

Audit of the Scottish Food Crime and Incidents Unit

Withdrawals, Recalls, Issue of Alerts.

2022/2023 - Quarter 1

Final Report issued October 2022



Foreword

Audits of Food Standards Scotland's Scottish Food Crime and Incidents Unit (SFCIU) are part of the arrangements to improve consumer protection and confidence in relation to food and feed.

The audit scope was detailed in the audit brief and plan issued to the SFCIU on 25 April 2022.

Food Standards Scotland's audits assess conformance against retained Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law and the associated planned arrangements. The provisions for conducting audits are provided for in Article 6 of retained Regulation (EU) 2017/625.

The Audit scheme also provides the opportunity to identify and disseminate good practice and provide information to inform Food Standards Scotland's policy on food safety, standards and feeding stuffs.

Specifically, this audit aimed to establish:

- Verification that official controls are carried out in compliance with planned arrangements.
- Verification that planned arrangements are applied effectively.
- Verification that planned arrangements are suitable to achieve the objectives of official controls.

Following the audit, it is expected that for any recommended points for action, the SFCIU will prepare and implement an action plan which will incorporate a root cause analysis of any non-compliance. A list of recommendations is provided in the action plan template at the end of this report.

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1.0 Introduction

- 1.1 This report records the outcomes of the audit of Food Standards Scotland's (FSS) Scottish Food Crime and Incidents Unit (SFCIU), with regard to their role in the delivery of withdrawals, recalls, and the issuing of alerts in response to food safety incidents.
- 1.2 It is recognised that the processes within the scope of this audit are only a part of the much wider spectrum of incident management within the SFCIU. While conducting this audit, the Audit Team focussed exclusively on those arrangements related to the delivery of withdrawals, recalls and the issuing of alerts. Consideration as to the validation and verification of other arrangements outside the scope of this audit has not been made.
- 1.3 While withdrawals, recalls and issue of alerts could be initiated in any of the four incident categories established within the SFCIU's arrangements, the Audit Team recognised the similarities in the delivery of these processes in the different categories. Auditors acknowledge the complexities and sensitive information which might be captured and documented as the incident level increases. In view of this, it was agreed that only incidents within the Level 1 and 2 categories would be reviewed as part of the verification exercises.
- 1.4 In terms of this audit, the SFCIU's core responsibility is the coordination and management of incidents involving withdrawals, recalls and alerts. It is recognised that enforcement and follow up actions at the Food Business Operator (FBO) level, are the responsibility of other Competent Authorities, such as a Local Authority, and FSS's Operational Delivery Division. Consequently, the delivery of these arrangements has not been audited.
- 1.5 The overarching criteria which detail the standards that the assessment has been made against are contained within the relevant sections of Retained Regulation (EU) 2017/625 and Retained Regulation (EC) No 178/2002.
- 1.6 The guidance relating to the current planned arrangements and referred to throughout this report will be the primary policy implementation and procedural references within:
 - Standard Operating Procedures (SOPs) and internal procedures provided by the SFCIU.
 - Food Standards Scotland's Incident Management Framework
- 1.7 This was a virtual audit. It consisted of a desktop documentation review, and was complimented with three interviews with different members of staff in the Incidents team within the SFCIU. Virtual presentations on the CLIO incident management system and the Efficacy of Recalls Project were delivered as part of the evidence provided.

1.8 The audit focused on the arrangements for meeting certain operational criteria, particularly in relation to guidance, procedures, capacity, capability, records, internal monitoring and transparency of the delivery of the withdrawal, recall (issue of alerts) processes.

Reason for the Audit

- 1.9 As detailed in the Foreword, Article 6 of retained Regulation (EU) 2017/625 requires Competent Authorities to carry out internal audits or have audits carried out on themselves.
- 1.10 The audit programme covering the official controls delivered by FSS is carried out as an internal audit by FSS's Audit Assurance Division. This audit forms part of that audit programme.

Scope of the Audit

- 1.11 It was agreed that the audit scope would cover:
 - An assessment of policies, plans and procedures for compliance with relevant legislation.
 - The verification of application of, and adherence to, documented policies, plans and procedures.
 - The identification and dissemination of good practice.
 - The provision of information to aid future FSS policy and operational development.

2.0 Executive Summary

- 2.1 The Audit Team recognised that the processes within the scope of this audit are only a part of the much wider spectrum of incident management within SFCIU. While conducting this audit, the Audit Team focussed exclusively on those arrangements related to the delivery of withdrawals, recalls and the issuing of alerts. Consideration as to the validation and verification of other arrangements outside the scope of this audit has not been made.
- 2.2 Standard Operational Procedures and protocols provide detailed and easy to follow instructions on how to manage and progress the processes audited, from the moment information is received to their closure.
- 2.3 While evidence indicated all officers' familiarity with routine day-to-day incident processes, the auditors were not presented with planned arrangements which contemplated the possibility of exercising less frequently encountered or complex scenarios.
- 2.4 In their position of managing and coordinating the processes audited, the Audit Team recognises that the SFCIU plays a vital role in the implementation of initiatives with the aim being the prevention of further occurrences of such non-compliances by the food operator. The auditors acknowledge that the developing

- Incident Prevention Strategy, which is being led by the SFCIU, is a key piece of work and should be recognised as such.
- 2.5 The auditors identified throughout the audit that there is capability within the team in the managing of day-to-day routine incidents and the processes audited.
- 2.6 Evidence indicated that, for the period audited, capacity levels and resilience arrangements have been sufficient to service all potential and declared incidents that required the managing of the processes audited.
- 2.7 Although training activities are captured in records, the auditors were not presented with a documented training programme linked to specific training needs and staff progression pathways. Auditors recognise that this is planned and anticipate its inclusion in the action plan's response to this audit. Further evidence was provided prior to the finalisation and final agreement of this report. The Audit Team is satisfied with the action taken to address and close the recommendation. This has been noted in the action plan section of this report.
- 2.8 There was evidence that, on occasion, limitations were apparent in the delivery of effective coordination and cooperation between Operational partners, Stakeholders and other Competent Authorities (CAs) delivering the associated official controls and activities. It was identified that the team within the SFCIU are aware of these issues and are seeking to address those that lie within their control. Further evidence was provided prior to the finalisation and final agreement of the report. The Audit Team is satisfied with the action taken to address and close the recommendation. This has been noted in the action plan section of the report.
- 2.9 While the number and type of recalls and alerts are published, this evidence could not be obtained in relation to withdrawals. Consideration should be given to retained Regulation (EU) 2017/625, Article 11, as to whether the current level and content of publication is sufficient.
- 2.10 Areas of good practice have been identified throughout this audit. These are noted in the report.

Level of Assurance

- 2.11 As detailed in FSS's Official Feed and Food Controls Delivery Audit Charter (FSS/ENF/18/001), the audit has been assigned as below:
- 2.12 The Recommendations within this report detail the limitations in the controls that the SFCIU should address.

Substantial Assurance	Risk, governance and control
Controls are robust and well managed	procedures are effective in supporting the delivery of any related objectives. Any exposure to potential weakness is low and the materiality of any consequent risk is negligible

Audit categories

2.13 The rating above is based upon four categories of audit assurance level that is applied in relation to individual reports.

Substantial Assurance Controls are robust and well managed	Risk, governance and control procedures are effective in supporting the delivery of any related objectives. Any exposure to potential weakness is low and the materiality of any consequent risk is negligible
Reasonable Assurance	Some improvements are required to enhance the
Controls are adequate but require improvement	adequacy and effectiveness of procedures. There are weaknesses in the risk, governance and/or control procedures in place but not of a significant nature.
Limited Assurance	There are weaknesses in the
Controls are developing but weak	current risk, governance and/or control procedures that either do, or could, affect the delivery of any related objectives. Exposure to the weaknesses identified is moderate and being mitigated.
Insufficient Assurance	There are significant
Controls are not acceptable and	weaknesses in the current risk, governance and/or control
have notable weaknesses	procedures, to the extent that

the delivery of objectives is at risk. Exposure to the weaknesses identified is sizeable and requires urgent mitigating action

3.0 Audit Findings

3.1 The findings reported below detail both corrective and preventive actions which are not confined to addressing specific technical requirements, but also include system-wide measures. Conclusions address the compliance with the planned arrangements, the effectiveness of their implementation and the suitability of the planned arrangements to achieve the stated objectives as appropriate.

Retained Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules as amended.

3.2 Article 5. General obligations concerning the competent authorities and the organic control authorities

Article 5	Audit Findings
Points 1 (a)	Planned arrangements are documented through an extensive number of Standard Operating Procedures (SOPs) and Protocols which describe the appropriate instructions related to the managing of incidents, including the withdrawals, recalls and issuing of alerts.
	While relevant SOPs were made available, and the evidence indicated all officers' expertise with routine incident processes, some concern was expressed around the level of familiarity with less frequently encountered and more complex scenarios. In order to adhere to the scope of the audit, the Audit Team only reviewed routine incidents which were within Level 1 and 2. Through this, it was noted that the last incident resulting in the issue of a Food Alert For Action (FAFA) was in 2018/19 and it was led by the Food Standards Agency (FSA). It was also noted that the last FAFA process led by FSS, was in 2017/18. The Audit Team recognises that this particular process falls under the routine incident management framework, but also it is our understanding that its implementation could require more complex interaction with Local Authorities (LAs) compared to for example, the issuing of a routine Product Recall Information Notice (PRIN), and if the incident management framework, if the incident is escalated The auditors

would express concern that there is a significant cross FSS risk as a result of this lack of experience of these less frequent encountered scenarios.

This is an organisational risk but the auditors also recognise that partial mitigation does sit within the direct span control of the SFCIU.

(Recommendation 1).

Point 1 (e, i)

(Capability) Auditors recognise there is capability within the team in the managing of day-to-day routine incidents involving the processes audited.

There is evidence of support arrangements as part of the full governance process around the management of incidents, chaired by the Head of Incidents where incidents are reviewed, actions allocated and decisions made. Daily morning meetings are held between all members of the SFCIU incidents staff with outcomes being captured in the Daily Management Meeting Document. This has been recognised as an example of good practice.

(Capacity) The number of declared incidents increased to 120 in the last year (2021-2022) compared to 94 and 98 in previous periods. These figures give an average of 8.4 incidents per month in the last three yearly periods. The evidence indicated a lack of a clear pattern in the number of potential and declared incidents, other than those related to On-Farm lead and shellfish contamination scenarios, in which there seems to be seasonal factors. This might add a factor of uncertainty when resourcing these tasks, which denotes the complexities around the managing of the processes audited. Operational capacity level within the current structure is serviced by one Head of Division, one Branch Head, one Incidents Manager, two Lead Incidents Officers, one Incidents Officer and two Support Officers at B3 and B2 level. All have different levels of expertise and experience based on their role and length of service. There is also the ability in the FSS/FSA's Memorandum of Understanding (MOU) to request assistance from each other when there is an increase in the number of incidents as well as complex non-routine incidents.

Further support can also be provided by a number of staff from the Crime Unit who were trained in the management of incidents in light of the anticipated increase in incidents post-Brexit. Evidence reviewed showed that there has not been a need to utilise these resilience arrangements

Auditors acknowledge that capacity levels may be stretched on high demanding occasional weeks, such as the week commencing 16th of May 2022 when 10 new incidents were declared, and a number of staff were on annual leave. Nevertheless, evidence indicated that the managing of the processes audited have been delivered by the current capacity levels, although it is noted that stretches have had an impact on the smooth running of other tasks, as per comments in Article 12 below.

Point 1(f)	(Equipment) Due to the Covid-19 pandemic, staff have been home based with a current move towards a hybrid pattern once restrictions were lifted. Members of the staff interviewed indicated the suitability of equipment needed to undertake their work.
Point 4	New members of the staff are given introductory basic training on joining and gain experience through shadowing other FSS branches and participating in the managing of incidents within the SFCIU team, before being assigned incident cases to manage on their own. This training covers operational procedures and specific technical knowledge through a number of mandatory, recommended and optional e-learning courses, and the provision of reading material. The Interviews conducted highlighted a satisfactory knowledge on these operational procedures and related technical matters by members of the staff. In addition to this, further "decision making" and "managing of risk" training has been identified by the SFCIU and scheduled to take place in September 2022.
	Training activities are captured in records; however, the auditors were not, at time of the audit, presented with a documented training programme linked to specific training needs and capability development programme. (Recommendation 2)
	This potential gap has clearly been identified by the SFCIU's senior management. Evidence shows that there is an ongoing action to develop and implement a matrix approach training programme linked to a Learning and Development (L&D) plan. This has been found to be a positive development to address these matters and the Audit Team anticipates the early closure of this recommendation once this action is finalised and implemented.
	Further evidence on this recommendation was provided prior to the agreement of this report. The Audit Team is satisfied that this recommendation has been addressed and can be closed, this has been noted in the action plan of this report.
Point 5	The review of eight incidents in the CLIO system showed the complexities around the managing of the processes audited, and the hard work behind the scenes provided by the Incidents Team and the different CAs, Stakeholders and Operational partners. Auditors identified several areas within some of these incidents which could have had a negative impact in the effectiveness and efficacy of the processes delivered.
	Although there is good evidence of concerted coordination and cooperation between the different CAs, Stakeholders and Operational Partners involved in what can be a complex set of processes, there was clear evidence that frequently this can pose a challenge. Whilst acknowledging that at least in part, some of this sits outside of the control of the SFCIU, auditors would consider that further work on an approach to ensuring prevention of these issues would be of benefit. (Recommendation 3)

Good Practice: Daily Management Meetings

There is a recognised governance process around the daily management of incidents. Daily Incident Management meetings are held within the team where current and ongoing incidences are reviewed, decisions discussed, and actions agreed. A record of the daily management document meeting is circulated to the Executive Leadership Team (ELT) and other branches across FSS for information. These arrangements have been fully recognised as an area of good practice.

Good Practice: SOPs and procedures

The SOPs and procedures approach were found to be a very positive indication of the organisational documentation within SFCIU. These were adequately stored and categorised for easy access. SOPs and procedures were complete in content with clear and easy to follow operational instructions for the intended audience.

Recommendations

- 1. To consider and take forward plans for the exercising of less frequently encountered scenarios to ensure competency and consistency in the effectiveness of the official controls delivered.
- **2.** To finalise the development of the training programme and present evidence of its implementation.
- **3.** To consider the further development of the coordination and cooperation arrangements with the aim being to ensure, at all times, efficient and effective coordination and cooperation between the different units involved in the withdrawals, recalls alert response.

3.3 Article 7. Right to appeal.

Article 7	Audit Findings
<u></u>	Through the course of the audit it came evident that the SFCIU's involvement is limited to the general coordination and managing of incidents including the associated processes audited (withdrawals, recalls, issue of alerts). The responsibility to establish the arrangements and to inform the Food Business Operator (FBO) of the right of appeal, when a measure following a non-compliance has been taken, lies with other CAs and FSS's Operational Delivery Division.

Recommendations

No recommendations for Article 7.

3.4 Article 11. Transparency of official controls.

Article 11	Audit Findings
Point 1 and 2	There are mechanisms in place to make available to the public the information on each individual recall and alert being issued by the CA. This information is being published in a timely manner in the "News & Alerts" section on the FSS Website. In addition to this, members of the public can also receive this information through text message and email by subscribing to this application.
	This procedure was tested by these auditors and found to be effective to deliver the general level of awareness to the public.
	This article also requires the regular and timely publication of information on the type and number of cases where measures were taken by the CA in accordance with Article 138, which includes withdrawal actions. Auditors concluded that further consideration of this point should be taken. (Recommendation 4)

Recommendations

- **4.** Consideration to be given to arrangements for the publication of information of the number of cases where withdrawal measures have been taken.
- 3.5 Article 12. Documented control procedures.

Article 12	Audit Findings
	Documents and procedures are available on the Electronic Record and Document Management System (ERDM) and the Central Logging of Intelligence Operations (CLIO) platforms. There are arrangements in place to provide reassurance that these are maintained and suitably stored. The last programmed revision was scheduled for 2019, however, there is evidence indicating this exercise having not been completed as yet. This has resulted in a number of current procedures in need of minor updates when referring to legislation, the currency of some of the links, and the availability of redundant SOPs such as "How to carry an incident review, version 1.0 Aug 2018". (Recommendation 5)
	Although staff capacity levels seemed to have had an impact on the implementation in the frequency and number of programmed internal monitoring activities in the past, this appears to have been properly addressed with the creation of the new SFCIU Support Team; the incorporation of a new Lead Incidents Officer earlier in 2021, and the implementation of the revised monitoring procedures as per SOP 2.7.12 - Carrying Out Incidents reviews. There is evidence of planned

arrangements and implementation of a qualitative monitoring programme of closed incidents which are captured in several documents such as the Routine Incident Review and Non-routine lessons learned. These documents were found suitable for these tasks.

Daily morning meetings are held between all members of the team to discuss and monitor actions and progress on open incidents.

General monthly team meetings are also implemented with an actions table documented and maintained for recording and follow up purposes.

Quantitative monitoring was supported by the provision of statistical information and trend analysis captured in Incident Statistics reports. This information is manually extracted from recording spreadsheets and the auditors recognise the high quality in content and form of these reports. This has been noted as an example of Good Practice.

Auditors were briefed in the CLIO Development Business Case which should enhance and facilitate both qualitative and quantitate monitoring procedures. This was found as a very positive innovation.

Good Practice: Incident Statistics reports

The high quality in content and detail of the information in the incident statistics reports, which are used to inform at an organisational level, is recognised as an area of good practice developed by the SFCIU.

Good Practice: CLIO Development Business Case

The commissioned work led by the SFCIU to enhance the functionality of the CLIO system has been recognised as an area of good practice. This is in line with the digital strategy for the organisation.

Recommendations

5. The review and revision of procedures to be completed as per planned arrangements.

3.6 Article 13. Written records of official controls.

<u>Article</u>	Audit Findings
<u>13</u>	
Point 1	There is an extensive number of operational recording forms to capture all
	information related to the processes audited. All evidence generated
	during the management of each incident, from the moment initial

information is received to its closure, is individually uploaded and retained in the CLIO system for record keeping and further monitoring purposes.

A review of eight full incidents on CLIO indicated the adequate completion and currency of these forms, as well as the quantity and content of the evidence recorded. This recording system was found to be robust.

Good Practice: Recording system

The quantity and content of the records and information retained in CLIO platform was found to be robust.

Recommendations

No recommendation for Article 13.

3.7 Article 138. Actions in the event of established non-compliance.

Article 138	Audit Findings
	The Audit Team recognises that the delivery of the enforcement action where a non-compliance is established is the responsibility of other CAs and FSS's Operational Delivery Division.
	In their position of managing and coordinating the processes audited, the Audit Team recognises that the SFCIU plays a vital role in the implementation of initiatives with the aim being the prevention of further occurrences of such non-compliances by the FBO.
	Withdrawals, recalls and the issuing of alerts form a small part within these processes but as a key component. The auditors acknowledge that the developing Incident Prevention Strategy, which is being led by the SFCIU, is a key piece of work and should be recognised as such.

Recommendations

No recommendations for Article 138.

3.8 Article 140. Reporting of infringements.

Article 140	Audit Findings
	There are mechanisms in place to enable reporting of actual or potential infringements. These include the reporting arrangements by other CAs,

Stakeholders and even directly by the public to the SFCIU. Adequate
information on these matters is provided through the FSS website.

Recommendations

No recommendations to Article 140.

Regulation (EU) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety and laying down procedures in matters of food safety.

3.9 Article 14. Food Safety requirements.

Article 14	Audit Findings	
	Evidence indicated that withdrawals, recalls and issue of alerts are only initiated following the identification of unsafe food and these actions are the result of the managing of this risk through the provision of the Scientific Risk Advice (SRA) and the Risk Management Advice (RMA).	

Recommendations

No recommendations to Article 14.

4.0 Annex A – Action Plan

Action Plan for Scottish Food Crime and Incidents Unit: Withdrawals, Recalls, Issue of Alerts, 2022/23 – Quarter 1

Recommended Point for Action	Planned actions	Target date for completion	Responsible Officer(s)
To consider and take forward plans for the exercising of less frequently encountered scenarios to	 A live level 2 incident is ongoing utilising the Incident Management Framework allowing all internal stakeholders to implement processes. 	On completion of the Incident.	Head of Incidents.
ensure competency and consistency in the effectiveness of the official controls delivered.	Develop and deliver a desktop exercise.	March 2023.	Head of Incidents/Senior Enforcement Manager.
	 Exercise a radiological incident with external partners. 	November 2022.	Head of Incidents/ Incidents Manager.
Priority: Medium			
2. To finalise the development of the training programme and present evidence of its implementation.		The recommendation has been closed following the review of further evidence provided by the SFCIU Division prior to the agreement of this report.	
<u>Priority: Medium</u>			

3. To consider the further development of the coordination and cooperation arrangements with the aim being to ensure, at all times, efficient and effective coordination and cooperation between the different units involved in the withdrawals, recalls alert response. Priority: Medium		The recommendation has been closed following the review of further evidence provided by the SFCIU Division prior to the agreement of this report.	
4. Consideration to be given to arrangements for the publication of information of the number of cases where withdrawal measures have been taken. Priority: Low	The withdrawal is a business to business process and not implemented by FSS. FSA do not publish this data so to maintain the Four Nations approach to food incidents it is not something we would look to do. We are only aware of one country in Europe that published this data. This decision has been made within SFCIU by the Head of Division.	Consideration has been completed by the SFCIU Division. The Audit Team accepts this outcome.	
5. The review and revision of procedures to be completed as per planned arrangements. Priority: Low	 Complete a full review of all desk instructions and SOPs. Amalgamate SOPs and desk instructions for a more streamlined document set. 	November 2022. November 2022.	Incidents Manager. Incidents Manager.

5.0 Acknowledgements

The Audit Assurance Team would like to acknowledge the help and co-operation of the SFCIU staff for their assistance with the conducting of this audit.

Auditors: Pepe Martinez

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Food Standards Scotland Audit Assurance Division

Abbreviations

CA Competent Authority

CLIO Central Logging of Intelligence Operations.

ELT Executive Leadership Team

ERDM Electronic Record and Document Management System

FAFA Food Alert for Action
FBO Food Business Operator
FSA Food Standards Agency
FSS Food Standards Scotland
KPI Key Performance Indicator

LA Local Authority

L&D Learning and Development

MOU Memorandum of Understanding

PRIN Product Recall Information Notice

RCA Root Cause Analysis
RMA Risk Management Advice

SFCIU Scottish Food Crime and Incidents Unit

SOP Standard Operating Procedure

SRA Scientific Risk Advice