

Audit of Operational Delivery

Enforcement

January – March 2021

Final Report issued May 2021



Foreword

Audits of Food Standards Scotland food law enforcement services 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 Operations on 30 July 2020. The aim of the audit is to maintain and improve consumer protection and confidence by ensuring that Operations are providing an effective food law enforcement service.

Food Standards Scotland audits assess conformance against 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 FSS Manual for Official Controls. The provisions for conducting audits are provided for in Article 6 of 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 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, Operations will prepare and implement an action plan which will incorporate a root cause analysis of any non-compliance. The completed action plan is shown at the end of this report.

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1.0 Introduction

- 1.1 This report records the results of the audit of Food Standards Scotland (FSS) Operations Division with regard to their delivery of Enforcement activities under relevant sections of retained [Regulation \(EU\) No 2017/625](#) and [The Food Hygiene \(Scotland\) Regulations 2006 \(legislation.gov.uk\)](#)
- 1.2 The [FSS Manual for Official Controls](#) was referenced throughout the audit, specifically and primarily relevant sections within: [FSS Chapter 7 Enforcement v0.1 \(foodstandards.gov.scot\)](#)
- 1.3 This was a virtual audit, conducted entirely under Covid-19 conditions and restrictions, and as such, there were no physical meetings and only remote review of documentation was possible. This presented a substantial challenge, particularly to the Auditors, with everything requiring to be done electronically.
- 1.4 Evidence production was reliant on auditee co-operation and auditor requests. A regular audit would have allowed auditors to select records, documents and make requests based on what was physically observed with the resulting added dynamics involved.
- 1.5 The limitations of this type of audit are many, and as a result it should be viewed as a restricted process that will require review and further refinement to ensure that all parties involved can understand and benefit from the outcomes in the report. It is essential that where possible any follow up to this report be physically delivered.
- 1.6 The audit focused on the arrangements for meeting certain operational criteria, particularly on guidance, procedures, records, training, authorisations, monitoring interventions and transparency about their enforcement activities.

Reason for the Audit

- 1.7 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.
- 1.8 The audit programme covering the official controls delivered by FSS is carried out as an internal audit by FSS's Audit Assurance Branch. This audit forms part of that audit programme.

Scope of the Audit

- 1.9 With the current, and future, constraints in place as a result of Covid-19 restrictions it was agreed that audit scope would cover:
 - An assessment of local plans and procedures in compliance with relevant legislation
 - The verification of application of, and adherence to, documented plans and procedures

- An assessment of the capacity and capability of the Branch to deliver the controls
- An assist in the identification and dissemination of good practice
- The provision of information to aid future FSS policy and operational development

1.10 There was no on-site element of the audit and it was fully conducted remotely.

2.0 Executive Summary

Procedures and arrangements.

- 2.1 The audit found procedures are in place but do not reflect or update, in full, legislation implemented post-2019 and so currently applicable. Specifically, and most significantly, the FSS Manual for Official Controls has not been updated in accordance with retained Regulations (EU) 2017/625, 2019/624 and 2019/627.
- 2.2 The required changes and updates to the FSS Manual for Official Controls are being introduced via a system of electronic Action Notes, but these do not reflect all legislative or enforcement system changes. A good process to ensure these were read by all officers is in place, but in the case of the introduction of significant changes to enforcement procedures and recording, there was an apparent inconsistency of approach and application.
- 2.3 There was substantial evidence of a good level of communication between FSS officers and Food Business Operator (FBO) through regular meetings that ensures FBOs are informed of the level of compliance, and where required, promptly informed of any case of non-compliance.
- 2.4 The limited evidence gathered as provided by Operations officers showed that enforcement was being performed satisfactorily by Official Veterinarians (OVs) and Meat Hygiene Inspectors (MHIs). Interviewees demonstrated a good understanding of procedures they were following. The inability of Auditors to carry out plant visits was, however, a significant impediment to verification of this.
- 2.5 Verbal discussions and supplied copies of notices evidence clearly indicated that the service of multiple and inappropriate Remedial Action Notices (RAN) at one establishment was not good enforcement practice.
- 2.6 It was evidenced that there are variations in the process and methods for enforcement amongst OVs and MHIs working in different areas, and whilst there is a mechanism for consistency, this does not appear to be fully functional.
- 2.7 Officer interviews indicated that there was evidence of a system being used for enforcement. The officers interviewed indicated that enforcement was a regular part of their “tool kit” and suitable resources were available for the efficient and effective performance of enforcement actions, but in view of the present restrictions, this could not be verified on site.

Level of Assurance

- 2.8 As detailed in the FSS OFFC Delivery Audit Charter the audit has been assigned as below:
- 2.9 The Recommendations within this report detail the weaknesses in the controls that Operations should address.

Reasonable Assurance Controls are adequate but require improvement	Some improvements are required to enhance the adequacy and effectiveness of procedures. There are weaknesses in the risk, governance and/or control procedures in place but not of a significant nature.
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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) No 2017/625

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

Article	
5.1	<p>FSS Manual for Official Controls provides procedures and arrangements to ensure the effectiveness and appropriateness of PMI (Post Mortem Inspection) but the Manual does not reflect or update, in full, legislation implemented post-2019 (i.e. Regulations (EU) 2017/625). The manual also refers to Regulation (EU) 2019/2014 which has been repealed.</p> <p>All of the above procedures were confirmed as available to all via the FSS website.</p> <p>Any update to the manual should formalise the good current practice where authorised officers check any significant</p>

	<p>enforcement actions with suitable colleagues before committing to service of notice.</p> <p>Inspection of FSS issued authorisation documents indicated that all legal powers to enforce official controls were in place.</p> <p>All staff interviewed were able to satisfactorily demonstrate a good understanding and use of enforcement actions.</p>
	<p>It was noted that there was no formal process or procedure for authorised officers to discuss enforcement issues generally to ensure consistency, which is particularly relevant during the Covid-19 pandemic.</p>

Good Practice – Escalation

Discussions during the audit demonstrated a repeated awareness from Officers of how, when and what should be escalated above the routine level of day-to-day work.

Recommendations

1. The requirements of the FSS Manual for Official Controls to be updated to accurately reflect the legal requirements.
2. Updates to the FSS Manual for Official Controls should reflect the informal working arrangements about consultation on significant enforcement before it is delivered by notice.
3. A way of allowing regular discussion of enforcement issues at authorised officer level would be useful to ensure consistency, familiarity and confidence.

3.3 Article 11. Transparency of Official Controls

Article	
11	<p><i>Competent authorities shall establish procedures to ensure that any inaccuracies in the information made available to the public are appropriately rectified.</i></p> <p><i>Competent authorities may publish, or make otherwise available to the public, information about the rating of individual operators based on the outcome of one or more official controls, provided that the following conditions are met:</i></p> <p><i>(a) the rating criteria are objective, transparent and publicly available; and</i></p>

	<i>(b) appropriate arrangements are in place to ensure the fairness, consistency and transparency of the rating process.</i>
	<p>Transparency of official controls</p> <p>FSS as a Competent authority are required to perform official controls with a high level of transparency and shall, at least once a year, make available to the public, including through publication on the internet, relevant information concerning the organisation and the performance of official controls. There appears to be no evidence this is being achieved.</p>
	<p>FSS should also ensure the regular and timely publication of information on the following:</p> <p><i>(a) the type, number and outcome of official controls;</i></p> <p><i>(b) the type and number of cases of non-compliance detected;</i></p> <p><i>(c) the type and number of cases where measures were taken by the competent authorities in accordance with Article 138; and</i></p> <p><i>(d) the type and number of cases where the penalties referred to in Article 139 were imposed.</i></p> <p>The information referred to in points (a) to (d) of the second subparagraph of this paragraph may be provided, where appropriate, through the publication of the annual report referred to in Article 113(1).</p>
	All of the above do not appear to being achieved as the figures reported through the MANCP have not been published.

Recommendation

4. All enforcement activities as required by legislation should be published.

3.4 Article 12. Documented control procedures.

Article	
12.1	Documented procedures are in place and cover all areas as referred to above – updating of these is required.
12.2	Documented control verification procedures are in place with instructions contained within the FSS Manual for Official Controls. Additionally, the availability and capability for carrying out a

	<p>programme of management checks using the OWS (Operational Workflow System) enforcement Module is available to ensure consistency, accuracy and performance reporting.</p> <p>At an Operational Division level and also for the FSS Executive this reporting tool is a good facility to have working. These management reports appear to be a developing area of work and should they be adopted and enhanced, and they would be very useful to have tabled and discussed regularly.</p>
12.3	Verbal and documentary evidence was provided to demonstrate that the procedures for enforcement were being followed.

Good Practice – Enforcement Reporting

The use of OWS to produce management reports on enforcement activity is to be encouraged as it provides managers with a method of verification.

3.5 Article 13. Written records of Official Controls

Article	
13	<p>As evidenced, all enforcement activity is entered and maintained on an enforcement module within OWS. This is a Systems Based approach with all interventions categorised as an aide to identify a root cause, and to better direct subsequent action.</p> <p>Additionally, formal letters and notices are retained electronically, within the plant’s Sharepoint folders. In plant Day Books may also be used to records actions prior to entry on OWS, though these could not be inspected due to remote nature of this audit. OWS provides full details of actions taken and under what legislation, and it provides a record of outcome. It can also be used to generate management reports at plant level.</p> <p>This information is available on OWS and also in plant on paper or in the Day Book (by exception). Evidence was provided that actions resulting from PMI issues were recorded appropriately in the Day Book and on the enforcement module of OWS (and on the Intervention Log and ENF 11/5).</p>
	<p>It was noted that the change to Systems Based Enforcement (SBE) is considered better at directing actions at plant level as it encourages all FSS staff to bring forward (and record) non-compliance, and informs a risk based approach to enforcement escalation. Full scale adoption of SBE has yet to be demonstrated as in some areas there are clear differences in OWS data storage.</p>

	<p>It was reported verbally that FBOs are informed on all occasions directly when an enforcement notice is served, as a matter of effective communication. Non-compliances are dealt with appropriately and informally as a routine, with evidence provided of escalation to operators as per documented procedures.</p>
	<p>A series of RANs served on the same day at one establishment were examined, as this is an unusual enforcement practice. These notices referred to two different pieces of legislation on the same notice and included reference to microbiological items</p> <p>Notices are generally only served on one specific item and rarely require compliance with specified microbiological requirements as these are very difficult to verify in practice.</p> <p>Standard enforcement practice is to serve a single and appropriate RAN accompanied by the relevant number of Hygiene Improvement Notices, which require the FBO to produce a better FSMS, and allow the enforcing authority the time to monitor the documented records.</p>

Recommendation

5. The use of multiple simultaneous RANs should cease, and be replaced with a single RAN supported by an appropriate number of Hygiene Improvement Notices.
6. SBE should be consistently supported by all authorised officers fully recording activities on OWS.

3.6 Article 138. Action in the event of established non-compliance

Article	
138.1	<p>1. <i>Where the non-compliance is established, the competent authorities shall take:</i></p> <p><i>(a) any action necessary to determine the origin and extent of the non-compliance and to establish the operator's responsibilities; and</i></p> <p><i>(b) appropriate measures to ensure that the operator concerned remedies the non-compliance and prevents further occurrences of such non-compliance.</i></p>

	<i>When deciding which measures to take, the competent authorities shall take account of the nature of that non-compliance and the operator's past record with regard to compliance.</i>
	<p>Examples of actions taken to achieve compliance with this article were evidenced by many of the authorised officers taking part in the audit.</p> <p>As demonstrated, the enforcement approach is systems based and encourages a risk based (and root cause) approach to dealing with non-compliance. Auditees indicated that this systems based approach encourages FSS staff to bring forward all non-compliance, and is of considerable benefit in driving a consistent and more effective approach to compliance improvement.</p>

The Food Hygiene (Scotland) Regulations 2006

3.7 Remedial action notices and detention notices

Regulation	
9a	<p><i>(1) Where it appears to an authorised officer of an enforcement authority that in respect of an establishment subject to approval under Article 4(2) of Regulation 853/2004 –</i></p> <p><i>(a) any of the requirements of the Hygiene Regulations is being breached</i></p>
	<p>An example was found where a single FBO was served with 6 RANs on the same day for very similar contraventions, These were lifted very shortly afterwards, indicating full compliance had been demonstrate.</p> <p>Accepted good enforcement practice for the service of RANs is to serve a single notice supported by complementary Hygiene Improvement Notices (HINs). The RAN is valid until the HINs are considered as being complied with, this compliance level generally takes some time to achieve, as in this case, suitable evidence of monitoring is required to be evidenced.</p> <p>Any reference in a RAN or HIN to microbiological compliance should be very carefully considered as it is challenging to verify as an enforcement authority. The steps that are required to control microbiological contamination become the subject of the notice, with FBO validation and verification the evidence of compliance.</p>

	Any timescales contained within a notice should be monitored and followed as two examples were found where the timescales given were not followed.
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Recommendation

7. The detailed wording of RANs requires a review and implementation across all enforcement of this type of notice.
8. Any specific timescales or dates stated within a notice should be monitored and actioned appropriately.

3.8 Certification. Food which has not been produced, processed or distributed in accordance with the Hygiene Regulations

Regulation	
27	<p><i>(1) On an inspection of any food, an authorised officer of an enforcement authority may certify that it has not been produced, processed or distributed in compliance with the Hygiene Regulations.</i></p> <p><i>(2) Where any food is certified as mentioned in paragraph (1) it shall be treated for the purposes of section 9 of the Act as failing to comply with food safety requirements.</i></p> <p><i>(3) Where any food certified as mentioned in paragraph (1) is part of a batch, lot or consignment of food of the same class or description, all the food in the batch, lot or consignment shall, until it is proved that it has been produced, processed or distributed in compliance with the Hygiene Regulations, be treated for the purposes of paragraph (2) as having been so certified.</i></p>
	<p>Operational Delivery have not used Regulation 27 Notices as an enforcement option, the FSS Manual for Official Controls refers to these as an option, however, it appears that alternative options for the removal of food that has not been produced according to the Hygiene Regulations have been implemented.</p> <p>It would be the advice of the auditors that the potential use of Regulation 27 certification be investigated and evaluated further.</p>

4.0 Annex A – Action Plan

Action Plan for Operational Delivery’s Enforcement Audit, January – March 2021

Recommended Point for Action	Planned actions	Target date for completion	Responsible Officer(s)
<p>Article 5</p> <p>1. The requirements of the FSS Manual for Official Controls are to be updated to accurately reflect the legal requirements.</p> <p><u>Priority - High</u></p>	<p>FSS Manual for Official Controls Enforcement Chapter under review. Chapter 7.</p>	<p>December 2021</p>	<p>Field Veterinary Manager</p>
<p>Article 5</p> <p>2. Updates to the FSS Manual for Official Controls should reflect the informal working arrangements about consultation on significant enforcement before it is delivered by notice.</p> <p><u>Priority - High</u></p>	<p>FSS Manual for Official Controls Enforcement Chapter under review. Chapter 7.</p>	<p>December 2021</p>	<p>Field Veterinary Manager</p>

<p>Article 5</p> <p>3. A way of allowing regular discussion of enforcement issues at authorised officer level would be useful to ensure consistency, familiarity and confidence. <u>Priority - High</u></p>	<p>Action to be included as standing agenda item during plant team meetings.</p>	<p>June 2021</p>	<p>Field Veterinary Managers/Official Veterinarians</p>
<p>Article 11</p> <p>4. All enforcement activities as required by legislation should be published. <u>Priority – Medium</u></p>	<p>Data from 2019 onwards to be published.</p>	<p>September 2021</p>	<p>FSS Communications Team</p>
<p>Article 13</p> <p>5. The use of multiple simultaneous RANs should cease, and be replaced with a single RAN supported by an appropriate number of Hygiene Improvement Notices. <u>Priority - High</u></p>	<p>To be included in the FSS Manual for Official Controls, Chapter 7.</p>	<p>December 2021</p>	<p>Field Veterinary Manager</p>

<p>Article 13</p> <p>6. SBE should be consistently supported by all authorised officers fully recording activities on OWS. <u>Priority - High</u></p>	<p>To be included in the FSS Manual for Official Controls, Chapter 7.</p>	<p>December 2021</p>	<p>Field Veterinary Manager</p>
<p>Article 138</p> <p>7. The detailed wording of RANs requires a review and implementation across all enforcement of this type of notice. <u>Priority - Medium</u></p>	<p>New guidance to be included in the FSS Manual for Official Controls, Chapter 7.</p>	<p>December 2021</p>	<p>Field Veterinary Manager</p>
<p>Article 138</p> <p>8. Any specific timescales or dates stated within a notice should be monitored and actioned appropriately. <u>Priority - Medium</u></p>	<p>New KPI (Key Performance Indicator) on enforcement to be implemented. New guidance to be included in the FSS Manual for Official Controls, Chapter 7.</p>	<p>June 2021</p>	<p>Field Veterinary Manager</p>
<p>All actions were completed following the receipt of evidence from the Operational Delivery Division – May 2022</p>			

5.0 Acknowledgements

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

Auditors: Graham Forbes
Tony Sykes

Administration: Neil Douglas

Food Standards Scotland
Audit Assurance Branch

Abbreviations

EU	European Union
FBO	Food Business Operator
FSMS	Food Safety Management System
FSS	Food Standards Scotland
HIN	Hygiene Improvement Notice
KPI	Key Performance Indicator
OWS	Operational Workflow System
OV	Official Veterinarian
PMI	Post Mortem Inspection
RAN	Remedial Action Notice
SBE	Systems Based Enforcement