Food Standards Scotland

Audit Charter

Audits performed by Food Standards Scotland in accordance with the Food (Scotland) Act 2015, The Official Feed and Food Controls (Scotland) Regulations 2009 and Article 6 of Regulation (EU) 2017/625.

March 2020
## Document Information

<table>
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<tr>
<th>Version</th>
<th>Date</th>
<th>Reason for Amendment</th>
<th>Summary of Changes</th>
<th>Author</th>
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<td>1.0</td>
<td>January 2018</td>
<td>Replaces Audit Policy Document of May 2016 (FSS/ENF/16/007)</td>
<td>n/a</td>
<td>Food Standards Scotland Audit Branch</td>
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<tr>
<td>1.1</td>
<td>December 2019</td>
<td>Replacing references with Regulation (EU) No 625/2017</td>
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<td>Food Standards Scotland Audit Branch</td>
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<tr>
<td>1.2</td>
<td>March 2020</td>
<td>Document review and General Update.</td>
<td></td>
<td>Food Standards Scotland Audit Branch</td>
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</table>
1.0  Background

1.1  Food Standards Scotland (FSS) has a key role in overseeing the delivery of feed and food law (any form of control that is performed for the verification of compliance with feed and food law). FSS seeks to work in partnership with Local Authorities and others to help them to enforce feed and food law and is therefore pro-active in setting and monitoring standards, auditing delivery of feed and food law and ensuring that this activity complies with the Scottish Regulators’ Strategic Code of Practice\(^1\).

1.2  In addition to our work auditing and assessing the performance of Local Authorities and other delivery bodies, FSS will apply the Scottish Government’s five principles of external scrutiny – public focus, independence, proportionality, transparency, accountability – to ensure our external scrutiny activity is targeted where needed, and applied proportionately, and that the costs of scrutiny are balanced with the benefits to service users and other stakeholders.

1.3  Article 6 of Regulation (EU) 2017/625\(^2\) requires that competent authorities shall carry out internal audits or have audits carried out on themselves, and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of this regulation. These audits shall be subject to independent scrutiny and shall be carried out in a transparent manner.

1.4  FSS is the central competent body with overall responsibility for the monitoring of enforcement of food legislation in Scotland. Enforcement of this food legislation is managed by relevant Local Authorities.

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\(^1\) http://www.gov.scot/Resource/0046/00467429.pdf
2.0 Legal Basis

2.1 The power to set standards, monitor and audit the performance of Local Authorities was conferred on FSS by Sections 3 and 25 of the Food (Scotland) Act 2015 and Regulation 7 of The Official Feed and Food Controls (Scotland) Regulations 2009.

- **Food (Scotland) Act 2015**
  
  **Section 3(1)(e)** gives Food Standards Scotland the power to monitor the performance of, and promote best practice by, enforcement authorities in enforcing food legislation.

- **Section 25 Reporting on enforcement action by others**
  
  (1) In consequence of the exercise of its function under section 3(1)(e), Food Standards Scotland may make a report to any enforcement authority on the authority’s performance in enforcing any food legislation.
  
  (2) A report under subsection (1) may include guidance as to action which Food Standards Scotland considers—
  
  (a) is necessary to enable the enforcement authority to meet any standards determined under section 23(1) which apply, or
  
  (b) otherwise, would help to improve the performance of the authority.
  
  (3) Food Standards Scotland may direct an authority to which a report has been made under subsection (1)—
  
  (a) to arrange for the publication (in such manner as may be specified) of
  
  (i) the report, or
  
  (ii) specified information relating to the report, or
  
  (b) to notify Food Standards Scotland (within such period as may be specified) of what action the authority has taken or proposes to take in response to the report.
  
  (4) In subsection (3), “specified” means specified in the direction.

2.2 Similar functions are also contained within section 7 of The Official Feed and
Food Controls (Scotland) Regulations 2009 which implement the requirements of Regulation (EU) 2017/625.

2.3 As a designated competent authority as defined within Schedule 5 of The Official Feed and Food Control (Scotland) Regulations 2009 Local Authorities are required to comply with Article 6 of Regulation (EU) 2017/625. In order to help Local Authorities fulfil this requirement, (as part of its central role under the Food (Scotland) Act 2015 and The Official Feed and Food Control (Scotland) Regulations 2009 FSS will deliver external audit arrangements.

2.4 FSS audits of official controls are external audits of these competent authorities. They may supplement internal audits conducted by the Local Authorities themselves to meet the requirements of Article 6 of Regulation (EU) 2017/625.

3.0 Mission, Objectives & Role

Mission

“**To effectively evaluate the performance of official controls and to confirm that the food and feed safety control network and planned arrangements adequately safeguard & protect consumers’ health & interests, and comply with food and feed law**”

Objectives

3.1 To comply with the requirements of Article 6 of Regulation (EU) 2017/625 an audit should cover the following three points set out in Article 3(30):

a) **Verification that official controls are carried out in compliance with planned arrangements.** This is to provide assurances that competent authorities meet their general obligations\(^{(1)}\) and that official controls are carried out as intended and that any instructions or guidelines given to staff carrying out such controls

\(^{(1)}\) Under Article 5 of Regulation (EU) 2017/625.
are followed. Verification of this requirement may largely be addressed by document review, but will also require on-site verification. The audit team will require good generic audit knowledge and skills to address this audit objective.

b) **Verification that planned arrangements are applied effectively.** Effectiveness is the extent to which the official controls produce an (intended) effect / achieve an objective. An adequately functioning official control system is expected, through its planned arrangements to verify compliance with the relevant legal requirements and, when non-compliances are detected, to take actions to mitigate or eliminate these non-compliances within an appropriate time interval. Additionally it should exercise a level of control and enforcement that can act as a deterrent to non-compliance and manage risks to safe food. Verification of this requirement should include an assessment of the quality, reliability and consistency of the controls and should involve on-site audit activities. The audit team will require the relevant technical expertise in order to address this audit objective.

c) **Verification that planned arrangements are suitable to achieve the objectives of official controls.** Suitability is about the "fitness for purpose" of the design and implementation of the control system to achieve the desired results. This aspect is particularly relevant when there are indications that controls, performed in accordance with planned arrangements, are not achieving their planned results or objectives. Verification of this requirement should include assessing the official controls, for example their planning, their frequency / intensity and the methods applied, having regard to the structure and risk profile of the production chain(s) and to production practices and volume. It should also look at constraints that may have influenced the planning or implementation of arrangements. The audit team should have substantial knowledge and understanding of system auditing, together with relevant technical input to address this audit objective.
Role

3.2 FSS audits of official controls involve verifying compliance by the Local Authorities with regard to relevant legislation and centrally issued guidance, implementation of the Multi Annual National Control Plan (MANCP) and adherence to local policies, procedures and plans to check that arrangements are being followed, whether they are effective and are suitable to achieve the objectives of Regulation (EU) 2017/625. These audits invariably involve on site verification at the Local Authority levels during which on the spot verification at the Food Business Operator (FBO) premises level will also be required.

4.0 Organisation of the Audit Function

4.1 FSS audit function sits within the Strategy and Governance Directorate reporting to the Director of Strategy. This directorate is separate from all policy and delivery functions. Overall accountability lies with the Chief Executive.

5.0 Implementation of the Audit Function

5.1 Implementation of the audit function is carried out using the guidance provided by the Commission on the implementation of the provisions for the conduct of audits under Article 6 of regulation (EU) 2017/625 and applies a systematic approach in relation to the planning, conduct, follow up and management of audits.

5.2 In accordance with the guidance provided, the audit programme is monitored and reviewed and any opportunities for improvement highlighted and incorporated into future planning.
Continuous Improvement Cycle

- Development of Audit Programme
- Audit Review
- Corrective and Preventive Action (and follow Up)
- Monitoring
- Reporting
- Audit Plan
- Audit Preparation
- On-Site Activities
- Audit Preparati
- On-Site Activities
- Reporting

Act

Plan

Check

Do
6.0 The Audit Process

6.1 Commission guidance provides guidelines for the conduct of the audit and describes the nature of the audit process in that it should display the following:

- Systematic Approach
- Transparency
- Independence
- Independent Scrutiny of the Audit Process

**Audit and Verification Activities**

6.2 FSS Audit Branch is responsible for verification of the performance of official controls by Local Authorities in accordance with their planned arrangements. These audits are performed in compliance with the FSS documents published on the FSS website at [Audit and Monitoring](#).

**On site Verification (Reality Checks)**

6.3 Verification visits have formed part of the audit system for some time and are a useful means of verifying compliance with the planned arrangements and these will continue to be an integral part of the audit. The approach to this will be dependent on the scope of the audit so in some cases there will be no prior warning given of the number of reality checks, locations or business details so as to ensure effective auditing of official controls.

**Audit Criteria**

6.4 Audit criteria should include objectives stemming from the MANCP, Regulations (EC) No 178/2002 and (EU) 2017/625, as well as specific requirements of relevant EU legislation and national legislation as applicable. Recommendations will be raised against the appropriate primary regulation. Recommendations for corrective and preventive action will be raised against the specific articles of this regulation, supported by any other applicable regulations and appropriate guidance.
‘Corrective action’ means action to eliminate the cause of a detected non-conformity or other undesirable situation.

‘Preventive action’ means action to eliminate the cause of a potential non-conformity or other undesirable situation.

6.5 Additionally, on the spot confirmation at the Food Business Operator (FBO) premises will also be required to verify full implementation of the necessary arrangements.

Audit Reporting

6.6 Audit reports should contain clear conclusions stemming from the audit findings which are supported by evidence and, where appropriate, recommendations. Where examples of good practice are identified these will, wherever appropriate be included in the final report.

6.7 Conclusions should address compliance with the planned arrangements, the effectiveness of the implementation, and the suitability of the planned arrangements to achieve the stated objectives, as appropriate. They should be based on objective evidence. In particular, where conclusions are drawn as to the planned arrangements’ suitability to achieve the stated objectives, evidence may be obtained from the compilation and analysis of results from several audits. In this case conclusions should extend beyond the boundaries of individual establishments and individual authorities.

6.8 Recommendations should address the end-result to be delivered rather than the means of correcting non-compliance. Recommendations should be based on sound conclusions.

6.9 Final reports and action plans will be published on the FSS Website.
Level of Assurance

6.10 A level of assurance will be assigned following each audit. The format for this will be based on Scottish Government auditing practices. See Annex 1.

Monitoring, Corrective Action and Follow up Activities

6.11 Where appropriate, an action plan should be drawn up and implemented by the auditee. It should propose time-bound corrective and preventive action to address any weakness identified by the audit or audit programme. The audit team will assess the suitability of the action plan and may be involved in verifying its subsequent implementation:

Follow-up of Audit Outcome / Root Cause Analysis

6.12 Corrective and preventive action should not be confined to addressing specific technical requirements but should, where appropriate, include system-wide measures. A root cause analysis of any non-compliance should be conducted by the auditee (and submitted as part of the action plan) in order to determine the most appropriate corrective or preventive action.

6.13 FSS audit team will close off the audit files following assessment of the implementation of the agreed action plan.

Dissemination of Best Practice

6.14 The Food (Scotland) Act 2015 gives Food Standards Scotland the power to promote best practice by Enforcement Authorities in enforcing food legislation, this will therefore be considered as part of any audit.
7.0 Types of Audits

7.1 Audit examine the effectiveness and appropriateness of official controls as implemented by Local Authorities in relation to food law and MANCP requirements and therefore be focused or targeted with respect to a specific aspect of food law.

8.0 Independent Scrutiny

8.1 Commission Guidance states that “The process of independent scrutiny should be carried out by a person(s) from outside both the audit body and the organisation subject to internal audits with sufficient level of independence and expertise to scrutinise the audit process. Where a body or a committee has been established with a view to independent scrutiny of the audit process, one or more independent persons should be members of such body or committee.”

8.2 Independent Scrutiny is defined as ‘A regular and planned process external to the audit body and the audited organisation with particular focus on the audit process to ensure that the process is capable of producing objective results and meeting its obligations’. FSS audit will be subject to independent scrutiny in accordance with the above.
### Annex 1 Definition of Assurance Categories

#### Assurance

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<th>Assurance Level</th>
<th>Description</th>
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<tr>
<td><strong>Substantial Assurance</strong>&lt;br&gt;<em>Controls are robust and well managed</em></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Reasonable Assurance</strong>&lt;br&gt;<em>Controls are adequate but require improvement</em></td>
<td>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.</td>
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<tr>
<td><strong>Limited Assurance</strong>&lt;br&gt;<em>Controls are developing but weak</em></td>
<td>There are weaknesses in the 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.</td>
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<tr>
<td><strong>Insufficient Assurance</strong>&lt;br&gt;<em>Controls are not acceptable and have notable weaknesses</em></td>
<td>There are significant weaknesses in the current risk, governance and/or control procedures, to the extent that the delivery of objectives is at risk. Exposure to the weaknesses identified is sizeable and requires urgent mitigating action.</td>
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