Chapter 4
Audit, HACCP and Verifying Operator’s Own Checks

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Chapter 4 – Audit, HACCP and Verifying Operator's Own Checks

Food Standards Scotland

Part 1 Audit

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1. Introduction

1.1 Definitions

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1.1 Definitions

The following definitions apply for the purpose of this chapter.

1.1.1 OV presence

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

Daily OV presence is not required for co-located cutting establishments and other establishments such as for standalone cutting plants and wild game handling establishments eligible for OV flexibility. However, co-located establishments operating at times coinciding with the slaughterhouse operational hours are under the supervision of the resident OV and the inspection team, who will carry out daily reality checks. In addition, all co-located CPs will be added to the FSS UAI schedule and will receive a UAI in accordance with the current audit system which defines the frequency and timing of UAs in standalone CPs and GHEs. UAs will not be charged during the first 12 months pilot unless non-compliances are found. The system, due to start in December 2017, will be reviewed after 12 months.

Co-located establishments operating at times different from the slaughterhouse operational hours are subjected to UAs same as standalone cutting plants.

1.1.2 Official visit

Official visits to any establishment (regardless of OV presence in slaughterhouses for carrying out inspection tasks), may be conducted for the purpose of carrying out a full audit, partial audit, follow up visit and / or an unannounced inspection.
1.1.3 **Full audit**

Assessment of the FBO food safety management systems (FSMS). All listed approved FBO activities must be audited (within one day, or more for bigger/complex plants). Full audits are carried out by Veterinary Auditors (VAs).

1.1.4 **Partial audit**

Following a full audit, when major non-compliances are identified, a partial audit will focus on specific themes identified as being non-compliant during the full audit. Partial audits can be carried out by an OV but not by NOVs.

1.1.5 **Unannounced inspection**

In addition to partial audits, and as part of the scheduled audit programme (see audit outcome and frequency of visits), unannounced inspections can take place to follow up specific issues identified during the audits or to verify continued compliance between audits. UAI visits can be carried out either by trained MHIs or OVs.

1.2 **Purpose of audits**

1.2.1 **Relevant premises**

These audit arrangements apply to all meat establishments approved in Scotland and under veterinary control.

These are:

- red meat / farmed game slaughterhouses
- poultry meat slaughterhouses
- cutting plants
- wild game plants
- minced meat, meat preparations and mechanically separated meat plants co-located with slaughterhouses or cutting plants
- meat product plants and ‘ready to eat’ establishments co-located with slaughterhouses and cutting plants
- co-located cold stores

1.2.2 **Risk assessment scheme**

The audit risk assessment scheme applies the requirement of (EC) 854/2004 Article 4 to determine the frequency of audit using the risk criteria set out in that Regulation:
• public health risks
• animal health risks (where appropriate)
• animal welfare risks (where appropriate)
• type of process carried out
• throughput
• FBOs past record of compliance with food law

**Note:** Risks associated with the throughput and type of process are not specifically listed in the AUD 9-3, but have been incorporated in the body of the audit report document.

### 1.2.3 Aim of audits

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

The audit sections in the audit report are based on the priorities set for the FSS that have been agreed between the FSS, Scottish Government and industry stakeholders.

Audit findings should provide individual FBOs as well as the relevant competent authority (FSS and Scottish Government) with information on non-compliance identified against regulatory requirements, and/or areas in need of correction or improvement. For the Competent Authority, this may result in the review of the MOC and/or MIG or the development of new guidance, procedures and training.

### 1.2.4 'Effective' audit

An effective audit of FBOs obligations in respect of public health, animal health and welfare is defined as follows:

• complies with the requirements of (EC) 854/2004 to determine the frequency of audit on the basis of risk
• applies appropriate standards in determining the level of assurance that can be given to the Competent Authority about the FBO management procedures and identification of risk
• accurately assess the FBOs level of compliance with legal requirements and identifies necessary enforcement actions
• recognises the FBOs good practices and identifies opportunities for improvement
• communicates audit findings to the FBO and the Competent Authority
• is consistent in its approach

1.2.5 Compliance audit and systems based audit

An effective audit of FBO controls will require the use of both ‘compliance audit’ and ‘systems based audit’ techniques, which are described below:
Audit technique | Description
--- | ---
Compliance audit | This is a review and examination of FBO records and activities to assess compliance with legislative requirements and the FBOs established policies and operational procedures.
Much of the audit work to support compliance assessment will take place in the operational environment. In establishments where there is frequent OV presence, this assessment work will be on-going as part of the FSS team’s normal duties between the production of audit reports.

Systems based audit | The auditor should seek to establish that the FBOs controls are fit for purpose and that the FBO has effective systems and processes in place to implement them on a continuous basis. Weaknesses and strengths in the FBOs control system should be recorded.
Much of the audit work to support the systems assessment is likely to take place outside the operational environment.

1.2.6 Publication of FBO’s audit report

The Freedom of Information Act 2000 gave individuals a general right to information held by public authorities (subject to certain exemptions) and to have this information communicated to them. The Environmental Information Regulations 2004 also provides a right of public access to a range of environmental information held by public authorities.

Important note: Audit reports will be published for FSS approved meat establishments in Scotland on the FSS website after the period for appeals has expired. For further details, refer to:


1.3 Relationship between audit visits and OV attendance

1.3.1 Overview

All audits of FSS approved establishments are to be carried out by Veterinary Auditors (VAs), who are independent and separate from operations and routine inspection duties.

The audit frequency represents the minimum number of times in a period that a completed audit report will be produced by a VA. This approach
applies to slaughterhouses with or without a co-located cutting plant, game handling establishments and standalone cutting plants.

1.3.2 Premises with frequent OV presence

OVs who work in a slaughterhouse approved for co-located operations may enter the production areas of other operations regardless of the audit timetable. However, the OV should consider the reasons for entry and ensure that it is part of their official control role. Daily checks in co-located operations are not required and the frequency of inspections should be determined based on risk assessment.

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

Co-located operations will be audited at the same time as the slaughterhouse, as part of the same process, with a single audit report being produced.

1.3.3 Premises with infrequent OV presence

Stand-alone cutting plants and any co-located operations will also be audited at the same time. In between audits or partial audits there may be unannounced inspections.

1.4 Commencement of FBO audits following approval or periods of closure

1.4.1 Premises with specific requirements

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

<table>
<thead>
<tr>
<th>Establishment</th>
<th>Audit regime</th>
</tr>
</thead>
<tbody>
<tr>
<td>All conditionally approved establishments (slaughterhouses, cutting plants and game handling establishments)</td>
<td>FBO audit by an auditor will not commence until full approval has been granted to the establishment following the Veterinary Manager (VM) approval assessment(s). The OV may be requested to conduct monitoring and enforcement visits during the period of conditional approval. This will be at the specific request of the Veterinary Manager; Where full approval has been granted, the first audit will take place in 3 months, from the date of full approval.</td>
</tr>
<tr>
<td>Existing premises:</td>
<td>A change of FBO marks the end of an existing</td>
</tr>
</tbody>
</table>
on change of FBO or legal entity | establishment’s approval. The new FBO is required to make an application for a new approval.

FBO audit by auditors will not commence until full approval has been granted following the VM approval assessment(s). If during an audit it is identified that the legal entity has changed and a new approval is required, the audit must be stopped and the approvals team informed. The OV / VM may be requested to conduct monitoring and enforcement visits during the period of conditional approval; this will be at the specific request of the Veterinary Manager.

Where full approval has been granted, the first audit will take place in 3 months, from the date of full approval.

Existing premises with full approval on application to extend or vary activities | In these circumstances, FBO audit by auditors should continue as already scheduled for the fully approved activity. The additional activity will only need to be audited once full approval for that activity has been granted following the VM’s approval assessment. Any revision to the audit frequency, made necessary by the additional activity, will be established at the next regular scheduled audit after full approval is granted. For example:

- where a fully approved slaughterhouse has applied for additional approval as a cutting plant, audit of the slaughterhouse should continue as scheduled; the audit will include the cutting operations once full approval for that additional activity has been achieved

- where a fully approved cutting plant has applied for additional approval to add minced meat operations, audit of the cutting plant should continue as scheduled, but the minced meat operations should not be included in the audit until full approval for that activity has been granted; once the next scheduled audit takes place after full approval of the minced meat operation, all approved activities will be audited, and the future audit frequency will be set based on the risks posed by all approved activities

Seasonal closure* and temporary or | Following a period of closure, the FBO is required to notify FSS at least 2 weeks prior to re-commencing

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*Note: Seasonal closure refers to periods during which the FBO is not operational due to seasonal factors.
1.4.2 Pre-opening assessments

Following a period of closure (seasonal, temporary or longer term) the FBO must not start operations until the FSS Head of Operational Delivery (HOD) has been notified in writing and a pre-opening assessment visit undertaken by the Veterinary Manager (VM). This visit is to assess that the establishment meets all structural and equipment requirements and other relevant requirements of food law, including the existence of a food safety management system based on HACCP principles.

The FBO’s food safety management system must be available at the visit but 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 food safety management system will therefore be assessed at the first scheduled audit visit undertaken by the auditor.

Reference: A pre-opening assessment aide-memoire is available via SharePoint. This is intended to act as a reminder of the areas to address when assessing whether the establishment meets all relevant legislative requirements.

1.4.3 Action following pre-opening assessment

Following the pre-opening assessment visit, if FSS is content that the establishment meets all of the relevant requirements of food law, the VM must notify the FBO in writing that operations may re-commence.

In the event that FSS is not content for operations to re-commence, the FBO will be notified of the deficiencies and appropriate enforcement action will be taken. Operations may not re-commence until the deficiencies are resolved on a permanent basis.
If serious deficiencies exist, the VM must refer the establishment to the Director of Operations who should arrange for a formal review of approval request to be submitted to the Veterinary Manager.

Reference: Refer to the ‘Operational policy for the approval of meat establishments undertaken by the FSS’ in Annex 4 in Chapter 1 for further information.

1.4.4 Unauthorised resumption of operations

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

- The VM will take 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’s action regarding withdrawal/ recall of food will be risk-based and proportionate. However, food not yet placed on the market may be detained until the FBO has been notified by the Director or Operations/VM that operations may re-commence.
2. **Legislation**

2.1 **Requirement for audit**

2.1.1 **General requirements for official controls**

It is a principle of (EC) 854/2004 that official controls will verify the FBOs compliance with (EC) 852/2004, (EC) 853/2004 and other EU and national regulations that apply to approved meat establishments.

Part of that verification process is the audit of good hygiene practices and HACCP-based procedures as required by (EC) 852/2004 Article 5 and (EC) 853/2004 Annex II, Section II, the FBOs food safety management system.

In addition to the audit of good hygiene practice, the auditor must verify the FBOs continuous compliance with their own procedures for, amongst others, all aspects of animal by-product handling (including SRM control), animal identification and animal health and welfare.

In addition to the audit of HACCP-based procedures the auditor must check that the operator’s procedures guarantee, to the extent possible, that meat is free from patho-physiological abnormalities or changes, faecal or other contamination and SRM (subject to Community rules).


2.1.2 **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.

2.1.3 **GHP audit**

Audits of good hygiene practices shall verify that FBOs apply procedures continuously and properly. A detailed list of pre-requisites to consider can be found in sub topic 3.2.2 on ‘HACCP and pre-requisites’ in Part 1.

2.1.4 **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 under EU legislation
- comply with EU legislation on residues, contaminants and prohibited substances
- do not contain physical hazards, such as foreign bodies

Reference: (EC) 854/2004, Article 4

When a FBO uses procedures set out in guides to the application of HACCP principles rather than establishing its own specific procedures, the audit shall cover the correct use of these guides.

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 (EC) 852/2004, (EC) 853/2004 other EU and national regulations that apply to approved meat establishments. These are the standards against which the auditor will assess the FBO performance at audit.

Food safety management systems must be implemented and must be sufficient to achieve the objectives of the Regulations.

Reference: MIG chapters with ‘Official control requirements’.

3.1.2 Role of the Meat Industry Guide

The MIG contains an interpretation of the EU Regulations and extensive, detailed guidance on how the FBO may achieve effective compliance with the legislative requirements.

3.1.3 Justification of procedures

The FBO is not obliged to follow the guidance in the MIG and may choose to achieve compliance with the Regulations by alternative means.

http://www.food.gov.uk/business-industry/guidencenotes/hygguid/euhygienereregulationsflexibilities/flexexmig

The FBO must be able to provide justification for the procedures put in place to manage food safety and hygiene, risks, especially if these differ from the MIG.

3.1.4 Access, records and assistance

The FBO is required to offer all assistance needed to ensure that official controls carried out by the competent authority 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 judging the situation
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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 of:

I. identifying any hazards that must be prevented, eliminated or reduced to acceptable levels

II. identifying 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

III. establishing 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

IV. establishing and implementing effective monitoring procedures at CCPs / control points required by regulations

V. establishing corrective actions when monitoring indicates that a CCP / control point required by regulation is not under control

VI. establishing procedures, which shall be carried out regularly, to verify that the measures outlined above are working effectively

VII. establishing 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 in the product, process, or any step, FBOs shall review the procedure 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 at all times.

**Regulation:** (EC) 852/2004, Article 5

**Reference:** See MOC Volume 2, on 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; MIG chapter 9 on ‘HACCP’ and in this chapter, part 2 on ‘HACCP based procedures’.
3.2.2 HACCP and pre-requisites

HACCP systems are not a replacement for other food hygiene requirements, but a 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
- 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, any accompanying documentation

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

Reference: EU guidance document on the implementation of procedures based on HACCP principles:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guide_en.htm

and on the facilitation of the implementation of the HACCP principles in certain food businesses and the MIG chapters 2 to 8, 10 to 12 and 14 to 17.

Note: Other requirements of Community law, such as traceability, the withdrawal of food and the duty of informing the competent authorities should, although not covered under the food hygiene rules, also be considered as prerequisite requirements.

## 4. FSS Role

### 4.1 Responsibilities

<table>
<thead>
<tr>
<th>Task</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrange audit visit date with FBO or their representative</td>
<td>Auditor</td>
</tr>
<tr>
<td>Confirm audit visit date in writing</td>
<td>Audit Business Executive</td>
</tr>
<tr>
<td>Audit preparation gathering information on FBOs food safety management systems</td>
<td>Auditor</td>
</tr>
<tr>
<td>Gather information on food safety management systems</td>
<td>MHI / OV / NOV</td>
</tr>
<tr>
<td>Carry out audit visit, including the discussion of audit findings and possible corrective actions, with</td>
<td>Auditor</td>
</tr>
</tbody>
</table>
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4.1.3 Auditor’s code of ethics

The following four principles are the standards of conduct that are expected from auditor carrying out FBO audits:

I. Integrity

Auditors shall demonstrate integrity in all aspects of their work. The relationship with 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.

III. Objectivity

IV. 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.

V. Competency

VI. 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 Intermediate level HACCP qualifications.

VII. Confidentiality

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

4.1.4 Auditor duties

The auditor is responsible for:

- arranging the audit visit with the FBO
- completing the audit within the calendar month of the designated audit frequency
- auditing the FBOs FSMS and FBOs compliance with animal health and welfare Regulations
- completing the Audit report (AUD 9-3)
• determining an audit outcome and audit frequency
• submitting the completed audit report to the Audit Business Executive
• advising the FBO on compliance with legal requirements in relation to the audit
• agreeing any necessary remedial action with the FBO, ensuring deficiencies are effectively addressed

4.1.5 **Auditor exclusions**

The auditor should not:

• assume accountability for FBO compliance
• take over tasks that are for the FBO to perform
• act as a quality assurance manager
• act as an advocate between industry and the FSS
• write company procedures or HACCP plans, although advice may be given
• provide the FBO with a copy of the un-checked audit report

4.1.6 **Field staff duties**

Field staff working regularly in an establishment must ensure that they are familiar with the procedures and systems put in place by the FBO, 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.

4.1.7 **FSS Audit administrative duties**

FSS Audit Business Executive will:

• monitor the scheduling of the audit visits in accordance with the minimum audit frequency determined by the audit category
• monitor the timely production of audit reports
• distribute the completed report to the FBO
• maintain audit records
• initiate the audit appeal process, as required
4.2 Audit schedule

4.2.1 Arranging visits
The auditor will contact the FBO, where possible, one month in advance of the audit being due (two weeks’ notice is acceptable but not best practice) to agree a date for the audit visit.

FBO audits should be arranged whilst the establishment is in operation and product being processed. If necessary, an audit may take place over a number of days of a week in order that as many processes as possible are audited. Where the establishment is not operational the audit may be delayed until the establishment is in operation with the agreement of the auditor.

The scheduling of the audit visits will be monitored in order to ensure that audit targets and frequencies are met.

The agreed date of the audit visit must be confirmed in writing to the FBO and contractor (Annexe 3). This letter will provide the FBO with prior warning of an audit; outlining the scope of the audit and the access and information that will be required.


Notification of the audit will allow the FBO to make themselves, or the relevant members of their management team, available. In addition, it allows the FBO to have any necessary documentation available for audit.

Note: Where applicable (for example, seasonal operations), in order to confirm that the establishment is truly not operational; a regular programme of unannounced inspections should be set up until the audit takes place.

Reference: See sub-topic 4.7.6 on ’Unannounced inspection’ in part 1 for additional information.

4.2.2 Target for subsequent audit completion
Subsequent audit visits will be within the month determined by the last audit category.

4.2.3 Alternative arrangements
Where the audit date has been scheduled with the FBO and the FBO needs to cancel/ rearrange, the auditor shall inform the Audit Business Executive of the re-scheduling to assist with tracking.
4.3 **Audit protocol**

4.3.1 **Collecting evidence as to the compliance of the FBO**

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

In cutting plants: FSS staff will normally only be present to conduct the audit, although the premises may have been the subject of an unannounced inspection (UAI) in the period since the last audit. Prior to a scheduled audit taking place, the auditor should establish whether any unannounced inspections have taken place and if so, what enforcement activity arose as a result.

Both the OV and MHI 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 (ENF 11/5)

Note: ‘Major’ or ‘critical’ non-compliances may trigger an immediate action.

4.3.2 **Assessment of operational records**

Prior to the audit, the auditor must review enforcement records for the period since the last audit and use this information when assessing the effectiveness of the FBOs food safety management procedures and HACCP based system, taking account of corrective actions. For the purpose of the assessment, the auditor might request and review other records they finds relevant, including hygiene, welfare, animal by-products forms and UAI reports. The up-to-date enforcement programmes should be available in plant folders on Share Point and UAI reports can be accessed through the Unity Live link from SCOTS laptops.

Auditors can obtain additional information about the level of FBO’s compliance in an establishment through contact with the local FSS team (MHIs, OV, and VM).

**Reference:** See sub-topic 5.2.1 on ‘FBO compliance history’ in part 1 for additional information.
4.3.3 **The opening meeting**

Start each audit 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 programme
- 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 and that all necessary approvals are in place
- highlight that if during an audit it is identified that there has been a change of legal entity, the audit will be stopped and the approvals team informed; a new approval is required
- review of the Non-Compliance Report (NCR) from the last audit
- highlight any issue identified from the review of operational forms

4.3.4 **When carrying out the audit**

During the audit, the auditor will:

- collect and record objective evidence of the FBOs compliance with legislative requirements for food safety management systems 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
- score individual questions and sections as compliant or non-compliant (minor, major, critical non-compliance)
- determine the overall audit outcome as Good, Generally Satisfactory, Improvement Necessary and Urgent Improvement Necessary

**Note:** In slaughterhouses some of this information will be gathered on a daily basis by MHIs / OV.

4.3.5 **Serious issues identified during audit**

If an issue of serious public health, animal health or welfare arises during an audit (for example, considered ‘critical’), the auditor should:
• inform the FBO, the OV (where appropriate) immediately, and the VM as soon as possible
• take / instruct the OV for any necessary enforcement action to be taken
• consider curtailing the current audit

4.3.6 Reference to previous audit reports
During subsequent audits, the auditor should refer to the previous Audit Report to direct priorities during audit in a risk based manner. The auditor should focus on areas where major or critical non-compliances were identified (assessed as ‘weak’ or ‘poor’ in the previous auditing system). Those will always have to be reassessed in the next audit.

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 auditor 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 and 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).

4.3.8 FBO involvement in audit
The auditor should expect to be accompanied by the FBO (or a nominated representative) during the visit.

4.3.9 The closing meeting
The audit must be concluded with a closing meeting with the FBO (or appropriate representative) which will:
• summarise the audit findings (positive and negative)
• outline any non-compliances
• discuss the corrective action required, including 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
• give details of publication of the audit categories
• 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 provide any further supporting evidence if they disagrees with any audit findings.

It may be appropriate to allow the FBO a short period of time following completion of the audit to provide any documentation not available at the time or to demonstrate immediate action taken to correct deficits identified.

The resident OV in slaughterhouses, co-located cutting plants and wild game handling establishments shall attend the closing meeting, whenever possible.

4.3.10 Further information provided by the FBO

The FBO may provide 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.

4.3.11 Audit report

The Audit report (form AUD 9/3) must be compiled from the audit findings and should not be materially different from the findings presented verbally during the closing meeting.

The completed report should be submitted by the auditor to the Audit Business Executive within 5 working days of the audit visit.

Reference: See topic 4.4 on ‘Completing the Audit Report’ in part 1 for additional information.

4.3.12 Submission of Audit report (AUD 9/3)

The following table details the process which should be followed after completion of the audit report.

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The auditor completes and submits audit report within 5 working days to the Audit Business Executive.</td>
</tr>
<tr>
<td>2</td>
<td>The Audit Business Executive proof reads the report and records submission of the audit report.</td>
</tr>
<tr>
<td>3</td>
<td>The Audit Business Executive distributes the completed audit report to the FBO, Contractor and to other parties</td>
</tr>
</tbody>
</table>

4.3.13 Auditor’s feedback to the FSS team

The contractor receives a summary of the audit findings within 48 hours after the audit and a copy of the completed audit report sent to FBO from Audit Business Executive. The resident OV is responsible for making all members
of the team aware of the audit results, including non-compliances, the corrective action and timescales.

4.4 Completing the Audit Report

4.4.1 Use of objective evidence

As the formal record of the audit findings, the audit report must contain objective evidence to support the overall findings of the audit and the results given to the FBO during the closing meeting of the audit visit.

Although it was agreed with industry stakeholders that the audit report will mostly contain exception reporting, good audit practice dictates that report should include both positive and negative reporting. The trigger for the auditor to make narrative entries in the supporting evidence box will be based on the score in the assessment box. Assessment boxes which have not been marked as ‘compliant’ or changing scores from the previous baseline audit will require an entry in the supporting evidence box.

Note: A document entitled ‘FBO audit report writing guidance’ has been developed to assist auditors with aspects of report writing. It includes tips on style, accuracy, consistency and objectivity. This document is located on SharePoint.

4.4.2 Use of positive language

The auditor should use positive language during the closing meeting and in the audit report.

This will help to 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 section of the audit report requires the auditor to gather evidence regarding the level of compliance with the stated outcomes and record it as compliant or minor, major, critical non-compliance.
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.

In slaughterhouses, co-located cutting plants and wild game establishments the resident OV owns and is responsible for the amendment and completion of the ENF 11-5 form. The resident OV is also responsible for updating the ENF 11-5 during the audit period.

In stand-alone cutting plants without RTE products, the local OV and appointed UAI inspector are also responsible for updating the ENF 11-5 during the audit period. In stand-alone plants with RTE the appointed OV will be responsible for updating the ENF 11-5. OVs/UAI inspectors are also responsible for updating the ENF 11-5 during the audit period when required.

4.6.2 Request to change the auditing frequency / early audit

Audit outcomes, and as a result audit frequencies, can be re-assessed at the request of FSS and / or the FBO. The date of the audit can be brought forward or backwards providing that certain conditions are met.

An early audit cannot be requested immediately after an unsatisfactory audit. In these circumstances scheduled audit frequency can be only changed if all major and critical non-compliances were signed off as complete and an UAI was completed as specified in requirements.

The auditor can decide, in agreement with FSS Operations, to carry out another full audit of an establishment prior to its scheduled date if there is evidence that the standards have dropped i.e. deficiencies that would result in major or critical non-compliances at audit that are identified during UAI audits or daily FSS attendance indicate the establishment is generally not compliant.

4.6.3 Critical and major non-compliances

OVs will carry out partial audits of establishments with critical and / or major non-compliances. These visits will be chargeable to the FBO and will be treated separately to the UAI programme.

Major and critical non-compliances shall be closed off by the auditor following an onsite visit by the OV.

4.6.4 Minor non-compliances

Minor non-compliances are followed up by the resident OV in the case of slaughterhouses, co-located cutting plants and wild game handling establishments or during unannounced inspections in the case of stand-alone cutting plants. VM/OV/MHI involved in the unannounced inspections
can assess the corrective action taken by the FBO and inform the auditor to close off a minor non-compliance.

The officer (VM/OV/MHI) involved in assessing the corrective action taken by the FBO can recommend that the auditor closes off a minor non-compliance once they are satisfied that compliance has been achieved.

Minor non-compliances can also be closed off by the auditor based on the information provided by the OV conducting a partial audit /OV at a partial audit or at the next full audit.

4.6.5 **Unannounced inspection**

Guidance can be found in chapter 1 on 'Introduction', section 3.
4.7 Enforcement

4.7.1 Slaughterhouses, game handling and co-located cutting plants

At **Full Audit** Auditor Identities NC (new & from ENF11-5)

- **Urgent Improvement Necessary**
  - **Next Full Audit** 2 calendar mths

- **Improvement Necessary**
  - **Next Full Audit** 3 calendar mths

- **Generally Satisfactory**
  - **Next Full Audit** 12 calendar mths

- **Good**
  - **Next Full Audit** 12 calendar mths

**Resident OV enforces /updates ENF 11-5 / feeds back to Auditor on NCs** (New & from ENF 11-5)

**Partial Audit within 1 Calendar mth** unless Full Audit Scheduled in that calendar mth

- **No**
  - All Majors / Criticals closed?
    - **Yes**
    - Auditor Closes NC

- **Yes**

**Partial Audit within 3 Calendar mths** unless Full Audit Scheduled in that calendar mth

- **No**
  - All Majors / Criticals closed?
    - **Yes**
    - Auditor Closes NC

- **Yes**
4.7.2 Stand-alone cutting plants

At Audit Auditor Identifies NCs (new & from ENF 11-5)

- Urgent Improvement Necessary
  - Next Full Audit
    - 2 calendar mths
  
- Improvement Necessary
  - Next Full Audit
    - 3 calendar mths

- Generally Satisfactory
  - Next Full Audit
    - 12 calendar mths

NEW Minor NCs
O.V serves enforcement / updates ENF passes ownership to UAI process

NEW Critical/Major identified at Full Audit
O.V serves enforcement / updates ENF 11-5 follows enforcement hierarchy until closed

- Partial Audit within 1 Calendar mth unless Full Audit Scheduled in that calendar mth
  - No
    - All Majors / Criticals closed?
      - Yes
      - No

  - Yes

- Partial Audit within 3 calendar mths unless Full Audit Scheduled in that calendar mth
  - All Majors closed?
    - Yes
    - No

UAI Process monitors All Minor NCs and Criticals and Majors on ENF 11-5 prior to Audit
Feeds back to Auditor

Auditor Closes NC
5. Risk Assessment

5.1 Audit report

5.1.1 Audit report form

The audit report form (AUD 9/3) is available via the Sharepoint system.

5.1.2 Summary of findings

The report contains an area to summarise the audit findings. The summary of findings should include positive findings (good practice), negative findings (non-compliances) and a brief description of any variations from the previous audit enabling the FBO and other interested parties to review the audit without needing to read the full detail contained within the report.

5.1.3 Non-Compliance Report (NCR) (Annexe 5).

In the audit report there is a section containing the Non-Compliance Report (NCR).

The NCR enables the auditor to clearly inform the FBO of areas identified as requiring corrective action and timescales for completion. Timescales for completion must be discussed, and when possible, agreed with the FBO at the closing meeting.

A draft NCR form is sent to the contractor and VM within 48 hours from the audit visit.

The FBO is responsible for rectifying the NC identified during the audit.

5.1.4 Correction of NC

During the next audit, the auditor must verify whether the FBO has taken corrective actions and indicate those which have been completed.
5.2 Audit compliance assessment

5.2.1 FBO compliance history

The history of compliance relates to the deficiencies identified against legislative requirements or the FBOs own procedures and requiring OV intervention during the audit interval or the on-going NC’s 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:

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliant</td>
<td>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.</td>
</tr>
</tbody>
</table>
| Minor   | A non-compliance that is not likely to compromise public health (including food safety), animal health and welfare or lead to the handling of unsafe or unsuitable food. An isolated low risk situation and does not compromise achieving control measures of the food safety program; that is, 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 |
| **Major** | A major non-compliance is a non-compliance that is likely to compromise public health (including food safety), animal health and welfare or may lead to the production and handling of unsafe or unsuitable food if no remedial action is taken. When viewed collectively a number of related major non-compliances may represent 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 in food safety or animal welfare  
- failure to follow good hygienic procedures specified in prerequisite programs |
| **Critical** | A critical non-compliance is non-compliance where the contravention poses an imminent and serious risk to public health (including food safety), animal health and welfare.  
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  
- the same chopping board and knife being used for ready to eat food after being used for raw chicken without being cleaned and sanitised  
- evidence of pest control chemicals such as rat bait in food  
- raw meat juices dripping onto uncovered ready to eat food  
- repetitive (more than once) major non-compliance for the same practice or circumstance |
5.2.2 Audit 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:

<table>
<thead>
<tr>
<th>Compliance rating</th>
<th>Description</th>
<th>Tolerance for audit outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good</td>
<td>No issues of significance for public health, animal health or animal welfare during the entire audit period.</td>
<td>No majors or critical on day of audit or during audit period</td>
</tr>
<tr>
<td>Generally Satisfactory</td>
<td>No immediate issues of significance for public health, animal health or animal welfare identified on the day of the audit. Any non-compliances identified during the audit period corrected promptly.</td>
<td>No more than 2 majors during audit or during audit period rectified promptly No critical during audit period</td>
</tr>
<tr>
<td>Improvement Necessary</td>
<td>Major non-compliances identified at audit and/or non-compliances during the audit period not always responded to and corrected promptly.</td>
<td>3-6 majors during audit or during audit period No critical during audit period</td>
</tr>
<tr>
<td>Urgent Improvement Necessary</td>
<td>Multiple major non-compliances or critical non-compliance identified during audit visit or interim audit period. Official intervention required to ensure public health safeguards.</td>
<td>1 critical or &gt;6 majors during audit or during audit period</td>
</tr>
</tbody>
</table>

5.3 Audit outcome and frequency of inspections

5.3.1 Determination of frequency

The frequency of audit reporting is determined on a risk basis; assessed, in part, on the outcome of previous audits as outlined in this chapter.

The Audit frequency for all plants ranges from 2 to 12 months.

In addition to a scheduled full audit, a follow up partial audit is to be carried out in some establishments, which is dependent on the full audit outcome.
5.3.2 Audit frequency

The tables below list the minimum audit frequencies applicable to specific types of food establishment. They also include the number of necessary partial audits and unannounced inspections that have to take place.

<table>
<thead>
<tr>
<th>Audit frequencies for all plants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit outcome</td>
</tr>
<tr>
<td>Good</td>
</tr>
<tr>
<td>Generally satisfactory</td>
</tr>
<tr>
<td>Improvement necessary</td>
</tr>
<tr>
<td>Urgent Improvement necessary</td>
</tr>
</tbody>
</table>

* Where there is sufficient evidence provided to the auditor by the FBO, and verified by the OV where possible, that the NC has been rectified, this can be closed off without the need for an establishment visit (it is at the discretion of auditor to decide if a visit is required). This is only possible if the audit outcome is ‘generally satisfactory’.

* RTE establishments will receive one additional unannounced inspection by a trained OV.

<table>
<thead>
<tr>
<th>Additional visits based on the audit outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit Outcome</td>
</tr>
<tr>
<td>Good</td>
</tr>
<tr>
<td>Generally Satisfactory</td>
</tr>
<tr>
<td>Improvement Necessary</td>
</tr>
<tr>
<td>Urgent Improvement Necessary</td>
</tr>
</tbody>
</table>
5.4  Review and right of appeal

5.4.1  Regulators code

The appeals route for FBO audits follows the regulators code:

https://www.gov.uk/government/publications/regulators-code

5.4.2  FBO right to seek review

If an FBO is dissatisfied with the outcome of discussions with the auditor after the closing meeting, or the audit report once received from the Audit Business Executive, the FBO has the right of appeal in line with the following procedures:

<table>
<thead>
<tr>
<th>Stage 1 Appeal</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Try to resolve informally</td>
<td>All efforts should be made to resolve any misunderstanding or dissatisfaction informally on a local basis between the auditor and FBO.</td>
</tr>
<tr>
<td>Direct FBO to Audit Business Executive to request an audit appeal form</td>
<td>If a FBO, or their representative, still wishes to appeal an audit report they should be directed to the Audit Business Executive to request the audit appeal form ‘Request for a review of the Full audit of the FBO’s food safety management system’ (Annexe 7).</td>
</tr>
<tr>
<td>Audit Business Executive receives request for audit appeal form.</td>
<td>On receipt of the FBO’s request for an audit appeal form, the Audit Business Executive will send the form to the FBO, ensuring that the auditor is notified of the request, to ensure that all possible efforts have been made to resolve the matter informally.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage 1 Appeal</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>FBO submits formal appeal, with supporting evidence</td>
<td>The FBO, or their representative, should complete their part of the form, stating which sections of the audit report the FBO is appealing against and giving objective evidence to support the claim that the auditor’s assessment is incorrect. Any supporting evidence should be copied and sent with the form to the Audit Business Executive within <strong>14 calendar days</strong> of receiving the initial audit report from the Audit Business Executive. Appeals which are not supported with objective evidence may be rejected.</td>
</tr>
<tr>
<td>Investigating Officer (IO) appointed</td>
<td>On receipt of the completed appeal form, the Audit Business Executive will provide the Head of Operational Delivery with a copy of the appeal, including any supporting evidence. The Head of Operational Delivery will be responsible for appointing an Investigating Officer (IO), and confirming the details to Audit Business Executive.</td>
</tr>
<tr>
<td>Note: Audit Business Executive will also advise FSS Finance that the audit is under appeal.</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td></td>
</tr>
<tr>
<td><strong>IO reviews the supporting evidence supplied by the FBO</strong></td>
<td></td>
</tr>
<tr>
<td>The IO will consider if the appeal has sufficient evidence to continue, if not the FBO will be notified that the appeal will not progress any further. IOs will focus on scores challenged and the submission of evidence to carry out the investigation. The IO is not obliged to examine other aspects of the audit to which the appeal is related; however, as findings are sometimes interrelated the IO will take these into account where it is appropriate to do so. The IO will not overlook other relevant information which may be used to inform any decision made.</td>
<td></td>
</tr>
<tr>
<td><strong>IO conducts an investigation</strong></td>
<td></td>
</tr>
<tr>
<td>The IO conducts an investigation and completes a report before the last date for completion (stated in part 1 of the appeal form). The IO will determine which considerations should be made when making the assessment. Examples as follows:</td>
<td></td>
</tr>
<tr>
<td>- refer to audit notes</td>
<td></td>
</tr>
<tr>
<td>- request documents from FSS / FBO</td>
<td></td>
</tr>
<tr>
<td>- discuss with auditor and FBO</td>
<td></td>
</tr>
<tr>
<td>- visit an establishment or not; telephone interviews may be sufficient to clarify doubts</td>
<td></td>
</tr>
<tr>
<td><strong>Note:</strong> IOs should always consider visits to premises where serious concerns are arising, such as critical or multiple major non-compliances.</td>
<td></td>
</tr>
</tbody>
</table>
### Stage 1 Appeal

<table>
<thead>
<tr>
<th>Investigation outcome</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>On conclusion, the IO distributes their completed report to Audit Business Executive, who will take the necessary actions, depending upon the outcome of the IO’s investigation. Audit Business Executive will email the IO’s report to the FBO, (including any amended audit report if applicable) and copy the correspondence to the Head of Audit, Veterinary Auditor, Head of Operational Delivery, Veterinary Manager and contractor. The IO is responsible for discussing the investigation findings with the Head of Audit, Veterinary Auditor and the FBO (or their representative) regardless of whether the investigation report resulted in an amendment or the score was upheld.</td>
<td></td>
</tr>
</tbody>
</table>

### 5.4.3 Stage 2 appeals

FBOs can only request a Stage 2 appeal following two successive audits which have been appealed at stage 1 and the FBO is not satisfied with the outcome. Only the second successive audit qualifies for a stage 2 appeal review. A £250 fee is payable by the FBO for a stage 2 appeal process as a contribution to the FSS’s costs. Stage 2 appeals will not commence until the fee has been paid. If the review/ appeal rules in the FBO’s favour and the audit frequency has been changed the £250 will be refunded. If the appeal changes the outcome of some sections, but this does not lead to a change in the overall audit outcome, the fee will not be refunded.

<table>
<thead>
<tr>
<th>Stage 2 Appeal</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>FBO exercises their right to appeal at stage 2</td>
<td>FBO notifies Audit Business Executive in writing (for example, via email or post) <strong>within 7 calendar days</strong> of receiving the stage 1 outcome notification of their intention to appeal the stage 1 outcome. The required £250 payment should also be enclosed.</td>
</tr>
<tr>
<td>Audit Business Executive receives FBO written confirmation and payment</td>
<td>On clearance of payment the Head of Audit will contact an independent IO appointed by FSS to carry out the investigation. Stage 1 appeals pack is sent to Independent IO for review.</td>
</tr>
<tr>
<td>Independent IO</td>
<td>The appeal will be determined within <strong>14 calendar days</strong> by the independent person nominated by the Food Standards Scotland. The Nominated Person:</td>
</tr>
<tr>
<td></td>
<td>- will give the business and the FSS an opportunity to make representations on the matter to be determined</td>
</tr>
<tr>
<td></td>
<td>- will determine the matter concerned</td>
</tr>
<tr>
<td></td>
<td>- will notify the FBO and the Head of Audit and Head of Operational Delivery of the final decision</td>
</tr>
<tr>
<td></td>
<td>If the independent IO decides in favour of the FBO and provided...</td>
</tr>
</tbody>
</table>
Part 2  HACCP Based Procedures

Section 1  Introduction
Section 2  Common issues for HACCP auditing
Section 3  Audit and enforcement

the audit outcome has been changed the £250 fee for initiating the appeals process would be refunded to the business.
1. Introduction

1.1 Legislation

1.2 Characteristics of HACCP based procedures

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.

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Issue</th>
<th>Who is responsible?</th>
<th>Other documents</th>
</tr>
</thead>
</table>
| Reg (EC) 852/2004 Chapter II, Article 5 | Put in place, implement and maintain a permanent procedure based on HACCP principles | FBO                  | • Commission Guidance  
• MIG  
• 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  
• MIG |
| Reg (EC) 853/2004 Annex II, Section II | List of HACCP based objectives for incoming animals accepted for slaughter | FBO                  | • Commission Guidance  
• MIG |
| Reg (EC) 854/2004 Chapter II, Article 4 | Audit and verification that FBOs apply HACCP principles continuously and properly | OV                   | • MOC  
• MIG  
• Food Safety Management Diary for Meat Producers |
1.1.2 **(EC) 852/2004 evidence**

The FBO shall provide the OV/VA with evidence of their compliance with the HACCP legal requirements, taking into account the nature and size of the business, and ensure that any documents describing the procedures are up to date at all times.

The instructions in this chapter reflect the minimum requirements expected to consider an FBO plan of HACCP-based procedures adequate and in compliance with the Regulations.

Regulation: (EC) 852/2004, Chapter II, Article 5.

1.1.3 **(EC) 854/2004 OV verification of HACCP based procedures**

The OV/VA is required to conduct audits to verify that food business operators apply HACCP based procedures continuously and properly to make sure, in particular, that:

- procedures guarantee that the requirements for incoming animals are met
- meat complies with the microbiological criteria
- meat complies with the community legislation on residues, contaminants and prohibited substances
- meat does not contain physical hazards, such as foreign bodies

Regulation: (EC) 854/2004, Chapter II, Article 4, 5.

1.1.4 **Key reference documents**

The MIG contains information for FBOs on the application of HACCP based principles to comply with the legal requirements as well as advice. It takes account of the Commission’s guidance on flexibility and includes generic HACCP plan material. It should be read by OV’s/VAs advising on or auditing the application of HACCP principles.

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:** MOC, Volume 2 Legislation for additional information.

http://www.food.gov.uk/sites/default/files/multimedia/pdfs/food-safety-diary-meat.pdf (‘the Diary’) has been produced by the 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.
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 (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:

- the nature of the operations
- the size of the business
### Flexibility taking into account

<table>
<thead>
<tr>
<th>Nature of the operations</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>In businesses handling food with no significant food safety hazards (for example, greengrocers) a hazard analysis confirming that is the case can be sufficient.</td>
<td></td>
</tr>
<tr>
<td>In businesses handling many foods (for example, restaurants) a simplified approach using a diary can be sufficient.</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>In food manufacturing businesses, particularly with procedures that will eliminate hazards (for example, canning plants) full technical HACCP is more appropriate.</td>
<td></td>
</tr>
<tr>
<td>OV/VA should consider whether the HACCP based procedures are appropriate for the type of business.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Size of the business/ documentation</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 achieve the safe production of food as well as a more complex system.</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Small and medium sized businesses rarely require the same level of documentation. They may choose to record when things go wrong, called ‘exception reporting’.</td>
<td></td>
</tr>
<tr>
<td><strong>Reference:</strong> See the topic 2.10 on ‘Principle 7: Documentation’ in Part 2 for additional information.</td>
<td></td>
</tr>
<tr>
<td>OV/VA 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.</td>
<td></td>
</tr>
</tbody>
</table>

### 1.2.5 Flexible application of HACCP principles

FBO application of HACCP principles should meet the following criteria:

- 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; the FBO may choose to have in the plan only CPs which are legal requirements
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)

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

Reference: See the MIG chapter 9 on ‘HACCP’ for additional information.

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 role

OV’s, 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. **Common issues of HACCP auditing**

2.1 **Introduction**

This section covers common issues for OV’s/Veterinary auditors to consider when auditing a food safety management system based on HACCP principles in compliance with the regulation.

2.2 **Training**

2.2.1 **Staff responsible for HACCP based procedures**

Those responsible for the development and maintenance of HACCP-based procedures have received adequate training in the application of HACCP principles. Regulation: (EC) 852/2004, Annex II, Chapter XII, 2.

2.2.2 **Training: common issues**

The following table contains examples of common issues that the OV/VA could find when auditing HACCP based procedures and guidance on how the OV/VA should make the assessment to determine FBO compliance:
No member of staff with formal training

Formal training is not a legal requirement; the FBO however, should show that they have received 'supervision, instruction and/or training'. This can be achieved in a number of ways including (list not exhaustive):

- one to one instruction
- day courses
- in house courses
- distance learning courses

These may or may not be accredited courses; however, there should be evidence of training. Examples include: certificates, completed test papers, questionnaires, personal assessment papers and individual training records showing instruction or training received.

Reference: See the MIG chapter 9 on ‘HACCP’ and the MOC volume 2 on ‘Commission guidance’ for additional information.

The FBO believes they do not require any training at all as the HACCP based system has been written by an external adviser / consultant

If external advisers / consultants are used, they should do so as part of a HACCP team, providing instruction and guidance rather than working independently and writing the system for the FBO. It may mean that the FBO is unable to answer questions or make amendments without reference to the adviser. This raises the question of whether the staff can be maintaining their HACCP-based procedures and has adequate training to do so. Instruction given by the external adviser / consultant to the FBO should be recorded on individual training records. Primary responsibility for food safety rests with the FBO, so ownership of the food safety system should be that of the FBO.

Reference: (EC) 852/2004, Chapter I, Article 1, 1(a).

### 2.3 Implementation and maintaining of HACCP based procedures

#### 2.3.1 HACCP implementation and maintaining

FBOs shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles taking into account the nature and size of the business.

Reference: See the MOC volume 2 legislation on (EC) 852/2004, Recital 15 and Article 5, paragraph 1 and the EC Commission Guidance document on implementation of procedure based on the HACCP principles.
2.4 Principle 1: Hazard analysis

2.4.1 Hazard identification

The FBO is responsible for identifying any significant hazards that must be prevented, eliminated or reduced to acceptable levels.

Regulation: (EC) 852/2004 Article 5, paragraph 2(a).

2.4.2 Hazard identification: common issues

The following table contains examples of common issues that the OV/VA could find when auditing HACCP based procedures and guidance on how the OV should make the assessment to determine FBO compliance:

<table>
<thead>
<tr>
<th>Common Issues</th>
<th>OV/VA advice / guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>The product description does not include technical information</td>
<td>Flexibility as to what is included should relate to the technical nature of the production process. For example, a meat plant producing a meat preparation and / or meat product is likely to require a greater amount of data such as microbiological criteria, moisture content than a meat plant that simply cuts and packs a raw product. Large meat plants that have qualified technical teams / advisers may have the necessary skills to write a very detailed and validated technical description of the process; this may not be the case in small – medium businesses with fewer resources.</td>
</tr>
</tbody>
</table>
| Flow diagram does not show all steps in a process                            | A flow diagram (CODEX HACCP guideline) used in a traditional HACCP system will describe all inputs into the food business (such as packaging and ingredients), the different stages of process and how different foods are stored. Generic systems based on HACCP principles may use a ‘simplified’ flow diagram; this is an identification (rather than description) of each process step. Certain process steps may be grouped together when the risks are the same, for example, removing bones from a carcase and cutting the boneless meat into cubes. Although these are two different procedures, the hazards will be the same, therefore the process step may be written and simplified as follows:  
  * remove bone and prepare meat  
  
  **Note:** It is essential that flow diagrams accurately reflect the whole process (are validated), so that the remaining HACCP principles are correctly considered and described. |
| Hazards identified do not specify individual contaminants such as salmonella, rust, chemicals, | A technical HACCP study completed by a multi-disciplinary team will be based on extensive research to ensure that all potential hazards, biological, physical, chemical and allergenic are identified for example, the effect of competition from spoilage bacteria on the survival of food-borne pathogens. This level of detail is unlikely to be achieved by small – medium businesses with limited resources, who |
peanuts may address individual hazards by groups, for example,

**Biological contamination:**

The naming of each type of pathogenic bacteria that may be a contamination / cross-contamination hazard would be appropriate for larger plants but not for businesses following a generic plan. At the chilling step a generic hazard will be ‘Growth of bacteria due to inadequate temperature control’. It is unnecessary for the FBO to have an in-depth understanding of microbiology. It is sufficient that the plan recognises the dangers of poor temperature control in relationship to bacterial growth. Importantly, FBOs should recognise the need to minimise the level of micro-organisms at each stage of the supply chain as there is a risk of cross contamination of ready-to-eat products by raw meat before it is itself cooked.

Hazard identified do not specify individual hazards such as *salmonella*, rust, chemicals, peanuts

**Physical contamination:**

Individual hazards, such as parts from machinery, contamination from building fabric, may be combined and identified as ‘contamination due to foreign objects’.

**Chemical contamination:**

The plan may not identify a significant chemical hazard. Cleaning chemical hazards should be controlled by the application of hygiene controls, such as cleaning procedures (adhering to a Cleaning Schedules) and a list of chemical used (Cleaning Record). In respect of allergenic reactions, few people display allergic reactions to meat, so in raw meat slaughter / processing it is unlikely to be a significant hazard, however this risk would need to be considered when processing a meat preparation or product, which may contain relevant products such as soya, egg, sesame.

**Reference:** See the MIG chapter 5 on ‘Cleaning’ for additional information.

OV’s/VAs should note the above differences applying flexibility.

Inaccurate control measures identified

‘Control measures’ are necessary to control significant hazards from contaminating a food, for example, the chilling of meat down to a desired temperature and the implementation of maintenance procedures. The plan of HACCP-based procedures may not distinguish control measures from monitoring procedures and may include visual inspections / observations as control measures. Visual inspection should be regarded as a monitoring procedure, however, although not technically correct, the inclusion of monitoring as a control measure does not have an adverse effect on the safety of food.
2.5 Principle 2: Determine critical control points (CCPs) / control points (CPs)

2.5.1 CCP / CP identification

Identify the Critical Control Points (CCPs) (or Control Points (CPs)) at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels.

**Regulation:** (EC) 852/2004 Article 5, paragraph 2(b).

2.5.2 Difference between CCP and CP

In the processing of raw meat it may not be possible to prevent or eliminate hazards and reduction steps may not be measurable in the same way as, for example, when food is canned. Therefore, FBOs may consider that for their product and / or operations there are no ‘traditional’ CCPs. There are process steps, however, where controls are necessary to meet legal objectives. If these process steps are not chosen as CCPs they should nevertheless be included in the plan of HACCP-based procedures as Control Points (CPs) required by legislation and which are to be monitored and corrective actions taken. Examples of those control points are:

- acceptance of animals for slaughter, to ensure animals are identified, clean and healthy
- evisceration and dressing, to ensure absence of visible contamination
- SRM controls, to ensure absence and proper disposal of SRM
- temperature controls to limit growth of micro-organisms
- receipt / pre-cut inspection of raw meat, to ensure raw materials are free from contamination

**Reference:** See the MIG chapter 9 on ‘HACCP’ for additional information.

2.5.3 CCPs / CPs common issues

The following table contains examples of common issues that the OV/VA could find when auditing HACCP based procedures and guidance on how the OV should make the assessment to determine FBO compliance:

<table>
<thead>
<tr>
<th>Common Issues</th>
<th>OV/VA advice / guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCPs either not present or not identified correctly</td>
<td>In certain food businesses there will be steps in the process that are critical to the safe production of food, for example, cooking a raw food to a specified core temperature. A decision tree may be used to determine CCPs. On the other hand, a small-medium slaughterhouse or cutting plant handling raw meat may follow a generic approach where CCPs / CPs are pre-determined and so a decision tree may not be needed.</td>
</tr>
</tbody>
</table>
2.6 Principle 3: Establish critical limits (CLs) / legal limits (LLs)

2.6.1 Establishing CLs and LLs

Establishing critical limits (CLs) (or legal limits (LLs)) at CCPs (or CPs) which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards.

**Regulation:** (EC) 852/2004 Article 5, paragraph 2(c).

Limits do not need to be a fixed numerical value that requires measurement. Limits can be monitored through visual observation, for example, faecal contamination of carcases.

2.6.2 Difference between CLs and LLs

CLs separate acceptability from unacceptability or safe from unsafe food at CCPs. CLs must be at least as strict as legal requirements that apply at that process step for example, temperatures for raw meat. LLs are values set out in the legislation to be used where FBOs have decided to have CPs (instead of CCPs) which are legal requirements.

2.6.3 CLs and LLs – common issues

The following table contains examples of common issues that the OV/VA could find when auditing HACCP based procedures and guidance on how the OV should make the assessment to determine FBO compliance:

<table>
<thead>
<tr>
<th>Common Issues</th>
<th>OV/VA advice / guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hygiene controls set as Critical Limits</td>
<td>In a technical HACCP system CLs may include:</td>
</tr>
<tr>
<td></td>
<td>• values of temperature, time</td>
</tr>
<tr>
<td></td>
<td>• maximum residue limits</td>
</tr>
<tr>
<td></td>
<td>• maximum levels (of contaminants)</td>
</tr>
<tr>
<td></td>
<td>• microbiological criteria</td>
</tr>
<tr>
<td></td>
<td>• levels of chlorine</td>
</tr>
<tr>
<td>Hygiene controls set as Critical Limits</td>
<td>In some cases the plan of HACCP-based procedures may not distinguish critical limits from the application of hygiene controls for example, cleaning procedures, maintenance procedures and pest control. Where FBOs have decided to have CPs (instead of CCPs) which are legal requirements, the LLs may include strict adherence to a hygiene control. This does not have an adverse effect on the safety of food.</td>
</tr>
</tbody>
</table>
2.7 Principle 4: Monitoring CCPs and CPs

2.7.1 Monitoring procedures

Establishing and implementing effective monitoring procedures at CCPs (or CPs). Regulation: (EC) 852/2004 Article 5, paragraph 2(d).

2.7.2 Monitoring procedures: common issues

The following table contains examples of common issues that the OV/VA could find when auditing HACCP based procedures and guidance on how the OV/VA should make the assessment to determine FBO compliance:

<table>
<thead>
<tr>
<th>Common Issues</th>
<th>OV/VA advice / guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring procedures not recorded</td>
<td>Monitoring procedures are an important part of a HACCP based system, in some cases monitoring may not be recorded, or recorded just to pass an audit, and have no bearing on what is actually happening in the meat plant. Reference: See topic 2.10 on ‘Principle 7: Documentation’ in part 2.</td>
</tr>
<tr>
<td>Plan not a true reflection of reality</td>
<td>The monitoring procedures described in the plan should reflect those actually carried out.</td>
</tr>
<tr>
<td>Disproportionate monitoring procedures</td>
<td>Extensive record keeping may prove to be burdensome for a FBO to maintain (for instance when documentation/ records have been produced by a third party (consultant) who does not understand the food business operations, for example,</td>
</tr>
<tr>
<td></td>
<td>• twice daily recordings carried out by staff of the temperature of all knife sterilisers using a probe thermometer; resulting in hundreds of manual checks per week</td>
</tr>
<tr>
<td></td>
<td>• daily manual recordings of the air temperature of a chiller using a probe thermometer that is already monitored automatically and linked to a warning alarm</td>
</tr>
<tr>
<td></td>
<td>Monitoring is ‘the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP (or CP) is under control’ therefore monitoring may or may not include written records of any checks carried out. Information recorded will be dependent on the risk of the operations; that is, the type of food and size of the business. Documentation should not cause an unnecessary burden to small – medium businesses. The FBO may choose to record by exception (using a diary such as the <a href="http://www.foodstandards.gov.scot/food-safety-management-fsm-diary-meat-producers">www.foodstandards.gov.scot/food-safety-management-fsm-diary-meat-producers</a>) in which case the amount and type of records will not be the same as those used in a traditional HACCP system. The Diary may also be the preferred choice of the FBO to record occasional checks, for example, product temperatures taken on a daily basis, rather than recording on separate sheets of paper.</td>
</tr>
</tbody>
</table>
2.8 Principle 5: Corrective action procedures

2.8.1 Establishing corrective actions

Establishing corrective actions when monitoring procedures at CCPs (or CPs). Regulation: (EC) 852/2004 Article 5, paragraph 2(e).

2.8.2 Corrective actions: common issues

The following table contains examples of common issues that the OV/VA could find when auditing HACCP based procedures and guidance on how the OV/VA should make the assessment to determine FBO compliance:

<table>
<thead>
<tr>
<th>Common Issues</th>
<th>OV/VA advice / guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan not a true reflection of reality</td>
<td>The corrective action procedures described in the plan should reflect those actually carried out.</td>
</tr>
<tr>
<td>Corrective actions not recorded</td>
<td>Corrective actions are an important part of a plan of HACCP-based procedures to bring production back under control. In some cases the actions taken may not be recorded as the FBO does not want to admit to failures. The impression given is that the FBOs never have any problems with their hygiene control procedures. In fact, the record of corrective actions shows that the plan based on HACCP principles is a ‘healthy’ plan that works effectively. Corrective actions should ensure that the risk to consumers are eliminated, prevented or reduced for example, trimming of faecal contamination.</td>
</tr>
<tr>
<td>Corrective actions not recorded</td>
<td>Problems always occur and records should be made when they do. These records are important for the FBO to enable verification of the HACCP based system. Examples on how to record corrective actions may include: a comment made on a cleaning check-sheet when problems have been identified during cleaning by staff entering the problem and the action taken by use of a diary such as the food safety management diary for meat producers</td>
</tr>
</tbody>
</table>

2.9 Principle 6: Validation, verification and review

2.9.1 Validation

The FBO is required to validate the plan before implementation and after any amendments or reviews.
2.9.2 Verification

Establishing procedures which shall be carried out regularly to verify that what is written in the HACCP plan is actually being carried out in the workplace and is working effectively. **Regulation:** (EC) 852/2004 Article 5, paragraph 2(f).

2.9.3 Review

When any modification is made in the product process, or any step, the food business operators shall carry out a review of the HACCP based procedure plan(s) to ensure that the plan(s) and associated documentation are up to date. **Regulation:** (EC) 852/2004 Article 5, paragraph 2.

2.9.4 Validation / Verification / Review: common issues

The following table contains examples of common issues that the OV/VA could find when auditing HACCP based procedures and guidance on how the OV/VA should make the assessment to determine FBO compliance:

<table>
<thead>
<tr>
<th>Common Issues</th>
<th>OV/VA advice / guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan not a true reflection of reality</td>
<td>The validation, verification and review procedures described in the plan should reflect those actually carried out.</td>
</tr>
<tr>
<td>No records of Verification / Validation / Review of the HACCP plan(s)</td>
<td>Plans based on HACCP principles allow for flexibility in the application. The FBO may combine validation (of the HACCP plan), verification and review (of the system); as it may be difficult for the FBO to distinguish between them. Absence of separate validation / verification / review checks does not necessarily mean these have not been carried out. Verification of these procedures may be completed by an internal audit / or external audit(s) carried out by the competent authority or third party auditors. Examples of separate validation, verification and HACCP plan review forms are provided in the <a href="http://www.foodstandards.gov.scot/food-safety-management-fsm-diary-meat-producers">www.foodstandards.gov.scot/food-safety-management-fsm-diary-meat-producers</a> which the FBO may choose to use. If the Diary is used the 4-weekly reviews also accomplish verification of the FBOs hygiene controls.</td>
</tr>
</tbody>
</table>
2.9.5 Microbiology

Microbiological testing is another way of verification of HACCP based procedures. Microbiological requirements are contained in Regulation (EC) 2073/2005 (as amended). Surface microbiological testing is not a legal requirement but the FBO may decide to do so as a way of verification of their cleaning procedures.

Reference: See part 3 section 3 on ‘Verification of microbiological criteria’ for additional information.

2.10 Principle 7: Documentation

2.10.1 Establish documents and records

Establishing documents and records commensurate with the nature and size of the business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f):

a. identifying hazards
b. identifying CCPs (or CPs)
c. establishing CL (or LL) at CCPs (or CPs)
d. establishing and implementing monitoring procedures
e. establishing corrective actions
f. establishing verification procedures (including validation and review)

Regulation: (EC) 852/2004 Article 5, paragraph 2(g)

2.10.2 Types of documents and records

Three types of paperwork are necessary:

- HACCP plan(s) documenting application of HACCP principles (may be a generic plan – amended to reflect the company procedures including prerequisites that are control measures)
- company’s HACCP-based procedures, policies, staff instructions (should include prerequisites as control measures)
- records of monitoring, corrective action, verification and review (the Food Safety Management Diary may be used)
2.10.3 Documentation: common issues

<table>
<thead>
<tr>
<th>Common Issues</th>
<th>OV/VA advice / guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan not a true reflection of reality</td>
<td>The documentation referred to in the plan of HACCP-based procedures should reflect those actually maintained by the FBO.</td>
</tr>
<tr>
<td>Disproportionate documentation</td>
<td>Documentation, especially if it is produced by an external adviser, may be disproportionate to the size, type of business and type of food produced. It may be too technical for the FBO or plant staff to understand or follow; it may duplicate existing records or seek to introduce a far more complex system of recording than is appropriate. In these cases it may be appropriate to encourage the FBO to consult with their adviser / consultant and work together to produce a workable, more easily managed HACCP based system, reminding the FBO that the HACCP based system is their control system and they should retain ownership.</td>
</tr>
</tbody>
</table>

2.10.4 Food safety management diary for meat producers (‘The Diary’)

The use of the FSS’s Food Safety Management Diary for Meat Producers (the ‘Diary’) is an acceptable method of record keeping. When using the diary, the FBO or other responsible person should sign the Diary every day to say:

- opening, operational and closing checks have been carried out
- hygienic production has been followed

These are not just a tick in a box, if these have been ticked the workplace must accurately reflect the check carried out for example, areas, equipment are / is clean, and knife sterilisers are working correctly. The daily Diary pages are not intended to replace all existing documentation. They will need to be supported by additional record forms and procedures / staff instructions such as:

- individual staff training records
- cleaning schedules
- maintenance plans

The Diary provides examples of such documents that FBOs may adapt for their own use. FBOs may choose to keep such prerequisite records in the Diary binder. The use of the Diary by FBOs is voluntary. It will not be appropriate in businesses that already have good existing records, and may not be entirely sufficient where, for example, the business is accredited to a Quality Assurance scheme or customers require more extensive documentation.
Reference: An electronic version of the Diary can be found at:

2.10.5 Exception recording

FBOs may choose to do exception recording, only to make record when a problem or something out of the ordinary is identified and the corrective actions to regain control. This applies particularly to checks that are more or less continuous for example, visual monitoring of each carcase, or where separate checklists are kept for example, cleaning checks. Examples of exceptional recording:

- record when temperatures exceed the critical / legal limit and the action taken to regain control instead of having to tick / cross a separate list
- instead of making ticks and crosses in a cleaning checklist every day, an alternative could be recording only when cleaning problems are identified including the corrective action
- trimming contamination from a carcase
- recording problems that occur during a process for example, gut spillage during evisceration
- action taken when there are signs of pest infestation
- action taken if refrigeration equipment requires repair
- problems with faulty equipment and what was done to put it right
- staff not adhering to pre-requisite or other procedures and what corrective actions were required for example, supplementary or refresher training, cleaning of a piece of equipment
- knife sterilisers that are not working at 82°C or above and what corrective actions were required for example, repair / renew equipment

FBOs should nevertheless be encouraged to record the results of occasional checks to demonstrate that their procedures are working effectively, for example:

- periodic checks of knife sterilisers
- chiller temperatures

Problems and corrective actions taken do not show a weak HACCP plan but a healthy HACCP plan that works effectively.
2.10.6 Management checks

Management checks are an integral part of FBO food safety management to ensure that prerequisite controls are working effectively.

Four weekly checklists are provided in the Diary to encourage FBOs to undertake a regular review of all aspects of their hygiene controls. There is space to record any persistent problems (which may include concerns raised by OV inspections or audits) or any significant changes that have been made and how they are being dealt with, including any consequences for their HACCP-plans.

Reference: See the topic 2.9 on ‘Principle 6: validation, verification and review’ in part 2 for additional information.
3. Audit and Enforcement

3.1 FSS audit of HACCP principles and microbiological testing

3.2 Enforcement: HACCP

3.1 FSS audit of HACCP principles and microbiological testing

3.1.1 Audit 9/3 form (Annexe 2)

FSS Veterinary Auditors should use the MS Excel audit report form AUD 9/3 to audit FBO compliance in the application of HACCP based procedures.

Reference: see MS Excel audit report form.

When one establishment has several HACCP based procedures plans, the VA only need to complete one ‘HACCP based procedures’ section of the form AUD 9/3 which will cover the audit findings for all the HACCP based procedures plans of one establishment.

3.1.2 FSS HACCP audit objective

The objective of the FSS audit should be to establish whether the FBO can show that they have implemented and are maintaining a system based on HACCP based procedures to a reasonable degree.

Note: HACCP based procedures will not work without sufficient / adequate / appropriate prerequisites (good hygiene practices) being in place (as required by Regulation (EC) 852/2004 in particular).

3.1.3 Technical deficiencies

The plan based on HACCP principles may not be technically correct but this does not make it invalid (or require formal enforcement action) as it may achieve the main purpose of controlling the main hazard for the production of safe food. Example: A flow diagram that does not correctly reflect the operations carried out; however, there is no risk for public health as the risks have been correctly identified.

Reference: See sub-topic 3.2.1 on ‘OV advisory role’ in part 2 for additional information.

3.1.4 FSS HACCP audit

The VA should determine through Part 2, (HACCP based procedures section) of the AUD 9/3 the FBO level of compliance as compliant, minor, major or critical. The decisions on which criteria is appropriate is a matter of
professional judgment of the VA based on the guidance provided in this chapter.

3.1.5 **FSS microbiological testing audit**

The OV/VA should verify that the FBO complies with the microbiological sampling requirements, laid down in (EC) 2073/2005 (as amended), in accordance with (EC) 882/2004. OV verification and reporting through part 2 of AUD 9/3 include FBO responsibility for:

- sampling at the required frequency
- following the sampling rules
- interpretation of the sampling results (do these look manufactured or unrealistic?)
- identification of patterns and trends in test results
- identification of failures in the processing techniques that should have been identified and addressed
- corrective action, where necessitated by the results obtained
- a product recall, where necessitated as a result of unsatisfactory food safety criteria results

**Reference:** For additional information see the MIG.

3.2 **Enforcement: HACCP**

3.2.1 **OV advisory role**

Where the VA/OV finds that the FBO has HACCP based procedures but there are deficiencies that do not pose a public health risk, the VA/OV should not serve a formal notice, but advice, educate and encourage rectification of the HACCP based procedures. The FBO may be directed to the MIG for guidance, and in particular the advice on HACCP training, as well as to the Meat Plant HACCP Manual and the Food Safety Management Diary sample documents.

**Reference:** For guidance on HACCP implementation refer to

http://www.food.gov.uk/business-industry/meat/haccpmeatplants

The electronic version of the Diary can be found at

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

### 3.2.2 Objective evidence

It is essential to gather evidence of legal contraventions for example,

- the slaughter for human consumption of animals whose identity cannot be reasonably ascertained
- carcasses presented with faecal contamination at post mortem inspection, when these are related to the inadequacy (or non-existence) of the FBOs HACCP-based food safety management procedures

### 3.2.3 Notification to the FBO of deficiencies

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 OV 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.

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

### 3.2.4 Plant functions

Separate HIN’s are to be served on each of the establishment’s approved functions, 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

### 3.2.5 Time scales for compliance with formal notices

The timescale for compliance with the HIN will depend upon the size of the establishment, the nature and complexity of the operations and the history of
compliance of the FBO. The OV 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).

3.2.6 Failure to comply with the notice

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

Reference: See chapter 9 on ‘Forms’.

The OV 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.

3.2.7 OV/VA records of FBO compliance

The OV must keep records in the plant daybook, in daily hygiene report form (AUD 9-1 and AUD 9-2) and the enforcement program (ENF 11-5) of the advice given to the FBO. VA will record the advice given in audit report form (AUD 9-3).
Part 3  Verifying operator’s own checks

Section 1  Introduction
Section 2  The use of lactic acid to reduce microbiological surface contamination on bovine carcases
Section 3  Verification of microbiological criteria
Section 4  Traceability
Section 5  Official Control Verification Sampling Procedures
1. **Introduction**

1.1 **Background**

1.1.1 **General obligations regarding the organisation of official controls**

Regulation (EC) No 882/2004 requires official controls to be undertaken to achieve the objectives of the regulations, taking account of:

- identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare

- feed or food business operators’ past record as regards compliance with feed or food law or with animal health and animal welfare rules

- the reliability of any own checks that have already been carried out

- any information that might indicate non-compliance

**Reference:** Regulation (EC) 882/2004, Chapter 1, Article 3.

1.1.2 **In development**

This section of the MOC will focus on official controls to be undertaken to verify the reliability of FBO’s own checks that have already been carried out. The section will be developed and expanded over the course of future amendments.
2. **Lactic acid to reduce microbiological surface contamination in bovine carcases**

2.1 **Background**

2.2 **Legislative reference**

2.3 **Concentration and applications of solution**

2.4 **Exceptions to the use of lactic acid**

2.5 **Minimum HACCP requirements**

2.6 **FBO duties**

2.7 **FSS role**

2.1 **Background**

2.1.1 **Substances to remove surface contamination**

EU hygiene legislation provides for the use of potable water to remove surface contamination from products of animal origin. However, it does also provide 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 measure was preceded by a thorough risk assessment by the European Food Safety Authority (EFSA), which resulted in a favourable opinion published on 26 July 2011 on the safety and efficacy of lactic acid.

2.2 **Legislative references**

2.2.1 **Relevant legislation**

- Commission Regulation (EC) No 2073/2005 on microbiological criteria for food stuffs
- Regulation (EC) No 1333/2008 on food additives
2.2.2 Commission Regulation (EU) No 101/2013

Commission Regulation (EU) No 101/2013 allows Food Business Operators to choose to use lactic acid to reduce microbiological surface contamination on bovine carcases, half carcases or quarters at the slaughterhouse, in compliance with the conditions set out in the Annex to the Regulation.

2.3 Concentration and application of solutions

2.3.1 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) No 231/2012.

Note: The specifications set out in Regulation (EU) No 231/2012 are reproduced in Annex 1 at the end of this chapter.

2.3.2 Concentration of prepared lactic acid solution

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

2.3.3 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
2.3.4 To what may the prepared lactic acid solution be applied?

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.

2.4 Exceptions to the use of lactic acid

2.4.1 Visible faecal contamination

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

2.4.2 Irreversible physical changes

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

2.5 Minimum HACCP requirements

2.5.1 HACCP

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

- Sampling of carcases for the purposes of assessing compliance with microbiological criteria within the meaning of Regulation (EC) No 2073/2005 (as amended) must be carried out before the application of lactic acid solutions to the carcases, half-carcases 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.

2.6 FBO duties

2.6.1 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.

2.6.2 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.

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

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

2.7 FSS role

2.7.1 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.

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

2.7.3 Frequency of verification at audit
Until further instructions are provided, should the FBO choose to use lactic acid as a decontaminant, the VM 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.
2.7.4 Verification at audit

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

- the lactic acid meets the requirements of Regulation (EU) No 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 audit report form in the HACCP section.

2.7.5 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 VM and OM.

Add in the same section as lactic acid – instructions on use of the steam vacuum in the slaughterhouses?
3. Verification of microbiological criteria

3.1 Background

3.1.1 Purpose of microbiological testing

FBO’s responsibilities in relation to compliance with microbiological criteria that apply to meat in accordance with the provisions set out in Regulation (EC) 2073/2005 (as amended) are outlined in this chapter in part 2, section 3 on ‘Audit and enforcement’.

Detailed guidance for FBOs is contained within the MIG chapter 13 on ‘Microbiology’.

OVs should ensure that they are familiar with the guidance contained within those sources.

The purpose of microbiological testing is to ensure that:

- 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 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 food safety criteria, are unsatisfactory (for example, by withdrawal or recall of non-compliant product)

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

3.2.1 Regulation (EC) No 2073/2005

Regulation (EC) No 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 Regulation (EC) No 852/2004.

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

- Commission Regulation (EU) 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

3.2.2 Regulation (EC) No 2160/2003

Regulation (EC) No 2160/2003 (as amended) on the control of Salmonella and other specified food-borne zoonotic agents applies in relation to Salmonella testing.

3.2.3 Regulation (EC) No 178/2002

Regulation (EC) No 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.

3.2.4 Regulation (EC) No 852/2004

FBOs are required to comply with microbiological criteria.

Regulation: (EC) No 852/2004, Article 4, paragraph 3.

3.2.5 Food Hygiene Regulations

The Food Hygiene (Scotland) Regulations 2006 (as amended) 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 (EC) No 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.
3.2.6 Guidance for auditors and OVs: FBO audit aide memoire (Annexe 6) appendix 1

VAs and OVs will find it useful to refer to Appendix 1 of the FBO Audit Aide Memoire, in particular:

- Section 3.9 (micro criteria in slaughterhouses)
- Section 3.13 (micro criteria in cutting plants)
- Section 5.13 (using results to verify HACCP based procedures)

Where full details of the microbiological criteria that are laid down by Regulation (EC) No 2073/2005 (as amended), under both Food Safety Criteria and Process Hygiene Criteria, are reproduced.

3.3 Testing requirements: slaughter operations

3.3.1 Testing requirements and sampling procedures: slaughter operations

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

Guidance for FBOs on sampling is provided in the MIG chapter 13 on ‘Microbiology’ and more information can be found in Appendix 1 of the FBO audit aide memoire.

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

The use of alternative analytical methods is acceptable when the methods are validated against the reference method in Annex I of Regulation (EC) No 2073/2005 (as amended) 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.

3.3.2 Red meat

Testing in red meat slaughterhouses is to verify process hygiene only; there are currently no food safety microbiological criteria. Process hygiene criteria set indicative microbiological values above which corrective actions are required in order to maintain the hygiene of the process.

One sample is taken from each carcase. Five samples are needed from each species, (one from each of five carcases). These should be taken at the intervals specified in Regulation (EC) No 2073/2005 (as amended)

Samples should be taken after the health mark is applied, but before chilling.
Four 100 sq.cm sites on the carcase should be tested for *Salmonella spp*, Enterobacteriaceae and ACC / APC. This can be by an excision method or a non-destructive swabbing method.

The simplest method is to use the abrasive sponge sampling method. A minimum of 400 sq. cm per carcase must be sampled with an abrasive sponge where this method is used.

**Note:** more detailed information can be found in Appendix 1 of the FBO audit aide memoire.

### 3.3.3 Poultry

Broilers and turkeys are tested for *Salmonella* to check food process hygiene criteria in slaughterhouses. Broilers are also tested for *Campylobacter* to check the process hygiene criteria in the slaughterhouse.

Five samples are required – one sample equals three neck skins, so 15 birds will have to be sampled in total. These should be taken at the intervals specified in Regulation EC (No) 2073/2005. Samples should be taken from chilled birds. The samples taken to check food process hygiene as per the above procedures can also be used to verify compliance with food safety requirements. To this effect, FBOs must carry out further tests where *Salmonella* sp results have been positive to identify whether *S enteritidis* or *S typhimurium* are present.

### 3.3.4 OV to monitor 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. The interval between checks will vary, dependent upon the sampling and audit frequency. 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. The aim should be to have compliant results.

### 3.4 Testing requirements: other operations

#### 3.4.1 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 meat products. Testing is required for minced meat, meat preparations, meat products and mechanically separated meat.
This topic deals with meat intended for consumption after cooking; the testing of ready to eat meat products is covered under a separate topic.

**Processed meat**

Testing is required for:

| Minced meat or meat preparations | Once a week take 5 x 25g samples from a minimum of one batch per establishment for products made from poultry meat and 5x10g 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      | Once a week take 5 x 25g 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) No 853/2004 |
| Meat products                    | Five x 25g 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.

Sampling is on a batch basis as 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.

### 3.4.2 Pooling

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.

### 3.4.3 Exception to testing

Minced meat and meat preparations in establishments producing an average of less than 2 metric tonnes 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 eat less than thoroughly cooked).
3.4.4 OV/VA checks

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

3.4.5 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 – please see Annex 9 of this chapter for guidance by FSA, also applicable to FSS officers.

3.5 Testing requirements: ready to eat products

3.5.1 Food safety criteria

The FBO should test for food safety criteria and this should include testing the product for *Salmonella* and *Listeria*. There should be 5 x 25g samples per batch. The laboratory used must test to relevant ISO standard – for *listeria* EN/ISO 11290-1 and *salmonella* EN/ISO 6579. See methods in Chapter I, points 1.2 and 1.3 of Annex I to Regulation EC (No) 2073/2005 (as amended). All samples from ready to eat products (RTE) 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 ready to eat (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- (for example, some cured meats), no testing is required other than food for infants or special medical purposes.

3.5.2 Processing areas and equipment

Article 5 of Regulation (EC) No. 2073/2005 (as amended) requires that FBOs producing RTE products sample the processing areas and equipment for *Listeria*.

All samples should show negative results.

3.5.3 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. See the link below which provides some information on testing for listeria:
Once the FBO has results over a period of time and there are no failures, then the FBO may increase the testing interval based on the evidence of testing and their food safety programme. In the event that the OV has any concerns surrounding the frequency of testing, they should escalate the matter to the VM.

3.5.4 Testing failures

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

For both the food safety and the process hygiene criteria the FBO shall take the measures laid down in paragraphs 2 to 4 of Article 7 in Regulation (EC) 2073/2005 (as amended) together with other corrective actions defined in their HACCP-based procedures.

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

For the food safety criteria, any product from batches that fail should be withdrawn or recalled. Recall would apply to product already dispatched and withdrawal would apply 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.

3.5.5 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.

Main contaminants regulations:

• Regulation EEC/315/93 Community procedures for contaminants in food (‘Framework regulation’)
• Regulation EC/1881/2006 Chemical contaminants in food (specific)
• Directive 2002/32/EC Undesirable substances in animal feed
• Various Sampling and Analysis regulations e.g. Regulation EC/401/2006 - Sampling and analysis of mycotoxins.
However, if required, FSS authorised officers would use the non-specific pieces of regulation for enforcement of breaches:

- **Regulation EC/178/2002** General food law
- **Regulation EC/882/2004** Official controls for food and feed
- **Regulation EC/852/2004** on the hygiene of foodstuffs
- **Regulation EC/853/2004** laying down specific hygiene rules for food of animal origin
- **Regulation EC/854/2004** laying down specific rules for the organisation of official controls on products of animal origin

FSS authorised officers 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

Levels set under EC/1881/2006 for 4 main toxins

- 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 & 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
3.6 **OV role: all establishments**

3.6.1 **OV responsibility**

The role of the OV is to:

- monitor the FBO’s compliance with microbiological criteria testing
- verify that this has been carried out in accordance with the requirements of the appropriate legislation
- verify method of despatch to the testing laboratory
- verify that the laboratory methods used are the reference method or an alternative in accordance with Article 5
- verify that the results fall within the required limits and are produced at the required frequency
- verify that where any further action by the FBO is required, this action is taken promptly and is documented with HACCP based procedures
- take appropriate enforcement action in the event that this is necessary

3.6.2 **Testing requirements and sampling frequencies**

The testing requirements and sampling frequencies which the FBO must follow are detailed at Annex 1 to Regulation (EC) No 2073/2005 (as amended). Details are also provided within the MIG chapter 13 on ‘Microbiology’.

The OV 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.

3.6.3 **Monitor the FBO’s compliance with microbiological criteria testing**

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

The OV should:

- Create a plant profile to include:
  - Frequency
  - Sampling method
  - Analytical method
  - Products sampled
  - Micro-organisms
3.6.4 Frequency of OV checks

<table>
<thead>
<tr>
<th>Premises</th>
<th>Verification</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slaughterhall</td>
<td>Sampling process including collection and storage</td>
<td>Monthly if weekly sampling Quarterly for all other sampling frequencies</td>
</tr>
<tr>
<td></td>
<td>Sample results</td>
<td>Monthly</td>
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<tr>
<td></td>
<td>FBO corrective actions</td>
<td>When necessary</td>
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<td>Plant Profile</td>
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<td>Cutting rooms and GHEs</td>
<td>Sample results</td>
<td>At audit and UAI</td>
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<td></td>
<td>FBO corrective actions</td>
<td>At audit and UAI</td>
</tr>
<tr>
<td></td>
<td>Plant Profile</td>
<td>Annually</td>
</tr>
</tbody>
</table>

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.
A note should be made on the Daybook when the verification checks are carried out with a clear description of what was checked and if FBO’s systems are satisfactory.

3.6.5 **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 carcasses or products in accordance with the provisions set out in Regulation (EC) No 2073/2005 (as amended).

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) No 2073/2005 (as amended), 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.

3.6.6 **Verify that the results fall within the required limits**

Regulation (EC) No 2073/2005, Article 9, requires the food business operator 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 summarised in simplified format in the table below. For full details refer to the resources already mentioned.

<table>
<thead>
<tr>
<th>Microbiological sampling results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process hygiene criteria</strong></td>
</tr>
<tr>
<td><em>Salmonella spp.</em></td>
</tr>
<tr>
<td>Results are reported as ‘detected’ or ‘absent’.</td>
</tr>
<tr>
<td>Results from a number of samples throughout the specified sampling period of 50</td>
</tr>
</tbody>
</table>
### Microbiological sampling results

<table>
<thead>
<tr>
<th>Food safety criteria</th>
<th>Salmonella (minced meat/meat products)</th>
<th>E coli</th>
<th>Aerobic colony count (ACC)</th>
<th>Campylobacter spp. (broiler carcases)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If any of the test results from samples of minced meat, MSM or meat products is positive for <em>salmonella</em>, 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.</td>
<td>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.</td>
<td>For mincemeat and mechanically separated meat (MSM), all five samples must return results of less than $5 \times 10^6$ cfu/g and of those five samples, three must return results of less than $5 \times 10^5$ cfu/g.</td>
<td>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.</td>
</tr>
</tbody>
</table>

### Food Standards Scotland

- **(carcases)**
  - 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.

- **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’.

- **Listeria (RTE foods)**
  - 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.

  - In foods that do not support the growth of *Listeria monocytogenes*: less than 100 cfu/g throughout shelf life.

  The following 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 $pH \leq 4.4$
  - products with $aw \leq 0.92$
3.6.7 Verify that the FBO takes further action where required

Where unsatisfactory results are obtained, the FBO must take action in accordance with Regulation (EC) No. 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 in accordance with the table in sub-topic 3.7.2 on ‘OV actions’ in part 3.

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 OV shall ensure that the FBO has reported the non-compliance for food safety criteria to the SFCIU.

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


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

Reference: See the MIG chapter 13 on ‘Microbiology’, D. Unsatisfactory Results for additional information on the type of corrective actions that the FBO should undertake.

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.

3.7 Enforcement: microbiological criteria

3.7.1 OV advisory role

When the OV finds that the FBO is not following the sampling, testing and corrective action requirements contained in Regulation (EC) No 2073/2005, the OV, as a first step on the hierarchy of enforcement, should consider informal action (see table below) to achieve compliance. This can include educating the FBO and encouraging rectification and providing advice. The FBO may be directed to the MIG.

3.7.2 OV actions

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

In addition, where the FBO has exceeded a reduced testing interval, the OV 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’.

<table>
<thead>
<tr>
<th>FBO fails to 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</th>
<th>OV informal action</th>
<th>OV formal action</th>
</tr>
</thead>
<tbody>
<tr>
<td>verbal advice/ written advice</td>
<td>HIN</td>
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<tr>
<td>perform removal from the market or not place on the market (for unsatisfactory food safety criteria)</td>
<td>written advice</td>
<td>Identify non-compliant product and detain the product that is in the establishment.</td>
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</table>
### 3.7.3 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 VM.

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

4.1 Introduction

4.2 Legislative references

4.3 Background

4.4 FBO responsibilities

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

4.6 Enforcement action examples

4.7 Summary

4.1 **Introduction**

4.1.1 **Definition and scope**

Traceability, as defined by article 3, paragraph 15 of Regulation (EC) No. 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 in monitoring and verifying FBO compliance with the traceability requirements.

4.2 **Legislative references**

4.2.1 **Traceability legislation**

4.3  Background

4.3.1  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.’


To achieve the traceability of food as set out in Article 18 of Regulation (EC) No 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.

4.3.2  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: Commission Implementing Regulation (EU) No. 931/2011
4.3.3 One step back, one step forward

To achieve the traceability of food as set out in Article 18 of Regulation (EC) No. 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 itself make food safe, but it is an essential way of providing assurance and assisting in containing food safety problems.

4.4 FBO responsibilities

4.4.1 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.

4.4.2 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.

4.4.3 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.
4.4.4 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.

4.4.5 Identify businesses supplied

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.

4.4.6 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.


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

4.4.7 Information to be made available by the FBO

Commission Implementing Regulation (EU) No. 931/2011, Article 3, states that:

I. 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 food business operator from which the food has been dispatched
- the name and address of the consignor (owner) if different from the food business operator from which the food has been dispatched
- the name and address of the food business operator to whom the food is dispatched
• the name and address of the consignee (owner), if different from the food business operator to whom the food is dispatched
• a reference identifying the lot, batch or consignment, as appropriate
• the date of despatch

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

4.4.8 Updated on a daily basis
The information referred to in paragraph 1 (as quoted above) is to be updated on a daily basis 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).


4.4.9 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.

4.4.10 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.
4.4.11 Always applicable

The traceability requirements of Article 18 of Regulation 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.

4.4.12 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.


4.4.13 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 years period could apply

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

4.5.1 Information requirements for frozen food of animal origin

For frozen food of animal origin, Regulation (EC) No. 853/2004 (as amended by Regulation (EU) No. 16/2012) requires Food Business Operators (FBOs) to make available to the FBOs they supply information concerning the date of production and, if different, also the date of freezing.
4.5.2 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


4.5.3 Information to be made available

Until the stage at which frozen food of animal origin is labelled for the consumer in accordance with Directive 2000/13/EC (the EU Food Labelling Directive) 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.


4.5.4 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.

4.6 FSS role

4.6.1 OV responsibility

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

4.6.2 OV to monitor traceability system

The OV 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 OV should familiarise themselves with it in order to understand and monitor it. The OV 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.

4.6.3 OV to verify traceability system

The OV 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 despatch 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 mislabelled (for example, meat substitutions) and/or as often as the OV considers necessary to ensure that the FBO satisfies the requirements of the regulations with regards to traceability.

4.6.4 OV to verify FBO takes further action

The OV 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.

4.6.5 OV to take enforcement action where appropriate

The OV should take appropriate and proportionate enforcement action when necessary, as described in MOC chapter 7 on ‘Enforcement’. Some specific examples are given on the following pages.
4.7 Enforcement action: examples

4.7.1 Health marked product

Where health marked products fail to comply with the traceability requirements of Article 18, Regulation (EC) No. 178/2002 as read with Commission Implementing Regulation (EU) No. 931/2011, this will constitute an offence under Regulation 4(c) of the General Food Regulations 2004.

4.7.2 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) No. 178/2002, Article 18, as read with Commission Implementing Regulation (EU) No. 931/2011 are excluded from the definition of ‘Hygiene Regulations’ and the requirements for traceability of ID marked products contained in Regulation (EC) No. 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 despatched 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, Regulation (EC) 178/2002 as read with Commission Implementing Regulation (EU) No. 931/2011. If serious/repetitive breaches have been identified, the FBO should be referred for investigation.

4.7.3 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.

4.7.4 ID marked product


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) No. 853/2004, Annex II traceability requirements will apply only to products that have been further cut or processed and have received an Identification Mark.

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

Where ID marked products fail to comply with the traceability requirements of Regulation (EC) No. 853/2004, enforcement should be escalated in accordance with MOC 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) No. 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.
4.8 Summary

4.8.1 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.

Reference: The FBO Audit Aide Memoire located on Sharepoint, contains pointers for the auditing OV and the VA to consider in relation to traceability. 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 despatched.
5. Official Control Verification Sampling Procedures

This section outlines the details of the sampling equipment, laboratory, despatch and recording arrangements for official control verification microbiological samples – full details of the sampling protocol can be found in Annex 8 - Microbiological Sampling Guidance.

5.1. Official Control Verification Sampling

5.2. Sampling equipment

5.3. Communication of intention to sample and despatch

5.4. Packaging and despatch of samples

5.5. Recording of sampling data

5.6. Sample Process Flowchart

5.7. Courier details

5.8. Laboratory (Public Analysts) Details

5.1 Official Control Verification Sampling

I. Food Standards Scotland (FSS) will conduct targeted sampling where there is evidence to support concerns that compliance with microbiological requirements, as stated in EC2073 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.

II. Officers will take samples where sampling is triggered by evidence of increased risk of non-compliance either through observation during inspection, audit outcomes or Food Business Operators (FBO) document checks and is designed to verify compliance or provide evidence in support of possible enforcement action.

5.2 Sampling equipment

I. The FSS Authorised Officers (AO) will each receive sample kits and despatch packaging which may be re-ordered as necessary via Operations Administration.

II. 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.

5.3 Communication of intention to sample and despatch to laboratory

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

II. The FSS AO taking the sample will contact the 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. You will be required to contact your 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 hr period.

III. The FSS AO should also advise the PA laboratory of what the sample material is and what it is to be tested for. The FSS AO may wish to seek advice from a Veterinary Manager, Area Veterinary Manager or Operations Manager.

5.4 Packaging and despatch of samples

The FSS AO will be responsible for the packaging and arranging despatch of the samples in compliance with the 24 hr 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.

5.5 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.
5.6 Sample process flowchart

- Agree intent to sample
- Day 1: Email Topspeed the day before sampling to arrange collection
- Day 1: Email/call lab the day before sampling to expect sample
- Day 2: Take sample(s) and same day despatch and delivery
- Record sample collection and results data in OWS
5.7 Courier details

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

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:

i. Establishment name and approval number
ii. Date of the sample collection (this information will allow Topspeed Couriers to plan the collections to include multiple pickups where possible)
iii. Destination laboratory (see below)
iv. Name and telephone number for the FSS contact at the plant
## 5.8 Laboratory (Public Analysts) Details

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<td>James Darroch</td>
<td></td>
<td>01224491648</td>
<td>Aberdeen Scientific Services Laboratory Communities, Housing &amp; Infrastructure Aberdeen City Council Old Aberdeen House Dunbar Street Aberdeen AB24 3UJ</td>
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<td>Glasgow Scientific Services Colston Laboratory 64 Everard Drive Springburn Glasgow G21 1XG</td>
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Part 4  Annexes

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Annex 2b  Full Audit Report Cutting Plant Template
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Annex 3  Full Audit Report Notification Letter
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