Chapter 4

Audit, HACCP and Verifying Operator's Own Checks

Part 1 Audit

Part 2 HACCP based procedures

Part 3 Verifying operator's own checks

Part 4 Annexes

Part 1 Audit

1. Introduction
2. Legislation
3. FBO responsibility
4. FSS Role

1. Introduction

1.1 Definitions and Background information
1.2 Purpose of OCV audits
1.3 Relationship between OCV audit visits and OV attendance
1.4 Commencement of FBO audits following approval or periods of closure

1.1 Definitions and Background information

1.1.1 Official Control Verification (OCV) audit system

The audit system has changed from January 2021 with the implementation of Official Controls Verification (OCV) audits, resulting in a more in-depth, practical and structured auditing process, which also introduced a new reporting template, the Establishment Live Report (ELR). The purpose of the OCV audit approach is to encourage sustained compliance by the Food Business Operators (FBOs) of FSS approved meat establishments.

The objective of the OCV system is to provide a framework which, when uniformly applied across all food Competent Authorities in Scotland, can ensure a methodical and consistent approach that meets the requirements of the legislation, secures a high level of public health and protects the reputation of Scottish food businesses. Generic OCV Guidance is available here.

1.1.2 OV presence

OVs are present in slaughterhouses to conduct regular inspection tasks (which include ante and post-mortem inspection) every operational day.

Daily OV presence is not required for cutting plants, either standalone or collocated with abattoirs. However, collocated establishments operating at times coinciding with the slaughterhouse operational hours are under the supervision of the abattoir OV and the inspection team, who may carry out daily reality checks. In addition, all collocated CPs may receive an unannounced inspection (UAI) in accordance with the current audit system.

1.1.3 Official visits

Official visits to any FSS approved establishment (regardless of OV presence in slaughterhouses for carrying out inspection tasks), may be conducted for the purpose of delivering the audit programme, approval visits or unannounced inspections.

1.1.4 Audit frequency

The new audit format consists of a range of inspections and documentary checks spread over a period of 15 months (this can, however vary, taking into account certain factors – see Audit Operational Guidance at Annex 2) for all FSS establishments. It ensures a systematic and structured approach applied to all FSS approved establishments, and includes the use of the OCV tools for planning, review of documentation and reality checks (see OCV Guidance).

Each establishment will receive a number of interventions (minimum 3), both announced and unannounced. The required resource is calculated at the start of the audit cycle by considering the nature of the establishment, the number and category of the activities undertaken within the establishment and the number of employees. The resource calculation methodology is described in the OCV Guidance.

Documentary checks can be undertaken remotely by using a data-sharing platform between each FBO and FSS (Objective Connect).

The audit cycle will not aim to verify all the FBOs' Food Safety Management System (FSMS) in one visit/ document review, but each visit will focus on some areas so that all FSMS will be verified by the end of the audit cycle.

An ELR is completed after each intermediate visit and sent to the FBO. The ELR is a live document and guidance for its completion can be found in Annex 2. The final ELR (FELR) is completed at the end of the audit cycle, and it provides the final audit rating. A reduced version of this is published on FSS website.

1.1.5 Announced Inspection

Audit inspections that are notified and agreed in advance with the FBO are called announced inspections. These are carried out by FSS Veterinary Auditors.

1.1.6 Unannounced Inspection (UAI)

As part of the scheduled audit cycle, unannounced inspections (UAIs) take place at least once during each audit cycle in standalone CPs; these are called Classic UAIs.

Targeted UAIs can take place in slaughterhouses, AGHEs, collocated and standalone CPs to follow up specific issues identified during the audit cycle or via other FSS OCs, or to follow-up on intelligence received. In addition to the auditors, UAI visits can be conducted by the Veterinary Advisors (VAs) or by trained MHIs or OVs.

1.2 Purpose of OCV audits

1.2.1 Relevant premises

These audit arrangements apply to all FSS-approved meat establishments and similar processes are also being gradually implemented in Local Authority (LA) approved premises.

1.2.2 Risk assessment scheme

The audit risk assessment scheme applies the requirement of Regulation (EC) 2019/627, Article 4, to determine the nature and frequency of audit using the following risk criteria:

- public health risks
- animal health risks (where appropriate)
- animal welfare risks (where appropriate)
- throughput and type of processes carried out
- FBOs past record of compliance with food law.

1.2.3 Aim of audits

The aim of the FBO audit is to verify compliance with relevant legal requirements and to ensure adequate FBO standards in relation to public health, animal health and welfare.

Audit findings should provide individual FBOs as well as the relevant competent authority (FSS and Scottish Government, via the Service Level Agreements with FSS) with information on compliance levels, and/ or areas in need of correction or improvement. For FSS, this may result in the review of the SMOC or the development of new guidance, procedures and training.

1.2.4 'Effective' audit

An effective audit methodology is defined as follows:

- complies with the requirements of Regulation (EC) 2019/627 to determine the frequency of interventions on the basis of risk
- applies appropriate standards in determining the level of assurance that can be given to the Competent Authority (CA) about the FBO management procedures and identification of risk
- accurately assesses the FBO's level of compliance with the legal requirements and identifies necessary interventions
- recognises the FBO's good practices and identifies opportunities for improvement
- communicates audit findings to the FBO and the Competent Authority (if different to FSS)
- is consistent in its approach.

1.2.5 OCV system

FSS in partnership with Scottish Local Authorities (LAs) developed an enhanced approach for protecting the consumer and supporting and regulating approved establishments, called Official Controls Verification (OCV). This approach applies focused scrutiny of risk areas and consequently provides a greater degree of assurance regarding consumer protection, safeguarding businesses and verifying food safety and compliance levels.

Audit technique	Description
Official Control Verification	Change from an outcome-dependent audit frequency to a minimum standard of 15 months inspection cycle for all establishments. Resource calculation undertaken for each establishment at the beginning of each cycle. Resource planning/allocation using remote documentation review, announced and unannounced inspections. Documentation review and on-site inspections carried out with the use of the OCV tools as described in the OCV Guidance. Use of only one report per plant (ELR) throughout the inspection cycle, which gathers up evidence collected from all inspections/interventions, including UAIs.

	The ELR is sent to the FBO after every intervention which includes, as a minimum: an outcome (intermediate/ final), a list of non-compliances and a description of all the objective evidence collected during the inspections.

1.2.6 Publication of FBO's audit report

The Freedom of Information (Scotland) Act 2002 (FOISA) gives individuals a general right to information held by Scottish public authorities (subject to certain exemptions) and to have this information communicated to them. The Environmental Information (Scotland) Regulations 2004 also provides a right of public access to a range of environmental information held by Scottish public authorities and some other bodies.

Important note: Audit reports of all FSS approved meat establishments in Scotland are published on the FSS website.

1.3 Relationship between OCV audit visits and OV attendance

1.3.1 Overview

Audits of FSS approved establishments are mainly carried out by qualified Veterinary Auditors, who operate separately from Veterinary Advisors and routine inspection duties. The only exception is around unannounced inspections (both classic and targeted), which, depending on their scope, can also be conducted by trained MHIs and OVs.

1.3.2 Premises with continuous or regular OV attendance

Activities collocated to abattoirs or GHEs will be subject to regular checks by the OVs, regardless of the audit timetable. Daily checks in collocated operations are not necessarily required and the frequency of inspections are determined based on risk assessment.

Reference: The Food Hygiene (Scotland) Regulations 2006 (as amended), Regulation 14 (2).

Collocated operations will be audited at the same time as the slaughterhouse or AGHE, as part of the same process, with a single ELR being produced. However, if there are activities regularly conducted out with the operational hours of the abattoir/ AGHE, the auditor may wish to inspect those separately.

1.4 Commencement of FBO audits following approval or periods of closure

1.4.1 Premises with specific requirements

The table below summarizes the circumstances under which specific types of establishments operate under a different audit regime.

Establishment	Audit regime
All conditionally approved establishments (slaughterhouses, cutting plants and game handing establishments)	The FBO Audit Cycle will not commence until full approval has been granted to the establishment following the FSS Officer's approval assessment(s). Where full approval has been granted, the audit cycle starts the day after the full approval letter has been issued, with the first intervention taking place after approximately 3 months.
Existing premises with full approval: on change of FBO or legal entity	A change of FBO marks the end of an existing establishment's approval. The new FBO is required to make an application for new approval, and the above procedure will apply.
Existing premises with full approval: on application to extend or vary activities	• if the establishment has already entered the audit cycle, this will be paused. • if the audit cycle was just completed, a new one will start after the full approval of the new activity/ies. Further information can be found in the Audit Operational Guidance (Annex 2)
Seasonal, temporary or long-term closures	Following a period of closure, the FBO must notify FSS at least 2 weeks prior to resuming operations. The FBO must not resume operations until a pre-opening visit by FSS AOs has been conducted. **Note:** Periods of closure are defined at paragraph 12.30 of the Scottish National Protocol (SNP). Where the outcome of the pre-opening visit confirms that the establishment meets all legislative requirements, the next audit cycle begins on the day operations resume. However, this may vary on a case-by-case basis, depending on the plant's operational pattern.

1.4.2 Pre-opening assessments

Following a period of closure (seasonal, temporary or long term) the FBO must not resume operations but must first notify the Area Operations Manager (OM) in writing. The OM should then inform FSS Approvals, and a pre-opening assessment visit will be planned by the Area Veterinary Advisor (VA). This can be conducted by any FSS staff, depending on risk and as directed by the VA.

This visit is to assess whether the establishment meets all structural and equipment requirements, as well as other relevant food law obligations, including the existence of a valid FSMS based on HACCP principles.

The FBO's FSMS must be available for review during the visit; however, as the establishment will not be operational, it will not be possible to assess how effectively this works in practice. The effectiveness of the FBO's FSMS will therefore be assessed at the first scheduled audit visit undertaken by the Veterinary Auditor.

Reference: A pre-opening assessment aide-memoire is available at Annex 11. This is intended to act as a reminder of the areas to assess at the time of the visit.

1.4.3 Action following pre-opening assessment

Following the pre-opening assessment visit, if the FSS area VA is content that the establishment meets all the relevant requirements of food law, FSS Approvals will notify the FBO in writing that operations may resume.

In the event that the FSS Area VA determines that the establishment is not fit for operations to restart, the FBO will be notified of the deficiencies and the required corrective action. Appropriate enforcement action will be taken as necessary. Operations may not recommence until the deficiencies are resolved on a permanent basis and timely reassessment visits should be coordinated by the VA.

If serious deficiencies exist, the Area VA must follow the Intervention Protocol, as described in SMOC Chapter 7.

1.4.4 Unauthorized resumption of operations

Where FSS becomes aware of an establishment that has recommenced operations without prior notification and a pre-opening assessment visit has not been undertaken, the following measures must be taken:

- The Area VA will coordinate the appropriate enforcement action to prevent the FBO operating the establishment until a formal assessment of compliance has been undertaken, or where deficiencies are identified, such deficiencies have been rectified.

- If food has been placed on the market prior to a formal assessment, the FSS action regarding withdrawal/ recall of food will be risk-based and proportionate and in discussion with FSS Incidents team. However, food not yet placed on the market may be detained until the FBO has been notified by Approvals that operations may re-commence.

For further details, refer to the SNP.

2. Legislation

2.1 General requirements for official controls

It is a requirement of Regulations (EU) 2017/625 and (EU) 2019/627 that official controls will verify the FBO's compliance with Regulations (EC) 852/2004, (EC) 853/2004 and other national regulations that apply to approved meat establishments.

As part of this verification process, auditors must assess good hygiene practices and HACCP-based procedures as required by Regulations (EC) 852/2004, Article 5 and (EC) 853/2004, Annex II, Section II – i.e., the FBOs FSMS.

The auditor must also verify the FBO's continuous compliance with their own procedures, including those related to animal by-product handling (including SRM control), animal identification, and animal health and welfare.

Regulation: Regulation (EU) 2017/625, Article 18 and Regulation (EU) 2019/627, Article 3.

2.2 Food fraud

The recommendation of the Food Fraud Task Report 2007 is that auditors and other officials visiting food premises should bear in mind the possibility of fraudulent activities. If any concerns exist, they should be raised immediately to foodcrime@fss.scot

2.3 GHP audit

Audits of good hygiene practices (GHPs) shall verify that FBOs apply procedures continuously and properly. A list of pre-requisites to consider can be found in subtopic 3.2.2 on 'HACCP and pre-requisites' of this Chapter - Part 1.

Reference: Regulation (EU) 2019/627, Article 3, Paragraph 1.

2.4 HACCP audit

Audits of HACCP-based procedures are to verify that FBOs are applying procedures continuously and properly. The auditor must determine whether the procedures guarantee, to the extent possible, that products of animal origin:

- comply with microbiological criteria laid down in the relevant legislation
- comply with the relevant legislation on residues, contaminants and prohibited substances
- do not contain physical hazards, such as foreign bodies.

Reference: Regulation (EU) 2019/627, Article 3, Paragraphs 2 and 3

When an FBO takes additional measures to guarantee food safety by implementing integrated systems, private control systems or independent third-party certification, or by other means, and where these measures are documented and animals covered by such scheme are clearly identifiable, the CAs may take such measures into account when carrying out audits to review good hygiene practices and the HACCP-based procedures.

Reference: Regulation (EU) 2019/627, Article 4.2.

3. FBO Responsibility

3.1 Compliance with the legislation

3.2 HACCP based systems

3.1 Compliance with the legislation

3.1.1 FBO standards

The FBO is required to comply with the requirements of Regulations (EC) 852/2004 and (EC) 853/2004 and other relevant national Regulations that apply to approved meat establishments. These are the standards against which the auditor will assess the FBO performance at audit.

A FSMS must be implemented and must be sufficient to achieve the objectives of the Regulations.

3.1.2 Access, records and assistance

The FBO is required to offer all assistance needed to ensure that OCs carried out by the CA can be performed effectively and in particular to:

- give access to all buildings, premises, installations or other infrastructures
- make available any documentation and records required under the Regulations or considered necessary for assessing compliance levels.

Reference: Regulation (EU) 2017/625, Article 15; The Food Hygiene (Scotland) Regulations 2006.

3.2 HACCP based systems

3.2.1 Obligation to implement

The FBO, considering the nature and size of the business, has a duty to implement a permanent procedure based on the 7 HACCP principles to:

1. identify any hazards that must be prevented, eliminated or reduced to acceptable levels
2. identify the CCPs / control points required by regulations at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels

3. establish critical limits / legal limits at CCPs / control points required by regulations which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards
4. establish and implement effective monitoring procedures at CCPs / control points
5. establish corrective actions when monitoring indicates that a CCP / control point required by regulation is not under control
6. establish procedures, which shall be carried out regularly, to verify that the measures outlined above are working effectively
7. establish documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined above.

When any modification is made to the product, process, or any step, FBOs shall review their procedures and make the necessary changes to it.

The FBO must also provide the competent authority with evidence of their compliance and ensure that any documents describing the procedures are up to date.

References: Regulation (EC) 852/2004, Article 5 & SMOC Volume 2 - EU guidance document on the implementation of procedures based on HACCP principles; the facilitation of the implementation of the HACCP principles in certain food businesses, and Part 2 on 'HACCP based procedures' of this chapter.

3.2.2 HACCP and pre-requisites

HACCP systems are not a replacement for other food hygiene requirements, but part of a package of food hygiene measures that must ensure safe food. It must be borne in mind that 'prerequisite' food hygiene requirements must be in place prior to establishing HACCP procedures, including in particular:

- checks on food chain information documentation
- the design and maintenance of premises and equipment
- pre-operational, operational and post-operational hygiene
- personal hygiene
- training in hygiene and in work procedures
- pest control
- water quality
- temperature control

- controls on food entering and leaving the establishment, and any accompanying documentation.

These requirements are designed to control hazards in a general way and they are clearly prescribed in law. They may be supplemented with guides to good practice established by the different food sectors.

Reference: Regulation (EU) 2019/629 Article 3 and the EU guidance document on the implementation of procedures based on HACCP principles and on the facilitation of the implementation of the HACCP principles in certain food businesses.

Regulation (EC) 178/2002, Articles 18 and 19.

4. FSS Role

4.1 Responsibilities
4.2 Audit schedule
4.3 Audit protocol
4.4 Completing the audit report (ELR)
4.5 Audit assessment
4.6 Actions following audit
4.7 Unannounced Inspections (UAIs)

4.1 Responsibilities

4.1.1 Who conducts the audit?

Only qualified FSS Veterinary Auditors will conduct intermediate and final audit interventions (reality checks or documentary assessments) at all FSS-approved meat establishments.

The minimum training requirements to conduct announced audit interventions and Classic or Targeted UAI can be found in the Audit Operational Guidance (Annex 2).

Note: OVs would not undertake full FBO audits but can provide supporting evidence for the audit if requested by the Auditors. All relevant evidence gathered by them during the audit period and recorded on the Enforcement Programme will be assessed by the Auditor for consideration during the audit cycle.

4.1.2 Audit tasks

Responsibilities and tasks are described in section 8.3 of the Audit Operational Guidance (Annex 2).

4.1.3 Auditor's code of ethics

The following four principles are the standards of conduct that are expected from any FSS auditor:

i. Integrity

Auditors shall demonstrate integrity in all aspects of their work. The relationship with Operational Management Team (OMT) colleagues, OVs, MHIs and with FBOs should

be one of honesty and fairness. This establishes an environment of trust which provides the basis for all activities carried out by the auditor.

ii. Objectivity

Auditors shall display professional objectivity when providing their opinions, assessments and recommendations. The auditor should not be unduly influenced by the views of others or by personal interest.

iii. Competency

The auditor shall not carry out audits if they feel they do not have the base auditor competency or if they lack technical competency in the area being assessed. All auditors are to hold Food Safety Lead Auditor and Advanced level HACCP qualifications.

iv. Confidentiality

Auditors shall safeguard the information they obtain while carrying out their duties. There should not be any unauthorized disclosure of information unless there is a legal or professional requirement to do so.

4.1.4 Auditor exclusions

The auditor should not:

1. assume accountability for FBO compliance
2. take over tasks that are for the FBO to perform
3. act as a quality assurance manager
4. act as an advocate between industry and the FSS
5. write company procedures or HACCP plans, although some advice may be given
6. provide the FBO with a copy of the draft audit report.

4.1.5 Field staff duties

Field staff must ensure that they are familiar with the procedures and systems put in place by the FBO of the establishment where they work, in particular for the processes for which they have an inspection role.

Note: The OV must ensure that MHIs working under their technical responsibility maintain a current understanding of the FBOs procedures and systems.

4.2 Audit schedule

4.2.1 Arranging first announced visit of the audit cycle

Audit cycle timescales are described in the Audit Operational Guidance (Annex 2).

FBO audit visits should, as far as reasonably practicable, be arranged whilst the establishment is operational and processing.

The scheduling of audit visits will be monitored in order to ensure that audit targets and planned resource allocations are met.

The first visit of a new audit cycle is planned 3 months after the end of the previous audit cycle. The 3-month gap between the last visit of the previous audit cycle and the first visit of the new audit cycle is considered to be part of the new audit cycle.

The FBO is informed by the Audit and Approvals Executive that their establishment is scheduled to receive the first intervention of the audit cycle via a letter sent by email a month before the planned intervention. This letter provides the FBO with the scope of the audit, guidance to access the shared workspace on Objective Connect and instructions for uploading the required documentation.

Reference: Regulation (EU) 2017/625, Article 9, Paragraph 4

Notification of the audit will allow the FBO, or the relevant members of their management team, to make themselves and any relevant documentation available.

Note: Where applicable (e.g. in the case of seasonal operations), ad-hoc unannounced inspections may be triggered by the Area VA and OM to confirm that the establishment is indeed not operational, until the audit takes place.

4.2.2 Arranging subsequent visits of the audit cycle

Subsequent announced or unannounced visits of the audit cycle (intermediate/final) are scheduled depending on the resource calculation.

Targeted UAIs are scheduled as/when required.

4.3 Audit protocol

4.3.1 Collecting evidence on the compliance of the FBO

In slaughterhouses: FSS staff are present every day when the plant operates. As part of day-to-day business FSS staff are required to record objective evidence as to the level of compliance by the FBO with both their own procedures and with legislative requirements.

In stand-alone cutting plants: FSS staff will normally only be present to conduct the planned inspections of the audit cycle; UAI are now part of the audit cycle, so all non-compliances found during unannounced visits are recorded on the plant ELR.

Both OVs and MHIs have an important role to play in identifying and recording non-compliances. Objective evidence of non-compliance issues may be recorded:

- on the relevant operational form
- in the daybook
- in the Enforcement Programme (OWS)

Note: 'Major' or 'critical' non-compliances may trigger immediate action and should be raised to the Area VA with immediate effect, as the Intervention Protocol may need to be triggered.

4.3.2 Assessment of operational records/ document review

Prior to each visit of the audit cycle, the auditor must review the shared workspace on Objective Connect and use this information to assess the effectiveness of the FBO's FSMS procedures and HACCP-based system with regards to the relevant sections/systems that will be inspected. For the purpose of the assessment, the auditor might request and review other records they find relevant, including hygiene, welfare and animal by-products forms.

The auditor must also take into account FBO's past record as regards compliance with food law, by reviewing the ELR of the current audit cycle and past Audit Reports/ELRs. These can be accessed through eRDM - the corporate documents and records management system accessible to all eRDM trained Scottish Government staff.

Reference: Regulation (EU) 2019/627 Article 3 Paragraphs 1-4

In slaughterhouses or AGHEs which require the continuous or regular presence of FSS staff, the auditor shall review:

- the most up-to-date Enforcement Programme, available through UnityLive by selecting the appropriate report, as described in the Audit Operational Guidance at Annex 2.
- the Monthly Plant Checks available in the plant folder on SharePoint.

Auditors can also obtain additional information about the level of FBOs' compliance in an establishment through contact with the local FSS team (MHIs, OVs, and Area VA and OM).

4.3.3 The opening meeting

The auditor shall start each audit cycle with an opening meeting with the FBO (or appropriate representative) and outline the:

- reason for and scope of the audit, anticipated length of the audit and the day program
- information and access that will be required

- purpose of the subsequent closing meeting
- publication of audit categories.

The opening meeting should also be used to:

- confirm that there are no changes to FBO, structures, equipment or activities since the last audit, that all necessary approvals are in place for all activities undertaken and these are supported by valid and verified HACCP plans
- highlight that if during an audit it is identified that there has been a change of legal entity, the audit may be stopped and the approvals team informed, as a new approval may be required
- review of any outstanding non-compliances
- highlight any issues identified from the review of operational forms.

4.3.4 When conducting the audit

During the audit, the auditors will:

- collect and record objective evidence in relation with FBO's compliance with legislative requirements for FSMS based on HACCP principles, including animal by-product and where appropriate, SRM, animal health and welfare procedures
- inspect the establishment ('reality checks') to observe whether the FBO's procedures in practice reflect the policies and procedures as documented

  Note: In slaughterhouses some of this information will be gathered on a daily basis by MHIs / OVs and Auditors will also be using that information.
- make use of the OCV tools (e.g. triangulation and gap analysis, random sampling, structured interview techniques) to verify FBO compliance
- where necessary, collect samples for laboratory analysis, to verify FBO's compliance, for example on cleaning or cross-contamination issues (further details in Part 3 section 5 of this chapter)
- consider sampling by another relevant CA if they have no legal powers or lack competency and refer to said CA any concerns (e.g. Local Authorities for food standards)
- based on recorded evidence, score individual questions and sections of the ELR as compliant or non-compliant (minor, major and critical non-compliance)
- determine the overall audit outcome as Good, Generally Satisfactory, Improvement Necessary or Urgent Improvement Necessary

- if any active major or critical non-compliances, inform the Area VA immediately, for monitoring purposes and potential to activate the Intervention Protocol.

4.3.5 Serious issues identified during audit

If an issue of serious public health, animal health or welfare arises during an audit (major or critical non-compliances), the auditor should:

- inform the FBO & the OV (where appropriate) immediately, and the area VA as soon as possible
- take any necessary enforcement action
- consider the addition of targeted UAIs, in discussion with the area VA.

4.3.6 Reference to previous audit reports

During each inspection, the auditor should refer to the previous ELR to direct priorities during audit in a risk-based manner. The auditor should always follow-up on open non-compliant areas and reassess those where major or critical non-compliances were previously identified, even if already addressed.

4.3.7 Audit notes

It is important that audit notes are taken during the audit as they constitute an essential element to support the audit findings and justify the audit assessments.

Audit notes do not need to be submitted with the audit report but they should be retained and made readily available for next audit or as/ when requested.

Audit notes must be retained for a minimum of 2 years (more than 2 years if there are on-going outstanding enforcement actions) and securely destroyed when not required any more.

4.3.8 FBO involvement in audit

The auditor should expect to be accompanied by the FBO (or a nominated representative) during the visit. However, if this is not possible, the auditor can also conduct the visit unaccompanied and collect adequate evidence of their findings.

4.3.9 The closing meeting

Each visit must be concluded with a closing meeting with the FBO (or appropriate representative) which will:

- summarize the audit findings (positive and negative)

- outline any non-compliances
- discuss the corrective action required, including agreeing any proposed timescales and possible enforcement action
- discuss the confidence in FBOs food safety management systems score
- give an indication of the expected future audit category
- give details of report procedure
- outline subsequent action and right of appeal.

The closing meeting provides an opportunity for the FBOs to respond to audit findings, to discuss their proposed actions and to bring any further supporting evidence if they disagree with any findings.

The resident OV in slaughterhouses and GHEs should attend the closing meeting, whenever possible. The auditor will ensure they make every endeavor in this regard.

4.3.10 Further information provided by the FBO

The FBO may submit additional evidence following discussions at the closing meeting. Provided this evidence is received by the auditor within 5 working days of the audit, it may be taken into consideration.

4.4 Completing the Audit Report (ELR)

The auditor/UAI inspector must document the objective evidence and the findings of the audit inspection on the ELR. Guidance on how to complete the ELR can be found in Annex 2.

The auditor should use positive language during the closing meeting and in the audit report. This will help promote constructive communication of audit findings between the auditor and the FBO, better participation and resolution of non-compliances through joint identification of action and opportunities for improvement, which is the main aim of the audit.

4.5 Audit assessment

4.5.1 Recording compliance

Each sub-section of the ELR requires the auditor to gather evidence regarding the level of compliance with the stated outcomes and record it as compliant or minor, major or critical non-compliance.

Non-compliances are recorded on the Non-Compliance Report of the ELR and on the Enforcement Programme as described in the Audit Operational Guidance (Annex 2).

4.5.2 Definitions

Title	Description
Compliant	Compliance with a food safety Programme, food regulatory requirements and animal health and welfare regulations (in the case of slaughterhouses) is achieved if the food business is operating in accordance with its food safety management systems, food safety standards and has met the requirements of the regulations.
Minor	Legislative breach unlikely to compromise public health (including food safety), animal health and welfare or lead to the handling of unsafe or unsuitable food. A minor non-compliance is an isolated low risk situation and does not compromise achieving control measures of the food safety program (i.e. overall the food safety program is still effective in controlling the food safety hazards). When viewed collectively a number of related minor non-compliances may represent a major non-compliance. Examples (not exhaustive): • a single monitoring lapse of a process that is shown to be otherwise under control • minor structural defects • minor failure to follow good hygienic procedures specified in prerequisite programs • ineffective pest control in a limited area • slight variation from documented procedures • inadequate cleaning in a limited area • a few signatures missing on a record over a short time period intermittent or poor completion of records • more concerning, but isolated issues, where the FBO took immediate and adequate action to address them.
Major	Legislative breach likely to compromise public health (including food safety), animal health and welfare or possible to lead to the production and handling of unsafe or unsuitable food if no remedial action is taken. In addition, the accumulation of minor non-compliances observed during the visit or enforced due to a systematic failure would also merit a major non-compliance scoring.

	When viewed collectively a number of related major non-compliances may represent a critical non-compliance. Examples (not exhaustive): • complete departure from procedures contained in the food safety, animal health and welfare program • incomplete action for washing and sanitising procedures • inadequate staff training leading to unhygienic practices • recurrent monitoring lapses of a process • numerous structural defects, with potential impact on food safety or animal welfare • failure to follow good hygienic procedures specified in prerequisite programs.
Critical	Legislative breach that poses an imminent and serious risk to public health (including food safety), or animal health and/or welfare. In addition, when viewed collectively, a number of related major non-compliances observed during the visit or recorded in the Enforcement Programme as a systematic failure may represent a critical non-compliance. Examples (not exhaustive): • systemic failure of critical aspects of the FBO practices and procedures for implementing food safety, animal health and welfare regulatory requirements • a serious pest infestation • intentional falsification of records major cross-contamination issues, such as: the same chopping board and knife being used for ready to eat food after being used for raw chicken without being cleaned and sanitised; raw meat juices dripping onto uncovered ready to eat food • evidence of pest control chemicals such as rat bait in food • repetitive (more than once) major non-compliance for the same (or very similar) practice or circumstance.

4.6 Actions following the audit

4.6.1 Audit outcome

The approach following the audit will depend on the outcome of the audit and the number of identified minor, major and critical non-compliances. Definition of the possible audit outcomes are given in section 4.6.4, below.

4.6.2 Follow up of non-compliances in establishments with regular FSS presence

Non-compliances identified during the audit visits (announced or unannounced) are followed up by the resident OV in the case of slaughterhouses, collocated cutting plants and AGHEs.

4.6.3 Follow up of non-compliances in establishments without regular FSS presence

Non-compliances identified during the audit visits (announced or unannounced) are followed up by the auditor/UAI inspector in the case of standalone cutting plants. Overall responsibility to monitor standalone CP compliance rests with each area Veterinary Advisor.

4.6.4 Audit compliance assessment

4.6.4.1 FBO compliance history

The history of compliance relates to the deficiencies identified against legislative requirements or the FBO's own procedures and requiring FSS intervention during the audit period or the active NCs from the previous full audit.

Note: FBO initiating corrective actions where the FBO has identified a breakdown in controls is a sign of a healthy food safety management system.

During the audit, the auditor will record evidence of the FBO compliance history, which will result in a risk score under each category based on the following criteria and type of non-compliance.

4.6.4.2 Audit outcome categories

Using objective evidence the type of non-compliances identified during an audit reflects the extent and effectiveness of compliance.

The following grading system is outlined in the table below:

Inspection Cycle Outcome	Description	Tolerance for Inspection Cycle Outcome
Good	No issues of significance for public health, animal health or animal welfare during the entire audit period.	No majors or critical during the audit cycle
Generally Satisfactory	No immediate issues of significance for public health, animal health or animal welfare identified at the time the ELR was issued. No more than 2 completed (addressed by the FBO within the agreed completion date) major non-compliances are accepted.	No more than 2 completed majors, no active majors and no critical (active or completed) during the audit cycle
Improvement Necessary	Major non-compliances identified at audit and/ or non-compliances during the audit period not always responded to and corrected promptly.	Up to 6 completed majors; or up to 2 majors still active; up to one completed critical.
Urgent Improvement Necessary	Multiple major non-compliances or critical non-compliance identified during an audit visit or during the audit period. Intervention Protocol required to ensure public health safeguards.	More than 6 completed majors; or more than 2 active majors; or more than one completed critical; or any active critical.

4.6.5 Audit frequency of inspections & Resource calculation

The number of inspections carried out during an audit cycle is established through a formula, based on the accepted ISO Standard - ISO 22003:2007. See Annex 1 of the OCV Guidance and section 7 of the Audit Operational Guidance (Annex 2) for further details.

The resource calculation will give an indication of the time required for the full inspection cycle, but this is subject to review by the auditors, using their professional judgement/previous compliance history/risk assessment/provided intelligence.

4.6.6 Review and right of appeal

If a FBO is dissatisfied with the outcome of an audit or any findings in the audit report once received from the Audit Business Executive, the FBO has the right of appeal following this procedure.

4.7 Unannounced Inspections

4.7.1 Scope of guidance

This section provides an outline of the UAI process and details areas of responsibility for relevant staff.

4.7.2 Background and purpose

UAIs were introduced as a supplementary method to verify FBO's compliance with relevant legislation. The frequency of UAIs is established following a risk-based assessment. Establishments with no regular FSS presence will receive at least one UAI during each 15-month audit cycle (Classic UAI). If findings indicate an increased risk (as per section 1.2.2), the frequency will be amended accordingly and targeted UAIs triggered.

Authorised Officers (AOs) may undertake UAIs to cutting plants and GHEs, as directed by the audit programme or Area VA. Those unannounced visits in some circumstances may also be joined by LA Food Enforcement Officers/ Environmental Health Officers (EHOs).

Domestic law indicates that official controls (which consist of audit or inspection tasks) should be carried out without prior warning (except audits). This process is intended to introduce unannounced inspections, which will be used to inform the OCV audit outcomes and provide further evidence of FBO's compliance levels.

Reference: Regulation (EU) 2017/625, Title II, Chapter II, Article 14

The purpose of UAIs is to:

- support the FSS Veterinary Auditors during the audit cycle as an important tool to provide evidence of continuous application of HACCP based procedures by FBOs
- bring an unannounced element to official controls at CPs and GHEs
- follow up on previous non-compliances (NCs) and update them via the ELR
- provide management information to the VA, OM, Head Veterinarian, Head of Field Operations and Head of Operational Delivery.

4.7.3 Programme of inspections

All cutting plants and GHEs must receive at least one UAI during the audit cycle. After this initial UAI, the need for further UAIs may be identified and the Area VA and OM will utilize a risk-based approach when scheduling further inspections. Time spent on UAIs will be variable, dependent on findings, and managed accordingly via local knowledge. The timesheet should be recorded in line with existing guidance.
For the UAI reports, the ELR will be used to allow appropriate benchmarking and to further inform future FBO audit visits carried out by Veterinary Auditors.
The general inspection theme is set out below and inspections will encompass some or all of the following:

- hygienic production/ operational practices
- environmental hygiene
- implementation of HACCP based procedures
- animal by products controls
- TSE/ SRM controls
- CCP documentation
- structure
- traceability
- health marks and identification marks
- approved site areas and activities as per FSS approval documents.

4.7.4 Roles for inspections

UAIs can be conducted by a number of FSS official roles and more detail can be found in Annex 2.

4.7.5 Process

The Area OM, being informed of any upcoming UAI visits at the start of each month, is accountable and responsible for the UAI process, and will allocate the UAIs to trained MHIs/OVs. The OM then informs the area Veterinary Advisor (VA) and the Veterinary Audit Team of any scheduled Classic UAI.

Note: Prior to an MHI/OV conducting such inspections, the Area VA and OM must ensure that the individual has received the necessary level of training, support and guidance.

Only trained MHIs/OVs will be allowed to undertake UAIs and any associated enforcement action. Names of MHIs/OVs who have completed the FSS in-house training course will be provided to the VA and OM. A central list of MHIs authorised to

carry out UAIs will be recorded on the Staff Authorisations Database. For further information about the UAI training, see Chapter 10.

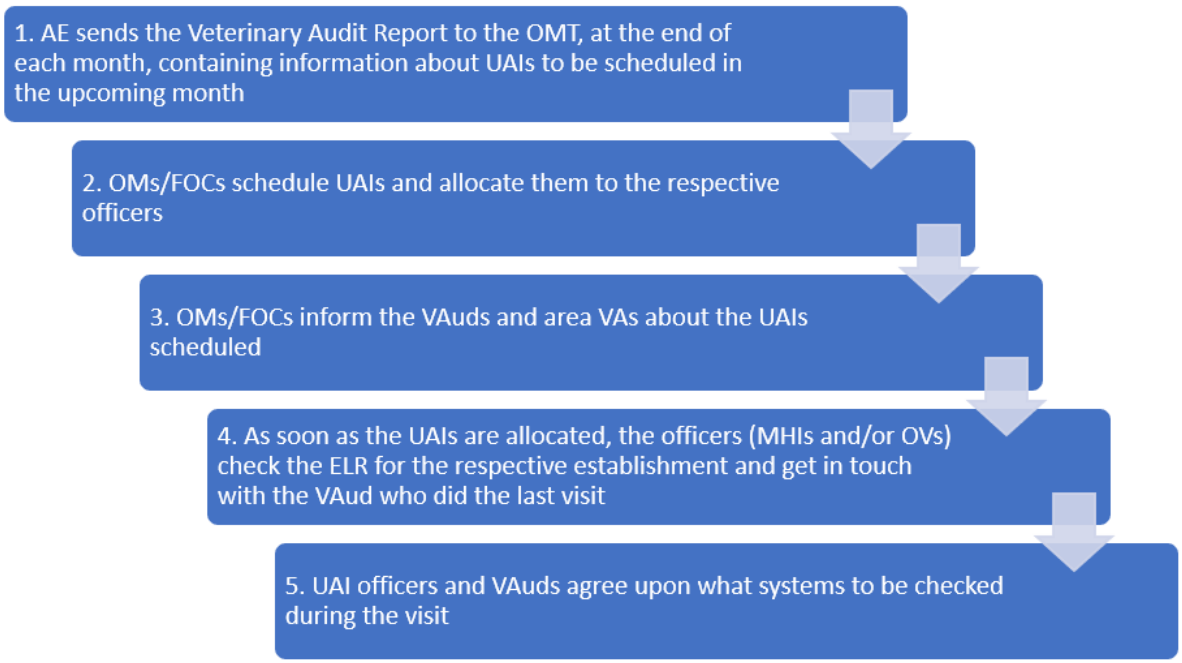
When quality checks have been completed by the Veterinary Auditor, the Approvals Executive should then be informed to update the UAI/ Audit log and complete the rest of administrative processes.

4.7.6 Pre-inspection preparation: Authorised Officer

Prior to carrying out any UAI to a cutting plant, the AO must ensure that:

- they have received the training, guidance and support to enable them to carry out an unaccompanied UAI
- they have received and assessed the current enforcement actions and most recent ELR for the respective plant
- they have had discussions with the Veterinary Auditor conducting the last audit visit and relevant VA prior to the inspection, if required, to clarify any areas of the enforcement programme or the operations to be reviewed
- they have the contact number for the relevant VA and that the VA and OM are aware of the day and time of the inspection
- they are equipped with:
    - FSS authorisation and ID card
    - If required as an aide-memoir, printed version of the ELR form for the inspection (note: this can be accessed and printed from the SharePoint site)
    - contemporaneous notebook
    - calibrated thermometer
    - camera
    - torch
    - appropriate enforcement forms (RAN, HIN, Detention Notice)
    - detention tape and seals.

The following process outlines the preparation for UAIs:



4.7.7 Refusal of AO access

If, when attempting to conduct UAI, the AO is refused access to the premises, they should immediately contact the VA to seek guidance and record the details in their contemporaneous notebook.

4.7.8 During the inspection

The AO should carry out the inspection following the protocols established in the guidance and following any instructions provided, specific to the plant in question. The AO can follow the printed UAI ELR form during the inspection, by making appropriate entries to aid subsequent electronic completion. AOs must take an overall view of the operating practices on the day of the inspection.

The AO must ensure that evidence is gathered to inform the Audit Team and relevant VA regarding any required enforcement action and update on the issues raised at the time of the last audit visit. Any non-compliance or updates on existing issues should be recorded on the ELR.

Note: If a serious public health contravention is identified during the course of the inspection, regardless of whether it is outside of the pre-defined scope of the inspection, the AO must immediately telephone the VA. Appropriate support should be given to the on-site MHI/OV immediately; if required, the OM should be asked to assemble and dispatch support to the site in question without delay. The VA will support the AO in relation to any necessary enforcement action required and appropriate evidence to be gathered.

Corroboration of findings should be sought as much as possible - see Chapter 7, Section 2 “Gathering and Preserving Evidence” for further detail.

4.7.9 After the inspection

Using their notes from the course of the inspection, the AO should electronically complete the ELR (see Audit Operational Guidance in Annex 2). The completed ELR should then be sent to the Approvals and Audit executive for cascade to a second officer, for verification.

After completion and verification, the VA and OM must be informed, and the enforcement module properly updated. If there are major or critical issues identified, the Area VA should be notified immediately via phone.

4.7.10 Time coding for UAI

The OWS Timesheet guidance should be followed by all staff.

Part 2 HACCP-based Procedures

1. Introduction

2. Key considerations on HACCP auditing

3. Enforcement of HACCP deficiencies

1. Introduction

1.1 Legislation

1.1.1 HACCP legislative framework

The following table summarises the different pieces of legislation that cover FBO and OV responsibilities in relation to HACCP based procedures.

Regulation		Key points	Who is responsible?	Other documents
Regulation (EC) 852/2004	Chapter II, Article 5	Put in place, implement and maintain a permanent procedure based on HACCP principles	FBO	Commission Guidance Food Safety Management Diary for Meat Producers
	Annex II, Chapter XII	Train staff responsible for the development and maintenance of HACCP-based procedures in the application of HACCP principles	FBO	Commission Guidance
Regulation (EC) 853/2004	Annex II, Section II	List of HACCP based objectives for incoming animals accepted for slaughter	FBO	Commission Guidance

Commission Implementing Regulation (EU) 2019/627	Chapter I, Article 3, Paragraphs 2 and 3	Audit and verification that FBOs apply HACCP principles continuously and properly	OV	Commission Guidance SMOC Food Safety Management Diary for Meat Producers

1.1.2 Key reference documents

The European Commission has produced a guidance document for the implementation of procedures based on HACCP principles and to facilitate the implementation of HACCP principles in certain food businesses.

Reference: SMOC Volume 2 Legislation for additional information.

The Food Safety Management Diary for Meat Producers ('the Diary') has been produced by FSS for smaller operators.

The Diary is specifically designed to facilitate FBOs to keep records relating to the hygienic operation of their businesses. It also includes draft documentation on prerequisites and HACCP. The use of the Diary by FBOs is voluntary.

Reference: See section 10 of Annex 3 on 'Principle 7: documentation' for additional information.

1.2 Characteristics of HACCP based procedures

1.2.1 Purpose

HACCP principles are a tool for FBOs to use to control hazards that may occur in food.

HACCP is a set of 7 principles used to assess hazards and establish control systems that focus on prevention of problems rather than relying solely on end-product testing.

1.2.2 Implementation requirements

The successful application of HACCP based procedures requires the following:

- the FBO must already have implemented the hygiene controls that are required by legislation (prerequisites / good hygiene practice)
- requires the full commitment of management and the involvement of the work force

1.2.3 'Traditional' HACCP vs. HACCP based procedures

'Traditional', 'classic' or 'technical' HACCP is not the same as 'HACCP based procedures'.

Traditional HACCP evolved from spacecraft manufacture to guarantee the safety of astronauts' food. It remains appropriate for industrial production of processed foodstuffs involving for example, sterilisation or pasteurisation steps.

It is, however, acknowledged in Regulation (EC) 852/2004 and particularly in the Commission's guidance on HACCP that such a technical approach may not be appropriate for all types and sizes of food businesses. In the case of meat plants, for example, it can be sufficient to apply the principles in a more flexible way following guides to practice.

1.2.4 'Flexibility': Nature and size of the operations

Flexibility regarding the application of HACCP principles may be applied, taking into account:

Flexibility taking into account	Comments
Nature of the operations	In businesses handling food with no significant food safety hazards (for example, greengrocers) a hazard analysis confirming that is the case can be sufficient. In businesses handling many foods (for example, restaurants) a simplified approach using a diary can be sufficient. In businesses involving simple processing (for example, slaughterhouses and cutting plants) a generic plan with a diary for record keeping can be sufficient as long as they are adapted to reflect company conditions. In food manufacturing businesses, particularly with procedures that will eliminate hazards (for example, canning plants) full technical HACCP is more appropriate. OV/Vet Auditor should consider whether the HACCP-based procedures are appropriate for the type of business.

Size of the business/ documentation	The size of business and resources available will have a bearing on the complexity of the HACCP based system; however a simple, easily managed system can also achieve the safe production of food, same as a more complex system. A traditional HACCP system relies heavily on recording that all the procedures are being followed correctly, probably by the Quality Control, Quality Assurance or HACCP team. Small and medium sized businesses rarely require the same level of documentation. They may choose to record when things go wrong, called 'exception reporting'. **Reference**: See Annex 3 section 10 on 'Principle 7: Documentation' for additional information. OV/Vet Auditor should note that there is no value in FBO documentation being disproportionate to the level of risk and the recording of HACCP-based monitoring procedures being a burden to small-medium businesses.

1.2.5 Flexible application of HACCP principles

FBO application of HACCP principles should meet the following requirements:

- identify the main hazards associated with the type of product produced and the operations carried out
- flexibility: hazards – generic descriptions of hazards may be sufficient
- identify those Critical Control Points (CCPs)/ Control Points (CPs) necessary to control those hazards
- flexibility: CCPs – generic guidance may include pre-determined CCPs in the preparation, manufacturing and processing of food
- establish critical (or legal) limits against which to monitor the effectiveness of control measures at CCPs/ CPs
- flexibility: critical limits – it is not always necessary to fix a numerical value, especially where monitoring procedures are based on visual observation (for example, the faecal contamination of carcases in a slaughterhouse), however acceptability should be clearly separated from unacceptability
- monitor CCPs / CPs
- flexibility: monitoring – may be a simple procedure, for example, a visual observation to monitor whether the correct de-hiding procedure is being applied during slaughter where this part of the slaughter process has been identified as a CCP for preventing carcase contamination

- take the necessary corrective actions based on the results of the monitoring activities
- record the observations and corrective actions taken; the requirement of retaining documents needs to be flexible in order to avoid undue burdens for small / medium businesses
- flexibility: recording – in the case of visual monitoring procedures it can be acceptable to record results only when there is a problem and the corrective action that has been taken; that is, 'exception reporting'; a diary can be a suitable method of record keeping
- verify the HACCP-based procedures
- flexibility: verification – checking all aspects of the HACCP plan can be spread throughout the year so that all aspects are verified at least once a year to meet the requirement for 'regular' verification

1.2.6 Review of HACCP-based procedures

The HACCP procedures should be reviewed and necessary changes made by the FBO when any modification is made in the product, process or any step.

1.2.7 OV/Vet Auditor role

OV/Vet Auditors, through auditing, need to determine the level of FBO compliance with HACCP principles, always taking into consideration the possibility of implementing simplified HACCP based procedures particularly in small / medium sized businesses.

2. Key considerations on HACCP auditing

Guidance can be found in Annex 3.

3. Enforcement of HACCP deficiencies

3.1 AO advisory role

Where the Veterinary Auditor or the OV finds that the FBO has HACCP-based procedures but there are deficiencies that do not pose a public health risk, the AO should not serve a formal notice, but advice, educate and encourage rectification of the HACCP-based procedures. The FBO may be directed to the Meat Plant HACCP Manual and the Food Safety Management Diary sample documents.

The AO advisory role does not extend to personally writing any part of the FBO's food safety system for example, HACCP plans and monitoring documentation.

Details on Enforcement are given in Chapter 7 of the SMOC: the following subsections are to be considered as a brief guideline of enforcement actions in relation to HACCP-based procedures.

3.2 Notifying the deficiencies to the FBO

If after verbal advice and an advisory letter the FBO has made:

- no effort to implement a food safety management system based on HACCP-based procedures, or
- negligible effort to implement a food safety management system based on HACCP-based procedures, or
- once implemented, the FBO has failed to maintain a system based on HACCP-based procedures,

the AO is to serve a Hygiene Improvement Notice (HIN) for each of the HACCP principles that are not being complied with. There are certain situations where serving a RAN for HACCP related issues (i.e. monitoring and corrective action) may be appropriate.

Reference: Regulation (EC) 852/2004, Chapter II, Article 5 and Regulation (EC) 853/2004, Annex II, Section II.

3.3 Approved activities

Separate HINs are to be served on each of the establishment's approved activities, such as slaughtering and cutting. Separate notices avoid:

- having to withdraw an entire notice that has only be partially complied with
- the suspension of entire notices because of appeals over one issue
- the service of more notices on those areas still outstanding.

3.4 Timescales for compliance

The timescale for compliance with the HIN will be minimum 14 days and will depend upon the size of the establishment, the nature and complexity of the operations and the history of compliance of the FBO. The AO is responsible for making an assessment of the specific circumstances for the plant to provide a reasonable timescale in line with the enforcement concordat and risk-based procedures (it is proportionate).

3.5 Failure to comply with a notice

If the FBO fails to comply with the HIN(s) or RAN(s), the AO should recommend the issue for investigation by completing the Referral for Investigation (ENF 11/6).

The AO must keep a record of the FBOs progress on HACCP implementation made after a referral for investigation has been made. This will help identify actions that should have been taken earlier and will help to counter any mitigating factors that the FBO puts forward if the case goes to court.

3.6 AO records of FBO compliance

The OV must keep records of the advice given to the FBO in the plant daybook and/or in the Enforcement electronic module.

The Veterinary Auditor must record the advice given to the FBO in the ELR.

Part 3 Verifying operator's own checks

1. Plant Monthly Checks

2. Verification of microbiological criteria

3. Traceability

4. Official Control Verification Sampling Procedures

5. The use of lactic acid to reduce microbiological surface contamination on bovine carcases

1. Plant Monthly Checks

Article 13 of Regulation (EU) 2017/625 requires the CAs to draw up written records of every official control that they perform and that those records can be on paper or in electronic form.

Plant checks forms have been established in slaughterhouses and AGHEs (available in Annex 4 and 5 respectively). OVs must carry out and record those checks at the frequency established (monthly, quarterly, six-monthly) for the systems listed and detailed in the table below.

Frequency	Systems
Monthly	Traceability Animal Welfare Maintenance Cleaning Microbiological testing Temperature controls ABP Labelling Cross-contamination checks
Quarterly	Livestock records and animal health Pest control HACCP Water OTM carcases Imports Staff training Staff health and medical programme
Every 6 months	Approval

The Plant checks form must be stored on SharePoint in every plant folder (Area/Plant/Enforcement/Year). Instructions on how to complete it are available in Annex 7.

2. Verification of microbiological criteria

2.1 Background
2.2 Legislation and guidance documents
2.3 Testing requirements: slaughter operations
2.4 Testing requirements: other operations
2.5 Testing requirements: ready to eat products
2.6 Testing failures
2.7 AO role: all establishments
2.8 Enforcement: microbiological criteria

2.1 Background

2.1.1 Purpose of microbiological testing

FBOs has the responsibility to comply with microbiological criteria that apply to meat in accordance with the provisions set out in Regulation (EC) 2073/2005, as established by Regulation (EC) 852/2004 Article 3 (a).

The purpose of microbiological testing is to ensure that:

- results support validation or verification of the correct functioning of FBO's procedures based on HACCP principles and good hygiene practice
- the supply, handling and processing of meat under the FBO control are carried out in a way that process hygiene criteria (PHC) are met
- process controls are reviewed where results indicate contamination is occurring
- food safety criteria (FSC) are met throughout the shelf life of the product under reasonable conditions of distribution, storage and use
- corrective actions are taken to protect the health of consumers when test results, under the FSC, are unsatisfactory (for example, by withdrawal or recall of non-compliant product)

The following pages provide expanded guidance on the role of the AO in monitoring and verifying FBO compliance with microbiological criteria.

2.2 Legislation and guidance documents

Regulation (EC) 2073/2005 (as amended) sets out the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by FBOs, when implementing the general and specific hygiene measures referred to in Retained Regulation (EC) 852/2004.

Regulation (EC) 2073/2005 has been amended by the following:

- Commission Regulation (EC) 2074/2005 (Implementing measures for certain products)
- Commission Regulation (EU) 217/2014 as regards *Salmonella* in pig carcases
- Commission Regulation (EU) 2017/1495 as regards *Campylobacter* in broiler carcases

Regulation (EC) 2160/2003 (as amended) on the control of *Salmonella* and other specified food-borne zoonotic agents applies in relation to *Salmonella* testing.

Regulation (EC) 178/2002 lays down general food safety requirements, according to which food must not be placed on the market if it is unsafe.

FBOs have an obligation to withdraw or recall unsafe food from the market.

Regulation (EC) 852/2004, Article 4, Paragraph 3 (a) states that FBOs are required to comply with microbiological criteria.

The **Food Hygiene (Scotland) Regulations 2006** make it an offence for any person to contravene or fail to comply with the specified community provisions.

Schedule 2 of these Regulations lays out the requirement in respect of Regulation 2073/2005 (as amended), in that the FBO will have to take the appropriate measures laid down in Article 7, Paragraphs 2 to 4 when test results prove unsatisfactory.

2.2.1 Vacuum and modified atmosphere packed chilled foods guidance

This FSA/FSS guidance provides best practice advice on vacuum packed and modified atmosphere packed (VP/MAP) chilled foods irrespective of the distribution channel, in relation to microbiological safety and shelf-life limitations associated with control of non-proteolytic *Clostridium botulinum*.

It was reviewed in 2020 after the report of the Advisory Committee of the Microbiological Safety of Foods (ACMSF) subgroup was published. It does no longer apply to chilled fresh beef, lamb and pork, which is packed without added ingredients or further processing beyond cutting, packing, chilling, freezing and quick-freezing. This exception to the scope of the guidance does not extend to any beef, lamb or pork that is subject to further processing such as mincing, cooking or mixing with any other ingredients such as herbs, spices or curing salts. The FSA/FSS best practice guidance continues to apply to these and all other VP/MAP chilled foods.

The ACMSF with the aforementioned report endorsed a recommendation that FBOs, including small and medium sized food businesses, may apply a maximum 13 day shelf-life for their VP/MAP chilled fresh beef, lamb and pork in relation to *C. botulinum* should they wish to do so, without additional controlling factors for *C. botulinum*.

2.2.2 Guidance on the approach to be taken on the enforcement of the legislative requirements regarding the number of days between slaughter and mincing of chilled meat

The guidance is available in Annex 9.

2.3 Testing requirements: slaughter operations

2.3.1 Testing requirements and sampling procedures: slaughter operations

The sampling frequencies vary for red and white meat slaughterhouses, dependent on throughput and historical data.

The analytical methods and the sampling plans and methods in Annex I of Regulation 2073/2005 shall be applied as reference methods.

The use of alternative analytical methods is acceptable when the methods are validated against the reference method and if a proprietary method, certified by a third party in accordance with the protocol set out in EN/ISO standard 16140 or other internationally accepted similar protocols, is used.

Sampling methods, rules and frequency are described in detail in Annex 8 (Microbiological Sampling Guidance) and Annex 7 Appendix 1 (Audit Aide Memoire).

2.3.2 Red meat

Testing in red meat slaughterhouses is to verify process hygiene only; there are currently no food safety microbiological criteria.

PHC set indicative microbiological values above which corrective actions are required in order to maintain the hygiene of the process.

For red meat carcases these are *Salmonella* spp, *Enterobacteriaceae* and Aerobic Colony Count (ACC).

2.3.3 Poultry

Broilers and turkeys are tested for ***Salmonella*** to check food PHC in slaughterhouses.

The samples taken to check food process hygiene as per the above procedures can also be used to verify compliance with FSC. To this effect, FBOs must carry out further

tests where *Salmonella* spp results have been positive to identify whether *S. enteritidis* or *S. typhimurium* are present.

Broilers are also tested for ***Campylobacter*** to check the process hygiene criteria in the slaughterhouse.

2.3.4 Monitoring testing requirements and sampling results

The OV should monitor the sampling, transport to the laboratory, laboratory methods and provision of results at slaughterhouses where sampling and testing is required.

Note: see section 2.7 on AO role for further details.

The requirement for the OV to verify the sampling arrangements is part of the Plant Monthly Checks for both red and poultry slaughterhouses and AGHEs (Annex 3 and 4).

The verification must be completed at least monthly or aligned with the FBO testing frequency, if this is less than monthly. The OV should liaise with the FBO or their representative at agreed intervals and review the results in comparison with the FSS monitoring of contamination results.

2.4 Testing requirements: other operations

2.4.1 Criteria requirements: other operations

Testing in operations other than slaughter falls into two broad sections:

- processed meat to be cooked before consumption, and
- ready to eat (RTE) meat products.

Testing is required for minced meat, meat preparations, meat products and mechanically separated meat (MSM). This topic deals with meat intended for consumption after cooking; the testing of RTE meat products is covered in section 2.5.

For processed meat, testing is required for:

Minced meat or meat preparations	5 x 25 g samples once a week from a minimum of one batch per establishment for products made from poultry meat, and 5 x 10 g for products made from all other species. **Note**: Only one batch per establishment is required to be tested selected using a risk-based approach.
Mechanically separated meat	5 x 25 g once a week samples from one batch. **Note**: This criterion applies to MSM produced with the techniques referred to in paragraph 3 of Chapter III of Section V of Annex III to Regulation (EC) 853/2004

Meat products	5 x 25 g samples from one batch at the frequency decided and recorded by the producer as part of the HACCP-based plan. This should be based on the risks involved with the process and historical data.

Note: more detailed information can be found in Appendix 1 of the FBO Audit Aide Memoire (Annex 7).

Sampling is on a batch basis as per table above. A batch is defined as a *'group or set of identifiable products obtained from a given process under practically identical circumstances, produced in a given place within one defined production period'* (Regulation (EC) 2073/2005 Article 2).

2.4.2 Pooling of samples

The pooling of samples for *Salmonella* testing is permitted only if it takes place at the testing laboratory and where evidence is available to show the sensitivity of the method is not reduced. A note explaining how to undertake pooling is included in the reference method for *Salmonella* ISO 6579: 2002.

2.4.3 Exception to testing

Minced meat and meat preparations in establishments producing an average of less than 2 metric tons per week of combined minced meat and meat preparations product intended to be eaten cooked are currently not required to take any samples. This exception is on the basis of a risk analysis carried out by FSS as the competent authority.

Note: This exception **does not** apply to MSM or minced meat / meat preparations intended to be eaten raw or undercooked (for example burgers intended to be eaten less than thoroughly cooked).

2.4.4 AO checks in stand-alone cutting plants

In a cutting plant, the AO should make verification checks on sampling and testing at every audit or UAI visit.

2.5 Testing requirements: RTE products

2.5.1 Food safety criteria

The FBO should test for FSC and this should include testing the product for *Salmonella* and *Listeria*.

The FBO shall collect 5 x 25 g samples per batch. The laboratory must test with the relevant ISO standard for *Listeria* (EN/ISO 11290-1) and for *Salmonella* (EN/ISO 6579).

Reference: methods are described in Chapter I, points 1.2 and 1.3 of Annex I to Regulation (EC) 2073/2005.

All samples from RTE products should have negative results for *Listeria*, unless the FBO retains control of the product, in which case the FBO will need to demonstrate that the level is less than 100 cfu/g in RTE meats that do not support the growth of listeria, or there is evidence to show that the *Listeria* levels will not exceed 100 cfu/g during the shelf life of the product. For products with a shelf life of less than 5 days (for example, sandwiches) or a pH ≤ 5 (e.g. some cured meats) no testing is required other than for food destined for infants or special medical purposes.

2.5.2 Processing areas and equipment

Article 5 of Regulation (EC) 2073/2005 requires that FBOs producing RTE products sample the processing areas and equipment for *Listeria*.

All samples should show negative results.

2.5.3 Frequency of testing

The legislation does not set a frequency. It is for the FBO to demonstrate that the testing shows satisfactory results and, based on this, determine the sampling interval. Initially, it may be best to test weekly, or at whatever frequency the FBO produces RTE foods if less than weekly.

The link below provides FBOs with some information on testing for *Listeria*:

Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry

Once the FBO has results over a period of time and there are no failures, the FBO may increase the testing interval based on the evidence of testing and their food safety programme. In the event that the AO has any concerns surrounding the frequency of testing, they should escalate the matter to the Area VA.

2.5.4 Testing of chemical contaminants

Chemical contaminants in meat and meat products have various sources: environmental (e.g. dioxins, PCBs, heavy metals), process (e.g. acrylamide, furans,

PAHs), mycotoxins (e.g. *Fusarium*), contact materials (e.g. phthalates), plant toxins (e.g. tropane alkaloids, pyrrolizidine alkaloids), veterinary medicines & pesticide residues.

The main contaminants retained regulations are:

- Regulation (EEC) 315/93 Community procedures for contaminants in food ('Framework regulation')
- Regulation (EC) 1881/2006 Chemical contaminants in food (specific)
- Various Sampling and Analysis regulations e.g. Regulation EC/401/2006 - Sampling and analysis of mycotoxins.

However, if required, FSS AOs would use the non-specific pieces of regulation for enforcement of breaches:

- Regulation (EC) 178/2002 General food law
- Regulation (EC) 852/2004 on the hygiene of foodstuffs
- Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin
- Commission Implementing Regulation (EU) 2019/627 laying down specific rules for the organization of official controls on products of animal origin

  FSS AOs may be presented with failed test results by the Local Authorities and required to take action. An example and legal levels are set below:

Polycyclic Aromatic Hydrocarbons (PAHs)	
Sources	Environmental: industrial processes, fires, vehicles Food processing: flame cooked/smoked meat & fish products, some dried foods
Maximum Levels set under Reg 1881/2006	Smoked meat and smoked meat products: • **2.0 µg/kg** - Benzo(a)pyrene (B(a)P), • **12.0 µg/kg** - Sum of B(a)P, B(a)anthracene, B(b)fluoranthene and Chrysene Higher levels still in place for traditionally smoked products.
Risk	• carcinogenic, genotoxic (especially B(a)P) • long-term/chronic rather than short-term acute risk
Management	Codex Code of Practice • fuel type • temperature/time

	• direct/indirect smoking • equipment cleanliness • post-process treatment

2.6 Testing failures

In the event of a testing failure, the process to be followed depends on where the product is.

For both the FSC and the PHC, the FBO shall take the measures laid down in paragraphs 2 to 4 of Article 7 in Regulation (EC) 2073/2005, together with other corrective actions defined in their HACCP-based procedures.

In addition, they shall take measures to identify the cause of the unsatisfactory results in order to prevent the recurrence of unacceptable microbiological contamination. These measures may include modifications to the HACCP- based procedures or other food hygiene control measures in place.

For the FSC, any product from batches that fail should be withdrawn or recalled. Recall applies to product already dispatched, while withdrawal applies to product the FBO still holds. If the product is still under the FBO's control, further treatment may be applied to the product to eliminate the hazard.

2.7 AO role: all establishments

2.7.1 AO responsibility

The role of the AO is to:

- monitor the FBO's compliance with microbiological criteria testing (2.7.3)
- verify that this has been carried out in accordance with the requirements of the appropriate legislation (2.7.5)
- verify method of dispatch to the testing laboratory (2.7.3)
- verify that the laboratory methods used are the reference method or an alternative in accordance with Article 5 (2.7.5)
- verify that the results fall within the required limits and are produced at the required frequency (2.7.6)
- verify that where any further action by the FBO is required, this action is taken promptly and is documented with HACCP based procedures (2.7.7)
- take appropriate enforcement action in the event that this is necessary (2.8)
- take official control samples to verify FBO compliance and/or use as evidence to take enforcement action. In considering the need for taking official

microbiological samples regard should be given to the overall level of compliance in the plant and the risks presented by the plant. For example, taking official control microbiological samples will be particularly important in plants where there is scope for cross contamination between raw meat and ready-to-eat foods and in cases where there is concern about FBO controls.

Further advice and guidance to help the AO considering the need of micro sampling as part of official controls can be found in section 2.9.

2.7.2 Testing requirements and sampling frequencies

The testing requirements and sampling frequencies which the FBO must follow are detailed at Annex 1 to Regulation (EC) 2073/2005.

The AO should refer to these resources as required and ensure that they are familiar with the requirements and testing frequencies for the establishments at which they are based.

2.7.3 Monitor the FBO's compliance with microbiological criteria testing

Article 18 of Regulation (EU) 2017/625 requires that official controls verify compliance with the microbiological criterion as defined in point (b) of Article 2 of Regulation (EC) 2073/2005.

The verification required and involvement of the AO will vary depending on the type of establishment, the product produced and the level of throughput.

In slaughterhouses and co-located cutting plants, the AO should:

- Create a plant profile to include:
    - Frequency
    - Sampling method
    - Analytical method
    - Products sampled
    - Micro-organisms
    - Number of samples
    - Acceptance criteria and interpretation of results
    - Other local arrangements (e.g. extended *Salmonella* sampling)
- Observe the sampling technique
- Check the transport arrangements for samples to the testing laboratory
- Check the storage arrangements for samples
- Check the methods used and the results reported by the laboratory

- In cases where the results require action to be taken, keep records to assist with verification of compliance
- Where observing the sampling technique may not be possible, verify that there is a robust sampling programme and protocols in place (e.g. cutting rooms, poultry)
- Where sampling is done on a risk basis verify that the FBO has a logical science based rationale for sampling - for example, *Listeria* sampling as food safety criteria in RTE foods
- Consider the need for and, where appropriate, take official control samples to verify FBO compliance and/or use as evidence to take enforcement action. In considering the need for taking official microbiological samples regard should be given to the overall level of compliance in the plant and the risks presented by the plant.

2.7.4 Frequency and record of AO checks

Premises	Verification	Frequency	Record
Slaughterhouses	Sampling process including collection and storage	Monthly if weekly sampling Quarterly for all other sampling frequencies	Plant Checks Form
	Sample results*[1]	Monthly	
	FBO corrective actions*[1]	When necessary	
	Plant Profile	Quarterly	Plant Profile stored in the plant folder on Sharepoint
Cutting rooms and GHEs	Sample results*[2]	During audit cycle	ELR
	FBO corrective actions*[2]		
	Plant Profile	N/A	

*[1] Regulation (EU) 2019/627, Articles 35 and 36 on practical arrangements for official controls for ***Salmonella*** **and** ***Campylobacter***, requires that the CA shall verify the correct implementation of the microbiological requirements for **carcases** of all species established in Regulation (EC) 2073/2005 by:

- carrying out official sampling or collecting information of the ***Salmonella*** positive samples taken by the FBOs

- carrying out official sampling or collecting information on the total number and the number of ***Campylobacter*** samples with more than 1000 cfu/g taken by the FBO

If the FBO fails on several occasions to comply with the aforementioned microbiological requirements, the CA shall require submitting an action plan and shall strictly supervise its outcome.

In order to comply with the Regulation (EU) 2019/627, FSS collect the data of Salmonella and Campylobacter in the 'Salmonella and Campylobacter data in SH' spreadsheet available on Sharepoint.

In case of the FBO's failure to comply with the PHC, the lead OV is to request an action plan from the FBO and submit it to the Area VA. Refer to section 2.7.7 for further details.

*[2] Staff carrying out audits, UAIs, or routine inspections in **RTE processing plants** are required to check ***Listeria monocytogenes*** sampling results since the last visit carried out, based on the sampling schedule provided. If the total number of test results for Listeria for the period inspected/ audited is above 20, FSS staff should do a random check on minimum 10 results or 10% of these (whichever is greater) and note in their personal notes/ report which dates/results were checked.

For example:

- Total of 7 Listeria results for the audited period – all will be checked
- 25 results – 10 will be randomly checked
- 110 results – 11 will be checked (10%).

Staff carrying out audits, UAIs, or routine inspections in RTE processing plants should request from the FBOs the corrective actions put in place when testing provides unsatisfactory results.

Note: In cutting rooms and GHEs, where verification of the sample process including collection and storage, is not possible, the AO should verify that there is a robust sampling programme and protocols in place.

2.7.5 Verify testing is carried out in accordance with relevant legislation

Depending on the size and nature of the operations, FBOs may be required to sample carcases or products in accordance with the provisions set out in Regulation (EC) 2073/2005.

The OV should verify that the samples are taken at the frequency dictated by the legislation. Samples should be tested at a laboratory at which confidence in results produced can be demonstrated. This can either be by accreditation by the United Kingdom Accreditation Service (UKAS) to ISO 17025 with the tests undertaken listed on the accreditation schedule, or by participation in proficiency testing for the tests to

be undertaken. The OV should verify that this is the case. There is no requirement for the laboratories to be accredited. The tests used should either be the reference method as specified in Regulation (EC) 2073/2005, or an alternative that complies with Article 5 of that Regulation.

Note: Modifications to the methods, such as the use of single plates for Aerobic Colony Count (ACC), may be used, provided that the laboratory undertaking the testing is accredited for the modified procedure. The pooling of the five samples for salmonella testing is permitted if it takes place at the testing laboratory which has demonstrated the pooling does not reduce the sensitivity of the method. ISO 6579: 2002 contains a note on how to undertake pooling.

The OV should verify that the tests being used comply with the relevant reference method or a validated alternative.

See Appendix 1 of Annex 8 for examples of reference methods.

2.7.6 Verify that the results fall within the required limits

Article 9 of Regulation (EC) 2073/2005 requires the FBO to analyse the trend of results and if the trend is towards unsatisfactory results, take action to prevent microbiological risks. The limits on acceptability/ unacceptability of microbiological results are summarized in simplified format in the table below. For full details refer to the resources already mentioned.

Microbiological sampling results	
Process hygiene criteria	
***Salmonella* spp (carcases)**	Results are reported as 'detected' or 'absent'. Results from a number of samples throughout the specified sampling period of 50 samples taken must be returned as 'absent'; if any sample shows a positive result detected, and then the test batch is unacceptable. The OV should advise the FBO to seek information from the supplier as part of due diligence and to take measures to avoid recurrence in the future.
***Campylobacter* spp (broiler carcases)**	The limit is 1,000 cfu/g. Satisfactory results if a maximum of 20 samples out of 50 (10 consecutive sampling sessions) are below this limit and unsatisfactory if more than 20 samples out of 50 are above this limit. The established maximum number of positive samples will decrease gradually to 15 in 2020 and to 10 in 2025.

Aerobic colony count (ACC)	For minced meat and mechanically separated meat (MSM), all five samples must return results of less than 5 x 106 cfu/g and of those five samples, three must return results of less than 5 x 105 cfu/g.
E. coli	For minced meat and MSM, all five samples must return results of less than 500 cfu/g and of those five samples; three must return results of less than 50 cfu/g. For meat preparations, all five samples must return results of less than 5,000 cfu/g and of those five samples, three must return results of less than 500 cfu/g.
Food safety criteria	
Salmonella **(minced meat/ meat products)**	If any of the test results from samples of minced meat, MSM or meat products is positive for *Salmonella*, then the batch must be removed from the market. Please refer to instructions later in this chapter in part 3, topic 3.7 on 'Enforcement: microbiological criteria'. If the product is at retail and is intended to be cooked before eating, it must be withdrawn as a minimum. The FBO may decide to instigate a recall. If the product is RTE, then a recall is required.
Listeria monocytogenes **(RTE foods)**	<u>In foods that support growth of *Listeria monocytogenes*</u>: • Absence in 25g before the food is placed on the market if the FBO is not able to demonstrate that the product will not exceed the limit 100 cfu/g throughout the shelf-life. • Less than 100 cfu/g where the FBO can satisfactorily demonstrate that the product will not exceed the limit 100 cfu/g at the end of the shelf-life. The operator may fix intermediate limits during the process that must be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of shelf-life. <u>In foods that do not support the growth of *L.* monocytogenes</u>: • Less than 100 cfu/g throughout shelf life. The following products are considered to fall into this category:

	➢ meat products which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (for example, products heat treated in their final package) ➢ products with pH ≤ 4,4 ➢ products with aw ≤ 0,92 ➢ products with pH ≤ 5,0 and aw ≤ 0,94 ➢ products with a shelf-life of less than five days

2.7.7 Verify that the FBO takes further action where required

Where unsatisfactory results are obtained, the FBO must take action in accordance with Regulation (EC) 2073/2005, Article 7, paragraphs 2 to 4, as well as the appropriate corrective action defined in their HACCP plans and any additional action to protect public health.

Depending on which microbiological limits have been exceeded, to fully comply with the criteria, the FBO is required to take different actions.

When testing against food safety criteria provides unsatisfactory results, the batch shall be withdrawn or recalled. However, products placed on the market, which are not yet at retail level, may be submitted to further processing by a treatment that eliminates the hazard in question. This treatment may only be carried out by FBOs other than those at retail level.

In most circumstances, withdrawal or recall of the affected product will not be possible due to the product having been consumed by the final consumer because of the length of time that it takes for the *Salmonella* serotyping to be completed. In these circumstances, the FBO should review its procedures to ensure the root cause is identified and processes streamlined to prevent from any re-occurrence.

The AO shall ensure that the FBO has reported the non-compliance for food safety criteria to the Scottish Food Crime and Incidents Unit (SFCIU).

Guidance and a link to the incident report form can be found at the following web page:

Food Incident Report Form | Food Standards Scotland

In the event of unsatisfactory results as regards process hygiene criteria the actions laid down in Annex I, Chapter 2 of Regulation (EC) 2073/2005 shall be taken. These might include:

- improvements in slaughter hygiene
- review of process controls
- review of origin of animals

- review of biosecurity measures in the farms of origin
- improvements in production hygiene
- improvements in cleaning procedures
- improvements in selection and/or origin of raw materials

The FBO should ensure test results are retained for inspection by the OV. As a minimum, results should be retained for at least 1 audit period or 50 samples, whichever is the greater.

2.8 Enforcement: microbiological criteria

2.8.1 AO advisory role/action

When the AO finds that the FBO is not following the sampling, testing and corrective action requirements contained in Regulation (EC) 2073/2005, the AO, as a first step on the hierarchy of enforcement, should consider informal action to achieve compliance. This can include educating the FBO and encouraging rectification and providing advice.

The following table contains examples of FBO non-compliance and the possible enforcement actions that the AO may take.

In addition, where the FBO has exceeded a reduced testing interval, the AO should inform the FBO that they must commence testing at the shortest interval and demonstrate that they meet the requirements of testing before moving to an extended or reduced testing level.

Before taking formal action the OV must ensure that enforcement actions are in line with the SMOC chapter 7 on 'Enforcement'.

FBO fails to	AO informal action	AO formal action
Comply with the size, number of samples and frequency of testing for the required microorganisms (see FSS guidance on reduced testing), Use the reference method or an alternative that complies with Article 5 of the Regulation	Verbal advice/ written advice	HIN
Perform removal from the market or not place on the market (for unsatisfactory food safety criteria)	Written advice	Identify non-compliant product and detain the product that is in the establishment. Seek voluntary surrender or seizure in accordance with procedures in SMOC chapter 7 on 'Enforcement', section 3.

		Note: For more detail please see below in section 3.7.2.1
Undertake trend analysis of results and take adequate corrective actions	Verbal advice/ written advice	HIN
Take adequate corrective actions (for unsatisfactory process hygiene criteria)		HIN (RAN if there is evidence of the process resulting in unacceptable levels of contamination.)
Heat treat MSM produced in accordance to Regulation (EC) 853/2004, Annex III, Section V, Chapter III, Point 3 with unsatisfactory *Salmonella* results if it is to go into the food chain		Detain, seek voluntary surrender or seizure in accordance with procedures in SMOC chapter 7 on 'Enforcement', section 3

2.8.2 Guidance on unsatisfactory food safety criteria results

If the product is not at retail level, AOs should determine:

- Whether the FBO wishes to submit the product for further processing to eliminate the hazard.
- Whether the FBO wants to use the batch for a purpose other than that for which it was originally intended. This is permissible if:
  - it does not pose a risk to public or animal health
  - the use has been decided within the procedures based on HACCP and good hygiene practice, and
  - the use has been authorised by the competent authority

This should be as detailed in the HACCP plan. The OV needs to refer to the Area VA.

If first two points above do not apply then product should be removed from sale and disposed as an ABP.

2.9 FSS Operations Micro Sampling Strategy

The FSS Operations Micro Sampling Strategy is outlined in the following table:

Activity	Rationale
Check if sampling is required and if so that the FBO is sampling at the correct frequency using the correct sampling technique, following the pre-set sampling rules as interpreted at the UK	There are pre-set testing frequencies and sampling rules including sampling techniques for carcasses, minced meat and meat preparations at the EU level and a national policy for "small quantities" and

national level, and testing for the correct micro-organisms.	sampling techniques for carcasses. FSS's current policy is not to require a sampling and testing programme in establishments producing less than 2 tonnes per week for minced meat and meat preparations (combined).
If sampling is required and samples taken correctly, the next check should be that samples are sent in an appropriate manner to a laboratory and the tests undertaken and reported by the laboratory are in compliance with the Regulation and the inspector has confidence in the results. If the laboratory is accredited to ISO 17025, check the methods and sample type are included on the accreditation schedule. If not, check the laboratory participates in a proficiency testing scheme for the sample type and method and achieves satisfactory results.	There is no requirement for the laboratory to be accredited, however accreditation to the ISO 17025 standard will cover the activities required to provide confidence in the results and for this reason it is recommended that laboratories used by FBOs are accredited. For non-accredited laboratories or laboratories accredited to a different standard, confidence in the results produced by the laboratory can be by participating (with satisfactory results for the appropriate methods and matrix) in proficiency schemes. If the laboratory is accredited to ISO 17025 proficiency testing is part of the accreditation process.
Check the FBO is recording results and producing trends and assessing if the results meet the levels specified in the relevant criteria and related limits.	The criteria have levels specified for the reference method detailed in the Annex to the Regulation (EC) 2073/2005, against which the batch (food safety criteria) or process (process hygiene criteria) tested is assessed for acceptability.
Check the FBO has included, within their HACCP-based procedures, appropriate action to be taken if the criteria limits are exceeded and this is followed.	Corrective action is triggered when the limits of a criterion are not met. A constant failure to meet the criterion limits is an indication of ineffective HACCP-based procedures. Batches of processed meat not meeting the *Salmonella* food safety criteria require removal from the market (withdrawal for product intended to be eaten cooked and recall for product intended to be eaten raw or undercooked).
Check that environmental monitoring is carried out appropriately. The use of environmental monitoring is required by	The validation of cleaning procedures should be required for all premises as part of HACCP-based procedures.

Regulation (EC) 2073/2005 when necessary to ensure the criteria are met and, in this context, the relevant ISO standard should be used as the reference method.	Environmental monitoring/validation of cleaning can be undertaken using standard microbiology or by the use of rapid methods.
Check how validation and verification of HACCP-based controls have been undertaken and the results of any testing including microbiological testing other than for compliance with 2073/2005.	In addition to the checks above described for compliance with Regulation (EC) 2073/2005, the FBO is required to validate and verify their HACCP-based controls, which may include the use of microbiological and other testing.
Action following checks and consideration for any sampling as part of official controls:	
Providing the assessment of compliance checks are **satisfactory** there is no requirement for the FSS AOs to carry out its own sampling and testing.	If the checks are **not satisfactory** the first action should be to work with the FBO with the aim of achieving compliance.
	Lack of compliance to the sampling and testing required can also be interpreted as lack of compliance with the requirement to validate and verify HACCP-based controls.
	Sampling and testing by FSS may be required when the assessment checks are not satisfactory and the FBO is unwilling/unconvinced of the requirement to put in place measures to achieve compliance. However this course of action should only be considered where there is suspicion that there may be microbiological risks and only implemented following consultation with the Area VA. It should also be noted that trend analysis is required for the process hygiene criteria and so one-off sampling and testing by the competent authority cannot replace compliance checks.

3. Traceability

3.1 Introduction
3.2 Legislative references
3.3 Background
3.4 FBO responsibilities
3.5 FBO responsibilities: provision of information on frozen food of animal origin
3.6 FSS role
3.7 Enforcement action examples
3.8 Summary

3.1 Introduction

3.1.1 Definition and scope

Traceability, as defined by Article 3, Paragraph 15 of Regulation (EC) 178/2002, means *'the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution'*. The following pages provide further background, a summary of the FBO's responsibilities and guidance on the role of the OV/auditor in monitoring and verifying FBO compliance with the traceability requirements.

3.2 Legislative references

3.2.1 Traceability legislation

Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Regulation (EU) 931/2011 on the traceability requirements set by Regulation (EC) 178/2002 of the European Parliament and of the Council for food of animal origin

Regulation (EU) 1169/2011 on the provision of food information to consumers

Regulation (EC) 853/2004, Annex II, Section I, Part A, Paragraph 4, laying down specific hygiene rules for food of animal origin.

Regulation (EU) 16/2012 amending Annex II to Regulation (EC) 853/2004 as regards the requirements concerning frozen food of animal origin intended for human consumption.

3.3 Background

3.3.1 Comprehensive system of traceability to be established

The aim is to ensure that unsafe food is not placed on the market and that the systems in place to identify and respond to food safety problems allow for the proper functioning of the internal market and the protection of public and / or animal health.

This level of protection can be jeopardised where it is impossible to trace food and feed. It is therefore necessary for FBOs to 'establish a comprehensive system of traceability within their businesses so that targeted and accurate withdrawals can be undertaken or information can be easily provided to consumers or control officials when required, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems.'

Reference: Regulation (EC) 178/2002, Recital 28

To achieve the traceability of food as set out in Article 18 of Retained Regulation (EC) 178/2002, the names and addresses of both the food business operator supplying the food and the food business operator to whom the food was supplied are needed (except when they are final consumers).

In the sector of food of animal origin additional information is required such as the volume or quantity of the food, a reference identifying the lot, batch or consignment, as appropriate, a detailed description of the food and the date of dispatch.

There is however no legal requirement for the origin of food to remain identifiable during production at an establishment.

3.3.2 Insufficient documentary records

Food or feed business operators must ensure that traceability of food, feed, animals or substances which may be incorporated into a further product can be assured at all stages.

Food crises in the past have revealed that documentary records were not always sufficient to allow full traceability of suspect foods. Furthermore, recent experience has shown that FBOs do not generally possess the information needed to ensure that their systems identifying the handling or storage of foods is adequate, in particular in the sector of food of animal origin.

Reference: Regulation (EU) 931/2011

3.3.3 One step back, one step forward

To achieve the traceability of food as set out in Article 18 of Regulation 178/2002, the names and addresses of both the FBO supplying the food and the FBO to whom the food was supplied are needed. The requirement relies on the 'one step back – one step forward' approach which requires that FBOs have in place a system enabling them to identify their immediate supplier(s) and customer(s), except when they are the final consumer. With regards to food, the implementation of a traceability system is an essential element in ensuring food safety and the reliability of information provided to consumers.

Traceability does not make food itself safe, but it is an essential way of providing assurance and assisting in containing food safety problems.

3.4 FBO responsibilities

3.4.1 FBO to identify suppliers and direct recipients

Traceability is a requirement to be complied with in addition to the food bearing a health mark or an identification mark. FBOs are required to identify the suppliers and direct recipients of their food/ feed. The responsibility to devise such traceability systems rests with FBOs that place such food or feed on the market as they are best placed to identify and manage their suppliers and customers.

3.4.2 Format of relevant information

Without prejudice to specific requirements, industry is allowed some flexibility concerning the format in which relevant information is made available. However, it requires both food businesses and the control authorities to take an active role in ensuring effective implementation. It is the need to maintain and provide traceability information that is of primary importance, rather than the format in which it is kept. However, the information needs to be sufficiently organised to enable availability 'on demand', without undue delay.

3.4.3 Traceability to be established at all stages

The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed must be established at all stages of production, processing and distribution along the food / feed chain.

3.4.4 Identify suppliers

FBOs must be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

To this end, such operators must have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3.4.5 Identify businesses supplied/customers

Food and feed business operators must have in place systems and procedures to identify the other businesses to which their products have been supplied. This information must be made available to the competent authorities on demand.

3.4.6 Food adequately labelled or identified

Food or feed which is placed on the market or is likely to be placed on the market in the Community must be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements.

Reference: Regulation (EC) 178/2002, Article 18.

Labelling/standards legislation is generally enforced by Local Authorities or by the Rural Payments Agency (Beef Labelling Scheme).

3.4.7 Information to be made available by the FBO

Regulation (EU) 931/2011, Article 3, states that:

1. FBOs shall ensure that the following information concerning consignments of food of animal origin is made available to the food business operator to whom the food is supplied and, upon request, to the competent authority:
    - an accurate description of the food
    - the volume or quantity of the food
    - the name and address of the FBO from which the food has been dispatched
    - the name and address of the consignor (owner) if different from the FBO from which the food has been dispatched
    - the name and address of the FBO to whom the food is dispatched

- the name and address of the consignee (owner), if different from the FBO to whom the food is dispatched
- a reference identifying the lot, batch or consignment, as appropriate
- the date of dispatch.

2. The information referred to in paragraph 1 is to be made available in addition to any information required under relevant provisions of retained EU legislation concerning the traceability of food of animal origin.

3.4.8 Regular updates

The information referred to in paragraph 1 of section 4.4.7 is to be updated regularly and kept at least available until it can be reasonably assumed that the food has been consumed. The period during which this information must be available depends on the shelf life of product and guidance is available (see later in this chapter).

Reference: Regulation (EU) 931/2011, Article 3, Paragraph 3.

3.4.9 Provision of information without undue delay

When requested by the competent authority, such information is to be provided without undue delay. The appropriate form in which the information must be made available is up to the choice of the supplier of the food, as long as the information requested in paragraph 1 is clearly and unequivocally available to and retrievable by the business operator to whom the food is supplied.

3.4.10 Internal traceability

The regulations do not require a link between incoming and outgoing products, (so called 'internal traceability'), nor is there any requirement for records to be kept identifying how batches are split and combined within a business to create particular products or new batches.

The decision on whether to implement an internal traceability system, and when implemented the level of detail of such an internal system, is a commercial decision left to the FBO and may be commensurate with the size and nature of the food business.

Nevertheless an internal traceability system would contribute to more targeted and accurate withdrawals. FBOs are likely to save costs in terms of time of a withdrawal and in avoiding unnecessary wider disruption which in turn would help maintain consumer confidence. Traceability systems can also provide information within food businesses to assist in process control and stock management.

3.4.11 Applicability

The traceability requirements of Article 18 of Regulation (EC) 178/2002 are general requirements and are always applicable to all food / feed.

FBOs should determine whether specific sectorial traceability provisions applicable to their sector or specific regulations laying down marketing and quality standards for certain products (for example, Beef Labelling Scheme, Poultry Meat Marketing Standards) already meet the requirements of the regulations.

3.4.12 Retention period for traceability records

The minimum period of time for keeping traceability records is not specified in the Regulations and it is for the business to decide. However failure to produce adequate records would constitute a breach of the requirements.

Current European Commission guidance suggests that a general rule of a 5-year period from the date of manufacturing or delivery to destination would meet the objective of the regulations.

Reference: Guidance on the Implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No. 178/2002 on General Food Law.

3.4.13 Specific examples of suggested record retention periods

The common rule above can be adapted for products with a short shelf life:

- for highly perishable products with a 'use by' date less than 3 months or without a specified date, destined directly to final consumer, records could be kept for 6 months after date of manufacturing or delivery
- for products with a 'best before' date, records could be kept for the period of the shelf life plus 6 months
- for products without a specified durability date, the 5-year period could apply.

3.5 FBO responsibilities: provision of information on frozen food of animal origin

3.5.1 Information requirements for frozen food of animal origin

For frozen food of animal origin, Regulation (EC) 853/2004 requires the FBO to make available to the FBOs they supply information concerning the date of production and, if different, also the date of freezing.

3.5.2 Date of production

In this context, 'date of production' means:

- the date of slaughter in the case of carcases, half carcases or quarter carcases

- the date of killing in the case of bodies of wild game
- the date of harvesting or catching, in the case of fishery products
- the date of processing, cutting, mincing or preparation, as appropriate, for any other food of animal origin

Reference: Regulation (EC) 853/2004, Annex II, Section IV

3.5.3 Information to be made available

Until the stage at which frozen food of animal origin is labelled for the consumer in accordance with Regulation (EU) 1169/2011 (FIC Regulation) or used for further processing, FBOs must ensure that they make the following information available to the FBOs they supply and, upon request, to the competent authority:

- the date of production; and
- the date of freezing, if different from the date of production

Where a frozen food of animal origin is made from a batch of raw materials with different dates of production and of freezing, the oldest dates of production and / or of freezing, as appropriate, must be made available.

Reference: Regulation (EC) 853/2004, Annex II, Section IV

3.5.4 Format of the information

The appropriate format in which the information must be made available is for the FBO supplying the frozen food of animal origin to decide, but they must ensure that the required information is clearly and unequivocally available to, and retrievable by, the FBO to whom the food is supplied.

Reference: Regulation (EC) 853/2004, Annex II, Section IV

3.6 FSS role

3.6.1 AO responsibility

As part of the official controls carried out by the Competent Authority for food, the AO has responsibility for ensuring that the traceability requirements are complied with.

3.6.2 AO to monitor traceability system

The AO should monitor the FBO's traceability system in place. This will be achieved by learning about how the FBO created it, uses it and how the system works in practice. Each FBO will have their own traceability system(s) and the AO should familiarise themselves with it in order to understand and monitor it.

The AO should ensure that any other relevant legislation with an impact on traceability data is also implemented by relevant FBOs in addition to the general traceability requirements.

3.6.3 AO to verify traceability system

The AO should verify that the traceability system in place is being carried out in accordance with the requirements of the relevant legislation. This should include a traceability check 'in situ' in addition to a check on the historical traceability records.

The traceability check 'in situ' should take the form of selecting a product from the intake or dispatch bays where finished products or ingredients are found, identifying the information available on the products and seeking the relevant traceability records: both intake and dispatch documents should have all the required information. This check 'in situ' may be performed in the event of finding raw materials, ingredients and / or products with poor or unclear traceability data, when there is suspicion that product may have been mislabeled (for example, meat substitutions) and / or as often as the AO considers necessary to ensure that the FBO satisfies the requirements of the regulations with regards to traceability.

3.6.4 AO to verify FBO takes further action

The AO should verify that where further action by the FBO is required, this action is taken promptly and efficiently. Where traceability details on the product and/ or records are not available and/ or are proven to be wrong, the FBO will need to demonstrate what action is taken to correct it.

3.6.5 AO to take enforcement action where appropriate

The AO should take appropriate and proportionate enforcement action when necessary, as described in SMOC chapter 7 on 'Enforcement'. Some specific examples are given in section 3.7.

3.6.6 AO to take official control samples to verify FBO compliance and/or use as evidence to take enforcement action

In considering the need for taking official microbiological samples regard should be given to the overall level of compliance in the plant and the risks presented by the plant. For example, taking official control microbiological samples will be particularly important in plants where there is scope for cross contamination between raw meat and ready to eat foods and in cases where there is concern about FBO controls.

Guidance on taking samples is given in section 4 of Part 3 of this chapter and in Annex 8 - Microbiological Sampling Guidance.

3.7 Enforcement action: examples

3.7.1 Health marked product

Where health marked products fail to comply with the traceability requirements of Article 18 of Regulation (EC) 178/2002 as read with Regulation (EU) 931/2011, this will constitute an offence under Regulation 4(c) of the General Food Regulations 2004.

3.7.2 Health marked product: enforcement action in cases of non-compliance

Health marked carcases and primal cuts which have not left the slaughterhouse or been further cut or processed in a cutting plant, may not be certified under Regulation 27 of the Food Hygiene (Scotland) Regulations 2006 as failing to comply with the 'Hygiene Regulations'. This is because Regulation (EC) 178/2002, Article 18, as read with Regulation (EU) 931/2011, are excluded from the definition of 'Hygiene Regulations' and the requirements for traceability of ID marked products contained in Regulation (EC) 853/2004, Annex II, Section I, will not apply in these circumstances.

Where health marked products which have not left the approved slaughterhouse or been cut or further processed in a cutting plant have associated commercial documentation that fails to comply with the traceability requirements, they should be formally detained until the commercial documentation has been altered to accurately detail the products being consigned from the establishment in accordance with the legal requirements.

Where products bearing a health mark have been dispatched without adequate traceability information, the FBO must be advised in the first instance in order that they take corrective action. Enforcement should be escalated to ensure that commercial documents reflect the information required under Article 18 of Regulation (EC) 178/2002 as read with Regulation (EU) 931/2011. If serious/ repetitive breaches have been identified, the FBO should be referred for investigation.

3.7.3 Health mark legibility

Where the traceability deficiency identifies a failure to comply with the food safety requirements, the FBO shall initiate procedures to withdraw or recall the food in accordance with Article 19 of Regulation (EC) 178/2002. Where health marked products have been consigned to another establishment, the FBO of the recipient plant(s) should be informed, as their ability to comply with the traceability requirements may be hampered as a result of the inaccurate information they receive, which may cause them to inadvertently mislabel products they subsequently supply.

The OV/enforcement authority responsible for enforcement action at subsequent establishments must be informed so that all appropriate action is taken. This may

include formally detaining product until commercial documentation has been provided that accurately details the products consigned by the supplier.

3.7.4 ID marked product

Where ID marked products fail to comply with the traceability requirements of Article 18, Regulation (EC) 178/2002 as read with Regulation (EU) 931/2011, they will also breach the provisions of Regulation (EC) 853/2004, Annex II, Section I, Part A, Paragraph 4.

This will constitute an offence under Regulation 17 of the Food Hygiene (Scotland) Regulations 2006, as well as Regulation 4 (c) of the General Food Regulations 2004.

Failure to comply with Regulation (EC) 853/2004, Annex II traceability requirements will apply only to products that have been further cut or processed and have received an Identification Mark.

The Approved Establishment Scottish National Protocol (AESNP) details further the requirements for the ID mark application. The ID mark can only be applied by an approved establishment and the establishment can only apply its own ID mark allocated by the CA.

3.7.5 ID marked product: enforcement action in cases of non-compliance

Where ID marked products fail to comply with the traceability requirements of Regulation (EC) 853/2004, enforcement should be escalated in accordance with SMOC chapter 7 on ‘Enforcement’.

An assessment should also be made with respect to any potential fraud, the FBO’s ability to trace all meat to comply with any product recall or withdrawal requirements and to determine whether the raw materials for the product were processed lawfully in approved establishments.

Where appropriate, non-compliant ID marked products may be formally certified under Regulation 27 of the Food Hygiene (Scotland) Regulations 2006, as not having been produced, processed or distributed in accordance with the ‘Hygiene Regulations’ due to its failure to comply with Regulation (EC) 853/2004. Where voluntary surrender is not forthcoming, non-compliant products may be formally seized and a Condemnation Order applied for at the Magistrates/ Sheriffs Court. Non-compliant product that has been so certified will be deemed to fail to comply with the food safety requirements and the FBO must initiate withdrawal or recall of the product in line with Article 19 of Regulation (EC) 178/2002. A referral for investigation may also be appropriate for serious or repetitive breaches or where public health protection is being compromised.

3.7.6 ID marked product: derogations from the ID mark application

In exceptional circumstances, FBOs may ask the CA to permit products to bear an approval number other than the one relating to the establishment where the product was manufactured or handled.

The AESNP allows in case of force majeure, derogations from the ID mark application requirements: the 'force majeure' is defined as an extraordinary event beyond the control of the parties involved for which no contingency arrangements could be made, and the FBO must satisfy the CA for the need to do so.

This flexibility can only apply to products that are placed on the UK market.

If an FBO may wish to request this flexibility, a thorough justification needs to support it along with details on the traceability procedures that will be put in place to ensure adequate separation and identification of products. The derogation will be time limited and the FBO needs to specify the period these temporary arrangements will be required.

The document to request the flexibility (Derogation Table - Annex 10) must be completed by the FBO and returned to FSS at approvals@fss.scot.

Lead OVs/auditor inspectors have to monitor any issues found in establishments and report back to the area VA with early indication of labelling/packaging issues so that timely advice can be given to the FBO.

Area VAs will be required to approve these requests for plants in their area, and make provision to ensure that the withdrawal of the measures is completed at the end of the derogation period.

3.8 Summary

Checks on compliance with traceability requirements will be achieved initially over the duration of the approval process, followed by audits at the appropriate frequency and during unannounced inspection to approved establishments.

A traceability system can be considered acceptable when it delivers accurate information in a timely manner. Assurance of this may be attained by checking product and records data against the system in place.

It is essential that the FBO's traceability system is designed to follow the physical flow of the product and helps to identify its location at a given moment in time.

This means that the FBO must provide evidence of the traceability for animals, raw materials and/ or ingredients received at the premises, allowing for the identification of their location. The same applies to any products manufactured on site that are to be dispatched.

4. Official Control Verification Sampling Procedures

This section outlines the details of the sampling equipment, laboratory, dispatch and recording arrangements for official control verification microbiological samples

Full details of the sampling protocol can be found in Annex 8 - Microbiological Sampling Guidance

4.1 Official Control Verification Sampling

4.2 Sampling equipment

4.3 Communication of intention to sample and despatch

4.4 Packaging and despatch of samples

4.5 Recording of sampling data

4.6 Sample Process Flowchart

4.7 Courier details

4.8 Laboratory (Public Analysts) Details

4.1 Official Control Verification Sampling

FSS will conduct targeted sampling where there is evidence to support concerns that compliance with microbiological requirements, as stated in Regulation (EC) 2073/2005 in relation to fresh meat, minced meat, meat products and processing environment, cannot be immediately verified as required in the SMOC Chapter 4 Part 3 Section 3 – Verification of microbiological criteria.

AOs will take samples where sampling is triggered by evidence of increased risk of non-compliance either through observation during inspection, audit outcomes or FBO's document checks and is designed to verify compliance or provide evidence in support of possible enforcement action.

4.2 Sampling equipment

The FSS AOs will each receive sample kits and dispatch packaging which may be re-ordered as necessary via the Area Field Operations Coordinator.

The sample kits will contain 6 sponge swabs, swab templates and 6 sample bottles. Instructions for use will be included in the kit.

PLEASE NOTE: The kit includes sponge swabs which may be used for carcase swabbing and/or surface swabbing and may differ from the training material.

4.3 Communication of intention to sample and despatch to laboratory

Samples are required to be analysed within 24 hours under BS EN ISO 17604:2015 Microbiology of the Food Chain - Carcass sampling for Microbiological Analysis.

The AO taking the sample will contact both the courier and the nearest PA (Public Analyst) laboratory as soon as the intention to sample has been agreed. The courier will need to collect sample(s) and deliver to the laboratory the same day as taken. the AO will be required to contact the nearest PA laboratory to advise when the sample(s) should arrive. The PA laboratory will need to make resource provision to ensure the sample(s) is analysed within the 24-hour period.

The AO should also advise the PA laboratory of the nature of the sample material and the microbiological analysis to be performed. The AO may wish to seek advice from the Area Technical Lead or OM.

4.4 Packaging and dispatch of samples

The AO will be responsible for the packaging and arranging dispatch of the samples in compliance with the 24-hour testing requirement. This dictates that the courier will need to be booked in advance and instructed to use same day delivery. The FSS AO also has the option of delivering in person if the laboratory is within reasonable proximity.

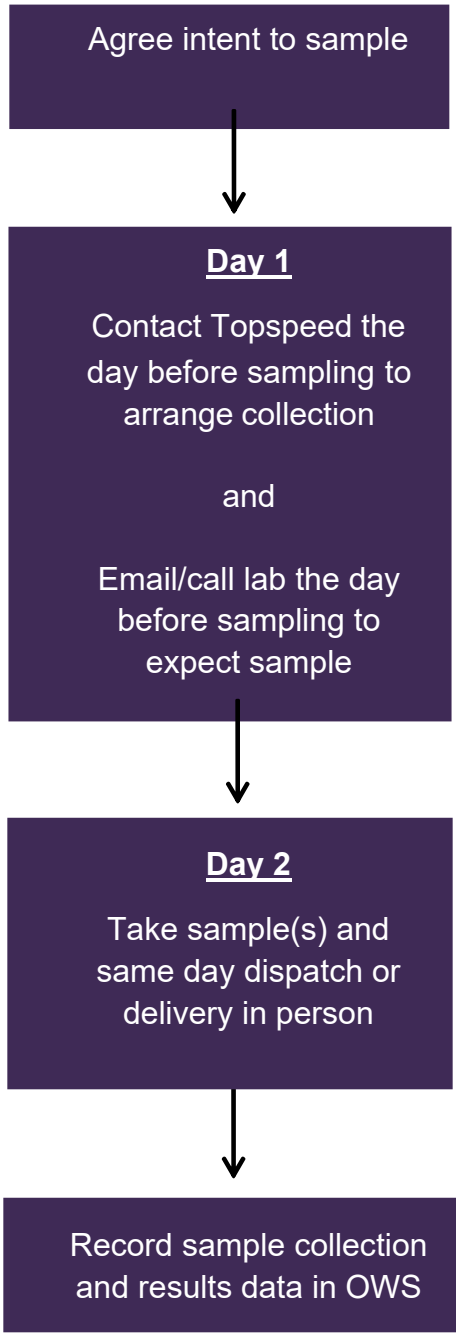
The FSS AO will be provided with flat pack, polystyrene insulated boxes and cool packs. These boxes and cool packs are single use only.

The cool packs will need to be kept frozen before use.

4.5 Recording of sampling data

The FSS AO will be required to enter samples data in the OWS Sample Requests Module. The following details are required: date, establishment, sample type, sample material, public analyst used (via free text) and results (when obtained). In addition to the PA used, the free text box is there to also record any other important information.

4.6 Sample process flowchart



4.7 Courier details

The current courier for the new sampling process is Topspeed Couriers.

As soon as the intention to sample has been agreed and you have been nominated as sample officer, you are required to book the courier online through www.topspeedcouriers.co.uk or by calling 0800 856 2464 with the following information:

- Establishment name and approval number
- Date of the sample collection (this information will allow Topspeed Couriers to plan the collections to include multiple pickups where possible)
- Destination laboratory (section 4.8)
- telephone number for the FSS contact at the plant

4.8 Laboratory (Public Analysts) Details

Lab	Email	Phone	Address
Aberdeen Scientific Services Laboratory	ASSL@aberdeencity.gov.uk	01224 491648	Old Aberdeen House Dunbar Street Aberdeen AB24 3UJ
Tayside Scientific Services Dundee	scientific.services@dundeecity.gov.uk	01382 307170	James Lindsay Place Dundee Technopole Dundee DD1 5JJ
Edinburgh Scientific Services	scientific.services@edinburgh.gov.uk	0131 5557980	4 Marine Esplanade Edinburgh EH6 7LU
Glasgow Scientific Services	GSS@glasgow.gov.uk	01412 760610	64 Everard Drive Springburn Glasgow G21 1XG

5. Lactic acid to reduce microbiological surface contamination in bovine carcases

5.1 Background
5.2 Legislative reference
5.3 Concentration and applications of solution
5.4 Exceptions to the use of lactic acid
5.5 Minimum HACCP requirements
5.6 FBO duties
5.7 FSS role

5.1 Background

EU hygiene legislation provides for the use of potable water to remove surface contamination from products of animal origin. However, it does also require for other substances to be used for this purpose, provided that they have been approved in accordance with a procedure laid down in Regulation 853/2004.

The first substance to be approved for this purpose is lactic acid used to reduce microbiological surface contamination on bovine carcases. It was adopted by the European Commission as Commission Regulation 101/2013 on 4 February 2013 and entered into force on 25 February 2013. The UK has retained it at the time of exiting the EU.

The measure was preceded by a thorough risk assessment by the European Food Safety Authority (EFSA), which resulted in a favorable opinion published on 26 July 2011 on the safety and efficacy of lactic acid.

5.2 Legislative references

- Regulation (EC) 2073/2005 on microbiological criteria for food stuffs
- Regulation (EC) 1333/2008 on food additives
- Regulation (EU) 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation 1333/2008
- Regulation (EU) 380/2012 amending Annex II to Regulation 1333/2008 as regards the conditions of use and the use levels for aluminum-containing food additives

- Regulation (EU) 101/2013 concerning the use of lactic acid to reduce microbiological surface contamination on bovine carcasses half carcasses or quarters at the slaughterhouse, in compliance with the conditions set out in the Annex to the Regulation.

5.3 Concentration and application of solutions

5.3.1 Requirements for lactic acid solutions

Solutions which may be used must be prepared from lactic acid that meets the specifications for use as a food additive, set out in Regulation (EU) 231/2012.

Note: The specifications set out in Regulation (EU) 231/2012 are reproduced in Annex 1 at the end of this chapter.

5.3.2 Concentration of prepared lactic acid solution

The prepared solution must be between 2% to 5% lactic acid solution in potable water.

5.3.3 Application of prepared lactic acid solution

The prepared solution must be:

- applied and used at temperatures of up to a maximum of 55°C
- applied either by spraying or misting
- applied under controlled and verifiable conditions integrated in a HACCP-based management system including, at least, the criteria set out below under HACCP

5.3.4 In scope product

The prepared solution must only be applied to entire carcases, half-carcases or quarters of meat from domestic bovine animals (including buffalo, water buffalo and bison), at the slaughterhouse.

5.4 Exceptions to the use of lactic acid

Lactic acid solutions must not be applied to carcasses with visible faecal contamination.

The application of lactic acid solutions must not result in any irreversible physical changes to the meat.

5.5 Minimum HACCP requirements

The FBO's HACCP plan should, as a minimum, incorporate the following elements:

- Sampling of carcasses for the purpose of assessing compliance with microbiological criteria within the meaning of Regulation (EU) 2073/2005 must be carried out before the application of lactic acid solutions to the carcasses, half-carcasses or quarters.
- Lactic acid concentration during treatment must be monitored as part of the HACCP plan, verified by periodic monitoring, documented and recorded.
- The temperature of the solution during treatment must, as part of the HACCP plan, be documented and recorded and continuously monitored using measuring instruments.

5.6 FBO duties

5.6.1 Use of lactic acid

The FBO must ensure that lactic acid is only used at the dilution specified in the legislation.

The FBO should, where possible, notify the OV of their intention to use lactic acid as a decontamination agent and ensure that the OV is familiar with the relevant sections of the HACCP plan.

5.6.2 Update to HACCP plans

The FBO must ensure that their HACCP plan includes a section detailing the conditions for the use of, controls and verification of the procedures for the use of lactic acid.

5.6.3 Communication of information

Slaughterhouse FBOs using lactic acid solutions to reduce microbial surface contamination of entire carcasses, half-carcasses or quarters, must inform the FBO receiving the treated carcasses or half-carcasses or quarters of such use.

This information should be documented – for example, included in the commercial documents which accompany treated meat.

5.7 FSS role

5.7.1 Check suitable HACCP plan in place

The OV and FSS team must ensure that where the FBO intends to use lactic acid as a decontamination agent, there is a suitable HACCP plan in place as detailed in the legislation.

The FBO HACCP plan and associated records should be verified during audit with particular reference to the records required by the legislation.

5.7.2 Monitor use

The use of lactic acid should be monitored to ensure that it is not applied to carcasses that have faecal contamination and is used at the correct dilution and within the specified temperature range.

5.7.3 Frequency of verification at audit

Until further instructions are provided, should the FBO choose to use lactic acid as a decontaminant, the Area VA should contact the FSS policy department to discuss the frequency at which the verification at audit as detailed in the following paragraph should take place.

5.7.4 Verification at audit

When carrying out audit of FBO controls where lactic acid is being used, OVs/Veterinary Auditors should verify the controls the FBO has in place to ensure that the requirements of Regulation (EU) 231/2012 have been met, namely:

- the lactic acid meets the requirements of Regulation (EU) 231/2012
- the lactic acid is made up in a solution of between 2% and 5% in potable water
- the lactic acid solution is applied at a temperature below 55°C
- the lactic acid solution is only applied to carcases free from visual faecal contamination
- microbiological testing is carried out before the use of lactic acid solution
- the FBO is notifying customers receiving treated carcases of the treatment applied with lactic acid

These checks should be recorded on the HACCP section of the ELR.

5.7.5 Health mark legibility

If the application of the lactic acid solution interferes with the legibility of the health mark, this should be resolved between the FBO and the OV, in full consultation with the Area VA and OM.

Part 4 Annexes

Annex 1 The Specification for Lactic Acid

Annex 2 Audit Operational Guidance

Annex 3 Key considerations on HACCP auditing

Annex 4 Slaughterhouse - Plant Checks Form

Annex 5 AGHE - Plant Checks Form

Annex 6 Plant Checks Form Instruction

Annex 7 Audit Aide Memoire

Annex 8 Microbiological Sampling Guidance

Annex 9 Guidance on the approach to be taken on the enforcement of the legislative requirements regarding the number of days between slaughter and mincing of chilled meat

Annex 10 Derogation table

Annex 11 VA/OV Approval Report (Seasonal Pre Operating Report)