Food Standards Scotland

For safe food and healthy eating

Audit of the Operational Delivery Division

TRICHINELLA OFFICIAL CONTROLS

Audit Programme: 2025/2026, Audit 1

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Foreword

This audit is part of the annual programme of internal audits directed at the official food and feed controls delivered by Food Standards Scotland as the competent authority and is carried out by Food Standards Scotland's Audit Assurance Division.

These 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 associated planned arrangements.

Article 6 of this Regulation requires that to ensure compliance with the Regulation competent authorities shall carry out internal audits or have audits carried out themselves and shall take appropriate measures in the light of the results of those audits.

The audit scope was detailed in the audit brief and plan issued to the Operational Delivery Division on 28th April 2025.

The aim of the audit is to maintain and improve consumer protection and confidence by ensuring that the Operational Delivery Division is providing effective delivery of official controls and enforcement related to Trichinella rules in those approved establishments under Food Standards Scotland's remit.

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.

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1.0 Introduction

1.1 Trichinella is a genus of parasitic roundworms responsible for trichinellosis, a zoonotic disease transmitted to humans primarily through the consumption of raw or undercooked meat containing Trichinella larvae. The most common sources are pork, wild boar, and horse meat.

1.2 The United Kingdom is considered to have a negligible risk of Trichinella. The last confirmed human case linked to UK-produced meat occurred in 1969, while the last reported case in a domestic pig was in 1979, and in wildlife (a fox) in 2009, both in Northen Ireland.

1.3 Despite the low risk of Trichinella in the UK, the global movement of people and meat products, along with the increasing population of feral wild boar in Scotland, underscores the need for continued vigilance by the competent authority (CA). This is essential to protect public and animal health and to maintain confidence in international trade.

1.4 In Scotland, the Food Standards Scotland (FSS) is the competent authority responsible for ensuring that official controls related to Trichinella in meat are implemented across all approved meat establishments that slaughter or process domestic pigs and wild boars. Currently there are not any approved facilities for horse slaughter in Scotland.

1.5 The overarching legislative requirements stipulate that carcases of domestic swine must be sampled in slaughterhouses as part of the post-mortem examination, where appropriate. Sampling is also required for all carcases of horses, wild boar and other wild animal species susceptible to Trichinella infestation in slaughterhouses or approved game handling establishments (AGHEs).

1.6 As an indication of the scale of surveillance, in Scotland in 2024, approximately 240,000 domestic pigs were slaughtered across 10 porcine approved establishments. Additionally, 107 feral wild boar carcases were processed in 2 AGHEs. In total, 20,518 samples were taken and analysed for the presence of Trichinella. All results were negative.

1.7 This report highlights the key findings and conclusions drawn from the assessment of official controls for Trichinella in meat delivered by the FSS through its Operational Delivery Division.

1.8 The overarching criteria which detail the standards that the assessment has been made against are contained within the relevant sections of:

- Regulation (EU) No 2017/625
- Commission Implementing Regulation (EU) 2019/627
- Regulation (EU) No 852/2004
- Regulation (EU) No 853/2004
- Commission Implementing Regulation (EU) 2015/1375

1.9 The planned arrangements assessed with regards to the delivery of these criteria were primarily contained within:

- The Scottish Manual for Official Controls, (SMOC) and
- Internal procedures provided by the Operational Delivery Division.

1.10 This audit was planned as a combination of documentary assessment, remote interview of FSS staff responsible for the operational management of the service, and on-site reality checks.

1.11 The on-site verification element was carried out in two red meat slaughterhouses located within Operational Areas 2 and 3. These sites represent approximately 93% of all pigs slaughtered in Scotland and they encompass the various testing routes.

Reason for the Audit

1.12 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.

1.13 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.

1.14 No previous audit specifically addressing this topic has been conducted since the establishment of FSS. The Audit Assurance Division identified the need for this assessment to ensure that the delivery of official controls continues to support and uphold the high level of confidence in public and animal health, as well as international trade related to this matter.

Scope of the Audit

1.15 It was agreed that the audit scope would cover:

- A review and assessment of those arrangements, policies and procedures developed/adopted by the Operational Delivery Division to discharge their obligations.
- An assessment of the capacity and capability to deliver these official controls.
- An assessment and verification of the implementation of those arrangements 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 Food Standards Scotland has established a comprehensive framework for managing the risk of Trichinella in meat production. The audit confirms that official controls are effectively implemented across Scottish establishments, with no significant risks identified to public or animal health.

2.2 There is notable variation in procedures across establishments, reflecting the flexibilities permitted under current legislation and the need to tailor processes to each establishment's operational requirements. This highlights the importance of having comprehensive documented FSS internal procedures at plant level for consistency and continuity.

2.3 In cases where legislation requires procedures to be formally approved by the CA – such as derogations related to health marking and the cutting of carcasses prior to receiving test results, we found that sufficient supporting evidence was not consistently available at the plant level to meet auditing requirements.

2.4 There appears to be regular cross office engagement and communication channels between FSS and different stakeholders / competent authorities in the topic. Contingency arrangements are in place for responding to a hypothetical positive Trichinella test result.

2.5 Laboratory capacity was found to be sufficient to meet current and potential future testing demands. Testing is conducted by both a designated external laboratory and an in-house self-testing slaughterhouse laboratory, with an approximately 83:17 split.

2.6 We had concerns regarding the designation of the in-house self-testing slaughterhouse laboratory. Specifically, we questioned whether sufficient consideration had been given to the requirements for impartiality and the avoidance of conflicts of interest, as outlined in the Official Controls Regulations (OCR).

2.7 The audit team observed a high standard of official control delivery and staff competency at the two establishments visited, which together account for the majority of Trichinella testing in Scotland.

2.8 An important part of the monitoring focusses on the reconciliation of data through the Operational Workflow System (OWS) and while this appears reasonable and adequate, we consider that the tools available to support this process do not enable staff to carry out these tasks efficiently. As a result, inconsistent data may be inadvertently passed through the system without detection.

2.9 Record-keeping practices were found to be robust and well-organised across sites, with both digital and handwritten documentation effectively maintained and readily accessible, ensuring traceability.

Level of Assurance

2.10 The audit's assurance category has been assigned as below. The four assurance categories are shown in Annex B.

2.11 The audit provides **Reasonable Assurance** that official controls for Trichinella are being delivered effectively across Scottish establishments. While the framework is comprehensive and no significant risks to public or animal health were identified, the audit highlighted areas for improvement, including:

- Inconsistent documentation of procedures requiring formal approval.
- Governance and impartiality concerns related to the in-house self-testing laboratory.
- Limitations in the OWS that hinder efficient data reconciliation.

These findings indicate that while controls are adequate, enhancements are needed to strengthen governance, transparency, and operational efficiency.

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.

3.0 Audit Findings

Article 5. General obligations concerning the competent authorities.

Planned arrangements

3.1 The overarching legislative requirements for Trichinella official controls in meat requires that FSS, as the CA, ensures meat samples from carcases of animals susceptible to trichinella infection are collected and tested at post-mortem examination. Meat may only be released for human consumption once negative tests results have been confirmed.

3.2 The audit confirms that Trichinella official controls are generally well implemented across Scottish establishments, with no evidence of non-compliance that would pose a risk to public or animal health.

3.3 Operational procedures and arrangements are detailed in chapter 2.4 of the SMOC. This was found to be current, clear and sufficiently detailed to meet the relevant obligations. Operational updates to this chapter have been communicated to all staff members via action notes when needed. Of particular interest were action notes 2023/12-01 and 2024/10-01 related to changes in controlled house conditions recognition following instructions by the Scottish Government, which evidences the engagement between different CAs on this topic.

3.4 There are currently nine approved slaughterhouses and two game handling establishments in Scotland where trichinella official controls are routinely implemented.

3.5 In addition to tasks directed to the verification of these official controls, FSS staff are actively involved in the collection, packing and dispatch of meat samples in all but one of these establishments. In this establishment, FBO staff are responsible for collecting and delivering the samples to the in-house laboratory for testing. Following a request from one of the establishments, FSS is currently developing new arrangements and conditions to allow FBO staff to assist with the collection, packing and dispatch of meat samples for trichinella to the designated external laboratory.

3.6 Arrangements contemplate not only certain legislative operational flexibilities with regards to health marking or cutting up of the carcases before receiving the required negative result allowing the carcase to be released, but also to provide flexibility at plant level to accommodate FBO operational needs - for example, but not limited to, antemortem and identification of animals requiring testing, detention procedures or the handling of animal by-products pending positive release.

3.7 Where written Standard Operational Procedures, SOPs, and/or local agreements between the FBO and FSS plant-based team were in place, or where verbal explanations were provided in their absence, it was evident that each establishment operates in a way that best suits its context, applying in some occasions the flexibilities permitted by legislation. As examples of flexibility, some of the establishments have arrangements in place allowing health mark application before test results are received. Cutting up of carcases prior to receiving results appears to take place in only one establishment. Typically, FSS staff are present during the release of the carcases, however, this might not be the case in some of the island abattoirs where the Official Veterinarian (OV) is generally only present on slaughter days. The flexible arrangements documented were found to be acceptable in providing control assurance.

3.8 Arrangements for the transport and delivery of the meat samples to the laboratory, when required, are in place and considered appropriate. On the mainland, this process is managed by an external contractor, while in the islands, public postal services are the preferred method. These arrangements appear to function effectively, with no significant non-compliances reported.

3.9 Operational arrangements are overseen by Veterinary and Operational Managers, while the management of and engagement with various contractors is handled by the Service Level Agreement (SLA) Coordinator.

3.10 Contingency arrangements are in place for responding to a positive Trichinella test result. These form part of the broader UK contingency plan, in which FSS participates alongside other competent authorities. This was partially tested in 2019 with a false positive result reported on a wild boar sample.

3.11 As part of the general arrangements, Trichinella falls within the portfolio of one of the Veterinary Advisors. This role involves maintaining subject matter expertise, disseminating relevant knowledge, and representing FSS in external meetings and forums with stakeholders and other competent authorities.

Designated laboratories.

3.12 In Scotland, arrangements include the use of two designated official laboratories; one is a laboratory that conducts testing of official samples on behalf of external clients, and the other is an in-house self-testing slaughterhouse laboratory. Both laboratories have been formally designated by the FSS under the OCR legislation, as outlined in documentation issued.

3.13 There appears to be sufficient laboratory capacity to meet current testing demands, with no concerns about handling increased sample volumes if required. In 2024 a total of 20,518 meat samples tested. Of these 3,614 were processed by the

designated external laboratory while 16,904 were tested in the in-house self-testing laboratory.

3.14 The governance of the designation, oversight and monitoring/auditing of these laboratories varies and falls under the responsibility of different FSS Divisions. As a result, effective communication and collaboration between the relevant teams play an important role in ensuring consistency and alignment across these responsibilities.

3.15 FSS's Science Division oversees the responsibilities associated with the designated external laboratory. However, this area was not explored within the scope of the current audit, therefore, no opinion has been provided.

3.16 For the in-house self-testing laboratory, the designation letter is issued by the Operational Delivery Division, while the initial assessment, ongoing oversight, and performance monitoring are carried out by the National Reference Laboratory (NRL). We found the governance arrangements for the latter somewhat complex and less straightforward; however, they remain consistent with legislative requirements.

3.17 The audit identified concerns regarding one aspect of the designation of the in-house self-testing slaughterhouse laboratory. Specifically, we questioned whether sufficient consideration had been given to the requirements for impartiality and the avoidance of conflicts of interest, as outlined in the OCR regulations.

We were not presented with evidence that these requirements had been formally assessed or met during the initial assessment and no subsequent assurance has been provided by the NRL.

While we acknowledge that the absence of documented evidence may be a legacy issue dating back to when FSS was part of the Food Standards Agency (FSA), we believe that, given the potential for perceived or actual conflicts of interest in self-testing arrangements, FSS should formally review and consider how this assessment is made during the approval and subsequent assurance processes. (**Recommendation 1**).

Recommendation 1: Article 5 and Article 37 of Regulation (EU) 2017/625
FSS should formally review and document how impartiality and conflict of interest requirements are assessed and managed in self-testing laboratory designations, in line with OCR regulations.

3.18 The NRL monitors the performance of the in-house laboratory through quarterly proficiency test and biannual audits (i.e. twice yearly). Audit reports are shared with the FSS Operational Delivery at the time of completion, while proficiency test results appear to be reported on an exceptional basis.

3.19 Findings and recommendations identified by the NRL are communicated to the FBO for corrective action. These are also discussed at the management level with FSS Operational Delivery, as the maintenance of the laboratory's designation depends on the outcome of these monitoring procedures and the adequacy of the corrective plan proposed by the FBO.

We found sufficient documented evidence of the implementation of these arrangements.

We noted, that following some certain findings by the NRL, the OV at the site attended a training session at the NRL to become familiar with laboratory practices and processes for trichinella testing. One of the intended outcomes of this training, as explained, was to enable the lead OV to act as a point of advice to the FBO when needed. We consider that appropriate caution should be exercised regarding this advisory function to ensure it aligns with the current monitoring, assurance and oversight framework.

3.20 As a final note, evidence was presented with regards to the designation letter by FSS / FSA of the NRL under Article 100 of Regulation (EU) 2017/625. This letter also encompasses oversight and performance monitoring responsibilities for the self-testing laboratory.

Plant reality checks

3.21 These auditors were highly satisfied with the delivery of these official controls at the two establishments visited, which together accounted for approximately 87% of all meat samples tested in 2024.

3.22 Both establishments demonstrated strong procedures to ensure compliance with regulatory requirements for Trichinella official controls in meat, particularly in the following areas;

- Animals requiring trichinella testing are correctly identified, and this information is communicated to the FSS team during antemortem inspection, and

- Full traceability is maintained throughout the process – from antemortem inspection, processing, and postmortem examination (including trichinella sampling), to the detention of carcases and offal, and finally to the release

and distribution of meat for human consumption following positive release upon receiving result.

In the hypothetical event of human error by the FBO at any stage of these processes, we are confident that such discrepancies would be promptly identified by the FSS plant-based team through the daily routine reconciliation and verification activities conducted, allowing timely corrective and enforcement action to be taken.

Article 12. Documented control procedures.

Plant procedures

3.23 In most, though not all, of the establishments within the scope of the audit, we found that some form of written information was available to the FSS team, outlining the specific arrangements for delivering these official controls at the site.

3.24 When present, this information typically consisted of daily task lists for the OV, and in some cases, was also complemented by the FBO's SOPs. In many instances, these documents provided sufficient detail to support operational resilience, particularly for team members less familiar with the site. However, in some cases, the information could have been more comprehensive and detailed.

3.25 When legislation requires procedures to be formally approved by the CA – such as derogations related to health marking and the cutting of carcasses prior to receiving test results, we found that sufficient supporting evidence was not consistently available at the plant level to meet auditing requirements. (Recommendation 2).

Recommendation 2: Article 12 of Regulation (EU) 2017/625
FSS should ensure that supporting evidence for procedures requiring formal approval by the FSS team — such as legislative derogations — is clearly documented and readily accessible at plant level. Additionally, general operational information necessary for the effective delivery of Trichinella - related tasks by FSS staff should be consistently available and up to date.

3.26 The auditors were satisfied with the level of adherence to internal procedures observed at the two establishments visited. All members of the FSS teams demonstrated a strong understanding of the general trichinella legislative requirements and their site-specific operational procedures, including those who had only recently joined the team.

3.27 In one of the establishments audited, we observed that the internal Trichinella procedures had been formally documented, dated and signed by both the OV and the FBO. This document was displayed on a wall in the office, ensuring clear visibility and promoting consistency among staff. We identified this as an example of best practice, which could be considered for wider adoption across other establishments, if deemed appropriate.

Good Practice: Trichinella Procedures – Documentation and Visibility
In one of the establishments audited, we observed that the internal Trichinella procedures had been formally documented, dated and signed by both the OV and the FBO. This document was displayed on a wall in the office, ensuring clear visibility and promoting consistency among staff.

Monitoring

3.28 Overarching monitoring and performance arrangements are in place at both contractors and plant level.

3.29 The SLA & Contracts Coordinator within the Operational Delivery Division maintains regular communication and holds routine meetings with the external laboratory to review performance indicators and operational matters. This ongoing engagement helps ensure the contract is delivered efficiently in terms of both service quality and cost, as evidenced by documentation provided. Any issues identified during these meetings are escalated to Operational Managers for appropriate action. For example, action note 2024/12/02 was issued to all staff instructing that the weight of each individual sample must be recorded on the appropriate recording form.

3.30 Monthly reconciliation of samples submitted and analysed, both at the external and in-house self-tester laboratories, is carried out by the Co-ordinator. For this, data is extracted from the OWS sampling module and crossed check against figures provided by the labs. Any discrepancies are escalated to Operations Management level for investigation at plant level. Evidence indicates that such discrepancies do occur. While they are ultimately resolved, addressing them requires considerable time and effort from both management and FSS plant-based team.

3.31 In addition monthly rotational checks of OWS modules entries in establishments are carried out by members of the Operations management team in each of the operational areas. There is evidence that a number of issues have been picked up through these checks and forwarded to FSS plant-based team for investigation and answer.

3.32 The audit team conducted a thorough review of OWS entries across all establishments within the scope of the audit. This process proved to be extremely

laborious, and numerous instances were identified where discrepancies required investigation at plant level for clarification.

We also encountered difficulties in reconciling food chain information counts, with slaughter and throughput counts. The records reviewed contained instances of duplication and missing entries, which significantly hindered accurate cross-checking. This was of particular concern as we consider that this is significant information and should be accurate and readily accessible for reconciliation purposes.

While our queries were ultimately resolved to our satisfaction, the common denominator was linked to genuine human errors during data entry, errors that had not been detected by either the FSS plant-based teams or through the existing rotational monthly checks.

3.33 In summary, while the current monitoring arrangements appear reasonable and potentially adequate, we consider that the tools available to support this process do not enable staff to carry out these tasks efficiently. As a result, inconsistent data may be inadvertently passed through the system without detection. (Recommendation 3). The auditors note that a new Operational Delivery IT Solution (ODITS) is currently being developed in-house by FSS to replace the existing OWS platform in the near future. While this new system has the potential to address the issues identified during this audit relating to OWS functionality, it remains in the development phase and was therefore not assessed.

Recommendation 3: Article 12 of Regulation (EU) 2017/625
FSS should ensure that the development of the ODITS system, intended to replace the current OWS platform, incorporates robust data validation features and user-friendly monitoring and reporting tools to address the limitations identified in the current OWS system regarding Trichinella related data.

Article 13. Written records of official controls

3.34 In addition to the records maintained in the OWS system, a significant volume of handwritten documentation related to Trichinella controls was observed. These include records from antemortem inspections (e.g., AMI 2–3), daybook entries, traceability records (e.g. PMI 17 and 18), operational processing logs, and laboratory result submission forms.

3.35 Both establishments visited maintained well-organised record folders, readily accessible to all staff. This included a dedicated Trichinella folder containing all relevant traceability and laboratory result reports. At other establishments not visited, the FSS teams were also able to provide via email the necessary records

when requested by the auditors, effectively addressing any data discrepancies identified.

3.36 Overall, these record-keeping arrangements were found to be appropriate for their intended purpose, with robust implementation observed across the sites.

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

3.37 Enforcement procedures and policy embedded in the SMOC provide operational staff with clear guidance on this area of official controls.

3.38 A review of Trichinella related enforcement entries across the establishments within the scope of the audit indicated a generally high level of compliance by the FBOs, with only a minimal number of interventions required for non-compliances observed by authorised officers. The auditors were satisfied with the level of compliance observed at the two establishments visited.

This supports the view that these official controls are being delivered effectively and FSS staff are able to identify and address issues through routine verification tasks.

4.0 Annex A – Action Plan

Action Plan for Operational Delivery Division – Trichinella Official Controls Audit – May – July 2025

Recommended Point for Action	Planned Actions	Target Date for Completion	Responsible Officer(s)
1. FSS should formally review and document how impartiality and conflict of interest requirements are assessed and managed in self-testing laboratory designations, in line with OCR regulations. ***Priority: High***	Bring this topic for discussion with FSA and NRL to include assessment and monitoring of impartiality and conflict of interest in the contract with the NRL	31/12/25	Interim Head Veterinarian
2. FSS should ensure that supporting evidence for procedures requiring formal approval by the FSS team—such as legislative derogations—is clearly documented and readily accessible at plant level. Additionally, general operational information necessary for the effective delivery of Trichinella-related tasks by FSS staff should be consistently available and up to date. ***Priority: Medium***	Review all FSS and FBO plant protocols and ensure they are robust enough and approved by FSS OVs when required. Include Trichinella protocols in the OV/MHI Duties Plant Protocols.	31/12/2025	Interim Head Veterinarian Veterinary Advisors

Recommended Point for Action	Planned Actions	Target Date for Completion	Responsible Officer(s)
3. FSS should ensure that the development of the ODITS system, intended to replace the current OWS platform, incorporates robust data validation features and user-friendly monitoring and reporting tools to address the limitations identified in the current OWS system regarding Trichinella related data. ***Priority: Medium***	To inform ODITS system development team and ensure this tool is built in within the system	April 2026	Interim Head Veterinarian Head of Operational Delivery

All action were completed following the receipt of evidence from Operational Delivery Division.

Audit has been closed in February 2026.

5.0 Annex B – Assurance Categories

Definition of Assurance Categories

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 **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.

6.0 Acknowledgements

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

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Food Standards Scotland
Audit Assurance Branch

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Abbreviations

AGHE	Approved Game Handling Establishment
CA	Competent Authority
FBO	Food Business Operator
FSA	Food Standards Agency
FSS	Food Standards Scotland
NRL	National Reference Laboratory
OCR	Official Controls Regulation
ODITS	Operational Delivery IT Solution
OV	Official Veterinarian
OWS	Operational Workflow System
SLA	Service Level Agreement
SMOC	Scottish Manual for Official Controls
SOP	Standard Operational Procedure