishments (IA Food 2401) is also planned for 2024.

An independent scrutiny audit review was carried out by an external contractor in 2023. The report was not reviewed by the audit team. Updates on internal audit programmes are provided to the FSAI at the bilateral internal audit meeting between the FSAI and the SFPA.

4.1.6 Methods and techniques for official controls

Article 14 of the OCR specifies the methods and techniques to be used during official controls and may include the examination of the controls that operators have put in place and of the results obtained, inspection of equipment, cleaning and maintenance products and processes, traceability, labelling and controls on the hygiene conditions in the operators' premises.

The Inspection of Fishery Products and Live Bivalve Molluscs Establishments (Sea Fishery Officers Guidance Document) (Ref: GNA01 25/01/2017) provides guidance on areas to be covered during an inspection and incorporates the requirements of Regulations 178/2002, 852/2004, 853/2004 and 2073/2005 as well as food contact materials, marketing standards and labelling requirements. A comprehensive 'Inspection checklist for Fishery Products and Live Bivalve Molluscs Establishments' (CLA01 Ver.16 14/01/2019) is used during official control inspections by

SFPOs to determine compliance with relevant food law in relation to the suitability of premises, hygiene, transport, equipment, HACCP, training, traceability and labelling. From several FBO files reviewed, the audit team confirmed that the checklist was utilised.

Guidance on Official Control Sampling for Microbiological Analysis (GN G02 (Ver 2) May 2013) provides guidance to SFPOs on the procedures for taking samples while Guidance for SFPA Official Controls: Microbiological Criteria for Fishery Products and Other Seafood (GN G01 Ver.6 24/01/2017) provides guidance to SFPOs regarding the obligations of FBOs and the official microbiological control sampling to be undertaken by the SFPA as the competent authority. Procedures on taking samples for chemical analysis are communicated via email.

Service level agreements are in place between the SFPA and relevant designated official laboratories that enable the SFPA annual scheduled sampling programmes for microbiological and chemical sampling to be undertaken. Each port office is allocated slots in the programme and in most cases, sampling tends to be notified to the FBO to ensure product availability and to facilitate logistics so that the allocated laboratory slot can be used. Official control samples of fishery products, water and ice are taken to verify compliance with criteria and limits set in legislation. In addition, environmental swab samples are taken to monitor for the presence of *Listeria monocytogenes* in RTE fishery products establishments.

Designated official laboratories are used for the analysis of compliance with legislative requirements with non-designated laboratories used for analysis for other purposes on a case-by-case basis with a recommendation by the FFSU that any such analysis is accredited. The Official Control Sample Result Criteria (FFSU FS NOC01 Version 3 08/09/2023) summarises the criteria set out in EU legislation, which are relevant to SFPA official control samples, and provides information to SFPOs on the test type, the food category, the chemical/microorganism to be tested for, the limit, how to interpret the result, the legislation reference and informative comments. Information on any official control samples is held on the laboratory's Laboratory Information Management System (LIMS) and is transmitted directly by the laboratory to the FSAI's Data Collection & Analysis team on a regular basis. During the review of inspection reports it was noted that some inspection reports included notes to record that the FBO's sampling plan had been reviewed by the SFPO and subsequently amended to increase the frequency or scope of sampling by the FBO where the SFPO deemed it necessary.

The audit team found that in general, the methods and techniques utilised by SFPOs during official controls were designed to incorporate all the relevant criteria outlined in Article 14 of the OCR.

4.1.7 Approval of establishments

Article 148 of the OCR requires competent authorities to establish procedures for FBOs to follow when applying for the approval of their establishments. It requires competent authorities to make an on-site visit and specifies that approval of an establishment for the activities concerned can only be given where the FBO has demonstrated that they comply with the relevant requirements of food law. The legislation stipulates that the competent authority may grant conditional approval if it appears that the establishment meets all the infrastructure and equipment requirements. Full approval can be granted only if it appears from a new official control of the establishment, carried out within 3 months of granting conditional approval, that the establishment meets the other relevant requirements of food law. If clear progress has been made but the establishment still does not meet all of the relevant requirements, the competent authority may prolong the conditional approval. In the case of land-based establishments, conditional approval must not exceed a total of 6 months.

The SFPA has procedures in place to support them in ensuring compliance with the provisions of Article 148 of the OCR in regard to the approval of food business establishments. The SFPA website provides information to the public on the registration and approval requirements for seafood establishments and the related application forms are available for download. A Guidance Note on Approving Establishments (Doc Ref: FFSU FS GN AP Version: 3) is available for SFPOs. This document is out of date as it refers to previous legislation on official controls, however a revision of this document was ongoing at the time of the audit. The updated document will be a standard operating procedure (SOP) rather than the current guidance note and is designed to standardise the process for the approval of land-based establishments and fishing vessels under Regulation 853/2004.

Under the procedure in place at the time of the audit, the FBO submits their application form to the FFSU who, following a review of the application, forwards it to the relevant port office for inspection. On completion of the approval inspection by the relevant port office, the inspection report is returned to the FFSU with an SFPO and SPO recommendation. Following a review of that

report and taking into consideration the comments and recommendations of the port officers, a certificate of conditional/full approval is issued by the FFSU. The certificate is sent to the FBO and is accompanied by a cover letter outlining pertinent issues relating to the approval and a copy of the inspection report. A copy of the communication is forwarded to the relevant port for filing with local records. The FFSU updates OAPI, any relevant databases and the website with the approval details and the SFPO logs the inspection details on OAPI.

Of the six files reviewed relating to the period of the audit scope (Jan 2022 to March 2024), all establishments were initially given conditional approval for 3 months followed by a second conditional approval for 3 months prior to granting full approval. A log of applications and the expiration date of the conditional approval is maintained by the FFSU, and an email reminder is issued to the port office by FFSU prior to the expiration date of the conditional approval. In all cases of the files reviewed, an on-site inspection took place prior to the expiration of the first and second conditional approval, and full approval was granted following a further inspection to all six businesses within 6 months of the commencement date of the first conditional approval. Of the sample files selected in the port office, a copy of the approval certificate and accompanying letter from the FFSU to the FBO was observed on the local file.

4.1.8 Review of the register of approved establishments

Article 148 of the OCR obliges competent authorities to keep the approval of establishments under review when carrying out official controls.

From a review of the register of approved establishments and the list of businesses that had been notified to the FSAI via the FFSU as having ceased operation from January 2022 to March 2024, the audit team found all FBOs listed as having ceased operations had been removed from the published approved list. Of three selected files in the port offices visited, a copy of the letter of revocation issued by the FFSU to the FBO was observed on the local file relating to the business.

A review of approval certificates issued by the SFPA had commenced in 2020 and was nearing completion at the time of the audit. Updated approval certificates were issued to a number of businesses to reflect amendments made to the activities for which the FBO was approved, however during on-site visits, it was observed that some approval certificates listed activities that the FBOs were not currently engaged in and in some cases had not been carried out by the FBO in the 6 months prior to the audit visit. In all cases the FBO stated that they requested the retention

of these activities on their approval certification to accommodate customer requests which were time sensitive.

It is recommended that when conducting official controls, inspections should include an assessment of the establishment's capability to perform all the approved activities in accordance with the applicable legislation.

4.1.9 General rules on official controls

Article 9 of the OCR requires competent authorities to perform official controls on all operators regularly, on a risk basis and with appropriate frequency. It also requires that official controls are performed without prior notice, except where such notice is necessary and duly justified for the official control to be carried out.

Risk Basis

The SFPA's Code of Practice for the Risk Assessment of Approved Establishments including Freezer and Factory Vessels (COP RA01 Ver 9 11 Feb 2020) outlines how an approved establishment may be categorised according to risk and how the frequency of official control inspections for that establishment is determined. Using the scoring system outlined in the COP and according to the risk associated with their activities and other influencing factors, establishments can be categorised as low, medium or high-risk. The establishment inspection frequency is then determined using the Figure of Minimum Inspection Frequencies per Annum contained in the document. In the case of RTE food products establishments, the minimum inspection frequency outlined in the COP (RA01 Ver 9 11 Feb 2020) is as follows:

- Low-Risk Category: two inspections
- Medium-Risk Category: three inspections
- High-Risk Category: three to four inspections

Relevant inspection types for the inspection frequency calculation are approval, full hygiene, routine and follow-up inspections. According to the COP, complaint/incident inspections and official control checks are treated as additional to and separate from the above.

In accordance with the SFPA Food Safety Control Plan, a risk assessment must be completed for all approved establishments when initially approved/recommended for approval or when a relevant legislative requirement changes. The control plan states that all risk assessments should be undertaken using the Approved Establishment Risk Assessment Form for Determination of Risk Category & Inspection Frequency (FRA01 Ver 6 11 Feb 2020). Subsequently, risk assessment reviews should be undertaken for all approved establishments annually (or more frequently if the need arises, e.g. significant non-compliance detected, change in activities). The review should be documented using the Record of Risk Assessment Review Form (FRA03 Ver. 4 Feb 20). Risk Assessment outcomes must be communicated to the FFSU where they are then updated in OAPI.

The audit team confirmed that all FBO establishments producing RTE fishery products within the scope of this audit had a risk category recorded on OAPI and that each RTE establishment assessed as high-risk had been allocated a SFPO and in some cases two SFPOs were allocated to some high-risk FBOs-

At the start of each year the FFSU sends an email to the port offices requesting the risk rating of each establishment under the port's supervision. An excel sheet that records the establishment risk rating and the inspection frequency set by the SFPO must be included in the sheet. It was found by the audit team that this excel sheet was returned by each of the port offices visited however the requirement in the SFPA documented procedure to complete a Record of Risk Assessment Review Form was not always completed for establishments within the scope of the audit. In one port, three files selected for review did not have a Record of Risk Assessment Review form for 2023 and 2024 and in one case the form on file was a previous version of the review form (COP RA01 Version 7 17/08/2016) rather than the version that was in use at the time of the review.

Frequency of inspections

RTE fishery products establishments are generally categorised as high-risk by the SFPA. All RTE fishery products establishments within the scope of this audit had a target recorded on OAPI for 2024 which was in accordance with the frequencies associated with their risk categorisation. It was noted that the Code of Practice for the Risk Assessment of Approved Establishments including Freezer and Factory Vessels (COP RA01 Ver 9 11 Feb 2020) outlines a frequency of 3 to 4 official control inspections for high-risk establishments, however no establishment file reviewed as part of this audit had a target of 4 inspections. In one port area the risk assessment completed for one

establishment in 2023 and 2024 had a frequency of 3-4 indicated on the 'Establishment Risk Assessment Form' which defaulted to 3 inspections in OAPI.

Each month a dashboard report is provided to the FFSU by the FSAI. This monthly report provides a count of the inspection type recorded for the previous month as well as a running total for the year to date both by port and a combined overall figure. It also provides an overview by quarter of the target number of inspections versus the actual number of inspections. This report is shared by FFSU with each port showing the target for that port versus the percentage achieved as well as the combined overall running total for all ports. Each establishment has a set target of the minimum level of inspection per calendar year. The Food Safety Annual Control Plan states that the following types of inspections count towards achieving the inspection target: approval inspections, full hygiene inspections, routine inspections and follow-up inspections. Routine inspections, by definition, encompass three or more sections of the approved establishment checklist.

Figure 2 below out shows the overall number of actual inspections in 2023 compared to the target inspections for all RTE establishments supervised by the SFPA.¹

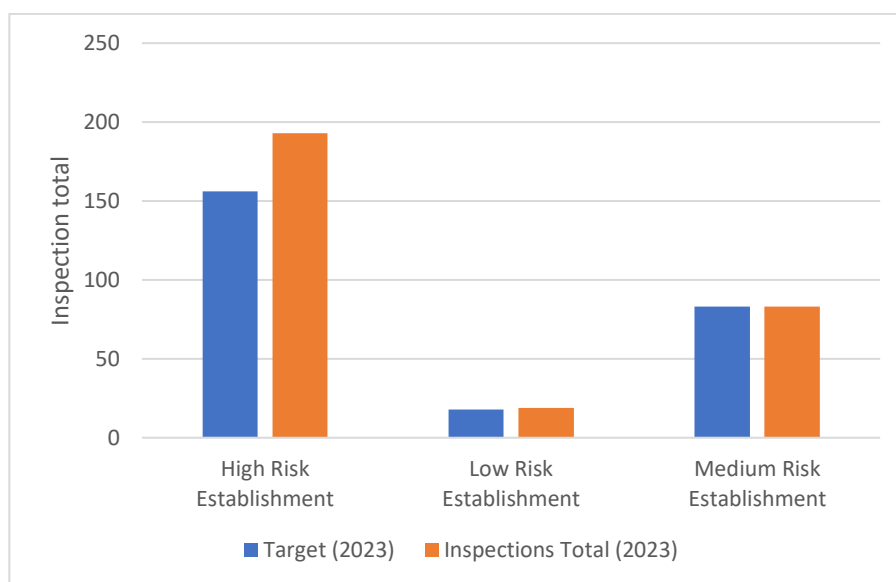


Figure 2: Comparison of actual inspections conducted versus minimum target inspections set for RTE fishery products establishments by risk category

¹ Some of the RTE establishments included in this calculation were outside the scope of this audit.

In 2022 and 2023, all high-risk RTE fishery products establishments were subject to official controls. In 2023, although the overall total number of inspections met or exceeded the targeted inspection frequency as outlined in the SFPA guidance, some small one to two person operated RTE fishery products establishments may not be inspected as per the target frequency set out in the SFPA food control plan for high-risk establishments due to their small size and limited seasonality for example there are some individually operated approved establishments producing cooked crab, which are risk assessed as high by the SFPA, which under SFPA guidance note would warrant a target of 3 to 4 inspections, however these FBOs only operate 5 to 6 months of the year and often will not operate daily during that period. This means that the SFPA does not always meet the target annual inspection number for these small FBOs even though they are classified as high-risk.

It was noted by the audit team that in the case of one port, no food safety inspections were recorded in OAPI for Quarter 1 at the time of the audit data download (21 March 2024) despite the requirement in the Food Safety Annual Control Plan that all records should be entered on OAPI within 11 days of the end of each month.

Article 9(4) of the OCR requires that official controls must be performed without prior notice, except where such notice is necessary and duly justified for the official control to be carried out. SFPA performs inspections, generally with prior notice. In 2023, announced inspections were recorded as almost 75% of all inspections, this was a drop from the previous year of 82%.

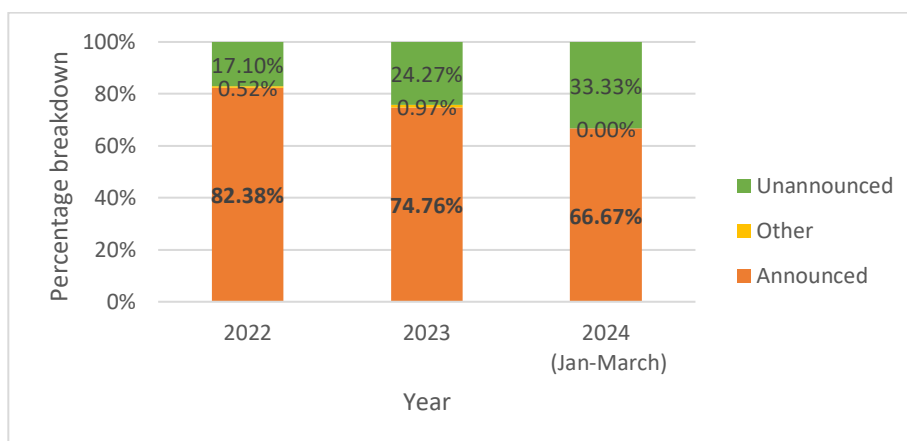


Figure 3: Comparison of announced versus unannounced inspections in RTE fishery products establishments, from 2022 to 2024 (January to March)

Of the three SFPA port offices visited, 55% of inspections in one region, 82% in the second and 90% in the third were performed with prior notice in 2023. All port offices had RTE fishery products establishments which were not subject to an unannounced inspection in either 2022 or 2023. The audit team identified 15 operators across SFPA regions that underwent prior notice inspections only for both 2022 and 2023 despite the requirement in the SFPA Food Safety Control Plan that in the case of land based approved establishments, at least one inspection per annum should be unannounced.

The main reason provided to the audit team for prior notice inspections was to guarantee that the premises are in operation and those responsible are available, especially in remote areas. However, some of the FBOs visited as part of this audit, had predictable working shifts.

Of the sixteen FBOs selected by the audit team for unannounced on-site verification of official controls, three were closed with no personnel on-site and only one establishment was producing RTE fishery products at the time of the visit of the audit team.

Official controls checks are carried out by SFPOs to verify compliance with a specific aspect of food law, examples include product temperature checks, labelling checks, product sampling, health certification check. All checks are recorded on OAPI. It was noted by the audit team that for one date, an establishment had a finding of both satisfactory and unsatisfactory recorded on OAPI, in this case an official control check was found unsatisfactory. It was reported that if an official control check is carried out as part of an inspection, an official control check record is created, in addition an official control check record is created for every check for e.g. if four different labels are checked then four official checks are recorded. This manner of recording was not standard practice across the ports visited, but the SFPA Annual Control Plan was not clear if checks conducted as part of an inspection should be recorded separately. It was noted by the audit team that one establishment had three full hygiene inspections recorded within a 20-day period in OAPI for 2022, the food safety inspection reports were not available on-site in the establishment on the day of the visit by the audit team and were not provided to the audit team by the SFPA to verify the accuracy of these entries in OAPI.

In conclusion, it was noted by the audit team that monitoring of inspections centrally was primarily quantitative rather than qualitative with a focus on achieving targets set for the risk category. An overall view of the content of the inspection reports was not available centrally to indicate trends or identify common issues across regions. Senior port officers had regular meetings with their staff where reports could be discussed however these meetings often did not have a written record of discussion.

4.1.10 Operators, processes, and activities subject to official controls

Article 10 of the OCR requires that to the extent necessary to ascertain compliance with the rules referred to in Article 1(2) of the Regulation, competent authorities shall perform official controls on animals and goods at any stage of production, processing, distribution, and use. The competent authority shall also draw up and keep up to date a list of operators.

The audit team verified that SFPA has established a system of official controls for establishments under their supervision that are producing or handling RTE fishery products. This system of official controls provides for SFPA authorised officers to assess compliance of FBOs with relevant legislation through inspection and sampling programmes. A list of all SFPA supervised operators is maintained on OAPI and a list of all approved establishments is available on the SFPA website.

4.1.11 Written records

Article 13 of the OCR requires competent authorities to draw up written records of every official control that they perform. Those records must contain a description of the purpose of the official controls, the control methods applied; the outcome of the official controls; and where appropriate, action that the competent authorities require the operator concerned to take as a result of their official controls.

The SFPA procedures state that a written report of the inspection for the following types of inspection: Approval, Routine, Follow Up, Full Hygiene, Complaint/Food Incident and Other must be provided.

The Inspection Checklist for Fishery Products and Live Bivalve Molluscs Establishments (CLA01 Ver16-14/01/2019) provides a comprehensive list of the areas to be covered in an inspection, with 8 of its 10 sections relevant to the RTE establishments within the scope of this audit. It was noted by the audit team that there was good use of the inspection checklist and completed forms were on file. However, it was also recognised that as it was a comprehensive checklist and paper based, it could be unwieldy if it was completed in one inspection. Under SFPA procedures all applicable sections of the checklist can be completed in a single inspection (e.g. full hygiene or approval inspection) or over a number of routine inspections. In the case where the full checklist is covered off in a number of inspections during the year, SFPA procedures state that the Establishment Inspection Tracking Form should be filled in after each inspection to record the sections checked. When all sections of the checklist have been completed, it should be signed and dated by the SPO. In the files reviewed, not all files included an Establishment Inspection Tracking Form as required by SFPA procedures. In one port area, one SFPO had a handwritten record of the areas covered during inspections on the cover of the local file in place of the Establishment Inspection Tracking Form.

In the review of 40 Establishment Inspection Reports, it was noted that in 5 instances a previous version of the inspection report form was used (Version 9 of 2017 rather than Ver 11 27/02/2020). On occasion where two inspectors were listed in the section 'SFPA Representative' only one officer signed the report. A few of the reports on file were not signed off by the SPO as per the requirements of the SFPA documented procedure. The content of a small number of reports viewed were repetitive with obvious cut and paste of text from previous inspections. Recording of inspection type was not always accurate. In one case an inspection was recorded as being an approval inspection to review a new process, yet the inspection report did not mention the new process. In another instance, two inspections were recorded as routine inspections but were a follow-up to an incident and did not encompass three or more sections in the Approved Establishment Checklist as specified for routine inspections in the Food Safety Control Plan. There were, however, some good examples of inspection reports with clear detail and comprehensive records of the inspection. There was some good use of photographs in support of the report findings which were very effective in recording non-compliances and were also used to record compliance following corrective action being taken by the FBO. A copy of the establishment inspection report is sent to the FBO. It was noted that clear details of the non-compliances were

provided to the FBO, including in some cases, photographic evidence of the issue, however not all cases included a date for compliance.

4.1.12 Non-compliances, follow-up, enforcement action, complaints, incidents and alerts

The audit team noted in each of the establishments audited, where non-compliances were noted during official controls, they were communicated to the FBO however on many occasions no date for completion was provided or it was stated that they were to be corrected before the next inspection which often did not take place for a number of months. In one case while a date of completion was provided this was extended on each of the following three inspections, thereby the non-compliance albeit recorded as minor remains open 18 months after it was first raised.

Section 1 of the Establishment Inspection Report Form requires that non-compliances from the previous inspection report are included in the report and the audit team found that generally non-compliances were listed individually in the subsequent report and were marked as completed when the necessary action was taken by the FBO.

There were no formal enforcement notices, product seizures or detentions in the establishments within the scope of this audit. The FFSU maintains a system for documenting food incident notifications from the FSAI, non-compliant laboratory results, and complaints forwarded to the SFPA regarding products from establishments under its supervision. This system, which uses an electronic excel sheet, records the date of notification, details of the FBO, the nature of the issue, and the actions taken by the SFPA. Upon receiving a notification of an incident, an unannounced inspection or official control is conducted, and the findings are reported to the FFSU. All inspections and official controls are also recorded in OAPI.

Of the 23 events recorded as food incidents by the SFPA in the period January 2022 to March 2024, 12 related to positive results from *Listeria monocytogenes* in smoked salmon. All samples were from official control sampling and additional testing was carried out by the SFPA. In one case the audit team found that the official control was recorded as satisfactory despite the positive result, however this was a clerical error in recording as the related inspection report outlined the

actions taken including the retesting carried out. A monthly review of the status of recorded events is carried out by the FFSU.

4.2 Food business operator findings

Sixteen food business establishments across five port regions were selected in order to verify the delivery and effectiveness of official controls carried out as well as the level of food business compliance with food law. The FBOs varied in size from one person operations, producing RTE fishery products only, to establishments employing over 70 personnel producing both RTE and non-RTE fishery products. The team could not enter three of the businesses selected, as they were not operating, and no personnel were present on-site on the day of the unannounced visit. Of the remaining thirteen businesses, only one was producing RTE foods on the day of the visit and two were packing RTE product. The remaining businesses were either not in production on the day of the visit (six FBOs) or were producing products outside the remit of the audit (four FBOs).

The audit team noted that in most of the food businesses visited, a satisfactory level of compliance with food law was observed. Food safety management systems had been put in place in order to comply with the requirements of Article 5 of Regulation (EC) No 853/2004 and were, for the most part, being effectively implemented and adequately maintained by the FBO concerned. The audit team reviewed the Certificates of Analysis on file and found them to be satisfactory. Additionally, mock recalls and traceability exercises conducted by the FBOs that were documented and relevant to the timeline of the audit were deemed satisfactory by the audit team. Minor non-compliances were identified in all establishments. One FBO, in addition to hygiene issues within the premises, also had a traceability non-compliance that warranted a compliance notice, which the SFPO issued promptly. In another premises, the audit team found that an extra day was being added to the shelf-life of products. The FBO explained that this was a technical error with the labelling machine due to the leap year and an IT expert was needed to correct the issue. Sample labels reviewed by the audit team at the FBOs visited were considered satisfactory bar two minor amendments raised on the date of the site visit in relation to an indication of 'UB' rather than 'Use by' in one FBO which was corrected immediately by amending the labelling device information. The team proposed amendments to the storage instructions on the label of smoked salmon in another premises.

All non-compliances identified during the on-site verification visit were verbally notified to the FBO at the time, and they were advised that the SFPA would follow up to close out on all identified issues.

4.3 Positive practices observed during the audit

The use of photographs to support of the provision of clear information to FBOs in relation to non-compliances identified during official controls and as evidence of the completion of corrective action.

Email updates of 'lessons learnt' that are circulated to staff to raise awareness of application of legislation during specific events both nationally and internationally.

5 Conclusions

The audit team confirmed that in general, there was a structured and well organised approach to the coordination, planning and prioritisation of SFPA official controls nationally a good level of communication was noted between the SFPA central and regional level. The SFPAs' annual food safety control plan provides a baseline framework for the official controls carried out by the SFPA. It outlines the food safety controls to be carried out in establishments which are under the supervision of the SFPA as well as the associated recording and reporting requirements.

Guidance for SFPO's on the implementation of the requirements of the food safety control plan is contained in a number of documented procedures and protocols. However, it was noted that the approvals guidance document makes reference to revoked legislation, though this document is currently under review. It was also noted that on occasion previous versions of forms and templates were used by SFPOs.

Food business operator establishments producing RTE fishery products have a risk category recorded on OAPI with each high risk RTE establishment allocated an SFPO. Official controls at these establishments had a target set which was in accordance with the frequencies associated with their risk categorisation. The audit team noted that the risk category entered on the inspection reports reviewed matched the record for the establishment in OAPI. All establishments producing RTE fishery products were subject to official controls in 2022 and 2023.

As part of the coordination and planning activities within the SFPA, meetings were organised at central level on a regular basis between headquarters and SPOs from each of the regional port offices and covered operational issues for both fisheries control and food safety activities. As part of the coordination of SFPA activities within the port offices, team meetings to discuss food safety matters are organised on an ad-hoc basis mainly due to rostering issues. There was, however, a lack of written records of these discussions.

Monitoring of the delivery of SFPA official control activities was being carried out principally by FFSU at central level. Evidence of this monitoring was provided in the form of communications issued to port offices in order to prompt completion of quarterly returns (official controls) in line with the requirements of the Food Safety Control Plan, and notification of deadlines in regard to approval inspections. Reviews of the Food Incident log are conducted on quarterly basis by the FFSU. However, the monitoring of official control activities is predominantly quantitative rather than qualitative with a focus on achieving targets set for the risk category

In relation to the performance of official controls, the audit team noted that in most cases these were announced controls which is not in accordance with OCR requirements. They were being carried out in accordance with documented procedures, however some gaps were observed in the completion of inspection reports such as signatures missing, sections not completed and dates for correction of non-compliances not set.

The audit team's view was that, in general for food business operation establishments visited as part of the audit, a satisfactory level of compliance was observed subject to certain minor non-compliances identified on the day of the audit. In one case, due to non-compliances with food law observed on the day of the site visit, a compliance notice was issued promptly by the SFPA.

In conclusion, the audit team's view is that a formal review process for evaluation of the performance and delivery of official controls and their effectiveness should take account of qualitative issues in addition to the current quantitative review. In addition, the reliance on announced inspections rather than unannounced official controls does weaken to some extent the overall effectiveness of the control system.

6 Recommendations

In order to facilitate the inclusion of approved activities not performed regularly to remain on a FBOs' approval certificate, it is recommended that when conducting official controls, inspections should include an assessment of the establishment's capability to perform all the approved activities in accordance with the applicable legislation.

7 Findings requiring corrective action

1. The requirement in section 1.6 of the Service Contract between the FSAI and the SFPA to submit an annual control plan within a specified time frame was not adhered to.
2. A Guidance Note on Approving Establishments (Doc Ref: FFSU FS GN AP Version: 3) is available for SFPOs. This document is out of date as it refers to previous legislation on official controls (Regulation 854/2005) which was revoked in December 2019 and European Communities (Food and Feed Hygiene) Regulations 2009 (S.I. No. 432 of 2009) which is also revoked.
3. The requirement in the SFPA documented procedures to complete certain forms was not always followed, as:
 - A Record of Risk Assessment Review Form was not always completed.
 - If a full inspection is not completed then according to documented procedures the Establishment Inspection Tracking Form should be filled in after each inspection to record the sections checked, this form was not always completed as per the SFPA documented procedure requirement.
4. The majority of SFPA inspections were carried out with prior notice, despite the requirement in the OCR, and repeated in the SFPA food safety control plan, that official controls should be performed without prior notice, except where such notice is necessary and duly justified. Such a high rate of prior notice inspections could negatively impact the effectiveness of official controls.
5. Monitoring of inspections centrally was predominantly quantitative rather than qualitative with the focus on achieving targets set for the risk category. An overall view of the content of the inspection reports was not available centrally to indicate trends or identify common

issues across regions.

6. Document control – in a number of cases previous versions of templates were used:
 - Establishment Inspection Report
 - Risk Assessment Review Form.
7. SFPOs need clear guidance on how to record official control checks conducted during inspections. Specifically, whether these checks should be documented as part of the inspection itself or recorded separately. Inconsistent interpretations among SFPOs can result in variations in reporting figures across regions.



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