



Food Standards Scotland

Audit of Enforcement Authorities

Policy Document



1. Introduction

- 1.1 Food Standards Scotland has a key role in overseeing delivery of feed and food law (any form of control that is performed for the verification of compliance with feed and food law). Food Standards Scotland 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 we 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.

2. Legal Basis for Audit

- 2.1 The power to set standards, monitor and audit the performance of enforcement authorities was conferred on Food Standards Scotland 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*

¹ <http://www.gov.scot/Topics/Business-Industry/support/better-regulation/BetterRegulationBillConsultation/CodeofPractice>

(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 (EC) No 882/2004.

3. Regulation (EC) No 882/2004 and Commission Decision 2006/677/EC²

3.1 Article 4(6) of Regulation (EC) No 882/2004 requires that competent authorities shall carry out internal audits or may have external audits carried out, 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. Independent scrutiny of Food Standards Scotland’s audits shall be provided by Food Standards Scotland Audit and Risk Committee.

3.2 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 4(6) of Regulation (EC) No 882/2004. In order to help local authorities fulfil this requirement, (as part of its central role under the Food (Scotland) Act 2015 and Official Feed and Food Control (Scotland) Regulations 2009) Food Standards Scotland will continue to deliver external audit arrangements (as done previously under Food Standards Agency). This however, does not preclude local authorities from implementing their own audit regimes and in fact this will be encouraged. Food Standards Scotland’s audit role therefore fulfils two different requirements.

3.3 Commission Decision 2006/677/EC provides guidelines for the conduct of the audit on official controls to verify compliance with feed and food law, animal health and animal welfare rules referred to in Article 4(6) of Regulation (EC) No 882/2004 and it is this guidance document that Food Standards Scotland will follow in relation to its audit system. This Commission Decision describes the nature of the audit process in that it should display the following:

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

3.4 Article 2(6) of Regulation (EC) No 882/2004 defines audit as ‘a systematic and independent examination to determine whether activities and related

² COMMISSION DECISION 2006/677/EC of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules.

results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.’

4. Implementation of the Audit System

4.1 In general, to comply with the requirements of Article 4(6) of Regulation (EC) No 882/2004, an audit system should cover the following three points set out in Article 2(6):

- (a) **Verification of compliance with planned arrangements** in order to provide assurances that official controls are carried out as intended and that any instructions or guidelines given to staff carrying out the controls are followed. This may largely be addressed by document review, **but will also require on-site verification.**
- (b) **Verification of the effective implementation of planned arrangements.** In order to assess effectiveness, that is the extent to which planned results are achieved, **on-site operational implementation must be included.** This should include an assessment of the quality and consistency of the controls and should involve on-site audit activities.
- (c) **The audit system should also seek to assess whether the planned arrangements are suitable to achieve the objectives of Regulation (EC) No 882/2004,** and in particular the single integrated multi-annual national control plan. This should include assessing the suitability of official controls, with regard, for example, to their frequency and the methods applied, having regard to the structure of the production chain(s) and to production practices and volume.

5. Audits Commencing After 1st April 2016

5.1 Food Standards Scotland and its predecessor organisation have had an audit system in place for a number of years. Transition to Food Standards Scotland has both necessitated and facilitated a review of the audit system, for example The Framework Agreement on Official Feed and Food Controls by Local Authorities (which has been in place since 2001 and is the standard against which local authorities were audited) requires to be reviewed, and while this document continues to provide excellent guidance it does not have any legal standing.

5.2 The audit system has therefore been taken back to first principles and so recommendations will be raised against the primary EU regulation supported by the domestic legislation, Codes of Practice and associated centrally issued guidance as appropriate.

6. Main Elements of the Audit System

6.1 On site Verification (Reality Checks)

6.1.1 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 numbers, locations or business details so as to ensure effective auditing of official controls.

6.2 Audit Standard

6.2.1 As the Standard within the Framework Agreement does not currently have any legal basis, any recommendations will be raised against the appropriate primary regulation, therefore in relation to official controls this will be Regulation (EC) No 882/2004. Recommendations for **corrective and preventive** action will be raised against the specific articles of this regulation, supported by any other applicable regulations, the Food Law Code of Practice and centrally issued guidance (including the Framework Agreement until this ceases). With regard to audits of other food legislation that is not official controls the same principle will apply in that any recommendations will be raised against the primary regulation (e.g Regulation (EC) No 178/2002 (which lays down the general principles and requirements of food law) supported by the Food Law Code of Practice etc. as appropriate.)

'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.

6.3 Audit Reporting

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

6.3.2 Conclusions should address the 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, units of authorities and authorities.

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

6.4 Follow-up of Audit Outcome / Root Cause Analysis

6.4.1 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:

6.4.2 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.

6.5 Level of Assurance

6.5.1 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

6.6 Dissemination of Best Practice

6.6.1 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.

Definition of Assurance Categories

Assurance

Substantial Assurance <i>Controls are robust and well managed</i>	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 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.
Limited Assurance Controls are developing but weak	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.
Insufficient Assurance Controls are not acceptable and have notable weaknesses	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.