Manual for Official Controls: Amendment 95 Chapter 7 Enforcement

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1. Introduction

1.1 Purpose

1.2 Relevant references

1.1 Purpose

1.1.1 FSA enforcement role

These enforcement arrangements apply to all meat establishments approved in England and Wales and under veterinary control.

Enforcement action should also be taken in accordance with the FSA enforcement policy.

1.2 Relevant references

1.2.1 Authorised Officers (AOs), Inspectors and Authorised Persons

Operational staff must have a delegated authority to act as an "Authorised Officer" under food hygiene and safety legislation, "Authorised Person" under animal byproduct legislation or an "Inspector" under TSE and animal welfare legislation. This will provide officers with the appropriate powers of entry and authority to undertake enforcement under the respective legislation.

For ease of reference, the MOC will refer to all officers as AOs, however, it is important to be aware of the designation that applies under respective pieces of legislation.

1.2.2 Food Business Operator (FBO)

FBO means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control (Regulation (EC) 178/2002, Article 3, Point 6).

The Food Safety Act 1990, Section 53 (1) uses the expression "Proprietor" to refer to the person who carries out the business.

The Animal By-Products (ABP) legislation identifies the "Operator" who must comply with the requirements of the EU and domestic ABP legislation. Operator is defined as the natural or legal person having an animal by-product or derived product under their control, including carriers, traders and users [Regulation (EC) 1069/2009, Article 3].

The EU and domestic welfare at slaughter legislation refers to the "Business Operator" as the natural or legal person having under its control an undertaking carrying out the killing of animals or any related operations falling within the scope of the Regulations [Council Regulation (EC) 1099/2009, Article 2 (I)].

1.2.3 Court

References to 'court' should be taken to mean, in England and Wales, a Magistrate' court or Crown Court.

1.2.4 Justice of the Peace

References to a 'Justice of the Peace' should be taken to mean, in England and Wales, a Magistrate.

1.2.5 Duly authorised representative

Duly authorised representative is a responsible person who has the authority to act on behalf of the FBO. This person should be identified either on the approval application document or through some other form of written correspondence.

1.2.6 Legal definitions

Most legislation includes a definition section that provides guidance on many of the phrases contained within it. The table below identifies where this guidance can be found in the main pieces of legislation that we enforce.

Legislation	Location of definition
(EC) 178/2002	Articles 2 and 3
(EC) 852/2004	Article 2
(EC) 853/2004	Article 2 and Annexes I, II, III
(EU) 2017/625	Article 3
(EU) 2019/625	Article 2

(EU) 2019/624 Article 2 (EU) 2019/627 Article 2 (EC) 999/2001 Article 3, Annex I (EC) 1069/2009 Article 3 (EU) 142/2011 Annex I (EC) 2073/2005 Article 2 (EC) 1099/2009 Article 2 The Food Safety Act 1990 (as amended) Sections 1,2 and 53 All domestic regulations, for example, the Regulation 2 'Interpretation' Food Safety and Hygiene (England) Regulations, the TSE Regulations, Animal By-Product (ABP) (Enforcement) Regulations, the Welfare of Animals at the Time of Killing Regulations

1.2.7 Guidance documents

- EU Commission Guidance on Implementation of HACCP.
- EU Commission Guidance on Implementation of EC 852/2004.
- EU Commission Guidance on Implementation of EC 853/2004.
- EU Guidance on Key questions relating to import requirements.
- EU Commission Staff Working Document on the understanding of certain provisions on flexibility provided in the Hygiene Package.
- EC 2073/2005 Microbiological Criteria for Foodstuffs.
- EC 178/2002 Guidance Notes for Food Business Operators on Food Safety, Traceability, Product Withdrawal and Recall.
- Food Law Code of Practice and Practice Guidance.
- Industry Guide on Edible Co-products and Animal By-products.
- Food Safety Management Diary for Meat Producers.
- The Wild Game Guide and Photo Annex.
- European Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses (2016/C 278/01).
- Chronos User Guide.

2. Legislation, Enforcement Roles and Provisions

2.1	Legislation and enforcement provisions
2.2	Division of enforcement responsibilities
2.3	Communication with FBOs
2.4	Recording and monitoring enforcement action
2.5	Gathering and preserving evidence
2.6	Information obtained from unauthorised sources (The Regulation of Investigatory Powers Act 2000 (RIPA))

2.1 Legislation and enforcement provisions

2.1.1 Code of Practice

The 'Food Law Code of Practice and Practice Guidance' have been issued under:

- Section 40 of the Food Safety Act 1990 (as amended)
- Regulation 26 of the Food Safety and Hygiene (England) Regulations 2013
 / Regulation 24 of the Food Hygiene (Wales) Regulations 2006, and
- Regulation 6 of The Official Feed and Food Controls (England / Wales)
 Regulations 2009

To provide guidance for food authorities on enforcement issues under the legislation.

Note: Whilst the FSA is not a food authority, it is an enforcement authority and the principles set out in the Code have been mirrored in this chapter.

2.1.2 Requirement to enforce

Competent Authorities (CAs) must enforce food law by monitoring and verifying that relevant legislative requirements are met through a system of official controls

and other activities. It is for each MS to prescribe the formal powers of an AO, time limits for investigation, rules on measures and penalties to be applied when infringements of food law are detected. Regulation (EC) 178/2002, Article 17, Paragraph 2.

Where non-compliance is established, the competent authorities shall take:

- any action necessary to determine the origin and extent of the noncompliance and to establish the operator's responsibilities; and
- appropriate measures to ensure that the operator concerned remedies the non-compliance and prevents further occurrences of such non-compliance.
 When deciding which measures to take, the competent authorities shall take account of the nature of that non-compliance and the operator's past record with regard to compliance.

Reference: Regulation (EU) 2017/625 Article 138.

Food law includes all statutes, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level. It covers all stages of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals.

2.1.3 General principles

(EC) 178/2002 sets out the general principles and requirements of food law and lays down procedures in matters of food safety. It contains:

- definitions (of food, food business operator, and other terms)
- basic principles FBO responsibility for food safety
- traceability requirements

2.1.4 Official Controls

(EU) 2017/625 and the associated Official Control Package sets out the official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare.

Key points covered are:

- organisation of official controls
- crisis management

- imports from third countries
- financing / charges
- national enforcement measures
- Commission controls for example, audits in Member States

2.1.5 EU hygiene regulations

The hygiene regulations include:

- (EC) 852/2004 dealing with the hygiene of foodstuffs. Key points:
 - · applies to all food businesses
 - looks for good hygiene practice and HACCP based procedures
 - · concept of industry guides
- (EC) 853/2004 laying down specific hygiene rules for food of animal origin.
 Key points:
 - requirements beyond 852/2004 for food of animal origin
 - approval of meat premises
 - identification marking
 - objectives of the HACCP based procedures
 - food chain information
- (EU) 2019/624 concerning specific rules for the performance of official controls on the production of meat. It contains:
 - nature of official controls for example, inspection, verification, auditing
 - role of OV and MHI and trained, qualified operatives, and
 - control on imports
- (EU) 2019/627 concerning uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption
- (EC) 2073/2005 on microbiological criteria for foodstuffs
- (EU) 2015/1375 laying down specific rules on official controls for Trichinella in meat and
- The domestic Food Safety and Hygiene (England) Regulations 2013 and Food Hygiene (Wales) Regulations 2006.

2.1.6 Legislative Amendments

Legislation is amended periodically, and it is important that the original published versions are read in conjunction with any amendments.

Note: Users must ensure that they access the latest <u>"consolidated" version of the EU legislation</u> by checking, or;

Volume 2, chapter 14 of the MOC carries published consolidated versions of all relevant EC Regulations.

2.1.7 Domestic regulations

The domestic regulations include:

 The Food Safety and Hygiene (England) Regulations 2013 and The Food Hygiene (Wales) Regulations 2006 - as amended.

Note: These provide enforcement powers in respect of the obligations that apply in Regulations (EC) 852/2004, 853/2004, 2073/2005 and 2015/1375, together with (EU) 2017/625, and the OCR package in so far as it relates to food. In practice the main OCR regulations that will be utilised will be (EU) 2019/624 and (EU) 2019/627.

 The Official Feed and Food Controls (England / Wales) Regulations 2009as amended.

Note: These provide enforcement powers in respect of the obligations that apply in (EU) 2017/625.

- The General Food Regulations 2004 (Wales) and The Food Safety and Hygiene (England) Regulations 2013 (England):
 - Provide enforcement powers in respect of the obligations that apply in Regulation (EC) 178/2002. For example:
 - Article 14 'the food safety requirements'
 - Article 19 'recall, withdrawal and notification requirements'

Articles 15 and 16 are the enforcement remit of the local "Food Authority".

The Agency has a duty to verify FBO compliance with traceability requirements under Article 18 as read with Commission Implementing Regulation (EU) 931/2011). Failure by FBOs to provide traceability information is a contravention of the EU legislation and may also constitute an obstruction of the AO.

Whilst responsibility to prosecute contraventions of Article 18 of (EC) 178/2002 is the remit of the local "Food Authority", [see Regulation 5(6) Food Safety and Hygiene (England) Regulations 2013], failure to comply with the traceability requirements of ID marked products of animal origin is a contravention of Regulation (EC) 853/2004, Annex II, Section 1, Part A, 4 and the FSA has responsibility for its enforcement.

Likewise, any obstruction of FSA personnel seeking traceability information during the performance of their functions under (EC) 178/2002, (EU) 931/2011 or the hygiene package can be enforced by the FSA.

Note: Domestic Regulations are also amended periodically and reference should be made to the consolidated text on "legislation.gov.uk" or the original legislation as drafted in conjunction with the respective amendments.

2.1.8 Regulators' Code

In addition to the legal requirements imposed by the EU legislation, the FSA must have regard to the statutory Regulators' Code (made under the Legislative and Regulatory Reform Act 2006) when setting standards, determining policies and procedures with respect to guidance provided and in the application of its regulatory functions. However, this will be subject to any legal requirements affecting the exercise of all regulatory obligations.

The principles of the Regulators' Codes are set out in the FSA Enforcement Policy [MOC Volume 1, Chapter 7, Annex 2]. 8

2.1.9 Premises file and contents

A premise file must be maintained by the OV at all slaughter establishments supervised by the FSA. This should include details of the plant approval, the FBO responsible for potential offences, all correspondence in date order, copies of all letters, formal notices, minutes of meetings, accounts of telephone conversations, audit reports and informal notes taken.

Audit reports, letters, formal notices and other correspondence served on FBOs of non-slaughter establishments must also be retained and sent to CSU York to be scanned and retained in electronic premises folders.

2.1.10 Security

The premises file and all enforcement literature must always be kept secure. When not being referenced or updated, the premises file should be kept in a locked filing cabinet. It will contain evidence that may be required at a later date, together with additional unused material that the prosecution (the FSA) may have to disclose should a case go to trial. All enforcement documents must be kept for 6 years in line with the FSAs retention policy.

2.2 Division of enforcement responsibilities

2.2.1 FSA enforcement responsibilities

- Red meat slaughterhouses (cattle, pigs, sheep and goats, domestic solipeds, large farmed game, ratites).
- White meat slaughterhouse (poultry, lagomorphs, farmed game birds).
- Game handling establishments (wild game dressing and cutting).
- Cutting plant.
- Establishments approved as 'slaughterhouses' for activities limited to the dressing of carcases.
- Any of the following activities, where co-located with a slaughterhouse, cutting plant or game handling establishment:
 - minced meat
 - meat preparation
 - mechanically separated meat (MSM)
 - meat products
 - processing plant (for meat products, rendered animal fats and greaves, treated stomachs, bladders and intestines, gelatine and collagen)
 - cold storage

2.2.2 Local authority (LA) enforcement responsibilities

- Hunters supplying small quantities of wild game or wild game meat directly to the final consumer / local retailers.
- Primary production of wild game carcases by hunters, including game larders they operate.

- Producers supplying small quantities of meat from poultry and lagomorphs slaughtered on farm directly to the final consumer / local retailers.
- Butchers' shops (retailing meat to the final consumer or exempt under marginal, localised and restricted).
- Any of the following **not** co-located with slaughterhouses, cutting plants or game handling establishments:
 - meat preparations establishment
 - minced meat establishment
 - mechanically separated meat establishment
 - processing plant (for meat products, rendered animal fats and greaves, treated stomachs, bladders and intestines, gelatine and collagen)
 - cold stores where storage is the only activity
- Premises manufacturing composite products containing meat and other edible co products.
- Collection centres and tanneries that handle raw material for the production of collagen and gelatine.

2.3 Communication with FBOs

2.3.1 Communication channels

Effective communication is essential when guiding an FBO on compliance with legal requirements as well as best practice.

The majority of day-to-day compliance can be achieved through verbal discussion.

AOs should work to establish agreed lines of communication with the FBO and their staff. It is also important that contingency arrangements exist to avoid difficulties when the FBOs normal contact person is unavailable.

Where a duly authorised representative exists, it is essential to have some written confirmation that the person may act on behalf of the business and/or as a central point of contact.

2.3.2 FBO contact details

The AO must have available at the establishment the contact details for the FBO. For example:

- full name(s) and address(es), including full limited company name and registered office address
- e-mail address and telephone number(s)

Where any ownership or approval details change at an establishment, the FBO is obliged to inform the competent authority of that change:

The FBO shall ensure that the competent authority always has up to date information on establishments, including the notification of any significant change in activities and any closure of an existing establishment.

Reference: (EC) 852/2004, Article 6, Paragraph 2.

This information should subsequently be provided to:

- FSA York Finance
- Approvals and Registrations Team
- Inspection team at a slaughterhouse/auditor

This will ensure that the AO is always aware of the legal entity responsible for any potential offences within the establishment, whether they are a sole trader, partnership or limited company.

2.3.3 Key communication functions

The AO is responsible for:

- advising the FBO on compliance with legal requirements
- advising the FBO on corrective actions when infringements of legal requirements have been detected

2.4 Recording and monitoring enforcement actions

2.4.1 Chronos / FSA enforcement programme

Enforcement action taken by AOs must be recorded accurately in Chronos.

The purpose of the system is to generate records of live and historic enforcement interventions and to help AOs in their:

- assessment and prioritisation of enforcement action
- communication of enforcement action in real time to other members of the inspection team and wider FSA audit and UAI colleagues
- tracking or monitoring of enforcement action through to compliance or a referral for investigation

The system:

- acts as an aide memoire, providing a comprehensive record of enforcement action taken in the establishment
- enables the FSA to assess the FBOs record as regards compliance with regulatory food, welfare, TSE and animal by-products legislation
- contributes to the risk assessment process and will help set the frequency of future audits
- provides an outline of the non-compliances to both (VAs) and internal audit staff

2.4.2 Ongoing enforcement action

When attending any establishment as a new AO, as an auditor or UAI, the AO must:

- familiarise themselves with all ongoing enforcement action
- where repeated contraventions on the same subject are identified, it is important to maintain the momentum of enforcement and continue to escalate it accordingly and not to restart the hierarchy each time. However, if there are no incidents for a 12-month period, begin the hierarchy again.

2.4.3 Completing Chronos

For Guidance on the completion of Chronos, see Annex 12 of Chapter 7 for the Chronos User Guide. Chronos is a 'live' system, updated as necessary every time enforcement action is taken.

2.4.4 Monitoring progress

The AO should regularly monitor progress towards compliance to identify whether the deficiency is likely to be rectified within the agreed time scale. If necessary, they should ask to see evidence of how corrective action is progressing, for example, planning permission application / copies of quotes for work / structural plans.

Where the work does not progress at the agreed rate, the AO should escalate the matter and consider serving a HIN to formalise a suitable time scale, thereby maintaining the momentum in enforcement.

However, it is important that an agreed action plan is set out at the start and that the AO takes a reasonable approach where certain issues arise that are outside the FBOs control.

2.4.5 Structural work

Where structural work must be undertaken, the 'corrective action' section of a Warning Letter or Hygiene Improvement Notice (HIN) should be specific enough to explain the legal requirement and the outcome to be achieved, without being too prescriptive about the exact way in which this must be achieved.

There may be many ways that the FBO can achieve compliance, but provided they comply with the legal requirement, they have the option to carry out work to an equivalent effect.

2.5 Gathering and preserving evidence

2.5.1 Introduction

The AO must gather evidence at the time the offence is witnessed, making detailed contemporaneous notes, which at a later stage can be relied upon in Court. It is often impossible to gather evidence retrospectively as it may no longer exist.

Evidence may come in a variety of forms and must supplement a witness statement as an exhibit in order that it may be admissible in court. It is also useful to obtain corroboration and assistance from other colleagues where possible.

Detailed evidence gathering at the time of the offence will provide the AO with as much material as possible to support their witness statement and prove the elements of the offence.

Note: Keep all evidence secure. It is fundamental to proving the offence should formal action be pursued.

2.5.2 Best evidence rule

The AO should also have regard to the 'best evidence' rule. Whenever possible, all original items of evidence should be preserved; for example, the original form of a document, rather than a photocopy. If the evidence is a part of a carcase, for example, SRM or a broken limb, it should be preserved to maintain its integrity and stop any deterioration that would limit its evidential value.

If it is not practical or not possible to preserve the evidence, at the plant, for example, if perishable goods are involved and no facilities are available to freeze the product or keep it secure, the AO should contact FSA management to organise alternative facilities.

FBOs should be given the opportunity to view physical evidence or oversee its examination or analysis by an expert before any potential court case.

The AO should take photographs wherever necessary and/or sample evidence where perishable goods are destroyed on testing. If there is doubt about what evidence should be retained, the AO should obtain further advice from FSA Legal.

2.5.3 Note taking

When gathering evidence, remember to record the details of any other persons present, to identify all potential witnesses in the case. This will enable corroborative witness statements to be taken; or for the investigating officer to test the strength of the evidence overall.

The AO should make full use of their pocketbook to make factual contemporaneous notes. These may be referred to in court to help recollect facts and figures that are impossible to recall in detail after the event.

Note: In court, a witness is able to refer to contemporaneous notes recorded in their pocketbook that were made either at the time of the incident or shortly afterwards, whilst the events are still fresh in their memory.

However, witnesses are not permitted to read from their witness statement when giving evidence, except in certain limited circumstances.

Note: Where an officer refers to their pocketbook when giving evidence in court, the defence is entitled to see that notebook.

2.5.4 Use of FSA official pocketbook

The pocketbook is essential for recording details of incidents at times when a plant daybook is not readily available in the slaughterhouse or generally to record events when in other further processing plants.

In slaughterhouses, the use of the pocketbook is not to replace the plant daybook for recording day-to-day activities but should supplement completion of the daybook.

2.5.5 Important points

Pocketbooks may be inspected in court; therefore the following guidance must be followed to maintain validity:

- Record name on front cover, designation and date started.
- Make all entries in pen and not pencil.
- Include only original entries and do not copy notes from elsewhere.
- Record the date and time at commencement, and upon completion.
- Enter the notes at the time 'the offence' is witnessed or as soon as possible afterwards (contemporaneously), whilst the facts are fresh in the memory.
- To make alterations, AOs must strike a pen through the error, make the
 correction and place their initials in the left-hand column to verify that they
 made the changes. Notes must not be erased or obliterated with tip-ex.
- Do not remove numbered pages from the notebook.
- Sign and date each entry at the base of each page.

Entries must be relevant, factual, legible, concise and written in English.

If accompanied by a colleague whilst witnessing a contravention, one AO may record the details in their pocketbook, whilst the other may read through the notes made and where they agree with what has been recorded, they may countersign at the end of the entry to acknowledge that it is a true and accurate account of events.

Where the AO and FBO have had a conversation regarding action to be taken to achieve compliance, it may be beneficial to ask the FBO to sign the notes taken by the AO as an accurate account of what was agreed.

2.5.6 Security

The AO is responsible for ensuring the security of their notebook and for producing it in court. Further notebooks are available from York – contact corporate support unit (CSU) by email or from SDP's.

2.5.7 Return of all notebooks

Notebooks remain the property of the FSA and **must** be returned to CSU York when an AO leaves FSA employment or retained by the SDP.

2.5.8 Disclosure of unused material

The Criminal Procedure and Investigations Act 1996 (CPIA) places an obligation on the prosecuting authority to retain and record all relevant information relating to any enforcement action.

The prosecuting authority – a term which includes all AOs, the wider FSA team, the Investigating Officer (IO), the prosecuting lawyers and the enforcement agency itself – has a duty to investigate all reasonable lines of enquiry and disclose to the defence all relevant unused material which:

- might undermine the case for the prosecution, or
- might reasonably be expected to assist the defence case

This material may include:

- informal and formal memos
- email traffic
- previously unreported offences and/or warnings recorded on operational paperwork
- daybook entries
- contemporaneous notebook entries
- minutes of meetings

- draft witness statements
- photographs used as exhibits, together with unused photographs. If an old style SLR camera was used, retain all photographs and negatives. If photographs are downloaded onto a CD Rom, retain both "Master" and "Working Copies".
- instructions to expert witnesses or analysts

2.5.9 Storage and availability

Anything that is relevant to the case and which is not used by the prosecution is unused material and can be potentially disclosable. It is therefore important that when notes are taken, emails written or drafts prepared, AOs should be mindful that the defence may be entitled to see them and refer to them in open court. Even where there are good reasons for arguing that some material is so sensitive that the defence should not see them, there is a high threshold which needs to be met to satisfy the court that this is the case.

The OA and FSA team should therefore ensure that:

- all material relevant to an enforcement intervention is recorded and retained
- all material is safely stored

The IO must be made aware of the existence of all relevant material as soon as possible after a referral for investigation is made.

2.5.10 Photographic evidence

Taking photographs in approved establishments for the purposes of evidence gathering is a fundamental part of the evidence gathering process.

The AO may inform the FBO of what is intended as a matter of courtesy, however, the FBO cannot stop an AO from taking photographs for the purposes of evidence gathering. Any attempt to obstruct the AO carrying out their duties is an obstruction and offences can be committed by that person.

 When photographs are taken, details should be recorded in a contemporaneous notebook, including the photograph number, the subject, location, date and time. Colleagues should assist one another in this process where they are available.

- Photographs should be taken with a suitable digital camera and a record must be kept of how the digital information was downloaded and on to what medium it was stored.
- Where the subject in the photograph is not clear, it may assist the court to have a colleague appear in the photograph to point to the item that needs identifying.
- Video filming is often essential to demonstrate particular high-speed operations / operational practices or animal welfare incidents.
- When printed, it is useful to add details to the reverse of the photograph, clearly indicating the subject matter, location and other relevant details.

Although all AOs have powers to take **photographs or videos for the purpose of evidence gathering**, they must always seek the permission of the FBO if they are taking photographs for any other reason than evidence gathering.

Where FBOs prevent AOs from taking photographs, the FBO should be reminded that they may be committing an obstruction offence. If the FBO states the establishment has a no camera policy, the matter should be taken up between FSA and FBO management. FBOs cannot prevent AOs undertaking enforcement or from using evidence gathering equipment in a food establishment.

Note: Any verbal comment recorded whilst any filming is being undertaken must later be transcribed verbatim and will constitute part of the evidence if the case goes to trial.

Tip: In high humidity areas, give the camera lens time to adjust to the temperature / humidity before taking pictures or videos in order to prevent fogging.

2.5.11 Capture and download of images using the mobile phone camera or video

Prior to using your works mobile phone, download and use the "Timestamp Camera App" for taking photographs and videos to be used for evidential purposes. This app will time-date stamp all photographs and videos.

The pictures/videos taken using the Timestamp Camera App can be automatically uploaded to the OneDrive and will be accessible wherever the AO accesses their work profile (for example, Laptop or Thin Client).

Please see Annex 13, Timestamp Camera App Guide for further information.

2.5.12 Capture and download of images using a digital camera

When the AO intends to capture images using a digital camera, they should ensure the following:

- Ensure the memory card is clear of previous images, unless you have come from another visit and not had the opportunity to download the images.
- Avoid using non-work issued camera phones to take evidential images.
 Personal devices will contain personal photographs and mistakes made
 when selecting and separating personal images from evidential images
 may risk evidential photographs being missed, thereby failing to comply
 with evidential disclosure rules. Likewise, private images may be selected
 and downloaded by mistake, which could result in personal images being
 inadvertently disclosed to the defence.
- If poor quality images are captured, photographs must not be deleted as they will be classed as "unused material" under the CPIA 1996 [see 2.6.8]
- Full details of all images in a case must be recorded on the "Supporting Evidence Photographic Report" and submitted with the referral [see Annex 6, Chapter 7].
- All images taken that relate to that case, together with the corresponding photographic evidence report, are downloaded onto the hard drive of a computer.
- When required for a referral for investigation, all the images relating to that case and supporting photographic evidence report are copied onto two separate non-reusable CD-ROMs
- One CD is marked as the 'Master Copy'; this must be bagged and tagged, and its details recorded in the daybook or in the AOs contemporaneous notebook and stored somewhere secure.
- The other CD is marked as the 'Working Copy'; it should also be tagged and its details recorded in the daybook or in the AOs contemporaneous note book, and stored in a secure place for collection by the Investigating Officer.
- Send all evidence to CSU York.

2.5.13 Supporting evidence photographic report

The 'Supporting evidence photographic report' has been introduced to provide a contemporaneous record of images taken whilst gathering evidence.

In ideal circumstances, the report should be completed at the time the evidence is gathered. However, when this is not feasible, it should be completed as soon as possible thereafter.

The report should be stored electronically in the same file as the images to which it relates.

A new report should be prepared to accompany images of each separate incident.

This is available at annex 6 on 'Supporting evidence photographic report' of this chapter.

2.5.14 Samples: physical confirmation of the failure

A variety of different types of sample may be gathered as evidence, for example:

- rust / dirt scrapings
- samples of meat / offal / SRM
- trimmings of faecal or other contamination
- heads, mandibles, ears or limbs of animals
- whole carcases or joints
- · bodies of dead animals

The AO should always inform the FBO of their intentions to sample a product. They should enlist the services of a colleague to witness the collection of the sample (if available) and record details of what the sample was, where the sampling took place and how it was sampled; recording the date and time the sample was procured in their pocket notebook.

Samples should always be bagged and labelled with all relevant details and sealed with a tamper evident seal.

All samples must be kept under secure conditions in an environment where they will not deteriorate. Details must be maintained of all locations where samples are stored, all transportation between such locations and the temperature at which the samples have been maintained to ensure continuity of evidence. A temperature log for chillers, freezers, transport etc. must be maintained and relevant calibration records for thermometers as they may be required as evidence in court.

2.5.15 Post-mortem evidence

There may be circumstances where an animal has died in transit or in the lairage, and a post-mortem examination would be required, for example to support a case for a breach of animal welfare legislation.

Before undertaking any post-mortem examination, the AO must have regard to the requirements in chapter 6 on 'Notifiable diseases'.

Where the AO is to perform a post-mortem examination on site consideration must be given to the following:

- there should be suitable isolation facilities in the lairage to carry out the examination
- hygiene procedures must be followed and Cleansing and Disinfecting (c and d) carried out following examination and disposal
- the AO should have the appropriate protective clothing and equipment required for the procedure
- a detailed report of the findings must be prepared at the time
- photographic evidence should be gathered having regard to the guidance contained in this chapter
- appropriate specimens should be retained, for example, fracture site, limbs or bodies of animals / birds and stored as outlined below to maintain continuity of evidence

Note: Once examined, the specimen should be retained in a secure location in case the FBO requires their own appointed representative to view the evidence.

Where an on-site post-mortem examination is not considered appropriate, the carcase can be sent to the nearest APHA laboratory for examination. Continuity of evidence must be maintained as outlined below.

The HOD / FVC should be consulted before initiating an off-site post-mortem examination or advising the laboratory that the carcase is being sent.

The HOD / FVC will advise on any financial implications involved in the cost of the APHA post-mortem and report.

Note: Body parts that are required as evidence, but are, by definition, ABP must be retained until the conclusion of the court case. Afterwards, they must be disposed of appropriately.

2.5.16 Temperature readings: factual figures

The AO should ensure that where thermometers are used for evidential purposes, the thermometer used is calibrated annually, and where required for evidence in court is recalibrated prior to the case file being submitted. The calibration certificate must be checked to ensure it matches the thermometer being used and must be kept safe as it will be required as an exhibit in prosecution cases.

All relevant temperatures must be recorded where necessary. Check the legislation to identify any legal requirements or the elements of the offence that need to be proved, e.g. ambient temperatures for animal welfare cases and cutting rooms, surface temperatures and internal temperature for meat transportation etc. It is useful to ask a colleague to help record temperature details at the time the readings are taken.

Tip: The AO should ensure that when asked, they can explain what temperature related to which carcase / animal etc. together with its location.

2.5.17 Light meter readings: factual figures

When gathering evidence of poor lighting conditions, light meters contained on reliable mobile phone applications may be used, but where formal action is being undertaken, a calibrated light meter must be sourced with an up to date calibration certificate to ensure it is of known accuracy on the date of use. Ensure that the light meter corresponds with the calibration certificate and is within calibration before taking the reading.

Tip: Take a light meter reading when normal processing conditions exist and not when the sunshine is streaming in and no processing is being carried out.

2.5.18 Humidity readings: factual figures

When gathering evidence of poor humidity conditions/ventilation etc., ensure that a recently calibrated hygrometer is sourced and used to ensure it is of known accuracy on the date of use.

2.6 Information obtained from unauthorised sources - RIPA

2.6.1 Introduction

This topic covers instruction on dealing with information which may be provided under RIPA.

2.6.2 Information received

Under the law, AOs should take extreme care when dealing with a case where plant staff or other contacts have provided information or intelligence about possible offences or misconduct.

Where this sort of information is provided, the AO must **always** inform their line manager, who must in turn notify FSA York who will be responsible for informing FSA Legal Division and Investigation Branch.

2.6.3 Questioning contacts

Plant staff or any other person that has provided intelligence must not then be asked to obtain additional information or pass on information about possible offences or misconduct. Failure to comply with these requirements will mean that it is almost impossible to conduct a successful investigation into the allegations, as the evidence obtained will be considered inadmissible.

2.6.4 Use of informers

It is essential that AOs remember not to ask or task plant staff or other contacts to obtain or pass on information about possible offences or misconduct even where they have first come forward of their own free will and given information about such matters.

AOs must not approach anyone to act as an informer or obtain information in an undercover way.

2.6.5 Example 1

A disgruntled employee contacts you to inform you that the operator of a licensed slaughterhouse and cutting plant is using the licensed premises at night and without FSA supervision to slaughter and process cattle which have no passports.

He is in a position to know when this is happening and to contact you at the time it is taking place.

2.6.6 Example 2

An AO is transferred to a new plant and becomes aware that the ITL and other AOs at the establishment are working in collusion with the plant management. The ITL and some other staff are returning condemned sheep carcases to the line after trimming them. In return, the FSA staff are receiving cash payments and meat cuts as compensation. The AO is willing to inform you of when these incidents take place and to collate information on the dates, times, persons involved, number of carcases and owners of the stock.

2.6.7 Example 3

A delivery driver from an approved establishment has delivered several consignments of over temperature sheep carcases to a large city market. He is concerned that he may be prosecuted with the originating plant operators if a load is intercepted at the market. He is willing to provide information relating to dates times and consignment details of future deliveries which he believes have not been chilled to the correct temperature before transportation.

3. Surrender, Detention, Seizure and Condemnation

3.1 Voluntary surrender
3.2 On line temporary detention
3.3 Detention under the Food Hygiene / Food Safety and Hygiene Regulations
3.4 Detention under the Food Safety Act 1990

3.1 Voluntary surrender

3.5

3.1.1 Meanings of voluntary surrender

Condemnation procedure

Where meat has **not** been produced in accordance with the hygiene regulations or is **unfit** for human consumption, the FSA should seek voluntary surrender of the meat.

Voluntary surrender is an everyday occurrence within a slaughterhouse and should always be evidenced by completing a 'Rejected Meat Receipt' (PMI 4/8). This will identify the carcase, part carcase, and offal and should be issued for all routine matters and signed by the AO and a responsible member of the plant management.

The FBO should be encouraged to sign an 'Agreement to Destroy Meet' (ENF 11/7) notice should be completed where any dispute arises, or where issues are more complex. For example, where:

- there are large quantities of meat
- the animal's identification is being questioned
- the farmer retains ownership of the carcase after processing and the FBO feels that their consent is required

This Notice should be completed before the meat is disposed of as an ABP and is in addition to the 'Rejected Meat Receipt'.

Reference: See chapter 9 on 'Forms for PMI 4/8 and ENF 11/7.

3.1.2 Legal powers

AOs have powers to detain food under:

- the Food Safety and Hygiene (England) Regulations 2013 and the Food Hygiene (Wales) Regulations 2006 (as amended)
- the Food Safety Act 1990 (as amended), via the above Regulations
- Articles 65, 66 and 67 of Regulation (EU) 2017/625. Action in the event of suspicion of Non-compliance and of Non-compliance of animals and goods entering the union.

3.2 On line temporary detention

3.2.1 Holding carcases identified for rectification

In many slaughterhouses, the majority of detained carcases are rectified on the detained rail, under the supervision of an MHI dedicated to that task.

Colour-coded plastic hook tags can be used to identify carcases for detention. The colour-coded tags are used to signify specific conditions and serve to alert the MHI to the action required. Make the FBO aware of the system. The colour-coded tags should be used to represent the following:

Colour	Use for
Red	Pathology
Yellow	SRM
Green	Contamination
Blue	Sample identification tag
Grey	TB carcases

3.2.2 Labelling detained carcases

Carcases and offal that have been detained for further inspection and that require more secure individual identification can be tagged using individually numbered talisman seal(s).

To maintain correlation between the carcase and offal, several talisman seals must be used. The individual seal numbers should be recorded with any other

relevant details for the carcase and cross-referenced on the formal detention notice.

The seals must remain in place until the carcase and offal have been re-inspected and a decision made on the fitness of the carcase and offal for human consumption.

3.2.3 Detention tape

Detention tape should be used to help identify any boxed meat or shrink-wrapped pallets of boxed meat and should be used in conjunction with the formal detention notice.

3.2.4 When to formally detain

There may be occasions where meat cannot be dealt with immediately on the detained rail because:

- the AO may wish to undertake a further examination of the carcase to identify any signs of oedema / emaciation, fever or other pathological conditions that may not be evident when the carcase is still warm
- the FBO prefers to carry out rectification work / removal of arthritic limbs when carcases are chilled
- the AO may wish to carry out an investigation into the traceability, marking, description, age, fitness, suitability of any meat or animal under the FBOs control
- the AO may wish to sample the product for the presence of any undesirable or illegal substance or veterinary residue

In such circumstances, the AO will require the FBO to store the suspect meat in a detained chiller and should ensure its security.

3.2.5 Assessment of the detention facilities and history and confidence in management

Detention facilities vary in type, size and security, the OV must assess how satisfactory the facilities are and how the FBO intends to detain meat that has to be stored for further examination / investigation.

The assessment should identify:

- how secure the facilities are, including number of people who are in possession of a key
- the level of confidence in management and their staff
- whether previously detained meat has ever been sold, gone missing or been moved contrary to the OVs instructions
- whether the size of the detained facility is sufficient to accommodate all the suspect meat
- whether the meat has already received a health mark or identification mark

The decision whether to formally detain meat with a Detention of Food Notice (ENF 11/1 or ENF 11/26) will depend on all the above factors.

Reference: See chapter 9 on 'Forms' for ENF 11/1 and ENF 11/26.

It **may not** be necessary to serve a formal detention of food notice on the FBO in many non-contentious day to day situations, for example:

- where meat is stored over night for routine rework and has not been health marked, and
- is secured in lockable detained facilities on the premises,
- where the FBO has always been compliant and has a good relationship with the FSA, or
- where carcases have been tested for BSE / trichinella and are awaiting a negative test result prior to being health marked

However, where there are contentious issues, a history of non-compliance at the plant and:

- the FBO refuses to voluntarily surrender product declared unfit for human consumption, or
- the FBO has detention facilities that are too small / not secure enough, or
- the AO has "Certified" the meat as not having been produced, processed or distributed in accordance with the "Hygiene Regulations" and intends to take the meat before a Magistrate / Sheriff to seek a condemnation order

the AO must as a matter of good practice, formally detain the meat using a formal detention notice (ENF 11/1 or 11/26). This is to ensure that all non-compliant meat is effectively secured, to demonstrate that the AO has formally detained the product **and** to allow formal action to be taken where the FBO breaches the requirements specified in a formal detention notice.

Note: (EC) 853/2004, Annex III, Section I, Chapter IV, Paragraph 12 also requires the FBO to follow the instructions of the OV to facilitate post-mortem of all animals. Where they fail to do so, this may constitute an offence of obstruction.

If the AO does not serve a formal detention notice, any movement of the product will not result in a breach of the detention notice.

3.3 Detention under the Food Safety and Hygiene (England) Regulations 2013 and Food Hygiene (Wales) Regulations 2006

3.3.1 Relevant legislation

Powers to serve a Detention Notice (ENF 11/26) derive from Regulation 10(1) of The Food Safety and Hygiene (England) Regulations 2013 or Regulation 9(5) of The Food Hygiene (Wales) Regulations 2006.

3.3.2 General principle

A Detention Notice provides powers to an AO to detain any animal or food of animal origin (specified in the notice), either on the premises, or at another location (specified in the notice).

Detention under the provisions of Regulation 10(1) or 9(5) is intended to be used in circumstances where further examination of the animal or food is required, or sampling is undertaken (for example, for potential residues or when a DNA test is being conducted by the LA to clarify an animals identity or trace the origin of an animal).

3.3.3 Declaring unfit

Formal detention is inappropriate where an AO is required to declare animals or material unfit for human consumption under Commission Implementing Regulation (EU) 2019/627, Articles 40 to 45, because once meat has been declared unfit, it will become an ABP, is no longer food for human consumption and disposal must be in line with all relevant provisions of the EU and domestic ABP and TSE Regulations. See annex 5 'Flow diagram' and chapter 2.8 'Animal by-products', section 5.

Note: where the FBO does not voluntarily surrender non-compliant product and the meat has to be declared unfit, this must be done in writing, setting out the rationale for the action.

3.3.4 AO duties

The AO should:

- discuss the reason for service of the detention notice with the FBO
- ensure the detained meat is accurately identified using an individually numbered talisman seal, the details of which must be recorded on the detention notice, or by using FSA detention tape for boxed meat
- once identified, ensure that the detained meat is secured so that it cannot be tampered with
- record details of the date and time of service of the notice on the back of the form, in a pocketbook, or in the plant daybook
- ensure that the FBO can easily identify what has been detained at the time of service
- advise the FBO of the likely timescale for the examination, so that they can take steps to prevent deterioration of the product; for example, boning under FSA supervision and freezing to preserve the value of the meat

3.3.5 Service of a Detention Notice

The detention notice:

- should be served by hand on the FBO or their duly authorised representative
- may be handwritten
- must be served as soon as practicable

The AO should always retain a copy of the notice served.

3.3.6 Time period

No time period exists within which the examination must take place, however, this must be completed as soon as practicable.

3.3.7 Right of Appeal

No right of appeal exists against the service of a Regulation 10(1) detention notice under the domestic Food Safety and Hygiene (England) Regulations 2013 or 9(5) of the Food Hygiene (Wales) Regulations 2006.

3.3.8 Withdrawal

The notice may be withdrawn by completing the withdrawal section at the base of the detention notice, once the AO is satisfied that the meat complies with the requirements of the hygiene legislation and there are no grounds for declaring it unfit for human consumption. The meat may then be released and ID Marked / Health Marked.

Decision Not to Withdraw

If the AO is not satisfied that the meat is fit for human consumption, they should seek voluntary surrender and disposal as an ABP.

Where voluntary surrender is not forthcoming, prior to the meat having been health / ID marked, the AO should first send a letter to the FBO explaining why they are declaring the meat unfit. Where the FBO continues in their refusal to surrender the product, the AO must serve an ABP notice requiring the disposal of the meat under the domestic ABP regulations.

Where meat has already been Health / ID marked and subsequently deteriorates or becomes unfit and the FBO refuses to surrender the product; the OV must formally seize the food under the provisions of Section 9 (3) (b) of the Food Safety Act 1990 (as amended) and take it before a Magistrate (Justice of the Peace) to apply for a Condemnation Order.

Note: Detention under the provisions of Regulation 10(1) or 9(5) of the domestic hygiene regulations is intended to be used for short term issues to allow for the further examination of the product or for a sample to be taken.

3.3.9 AO checklist

Where the detained food is not released, specify the following information on the reverse of the Detention Notice:

 the nature of disposal and the category of ABP that the food was consigned under

- whether an agreement to destroy food Notice was signed by the FBO and the notice reference number
- whether the detention led to the food being certified, seized and taken before a court to seek condemnation

3.4 Detention of Food under the Food Safety Act 1990

3.4.1 Relevant legislation

Regulation 25 of the Food Safety and Hygiene (England) Regulations 2013 and Regulation 23 of The Food Hygiene (Wales) Regulations 2006 also allow the AO to detain suspect food for further investigation, but not to detain live animals.

This is achieved via the detention provisions contained in Section 9(3)(a) of the Food Safety Act 1990, which provides powers for the AO to detain, inspect and seize any food that is thought may not comply with the "food safety requirements" in Article 14 of Regulation (EC) 178/2002 and is intended for human consumption. The "Detention of Food Notice" (ENF 11/1) is the appropriate formal detention notice to use in these circumstances.

Note: Service of a formal "Food Detention Notice" (ENF 11/1) is inappropriate when the AO is required to declare material unfit for human consumption. This is because it has already been determined that the meat is unfit for human consumption and is therefore an animal by-product. Disposal as an ABP should therefore be in line with the requirements of the ABPs Regulations. See Annex 5 'Flow diagram' in this chapter and chapter 2.8 on 'Animal by-products', section 5.

3.4.2 When to serve a Food Detention Notice (ENF11/1)

When FBOs are

- unwilling to surrender food that the AO has judged unfit, or
- un-cooperative with respect to the voluntary detention of meat after the ID Mark / Health Mark has been applied and is part of a further investigation into its fitness / compliance with the food safety requirements

the AO must formally detain and or seize (as appropriate) the food in accordance with Food Safety Act Section 9.

Note: The AO shall as soon as is reasonably practicable, and in any event within 21 days, determine whether or not they are satisfied that the food complies with the food safety requirement.

Certification of Food

Legislation:

- Regulation 29 (3) of the Food Safety and Hygiene (England) Regulations 2013 and Regulation 27(3) of the Food Hygiene (Wales) Regulations 2006 allows for the Certification of food where it has not been 'produced, processed, or distributed' in accordance with the regulations, it shall be treated for the purposes of Section 9 of the Food Safety Act, as failing to comply with the food safety requirements.
- Art 14 (EC) 178/2002 identifies the food safety requirements.
- (EU) 2019/627, Articles 40, 41, 43 and 45 identify the circumstances where meat is required to be declared unfit for human consumption.

3.4.3 Reasons for service

Meat which fails to comply with food safety requirements under Article 14, (EC) 178/2002 includes:

- meat that is unsafe
- meat that is unfit for human consumption
- meat that is injurious to health.

3.4.4 Service of notice

Prior to serving a notice, the AO must have in their possession all the evidence to justify its service. The Detention of Food Notice should be served by hand on the person in possession of the meat who is deemed to be 'the owner'. A copy of the notice can be forwarded to the monetary owner, if different.

The AO must ensure that all detained food is suitably stored to minimise any deterioration; and securely stored in a lockable room where a security talisman tag has been applied to the chiller door to prevent its distribution.

Note: The owner of the meat could be the owner of the animal from which the meat was produced, for example, the farmer.

3.4.5 Content of notice

The notice must specify:

- description (carcase / box type, lot mark, colour, markings)
- quantity
- identification marks if any (detained tags, numbers or labels)
- the location where the product is being detained and any alternative location to where it may be moved (if applicable)
- why, in the officer's opinion, the food does not comply with the food safety requirements, linking the matter to Article 14 of Regulation (EC) 178/2002

3.4.6 Number of notices

Where a quantity of meat of different types or batches is being detained, the AO can issue a separate Detention of Food Notice for each type or batch.

To avoid the need to issue multiple Notices, the AO may also create a separate schedule or appendix to a notice listing all detained products. The schedule may be referenced in the box identifying the product in the body of the actual detention notice itself. This will allow food that has subsequently been inspected and found to be compliant to be positively released without the need to re issue notices each time the details of a detained product changes.

Where the meat that fails to comply with the hygiene requirements is part of a batch of the same class or description, it shall be presumed unless the contrary is shown that the whole batch fails to comply and the AO should detain all of it. Part of the food may subsequently be seized if necessary and an Order for Condemnation of Food applied for. The Detention Notice must be withdrawn in respect of the remainder if the AO is satisfied that the problem affects only part of the batch.

Reference: 29 (3) of the Food Safety and Hygiene (England) Regulations 2013, Regulation 27 (3) the Food Hygiene (Wales) Regulations 2006 and Food Safety Act 1990 Section 8 (3).

3.4.7 Right of appeal

No right of appeal exists for a Detention of Food Notice under the Food Safety Act 1990. However, where voluntarily surrender is not forthcoming, the meat must be formally seized and taken before a Justice of the Peace to seek a Condemnation Order.

3.4.8 Time limit

The AO shall, as soon as is reasonably practicable, and in any event within 21 days, determine whether or not they are satisfied that the meat complies with the food safety requirement.

If they are satisfied that the food complies with food safety requirements, the AO must immediately withdraw the notice and if not, immediately seize the food to seek a Condemnation Order.

3.4.9 Withdrawal

If the notice is to be withdrawn, the AO must immediately serve a Withdrawal of Detention of Food Notice upon the recipient of the original Detention Notice - ENF 11/2.

If a Detention of Food Notice is withdrawn, or Condemnation Order is refused by the Court, compensation is payable to the owner of the food for any depreciation in its value which can be shown to result from the AOs actions

3.4.10 AO checklist

Where the detained food is not released, specify in the AO checklist on the reverse of the Detention Notice:

- the nature of disposal and the category of ABP that the food was consigned under
- whether an Agreement to Destroy Food Notice was signed by the FBO and the Notice reference number
- whether the detention led to the food being certified, seized and taken before a court to have it condemned.

3.5 Condemnation procedure

3.5.1 When to apply for a condemnation order from the court

Where meat has been Health Marked / ID marked and it has not been produced, processed or distributed in accordance with the hygiene regulations, or breaches the 'food safety requirements' the OV should:

formally detain the food (ENF 11/26 or 11/1)

- certify the food as non-compliant (ENF 11/25)
- formally seize the food (ENF 11/27) within 21 days of the issue of any "Food Safety Act Detention of Food Notice" (ENF 11/1)
- apply to a Magistrate for a Condemnation Order

3.5.3 Obtaining a condemnation order

In England and Wales, a Condemnation Order may be obtained from a Justice of the Peace at the Magistrates' court.

3.5.4 Action to take

The AO is to follow the steps in the table below, making sure that all formal documents are served on the FBO in line with Regulation 30 of the Food Safety and Hygiene (England) Regulations 2013 or Regulation 28 of the Food Hygiene (Wales) Regulations 2006 and copies are handed to local management.

Reference: The Food Safety Act 1990 Section 9 (3) (b), Section 9(4) (b).

Detain the food (ENF 11/1)	Ensure that any food that you suspect does not comply with the food safety requirements is formally detained using a Food Safety Act Detention of Food Notice (ENF 11/1) or Detention Notice (ENF 11/26). Reference: See chapter 9 on 'Forms' for ENF 11/1.
Complete and serve Certification of Meat Notice (ENF 11/25)	Once the AO has determined that the food has not been produced, processed or distributed in accordance with the provisions of the Hygiene Regulations they must serve notice on the FBO with the reasons why it fails to comply. They must also inform FSA Legal to make them aware that legal representation may be required.
Complete and serve a Seizure of Food Notice (ENF 11/27)	Reference: See chapter 9 on 'Forms' for ENF 11/25. If after certifying the meat, the FBO refuses to voluntarily surrender the food, complete a Seizure of Food Notice (ENF 11/27) and serve it on the FBO and a copy on the owner of the food where relevant. Reference: See chapter 9 on 'Forms' for ENF 11/27.
Complete and serve a Food Condemnation Warning Notice (ENF 11/3)	ENF 11/3 should be served on the owner / person in charge of the food (FBO). If relevant, a copy of the Condemnation Warning Notice should also be served

	on the owner of the animal from which the meat was produced, for example, the farmer.
Advise FSA legal adviser	FSA will arrange legal representation. A summary of events in the form of a witness statement and copy of all legal notices and relevant documents must be sent to FSA Legal.
Contact FSA Legal	Establish which court covers the area for the establishment where the detained food is held.
Contact the court	 In England / Wales - speak to the Clerk of the Court to establish local procedures. Explain: the officer is authorised under the Food Safety Act 1990 and Food Safety and Hygiene (England) Regulations 2013 or Food Hygiene (Wales) Regulations 2006 that the AO is seeking an Order for Condemnation of Food from a Justice of the Peace the nature, quantity and location of the product detained, and confirm that the premises fall within that court's jurisdiction the reason the Order is being sought referring particularly to the legislation under which the case is brought In England and Wales establish with the Clerk a date, time and location for the court hearing. The location will generally be the local courtroom but could be the plant
	where the product is detained.
Complete and serve Food Condemnation Warning Notice (ENF 11/3)	Ensure that the notice is served by the most appropriate method available in the circumstances to ensure that all relevant parties are informed of the time and place of the hearing in good time. Document and retain records of service to show the court. Retain copies of the Condemnation Warning Notice, Certification of Meat Notice and Seizure of Food Notice to produce to the Justice of the Peace, the Clerk to the Court and the FSA legal representative. Reference: See chapter 9 'Forms' for ENF 11/3.

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Attend the hearing

Prepare three copies of the Complaint for

Condemnation of Food Order (ENF 11/15) and of the Order for Condemnation of Food (ENF 11/16) itself for the Justice of the Peace to sign.

Read the papers again before going to court.

Attend court early to meet the FSA advocate.

On attending the hearing, the AO should take:

- their Authorisation Certificate / Warrant for the legislation being enforced
- copy of the Certification of Meat failing to comply with the requirements of the Hygiene Regulations
- copies of the Detention and/or Seizure Notice and a record of service
- copies of the Condemnation Warning Notice and record of service
- copies of the Complaint for Condemnation of Food Order
- copies of the Order for Condemnation of Food
- contemporaneous notes which may be referred to (notebook or plant daybook)
- a consolidated copy of the relevant legislation (highlight sections for easy reference)
- copies of the Code of Practice
- any additional evidence, for example, copies of a public analyst or expert report
- a representative sample of the food if the hearing is to be held in court and the entire batch cannot be transported (where appropriate)

Reference: See chapter 9 'Forms' for ENF 11/15 and ENF 11/16.

Explain clearly when presenting the evidence in court:

- why the meat should be condemned
- quote the Regulation(s) which has / have been breached
- what the problems are if the meat is not condemned
- what the risk is to public health

If successful: maintain	If the Justice of the Peace issues an 'Order for
supervision to ensure meat	Condemnation of Food', upon receipt of the Order,
is disposed of	ensure that the person in charge of the meat (and the
	owner if notified) receives a copy. Ensure that the
	details of disposal have been recoded and that a copy
	of the waste transfer note has been kept on file.
If unsuccessful: meat is	Where any issue of compensation arises, the AO must
restored to owner	not discuss or negotiate any compensation for
	depreciation in value of the meat or food. The AO
	should ask the FBO / Owner of the food to put any
	complaint in writing to the HOD.

4. Hierarchy of Enforcement

4.1	Introduction
4.2	Informal enforcement action: Written
4.3	Formal enforcement action: Statutory Notice
4.4	Statutory Notices for Hygiene Contraventions
4.5	Remedial Action Notices (RAN)
4.6	Hygiene Improvement Notices (HIN)
4.7	Hygiene Emergency Prohibition Notices (HEPN)
4.8	Hygiene Emergency Prohibition Orders (HEPO)
4.9	Referral for investigation
4.10	Protocol for referral for investigation
4.11	Referral for investigation: FSA Legal
4.12	Change of FBO during enforcement action
4.13	Warrant to enter premises
4.14	Process for obtaining warrant to enter premises in England and Wales

4.1 Introduction

4.1.1 The hierarchy of enforcement

The hierarchy that an AO follows will be dependent on the legislation contravened, the enforcement powers available and the risk associated with the non-compliance.

Matters Requiring Immediate Rectification

Where contraventions need to be remedied immediately based on public health / animal health or animal welfare risk, AOs must first verbally request the FBO rectifies the issue, but where they fail to respond, the advice may be followed immediately with the service of a formal notice requiring immediate rectification, such as a Remedial Action Notice for breaches of the Hygiene Regulations, a Welfare Enforcement Notice for breaches of animal welfare legislation or Notice requiring the Disposal of an ABP (see later).

The officer may wish to formally detain or quarantine product suspected to be unfit and/or sample food they suspect to be non-compliant at the same time as the service of a RAN.

In less urgent cases, the AO must follow the hierarchy available to them under the respective legislation that they are enforcing.

Potential Hierarchy if compliance has not been achieved				
Legislative Area Contravention	Verbal	Written	Formal Notice Available	Referral for Investigation
Hygiene Regulations- (EC) 852/2004, (EC) 853/2004, (EU) 2019/627 (EC) 2073/2005 (EU) 2015/1375 The Food Safety and Hygiene (England) Regulations 2013 and The Food Hygiene (Wales) Regulations 2006	Yes	Not required	RAN's are available to require immediate rectification for breaches of the "Hygiene Regulations". See Regulation 9(1) of The Food Safety and Hygiene (England) Regulations 2013 and devolved equivalents.	Yes
Hygiene Regulations- (EC) 852/2004, (EC) 853/2004, (EU) 2019/627 (EC) 2073/2005 (EU) 2015/1375 The Food Safety and Hygiene (England) Regulations 2013 and	Yes	Yes	HIN's are available for breaches of the "Hygiene Regulations" that do not pose an immediate risk or cannot be rectified immediately. See Regulation 6(1) of The Food Safety and Hygiene (England) Regulations 2013 and devolved equivalents.	Yes

The Food Hygiene (Wales) Regulations 2006.				
Food Safety Regulation (EC) 178/2002 and (EU) 931/2011 The Food Safety and Hygiene (England) Regulations 2013 and the General Food Regulations 2004	Yes	Yes	No formal notice is available because (EC) 178/2002 is the EU Food Safety Regulation and is not part of the "Hygiene Regulations"	Yes
The TSE Regulations (EC) 999/2001, The TSE (England) Regulations 2018 and The TSE (Wales) Regulations 2018	Yes	Yes	No formal notice is available under the domestic TSE Regulations	Yes
The Animal By-product Regulations (EC) 1069/2009, (EU) 142/2011, The Animal By-products (Enforcement) (England)			Formal notices are available under the Animal By-Products (Enforcement) (England) Regulations 2013, however, often such notices may not be relevant to the issue observed and a referral may follow verbal and written advice.	
Regulations 2013 and The Animal By-products (Enforcement) (Wales) Regulations 2014	Yes	Yes	ABP Notice for the Disposal and where applicable storage pending disposal of ABP Regulation (25(2)(a) of The Animal Byproducts (Enforcement) (England) Regulations 2013 and the Wales equivalent.	Yes
	Yes	May or may not be required depending on the imminent risk	ABP Notice requiring the cleansing and disinfection of premises and where applicable the method of such cleansing and disinfection. Regulation (25(2)(b) of The Animal By-products (Enforcement) (England) Regulations 2013 and the Wales equivalent.	Yes
	Yes	May or may not be required depending on the imminent risk	The prohibition of ABPs being moved or brought into food premises. The Animal Byproducts (Enforcement) (England) Regulations 2013 and the Wales equivalent.	Yes
Animal Welfare Regulations (EC) 1099/2009, WATOK (England) Regulations 2015 and WATOK (Wales) Regulations 2014			Welfare Enforcement Notice are available under Regulation 38 of the WATOK (England) Regulations 2015 and their Wales equivalent.	
	Yes	Not required	WEN's are available to require immediate rectification for breaches of the welfare at slaughter legislation where any avoidable pain, distress or suffering is evident	Yes

Yes	Yes	WEN's are available to require rectification	Yes
		for more systemic breaches of the welfare	
		at slaughter legislation e.g. SOP's	

4.1.2 Approach to the hierarchy

The approach to the hierarchy of enforcement and level at which the AO commences enforcement action will be dependent upon:

- the urgency / severity of the situation
- the most appropriate course of action that will control the risk
- the enforcement tools available under that piece of legislation
- the history of the FBO and their willingness to comply
- the FSA Operations Enforcement Policy

4.1.3 Enforcement; informal and formal action

The term 'Enforcement' is not defined in legislation, but according to the Enforcement Concordat: Good Practice Guide for England and Wales Paragraph 88), includes advisory visits, assisting the FBO with compliance and formal enforcement action.

Verbal advice, written advice and written warnings all constitutes informal enforcement action.

Formal enforcement action includes official detention of food, the service of formal notices, cautions, referrals for investigation and prosecutions.

4.1.4 Subject of enforcement action

Any FBO or person who is the subject of enforcement action should be kept fully informed of any intended or actual enforcement intervention by the AO.

4.1.5 The health mark and enforcement hierarchy

The application of the health mark is not part of the hierarchy of enforcement. However, the AO must refuse to apply the health mark in red meat plants under the following circumstances:

- where the animal has not undergone ante-mortem and post-mortem inspection in accordance with (EU) 2017/625 Article 18, paragraph 4 and paragraph 2 (a) and 2 (c)
- where there are grounds for declaring the meat unfit for human consumption, or in the OVs opinion, after examination of all relevant information, the meat constitutes a risk to public or animal health, or is not suitable for human consumption in accordance with (EU) 2019/627, Article 40, 41, 43, 45.
- where the meat fails to comply with the provisions of Article 14.5 (EC)
 178/2002 in that the food is unacceptable for human consumption
 according to its intended use, for reasons of contamination (whether by
 extraneous matter or otherwise), or through putrefaction, deterioration or
 decay

Similarly, the Identification Mark ((EC) 853/2004, Article 5,2) must only be applied by the FBO to products in poultry slaughterhouses and all cutting plants if the product has been manufactured in accordance with the requirements of (EC) 853/2004, in establishments meeting the requirements of Article 4 of (EC) 853/2004.

This breach will:

- constitute an offence under Regulation 19 of the Food Safety and Hygiene (England) Regulations 2013 and Regulation 17 of the Food Hygiene (Wales) Regulations 2006
- potentially warrant the service of a Remedial Action Notice under Regulation 9(1) of the same Regulations, immediately prohibiting the use of the mark

4.1.6 When to give verbal advice

The first stage of enforcement action considered by the AO should always be education and advice. Whilst it is the FBOs responsibility to know which legal provisions are applicable to their business, the AO should ensure that, where necessary, they clarify and update the FBO on any relevant legal requirements. This is to ensure that the FBO understands the outcome to be achieved.

Verbal advice should go hand in hand with all stages in the enforcement process to help the FBO achieve compliance, and understand why enforcement action is being taken. For example, AOs must always try to explain to the FBO why immediate action may be required, why a statutory notice is being served, or why the matter is being referred for investigation, if appropriate.

Where verbal advice is of a technical nature, it may be helpful for this to be followed up with a letter in writing confirming the discussion / meeting.

It is important that the AO does not continue to give verbal advice where this is being ignored, without escalating enforcement action in the appropriate way.

Note: Where immediate action is required on public health or animal welfare grounds, verbal advice should be given, but if ignored it may be appropriate to move straight to formal enforcement action to secure compliance as soon as possible (for example, Public Health - RAN, Animal Welfare – WATOK Enforcement Notice).

4.1.7 Records

Unless the AO witnesses a one-off low risk issue; if it appears likely that enforcement may be escalated, or the FBO has a history of non-compliance, verbal advice should be recorded on Chronos, the FSA enforcement system.

4.2 Informal enforcement action: Written Warnings

4.2.1 Warning letters

Warning letters are considered 'informal' enforcement action and when produced later in court will help to demonstrate fairness and proportionality in the enforcement approach and that the FBO may have ignored previous advice.

Warning letters should be sent by the AO to the FBO when:

- the FBO or a staff member has failed to take appropriate corrective action following verbal advice and/or
- where there is a contravention of the Regulations which does not have an immediate impact on public health or animal welfare

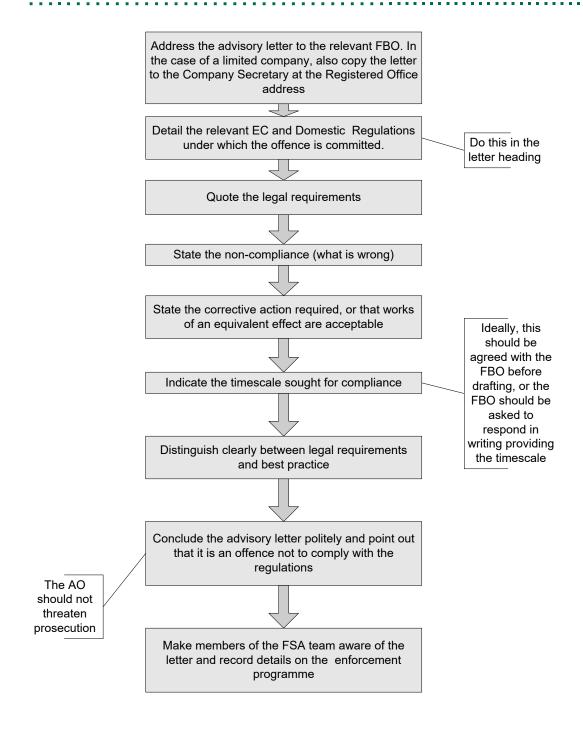
The AO should inform the FBO of the intention to write a warning letter. Ideally, the AO should meet with the FBO or their representative before issuing such an advisory letter to discuss all the issues including the timescale for completion. It is good practice to ask the FBO to confirm in writing their agreement to any timescale. Accurate minutes of any meetings in respect of compliance should be taken.

When drafting warning letters, the AO must not warn of prosecution action in the event of future contraventions, as this could prejudice any future formal investigation.

Warning letters must be typed and sent on FSA official letterhead paper. In the case of advisory letters sent to limited companies, these must be addressed to the FBO c/o The Company Secretary at the Registered Office address and a copy handed to plant management.

4.2.2 Checklist for advisory letters

The table below lists the points that an OV should follow when drafting an advisory letter. The OV should:



4.3 Formal enforcement action: Statutory Notice

4.3.1 Preparation for formal action

Before taking formal enforcement action, the AO should:

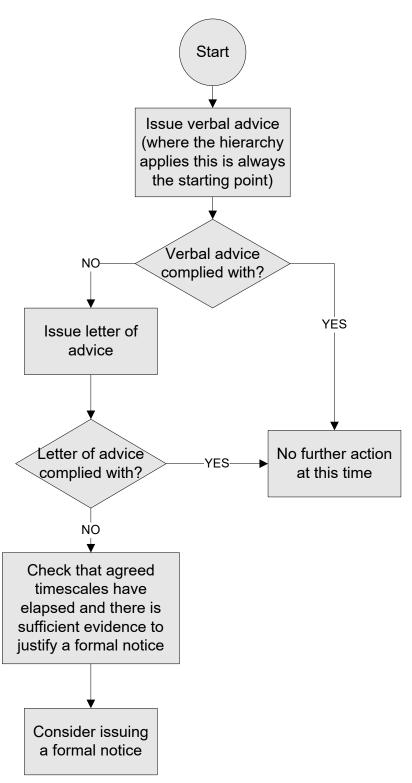
- advise the FBO verbally of this intention
- be aware of all ongoing enforcement action by reviewing the enforcement history on Chronos
- have regard to the FSA Operations Enforcement Policy
- ensure that evidence has been secured to demonstrate that the contravention still exists that will warrant the escalation of enforcement action
- gather evidence to justify the service of the formal notice and to support any potential appeal against the service of the notice.

4.3.2 Statutory notices

Statutory Notices are legal documents and care must be taken to ensure they are completed correctly and used appropriately. They should only be served by FSA AOs authorised to do so.

4.3.3 Checklist prior to serving statutory notices

The diagram below lists the points that an AO should follow before serving a Statutory Notice. The AO should:



At the time of serving a formal Statutory Notice, the AO should ensure that *all* the following checks are complied with:

- the formal notice is addressed to and served on the correct person / partners or legal entity
- the local plant management has received a copy of any formal notice where the original was served on the limited company and sent c/o 'The Company Secretary' to the Registered Office address
- the notice is clearly worded, concise and easily understood; it is typed (unless drafted by hand and served immediately), dated and signed by the AO
- the notice accurately describes the non-compliance and associated risk without just copying the wording of the legislation,
- the notice clearly describes the action required to remedy the breach of the legislation and should match the problem identified in the contravention box,
- the notice provides a relevant time frame within which compliance should be achieved,
- an official up to date version of the notice should be used (taken from the MOC),
- all sections must have been completed correctly and where options exist in the notice, any references that are not relevant should be deleted as necessary
- the notice includes all required information on rights of appeal,
- a copy of the notice served must be retained and copied / scanned as a permanent record

If **any** of the above checks are not complied with, the AO must ensure action is taken to secure compliance before proceeding to serve the Notice.

4.4 Statutory notices for hygiene contraventions

4.4.1 The Food Safety and Hygiene (England) Regulations 2013 and the Food Hygiene (Wales) Regulations 2006

The Food Safety and Hygiene (England) Regulations 2013 and the Food Hygiene (Wales) Regulations 2006, provide powers to serve 3 notices for hygiene non-compliances:

- Remedial Action Notice (Regulation 9(1))
- Hygiene Improvement Notice (Regulation 6)
- Hygiene Emergency Prohibition Notice and Order (Regulation 8)

Reference: See section 3 on 'Surrender, detention, seizure and condemnation' in this chapter for details of detention for examination and sampling under Regulation 10(1) of the England Regulations and 9(5) of the Scottish and Welsh Regulations and detention for further investigation under Section 9 of the Food Safety Act 1990, via the provisions of Regulation 25 of the domestic England Regulations and Regulation 23 of the domestic Scottish and Welsh Regulations.

4.4.2 Service details

Regulation 10(1) and 9(5) Detention Notices served under The Food Safety and Hygiene (England) Regulations 2013 and Food Hygiene (Wales) Regulations 2006, should be served on the FBO, or their duly authorised representative.

The Food Safety Act Detention Notice should be served on the person in charge of the food.

4.4.3 Formal service and delivery of notices

Formal notices must be served on the correct legal entity responsible for any potential offences and to the correct address for that entity.

4.4.4 Finding company addresses

<u>Checks on a company's registered office details</u> may be done by logging on to Companies House website and clicking on to the free company details link under the 'find company information' heading.

The organisation can also be contacted on 03031234500, or by email at enquiries@companies-house.gov.uk between 08:30 and 18:00, Monday to Friday.

Type of Notice	Legislation	Purpose	Should be
			served upon
Detention of	Section 9 Food Safety	To detain food while	The person in
Food Notice	Act 1990 [via	further investigation	charge of the
	Regulation 25 Food	is carried out	food (the FBO)

Certification of Meat Notice	Safety and Hygiene (England) Regulations 2013/ Regulation 23 Food Hygiene (Wales) Regulations 2006] Regulation 29 Food Safety and Hygiene (England) Regulations 2013/ Regulation 27	To certify that food has not been produced, processed or distributed in	The FBO or person in charge of the food.
	Food Hygiene (Wales) Regulations 2006	accordance with the Hygiene Regulations and fails to comply with the food safety requirements	
Seizure of Food	Section 9 Food Safety	To seize food in	The person in
Notice	Act 1990 [via	order that it may be	charge of the
	Regulation 25 Food	taken before the	food (the FBO)
	Safety and Hygiene	court to be	
	(England) Regulations	condemned	
	2013/ Regulation 23		
	Food Hygiene (Wales)		
	Regulations 2006]		
Remedial	Regulation 9 Food	To seek compliance	FBO or Duly
Action Notices	Safety and Hygiene	with hygiene matters	Authorised
	(England) Regulations	that pose an	Representative
	2013 / Regulation 9	immediate risk to	
	Food Hygiene (Wales)	public health	
	Regulations 2006		
Hygiene	Regulation 6 Food	To seek compliance	FBO
Improvement	Safety and Hygiene	with hygiene matters	
Notice	(England) Regulations	that do not pose an	
	2013 / Regulation 9	immediate risk to	
	Food Hygiene (Wales)	public health	
	Regulations 2006	- .	
Hygiene Emergency	Regulation 8 Food Safety and Hygiene	To impose a prohibition on the:	FBO
Prohibition	(England) Regulations	use of a process	
Notice (and	2013 / Regulation 9	or treatment	
Order) `	Food Hygiene (Wales)	 use of the 	
	Regulations 2006	premises or	
		equipment	

П			
Hygiene Prohibition Order	Regulation 7 Food Safety and Hygiene (England) Regulations	relating to its construction use of the premises or equipment relating to its state or condition Prohibition of a food business proprietor or manager from	FBO
	2013/ Regulation 7 Food Hygiene (Wales) Regulations 2006	participating in the management of any food business	
Welfare Enforcement Notice	Regulation 38 WATOK (England) Regulations 2015 and WATOK (Wales) Regulations 2014	To: require a person to take steps to remedy a contravention of the EU or domestic welfare at slaughter Regulations require a person to reduce the rate of operation to the extent specified in the notice, prohibit a person from carrying on an activity, process or operation or using specified facilities or equipment.	
Animal By- products notices	Regulation 25 Animal By-Products (Enforcement) (England) Regulations 2013 and Animal By- Products (Enforcement)(Wales) Regulations 2014	 Requiring disposal and where applicable, storage pending disposal of ABP, Requiring the cleansing and disinfection of premises and where applicable the method of such cleansing and disinfection, 	The occupier or person in charge of or responsible for the premises

Prohibiting ABP
being moved in or on
to premises or
specifying the
conditions of such
movement in
conjunction with the
satisfactory
cleansing and
disinfection.

4.5 Remedial Action Notices

4.5.1 When to use a Remedial Action Notice (ENF 11/24 (E and W))

RAN may only be used:

- when any of the requirements of the Hygiene Regulations* are being breached, or
- when inspection under the Hygiene Regulations is being hampered

*"The Hygiene Regulations" in this context means either the provisions of the EU Hygiene Regulations (852/2004, 853/2004, 2073/2005 and 2015/1375), Regulation 2019/624 and Regulation 2019/627, and the Food Safety and Hygiene (England) Regulations (2013)/ Food Hygiene (Wales) Regulations 2006.

Note: Regulation (EC) 178/2002 is not included as part of the "Hygiene Regulations".

It should be used specifically where the AO considers that the FBO should take immediate action to achieve compliance, or where the rate of operation of the plant is detrimental to its ability to comply with the Hygiene Regulations.

The AO must verbally request that the FBO rectifies the situation and serve the notice if compliance is not met. It is essential to gather the necessary evidence at the time the contravention is identified to justify its service in case an appeal against the RAN is lodged by the FBO.

The AO must verbally inform the FBO of the intention to serve the notice and record the information in the enforcement programme.

4.5.2 Purpose of a RAN

A RAN places a legal requirement on a FBO to take immediate action to achieve compliance with the Hygiene Regulations. The AO must specify on the notice whether the RAN is intended to:

- prohibit the use of any equipment or any part of the establishment specified in the notice, or
- impose conditions upon or stop a process, or
- require the rate of operation to be reduced to such extent as specified in the notice, or to be stopped completely

RANs can be used to direct a FBO to immediately rectify any of the deficiencies, which fall under (EC) 852 and 853/2004, (EC) 2073, (EC) 2015/1375, (EU) 2017/625 and the (EU) 2017/625 package in so far as it and they relate to food and the domestic hygiene regulations themselves.

In the case of maintenance and structural problems, that do not pose an imminent threat to public health and can be rectified in the longer term, a Hygiene Improvement Notice should be used. This would be served under Regulation 6 of The Food Safety and Hygiene (England) Regulations 2013/ Regulation 6 of the Food Hygiene (Wales) Regulations 2006.

4.5.3 Identification of the non-compliance

Where the RAN is being served under section 9(1)(a), because a requirement of the Hygiene Regulations is being breached, the AO is required to:

- specify how the requirement(s) of the Hygiene Regulations have been breached in the "contravention" box of the RAN. It is not sufficient to merely repeat the legal requirement set out in the legislation, as this does not specify the precise nature of the breach.
- The specific contravention observed should be described, its location and enough information to differentiate it from other areas with which it could be confused. The description of the issue should specify how it fails to meet the legal requirement and identify any relevant risks to the product,
- cite the relevant legal reference(s) of the Hygiene Regulations that are being breached, ensuring this identifies the exact provision(s) that place an obligation on the FBO. This should include the general obligations to comply with the relevant provisions in the Annexes to the EU Regulation, and the specific requirement contained in that Annex, for example,

Regulation (EC) 853/2004, Article 3 and Annex III, Section I, Chapter IV, Paragraph 7(b) (i),

- if the FBO is breaching more than one legal provision by their conduct, cite the most relevant provision that applies. Where there are no specific requirements, use the more generic references which apply to the scenario in question.
- describe the measure(s) / action(s) which, in your opinion, the FBO must take to remedy the breach identified in the "contraventions" box of the notice. Sometimes, it may not be possible to identify the exact solution to a problem, for example, an engineering solution to a ventilation / humidity issue. In such cases, it is acceptable to set out the requirements of the regulations that must be complied with and any objectives of that regulation to avoid contamination. The FBO should have been encouraged to contact an engineer to try and find a solution to such problems.
- ensure that the contravention(s), legal reference(s) and action(s) all link to
 one another; the measure(s) to be taken must be relevant to the
 contraventions identified earlier in the notice; the AO must not require the
 FBO to undertake actions which they have not identified as contraventions
 in the earlier part of the notice
- if a RAN is served under Regulation 9(1)(d), allowing conditions to be imposed on a process in the establishment, ensure that the process in question is specified in the notice; examples of a process might be "evisceration", "dressing" and "skinning" or "wrapping", "packaging" etc.

FBOs have a responsibility to monitor all significant hazards in a process, determine where a process is out of control through effective monitoring of a critical limit, identify the root cause of such non-compliances and rectify them through effective control measures / corrective actions, as part of their HACCP based procedures. However, in many cases FBOs will have failed to monitor and failed to undertake the corrective actions identified in their HACCP plan.

Whilst HINs can be used to require compliance with the systemic HACCP deficiencies, RAN can be used to address any hygiene risks evident as a result of the FBOs failure to have taken any appropriate corrective actions.

In some cases – for example, where a slaughter process is clearly out of control, where the root cause of a serious problem is unknown, or where an AO has already served a RAN which has been breached by the FBO – the AO should consider serving a RAN which prohibits the carrying out of a process (under Regulation 9(1)(d)) or requiring the FBO to stop operations completely (under Regulation 9(1)(e)).

RANs to Stop a Process

In cases where:

- the process is clearly out of control and the FBO is not taking responsibility to address the root cause(s),
- where the root cause(s) is/are varied, or
- where an AO has already served a RAN, which has been breached by the FBO

The AO should consider serving a RAN which prohibits the carrying out of a process (under Regulation 9(1)(d)) or requiring the FBO to stop operations completely (under Regulation 9(1)(e)). This may be done in conjunction with a refusal to apply a health mark or the detention of meat if applicable.

A RAN may be used to stop the operation completely in circumstances such as pest infestation, failure of sterilisers, inadequate overnight cleaning, failure of the hot water supply, lack of potable water supply or where the behaviour of the FBO is hampering adequate health inspection.

Note: Where the notice has the effect of stopping the operation completely, the AO must consult with their line manager to ensure that the action requested of the FBO is proportionate to the risk.

4.5.4 Service and withdrawal

A separate RAN should normally be served on an FBO in respect of each separate deficiency (except in cases where there are multiple breaches of the same theme, see below in 4.5.13).

Only the AO who observes the deficiency should serve the formal notice. The notice must be handed to someone in charge at the plant and a copy sent by post, with proof of posting obtained.

If the business is a limited company, service is not deemed to have occurred unless the notice has been sent to the registered office address of that company by post – See Regulation 30, Food Safety and Hygiene (England) Regulations 2013 and devolved equivalents. If the Notice has been served by post on the FBO, a copy of the Notice should still be handed to someone at the plant address.

4.5.5 Tagging

All equipment that has been the subject of a RAN must be clearly identified and cross referenced. Tagging the equipment using a numbered security seal, may be used to clearly identify it for the FBO to action any deficiency.

4.5.6 Who to serve the notice on

RANs must be served on the FBO or a "duly authorised representative" of the business. Information on the identity of any duly authorised representative will be contained in the approval document for the business. If this person is not defined by the business or that person is not present / has left the business; the notice must always be directed by default to the FBO.

The notice may be handed to an FBO if they are a sole trader or to all partners in the business, if they are present at the plant.

4.5.7 Alternative service methods

Where it is not possible to identify the name and address of the FBO on whom the notice should be served, it can be served by addressing it to the FBO in their capacity as "occupier" of the establishment at which corrective action is required (naming the establishment). The notice may then either be handed to someone else at the establishment who appears to be in charge, or by attaching the notice or a copy of it to some conspicuous part of the establishment.

The provisions relating to the service of notices are contained within Regulation 30 of the Food Safety and Hygiene (England) Regulations 2013/Regulation 28 of The Food Hygiene (Wales) Regulations. They correspond with the provisions of Section 50 of the Food Safety Act 1990.

4.5.8 Information for notices

A copy of the Notice served must be retained and the following information is to be recorded on the reverse of the Notice:

- the name of the plant representative to whom any copy notices have been handed (in circumstances where the original has been posted to the FBO at the plant or served at the registered office address of a limited company)
- any comments made by the FBO or plant representative when handed the notice

- details of any food detained at the same time as the service of the RAN
- the reference number of any Detention Notice served
- details of any appeal that is lodged by the FBO in respect of the service of the RAN

4.5.9 Rights of appeal

The FBO has the right of appeal (Regulation 22 (England), Regulation 20 (Wales) to a Justice of the Peace regarding the decision of the AO to serve a Remedial Action Notice. If the FBO appeals, the AO must notify CSU York Transactions Team immediately.

The provisions of the Remedial Action Notice remain in force until such time as the appeal is upheld.

4.5.10 If removed or defaced or destroyed

The notice is the property of the FSA. If the AO discovers that any notice affixed to an establishment has been removed, defaced, or destroyed, the notice should be replaced as soon as possible, and the events recorded in the officer's pocketbook and/or plant daybook if at a slaughterhouse.

4.5.11 Failure to comply

Failure to comply with a RAN is an offence (Regulation 9(5) The Food Safety and Hygiene (England) Regulations 2013 / Regulation 9 (7) The Food Hygiene (Wales) Regulations 2006). If the operator has failed to comply with such a notice, complete a Referral for Investigation report - ENF 11/6.

4.5.12 Corroborative evidence rules

The service of a notice should be evidenced or corroborated in some way wherever possible. If a notice is served by hand, either secure a second AO to corroborate this fact or ask the FBO to sign your pocketbook to acknowledge receipt. Both, the AO who served the original notice and the corroborating officer should sign a copy of the notice and indicate the date and time of service and should also make a note of the details of service in the Plant Daybook and/or their pocketbook.

A witness is required to observe any AO fixing a notice to the premises wherever possible, or a photograph is required to evidence it has been attached.

When posting a notice, the OV should obtain a proof of postage certificate and retain this as evidence. Where this is not possible, the AO should record the details of where the notice is posted and the postage address in their pocketbook and have a colleague corroborate the postage and countersign the entry. Where no colleague is available to corroborate postage, record details of posting in the same way as above and photograph the envelope.

4.5.13 Multiple contraventions

Where different contraventions have been identified, a different notice should be served for each and every separate contravention.

A notice containing multiple contraventions:

- will be more complicated to draft and it is more likely that an FBO may be confused by what the AO is trying to convey; this may affect the validity of the Notice as it is important that enforcement requirements placed upon an FBO are clear,
- will require actions that must be capable of curing all the issues cited in the contravention section,
- cannot be withdrawn if there are certain issues still outstanding, even where some issues have been complied with,
- cannot be referred for investigation as certain aspects of the notice may have been complied with and some not,
- if appealed, will result in all of the issues being the subject of the appeal, even where some may have been actioned.

In limited circumstances, it may be acceptable to cite more than one issue and legal reference on a RAN or HIN (see section on HINs), provided that:

- the legal references and contraventions relate to the same theme, for example, maintenance, cleanliness of the premises
- the actions the AO requires the FBO to take are capable of curing all the contraventions identified earlier in the notice,
- where multiple issues of the same theme are identified, it may be useful to list them on a schedule that is annexed to the Notice.

4.5.14 Withdrawal of a RAN

A RAN is often used to correct problems with operational practices that pose a potential risk to the safe production of food. They may be left in place until the AO is satisfied that the FBO has complied with the legal requirement. There may often be occasions where the non-compliance is intermittent and the AO wishes to be satisfied that the FBO / their staff have changed their behaviour before withdrawing the notice.

However, the AO must monitor the situation and come to a determination within a reasonable time frame given the non-compliance they are requiring the FBO to correct. The time frame for removing the notice may vary depending on the nature of the non-compliance; however, if the Notice is breached, it must be referred for investigation.

If the officer is satisfied that the actions required by the Notice have been complied with, it must be withdrawn and it is not appropriate to leave the notice in place for long periods after this point as it does not offer certainty for the FBO as to whether they will face any future legal proceedings, since they are now complying with the Hygiene Regulations.

However, in situations where compliance with the requirements are intermittent, it is important to remember that there is no maximum timeframe to leave a RAN in place, and no requirement about when a RAN has to be withdrawn, except that it should be withdrawn once the AO is satisfied that it has been complied with.

Notification of withdrawal of a RAN must be achieved in the same way that the notice was served. If the FBO is a limited company, and the Notice was served at the company's registered office address (with a copy of the Notice having been handed to a member of staff in charge at the production plant), the withdrawal notice must also be sent in the posted to the registered office address, and a second copy should be handed to someone appearing to be in charge / duly authorised representative at the plant.

4.6 Hygiene Improvement Notices

4.6.1 When to use a Hygiene Improvement Notice (ENF 11/23 (E and W))

HIN should be used:

- where there is a record of non-compliance with breaches of the regulations
- where the history of compliance by the FBO is such that the OV has reason to believe that an informal approach will not be successful

• where formal action is proportionate to the risk to public health

A HIN should not be used for non-hygiene related matters, for example, failure to comply with the provisions of the Animal By-Product Regulations, WATOK or TSE Regulations.

Both verbal and written advice should be given to a FBO prior to a HIN being served. However, there may be circumstances where the AO believes this informal approach will be unsuccessful or the issue is a repetitive one. If these informal stages are to be bypassed, the AO must have suitable evidence to demonstrate that the FBO has ignored previous informal advice in this area, prior to circumventing these requirements.

4.6.2 Purpose of a HIN

The purpose of a HIN is to place a legal requirement on a FBO to take action to achieve compliance with the EU Food Hygiene Regulations.

A HIN may require the FBO to:

- address any hygiene deficiency that does not require immediate action
- repair a structural defect with the building
- to build or construct additional facilities to cope with an increased throughput
- address failures to implement and maintain a sound HACCP based system

The identified action must be stated on the HIN.

4.6.3 When not to issue a HIN

A HIN cannot be used to impose a continuing burden, and should not be used in the following circumstances:

- where the contravention might be a continuing one, for example, wooden
 pallets stored in the presence of unprotected fresh meat and the Notice
 would only secure an improvement at that point in time
- where breaches exist that pose a potential and imminent risk to health and urgent action is needed; in these cases, it is more appropriate to use a RAN and in more serious situations (subject to agreement from the relevant Head of Operational Delivery) a Hygiene Emergency Prohibition Notice
- for the failure to implement good hygiene practice

An HIN cannot be issued unless a contravention of the Hygiene Regulations is identified.

4.6.4 Service

HINs can only be served on the FBO (i.e. a sole trader / on each partner / a limited company). Only the AO who observes the deficiency should serve the formal notice.

Note: Where the FBO is a limited company, the envelope is to be addressed to the limited company c/o The Company Secretary at the Registered Office. However, details of the Company Secretary must never be used on the formal notice itself, as that must only be addressed to the FBO.

If the Notice has been served by post on the FBO, a copy of the Notice should be handed to someone at the plant address by the AO that observed the deficiency. Details of how the notice was served should be recorded on the back of the HIN.

4.6.5 Service checklist

When serving a HIN the AO must:

- have in their possession all the evidence to justify its service
- verbally inform the FBO of the intention to serve the notice
- state why it is served and the action needed to remedy the breach
- sign, date and if possible type the HIN

4.6.6 Drafting and serving a notice to a sole trader

Ensure that the name of the individual FBO on the formal Notice clearly identifies that individual beyond doubt and will need to include both their forename(s) and surname.

Where family members have the same names, try to include any additional forenames that the person may have, to avoid confusion. The notice may be served by hand on the sole trader at the plant or addressed to them personally at the plant address. A copy of the Notice should be posted to the FBO at the plant address and proof of posting obtained.

4.6.7 Drafting and serving a notice to a partnership

Where a number of individuals act as the FBO under a partnership arrangement, a copy of the Notice must be served on each and every partner. The box identifying the FBO must include each and every partner's full name.

The notices may be served by hand on each partner at the plant or addressed to each of them personally at the plant address, with a covering letter explaining that the **same** notice has been served on the other partners in the business. Proof of posting should be obtained.

4.6.8 Drafting a notice to a FBO with limited liability status

Where the FBO has limited liability status, the name of the FBO will be the full name of the limited company, as registered at Companies House, for example, 'ABC Meat Ltd'. The Notice must be sent by post to the registered office or principal address of the company, with a copy of the Notice handed to the relevant person in charge at the plant. The **envelope** must be addressed to the limited company c/o 'The Company Secretary', where one exists.

Note: Whilst a company secretary is no longer a legal requirement within a limited company structure, where they exist, they are generally the person responsible within a limited company structure, who is responsible for receiving formal documentation. They are **not** the FBO or proprietor, and therefore should **not** be referred to on the formal notice.

4.6.9 Content of notice

The notice must specify the:

- grounds for believing the FBO is failing to comply with the Hygiene Regulations
- precise nature of the alleged breach
- measures needed to be taken to secure compliance
- timescale (date) for compliance (minimum 14 days)
- appeal provisions, including the name and address of the relevant local court

Note: Where an FBO undertakes alternative works of equivalent effect, this may be acceptable.

4.6.10 Drafting the notice

The AO is required to:

- describe the contravention that has been observed that constitutes a
 breach of the Hygiene Regulations. It is not sufficient to merely repeat the
 legal requirement set out in the legislation, as this does not specify the
 precise nature of the breach
- cite the relevant legal reference(s) within the Hygiene Regulations, ensuring that this identifies the exact point or paragraph that places an obligation on the FBO, including the general obligation for the FBO to comply with the relevant provisions within the Annex(es) of the legislation where applicable; for example, Article 3 and Annex II, Chapter X, Point 1 of Regulation (EC) 852/2004
- where the contravention breaches various legal requirements, use the most relevant and specific provision where this exists; however, where there are no specific requirements, use a more generic references which applies to the contravention in question
- describe the measure(s) / action(s) in the AOs opinion the FBO must take to secure compliance with the contravention(s) identified earlier in the notice
- ensure the contravention(s), legal reference(s) and action(s) must all link to
 one another. The AO must not require the FBO to undertake actions or
 measures that were not identified as contraventions earlier in the notice
- set out a timescale which is a minimum of 14 clear days from the date the
 notice is served; it is important that if the AO identifies more than one legal
 reference and contravention, that these are of a similar theme and that the
 time frame for compliance is suitable for all issues

4.6.11 Drafting notices with more than one legal breach identified

A notice should generally only deal with one contravention. This will avoid potential problems if the Notice is appealed. If appealed, all of the issues cited on the notice will be held in abeyance until the court makes a determination on the validity of the Notice.

Where different contraventions need to be remedied within different time frames; for logistical and operational reasons, you cannot place separate time scales for different issues on the same notice.

The more contraventions that are cited in a Notice, the more complicated the Notice will be to draft, and it is more likely that an FBO may be confused by what the AO is trying to convey. This may also affect the validity of the Notice as it is important that enforcement requirements placed upon an FBO are **clear**.

The actions the FBO must take that are specified by the AO in the notice, they must be capable of curing all the issues cited in the contravention section. Failure to do so will make it more problematic to ensure that the actions the FBO must take, will secure compliance with all the relevant contraventions identified by the Notice.

It may be acceptable to cite more than one legal reference or issue on a notice, provided that:

- the legal references link to all the contraventions described by the AO
- they relate to the same theme
- the actions the AO requires the FBO to take are capable of curing all the contraventions identified in the notice and ensure all legal obligations are adequately dealt with.

4.6.12 Posting

Ideally, all HINs should be posted at a Post Office and a certificate of posting obtained. Where it is impractical to gain access to a Post Office the notice should be posted in a post box, corroboration obtained by a colleague where they are available, and a record made in the AOs pocketbook which should be countersigned.

4.6.13 Right of appeal

Recipients have a right of appeal against the service of a Hygiene Improvement Notices to the Magistrates' Court. During the appeal period, the requirements of the notice are suspended.

In the event of an appeal by someone who is aggrieved by the service of the HIN, the AO is to inform CSU York Transactions Team immediately, who will arrange legal representation through FSA Legal for the appeal hearing.

4.6.14 Requests for notice extension

If the FBO were to request an extension to a HIN, this request must be in writing and requested prior to the expiry of the notice. This will be an informal arrangement between the AO and FBO as there is no legal basis for the AO to extend the notice. It will constitute an informal undertaking by the AO not to refer the matter for investigation unless the FBO continues to be non-compliant after the agreed extension date.

Where there is a genuine reason for such an extension, the AO should discuss with the FBO the length of time required to comply and confirm their agreement to the extension in writing.

The AO must review the works carried out by the FBO after the agreed extension date specified in the letter has expired. They should either withdraw the Notice or refer the breach of the Notice for investigation; see below.

4.6.15 Failure to comply

Failure to comply with an HIN is an offence.

If the FBO has failed to comply with a notice, complete a Referral for Investigation report for the breach of the formal notice as well as a breach of the substantive offence that led to the notice being served in the first place.

Reference: See the topic 4.9 on 'Referral for investigation' for additional information.

4.6.16 Compliance and withdrawal

After the service of a HIN, the AO must check that it is complied with by the stated date.

Where compliance is achieved, the AO must confirm formally in writing that they are satisfied with the works carried out.

Measures that achieve the same outcome as those specified in the notice must be accepted as achieving compliance.

A template letter is available in Annex 4 to this chapter that can be used as the basis of a letter to the FBO where:

 the OV is satisfied that the action required in the HIN has been carried out and compliance has been achieved to their satisfaction, or

 the OV has served the HIN in error and/or it has to be withdrawn due to a technicality or is legally defective in some way.

Reference: See Annex 4 (a) and (b) for letter templates on 'Hygiene Improvement Notice and defective notice withdrawal.

4.7 Hygiene Emergency Prohibition Notices

4.7.1 Caution

Hygiene Emergency Prohibition Notices (HEPN) should only be issued after consultation with FSA Legal.

4.7.2 When to use

Issuing a HEPN should only be considered after discussion with the FVC, and where there is an imminent risk of injury to health that requires the backing of the court, for example, contamination of the potable water supply.

Reference: Specific examples and further guidance are given in the Code of Practice made under Regulation 26/Regulation 24 of the Regulations.

The HEPN must be served on the FBO by using the same procedures as outlined in the topic 'Hygiene Improvement Notices'.

Note: Limited timescales are imposed for the service of the HEPN on the FBO and the subsequent Notices required before the application to the court for the Order (see below).

4.8 Hygiene Emergency Prohibition Orders

4.8.1 Application process

The table below provides an overview of the application process for a HEPO.

Stage	Description
1	A HEPN must first be served on the FBO. It has an immediate
	prohibition effect on a process / equipment or the premises. Once served the AO should contact FSA legal to immediately arrange for a hearing at the local Magistrates Court.

	The AO must give the proprietor at least 1 full day's notice of their intention to apply to the court for a HEPO by serving a HEPN on the FBO. Once served the AO should contact the local court to immediately arrange for a hearing. Note: A copy of the HEPN must be affixed in a conspicuous position to the premises at which the notice relates.
2	The AO must apply for a HEPO from a magistrates' court with jurisdiction in the area where the plant is located. The application to the Court must be made within three days of the service of the HEPN. The day of the service of the notice is regarded as day one. There is no legal requirement for the application to be heard in three days, although the court should be asked to list the hearing at the earliest opportunity. Once made the HEPO supersedes the HEPN. The AO must also affix a copy of the HEPO in a conspicuous position to the premises at which the HEPO relates.
3	The AO must serve on the FBO a Notice of Intention to Apply for a HEPO at least one day prior to making an application to the Court for a HEPO.
4	Once a HEPO is granted, it supersedes the HEPN. The AO must also affix a copy of the HEPO in a conspicuous position to the premises at which the HEPO relates.
	Once the FBO applies, in writing, for the HEPO to be lifted, the application must be determined as soon as practicable and within 14 days. Once the AO is satisfied that the proprietor has taken significant steps to remove the health risk(s) specified in the notice, the OV should sign the withdrawal certificate at part 5 of the HEPN.
	Regulation: The Food Safety and Hygiene (England) Regulations 2013/ The Food Hygiene (Wales) Regulations 2006, Regulation 8.

4.8.2 Sources of advice

Advice should be sought from FSA Legal, who will assist in vetting the HEPN and preparation of the case prior to the court's hearing of a HEPO.

4.8.3 Evidence

Monitoring of the prohibition and any action taken by the proprietor must be recorded. Suitable evidence should be gathered prior to serving the HEPN for

production in court. A statement should be produced setting out the incident and evidence that supports the application to the Court.

4.8.4 Procedure

The table below shows the steps for an AO to follow when applying for a HEPO.

Stage	Description
Contact local court to arrange hearing	The hearing must take place within three days of service of the HEPN. On establishing dates and times, the AO must notify the FBO by serving a Notice of Intention to Apply for a HEPO.
Prepare for hearing	 Prior to the hearing the AO should: read all the relevant papers prepare to be questioned as a witness bring all relevant evidence to court The AO should also prepare three copies of: the HEPN the Notice of Intention to Apply the Complaint for a HEPO the draft HEPO duly completed and ready for signing by the Justice of the Peace The AO must monitor the premises whilst awaiting the hearing and record any breaches of the notice or changes in circumstances at the plant.
At the hearing	It is crucial that the AO gathers appropriate evidence at the time the HEPN was served and that this evidence is presented to the court.

Stage	Description
Court will	If the order is granted the AO should have produced a draft
decide	HEPO for signing by the Magistrate. The Order must then be
whether to	served on the FBO as soon as possible and a copy affixed to
issue the	the premises in a conspicuous place.
HEPO or not	

	Any breaches of the order whist in force should be recorded and evidence collected. The matter should then be referred for investigation.
Risk is removed	The AO must then formally cancel the HEPO by writing to the FBO. The withdrawal of such a HEPO must not be unreasonably withheld. Once the order has been complied with, the business can recommence the process / operation or use of equipment / the premises connected with their business.

4.9 Referral for investigation

4.9.1 Appropriate uses

An immediate referral for investigation is required in the following circumstances:

- Presentation of SRM on three or more occasions in any given 12-month period. However, if there are no incidents for a 12-month period, the hierarchy should be restarted
- SRM being consigned from the premises still attached to the meat (except in the case of VC being consigned to approved cutting premises)
- Where contraventions of the legislation have been escalated through their natural hierarchy and the FBO continues to breach the requirements.
- Where FBOs have failed to test bovine animals which require BSE testing
- contraventions of Regulation (EC) 1099/2009 and / WATOK, where avoidable pain, distress or suffering has occurred during handling or slaughter
- breaches of the European Regulations and domestic food safety or hygiene legislation leading to an imminent risk to public health
- obstruction of FSA personnel engaged in official duties
- failure to comply with any formal enforcement notice

4.9.2 Evidence

The AO must collect adequate evidence at the time of the offence before referring the matter for investigation.

Where a formal notice is being served, the AO must gather evidence at the time, to justify its service in case of an appeal and to evidence the original contravention of the EU requirements.

Evidence must be gathered again if the notice is breached, because breach of the notice is a separate offence.

The AO must identify the contravention(s) and update Chronos

Regard should be given to the Enforcement Policy and relevant codes of practice prior to any referral for investigation being put forward.

4.9.3 Referral to FSA Legal

Where the AO considers that an incident requires investigation, the matter will be referred to FSA Legal for an investigation to be undertaken.

Note: The process to follow when making a referral for investigation is detailed in the table in topic 4.11 on 'Protocol for a referral for investigation', in the table onwards.

4.9.4 Decision to prosecute

In England and Wales, the decision whether or not to prosecute for contraventions of hygiene and SRM rules is made by an experienced prosecutor in FSA Legal, having been investigated fully by an FSA Investigating Officer.

The decision to prosecute for contraventions in England of the animal welfare, TSE (RMOP and BSE testing) and animal by-product legislation will be made by a lawyer at the Crown Prosecution Service (CPS), on the basis of an investigation carried out by an FSA Investigating Officer. The decision to prosecute for contraventions of the equivalent legislation in Wales is the responsibility of the Welsh Government on the basis of an FSA investigation.

4.9.5 Rules of evidence

The AOs main task will be to gather of facts and evidence at the time of the offence, which may be used in court at a later stage. An AO must not attempt to conduct a full investigation as specific training is needed to ensure that the investigation is carried out in compliance with the Police and Criminal Evidence Act 1984 (PACE) (or equivalent) requirements. Only specially trained FSA

Investigation Officers conduct investigations. AOs must not attempt to caution or interview suspects or to take statements.

Note: Remember the requirement for corroboration in the Scottish courts.

4.9.6 Statements

Statements will be taken by an FSA Investigation Officer. They are a record of specific events an individual witnessed in a chronological order. They must refer to all relevant evidence and produce these as exhibits for the case, e.g.:

- photographs / videos
- physical samples
- · copies of notices
- copies of daybook entries
- copies of relevant parts of the FBOs HACCP plan

Exhibits are usually identified by the initials of the AO and then consecutively numbered. The IO will assist with numbering when preparing the final statement.

Note: Where the AO is satisfied that the action required or work specified in a formal notice has been completed, the date that it was completed should be specified in a witness statement and on the back of the copy notice.

4.10 Protocol for a referral for investigation

4.10.1 Protocol for a referral for investigation

The table below outlines the process and rationale for a referral by the AO for formal investigation.

Process	Rationale	
The AO is to discuss the issue with the	This will ensure that the entire	
rest of the inspection team (in	inspection team is aware of all formal	
slaughterhouses), where relevant when	enforcement action taking place at the	
the contravention occurs, and prior to	plant.	
completing Chronos and the 'Referral for Investigation'.	All members of the Inspection Team are Authorised Officers and must assist in all enforcement action as and when	

	required, including acting as a witness
	in court if necessary.
The AO is to ensure the inspection team is aware of any proposed enforcement action before the FBO is advised of referral.	This will forewarn and forearm colleagues that a contravention has been referred for investigation.
A summary of all enforcement should be shared at team meetings, detailing the stage to which any investigation has progressed.	The team as a whole will be more effective in identifying similar breaches, and no individual AOs will unknowingly condone activities that another AO has attempted to stop.
If advice is needed on the correct enforcement approach, the AO should consult their Contract Manager / FVC / or FSA Legal at an early stage if necessary.	Early advice will provide the necessary support to quickly address any queries regarding the enforcement approach. Likewise, it will avoid unnecessary mistakes, lead to a more consistent approach, reduce legal challenges, improve evidence gathering and ultimately improve the success of cases in court.
AO decision made to refer the case for formal investigation.	Remember that at this stage it is just a recommendation – the FBO is innocent until proven guilty in a court of law.
The AO is to collect all evidence relating to the referral	All relevant evidence must be identified, secured and supplied with the prosecution file to enable the referral for investigation to be considered by the lawyer assessing the case. In particular, photographs must be taken to assist the court, especially where the nature of the offence may be difficult to visualise and where the photograph proves the elements of the offence.
The AO is to send all evidence along with the ENF 11/6 and the latest FBO audit report, to the CSU at FSA York within 10 working days of the offence being identified and the AOs decision being made to refer for investigation.	Hygiene offences carry a 12-month time limit from when they are discovered by the AO; within which charges should be laid at the court. The time limit between identifying obstruction contraventions and laying charges at the court is 6

	months. The time limit between identifying animal welfare cases and laying charges is 6 months, beginning with the date on which evidence which the prosecution thinks is sufficient to justify the proceedings comes to the
	prosecutor's knowledge. The IO must be afforded enough time to investigate the offences identified.
Once received, CSU will acknowledge receipt of the recommendation and associated paperwork and allocate a unique number to the referral. This number will be notified to the AO in the confirmation email. (If confirmation is not received within 5 working days the AO should contact CSU.)	Confirmation will be sent to provide assurance that the documentation has been received.
Inform the FBO as a matter of courtesy	After a recommendation for investigation has been passed forward, it is inappropriate for Officers to pass comment on the potential outcome of any investigation under consideration.

4.10.2 Process to be followed

Process	Rationale	
If compliance is achieved after a referral for investigation has been made, the OV must record this, including compliance with any formal notice.	This will demonstrate the effectiveness or not of the operator's 'Due Diligence' systems and identify any defences or mitigation that the operator may wish to put forward.	
Where additional information is required, FSA Legal will request further details, to gain a better understanding of the issues involved.	Where evidence is lacking, the issue is complex, the approach taken by the AO requires further explanation. FSA Legal may contact relevant colleagues to ensure that a comprehensive and informed picture can be gained of the issues surrounding the referral.	

	T
This may include checking that:all the necessary evidence has been	To prove the elements of the offence beyond all reasonable doubt.
gathered	beyond an reasonable doubt.
the correct course of action has been taken	To stand up to legal scrutiny.
all formal notices have been correctly	To make sure that all the procedural
drafted and served	requirements relating to enforcement
	have been followed.
all formal notices must only request	To ensure that the notice is legally
the FBO undertake a course of	compliant and defendable in case of an
action required by the Regulations	appeal.
time limits within which	To ensure that long delays are not
recommendations should be put	holding up the recommendation
forward by the AO after an offence	process and the FSA does not have to
has been identified	defend any 'abuse of process
	arguments' by the defence alleging
	delays in investigating offences
the hierarchy of enforcement has	To ensure that all operational
been followed and the approach to	instructions in the MOC and the FSA
enforcement has been both	Operations Enforcement Policy have
reasonable and proportionate to the	been complied with.
contravention identified	
all formal notices have been correctly	To make sure that all the procedural
drafted and served	requirements relating to enforcement
	have been followed.

4.11 Referral for investigation: FSA Legal

4.11.1 FSA protocol

The table below outlines the process and rationale for formal investigation by the FSA.

Process	Rationale	
FSA Legal Services will review the referral and	FSA Legal will inform the AO and	
appoint an IO to formally interview the alleged	CSU, which IO has been appointed	
defendant(s), take statements from the	to each case.	
Inspection Team and any other potential		
witnesses.		
When the investigation is complete:		

 FSA lawyers will review all case files relating to hygiene and SRM contraventions Crown Prosecution Service (CPS) lawyers will review all welfare, ABPR and RMOP and BSE testing infringements in England Welsh Government will review all welfare, ABPR, RMOP and BSE testing infringements in Wales Potential actions could be: not enough evidence exists to pursue the case procedural errors have been identified and no further action is taken, but it is recommended that enforcement action is restarted it is not in the public interest to take formal action 		When a decision is made NOT to take the case forward FSA Legal
		will advise the AO / ITL and CSU.
Process		Rationale
The case is pursue prosecute the FBC	ed with a view to and/or defendants and ith the local Magistrates	When a decision is made to take the case forward to court, the IO must inform the AO / ITL and CSU prior to informing the FBO of this intention. This will ensure the Inspection Team is aware of the fact that the FBO will be facing formal action, so that they are aware of any potential conflict.

 When the case has gone to court and the outcome determined, this information will be cascaded back to the AO and CSU team through FSA Legal. Witnesses are not required to attend court when the FBO offers a guilty plea, however, the outcome of the case will be cascaded to all witnesses.

4.12 Change of FBO during enforcement action

4.12.1 New FBO

From the moment the new FBO takes over the establishment they are responsible for its condition and operation. Any enforcement action initiated prior to the change of ownership should be reassessed. Where the new FBO fails to immediately address any outstanding issues, these should be pursued by the AO, through the hierarchy in the normal way.

4.12.2 Re-issue of notices

In the event of the premises changing ownership whilst a formal Notice is still in force, the existing Notice should be cancelled because it will not be enforceable against the new FBO. If the new FBO fails to address the outstanding issues a hierarchy must be followed and a similar Notice may be necessary. Evidence must be regathered at the time the notice is served to justify the service of the new Notice.

The situation should always be reconsidered prior to re-issuing the Notice. The AO may have to justify to a court on some future occasion why they (re-)issued the Notice.

Note: Where the FBO has changed, the Approvals and Registrations Team should be informed so that an FVC can assess the new FBOs operating practices.

4.13 Warrant to enter premises

4.13.1 Access refused

An AO who has been refused entry to an establishment should contact their FVC/HOD immediately for further advice. In the event that access to an establishment is refused, it may be necessary for an AO to apply to a Justice of

the Peace, for a Warrant to Enter Premises, to gain access to carry out their duties.

FSA Legal should be contacted for advice on any refusal by the FBO to grant entry to an AO. Where there is a threat of violence, reference should be made to the bullying and harassment policy for guidance. A report must also be made to the local police force.

Examples of when it is necessary to apply for a Warrant to Enter Premises include:

- circumstances where the AO needs to enter to find out if there has been a contravention of any relevant legislation, or
- entry is required to find out if there is evidence of any such contravention
- reasonable access has been refused or the AO believes it will be refused,
 the AO has given the occupier notice of intention to apply for a warrant
- · the premises are unoccupied
- asking for permission, or giving notice of asking for permission would defeat the object of the entry
- where urgent access is needed

4.13.2 Execution of the warrant

The warrant must be executed within one month and is no longer valid once the AO has used it to gain access. It cannot be used twice. When executing a Warrant to Enter Premises in England or Wales, Code B of the Codes of Practice, made under the Police and Criminal Evidence Act 1984 (PACE), should be complied with. Legal advice on this and other aspects of the Warrant should be obtained **before** entry is attempted. FSA Legal will advise further.

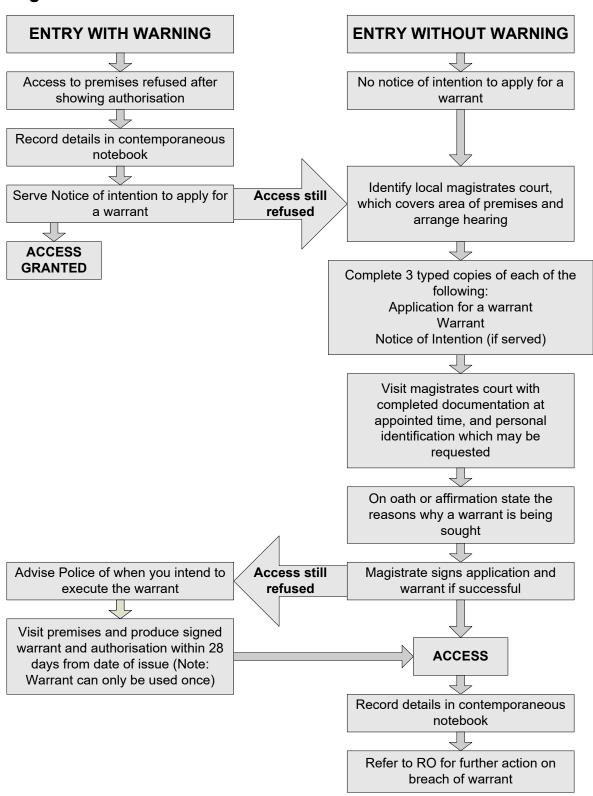
4.13.3 Access

Advise the local police of the intention to execute the Warrant at a certain time and date. The establishment must be visited as soon as possible and, on production of the Warrant to Enter Premises, the occupier should grant access. If the occupier fails to grant access, he or she will be in breach of the warrant. Record the events in the contemporaneous notebook and inform the FVC/HOD.

4.13.4 Forced entry

The Warrant to Enter Premises allows the use of force to gain entry when necessary. However, the AOs should never attempt a forced entry themselves, but should contact the Police for assistance.

4.14 Process for obtaining a warrant to enter premises in England and Wales



5. Risk Based Enforcement

- 5.1 Why a 'risk Based' approach: Legal references
- 5.2 Risk management
- 5.3 Risk assessment: Defining impact and likelihood
- 5.4 Recording procedure

5.1 Why a 'risk based' approach: Legal references

5.1.1 Introduction

The FSA adopts a risk based system of assessing public health and animal welfare risk in line with both legal requirements and codes of enforcement practice.

5.1.2 Risk analysis and risk assessment

Food safety and hygiene legislation makes various references to the competent authority applying a risk based approach to the delivery of official controls.

Regulation (EC) 178/2002, Article 6, Paragraphs 1 and 2 state:

'in order to achieve the general objective of a high level of protection of human health and life, food law <u>shall</u> be based on risk analysis, <u>except</u> where it is not appropriate to the circumstances or the nature of the measure', and that 'Risk assessment <u>shall</u> be based on the available scientific evidence and undertaken in an independent, objective and transparent manner'.

5.1.3 General rules on official controls

Regulation (EU) 2017/625, Article 9, 1 requires Competent Authorities to perform official controls on all operators regularly, on a risk basis and with appropriate frequency, taking account of identified risks associated with animals and goods, the activities under the control of operators, the location of the activities or

operations of operators, the use of products, processes, materials or substances that may influence food safety, integrity and wholesomeness, or feed safety, animal health or animal welfare, plant health or, in the case of GMOs and plant protection products, that may also have an adverse impact on the environment;

Any information indicating the likelihood that consumers might be misled, in particular as to the nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production of food;

The operators' past record as regards the outcome of official controls performed on them and their compliance with the rules referred to in Article 1(2);

The reliability and results of own controls that have been performed by the operators, or by a third party at their request, including, where appropriate, private quality assurance schemes, for the purpose of ascertaining compliance with the rules referred to in Article 1(2); and

Any information that might indicate non-compliance with the rules referred to in Article 1(2).

Article 9,2 - Competent authorities shall perform official controls regularly, with appropriate frequencies determined on a risk basis, to identify possible intentional violations of the rules referred to in Article 1(2), perpetrated through fraudulent or deceptive practices.

5.1.4 Risk based enforcement

Regulation (EU) 2017/625, Article 138,1 states:

When deciding which measures to take, the competent authorities shall take account of the nature of that non-compliance and the operator's past record with regard to compliance.

5.1.5 Enforcement concordat

As a signatory to the DTI Enforcement Concordat (See Annex 3), any enforcement action taken by the FSA should be proportionate to the risk. The DTI Enforcement Concordat: Good Practice Guide for England and Wales, also states:

'apart from taking a progressive approach, enforcement will mean applying the principles of risk assessment to enforcement activity, and enforcement

bodies should focus their attention on the most serious risks, or where potential hazards are least well controlled'.

5.1.6 Suspected breaches

Where breaches have been identified:

- persistent offenders should be identified quickly and face proportionate and meaningful sanctions
- regulators must act in a way that is proportionate to the risks as they understand them, except where immediate action is required

5.1.7 Risk based enforcement, not risk based compliance

FBOs have a duty to comply with the general hygiene requirements laid down in Annex II to (EC) 852/2004, (see Article 4) as well as specific requirements contained in Annex II and III of (EC) 853/2004, (see Article 3).

All legal references applicable to a risk based approach apply to the competent authority and not the FBO. Therefore, whilst the FSA must take a risk based and proportionate approach to enforcement, the FBO must comply with **all** relevant hygiene / welfare / by-product requirements and may not conduct a risk assessment and decide to comply only with certain areas that **they** consider to be medium to high risk.

5.2 Risk management

5.2.1 Purpose of a risk management system

The purpose of a risk management system is to communicate effectively between colleagues when describing and comparing risks and to ensure that the different components of the risk assessment process have been defined.

In this way, we can objectively compare both food hygiene and animal welfare risks at different premises, where FBOs employ different food safety management systems and have different attitudes towards compliance.

5.2.2 Defining risk

The risk assessment consists of two independent components:

- likelihood how likely is it, that the risk is realised
- impact how bad the outcome could be if it were realised

When describing risk, it is helpful to use the 'XYZ' model to help avoid ambiguity:

- that is, the 'risk' that a specific event or issue [X] occurs in the plant,
 - for example, the risk of microbiological contamination through offal being dragged across the floor
- because of a set of circumstances [Y] the 'likelihood',
 - for example, that there will be massive microbiological contamination on dirty slaughterhouse floors and offal are being removed by new staff member who has had no training
- resulting in [Z] the 'impact',
 - for example, food poisoning of consumers, from bacteria on offal leading to death in vulnerable groups

5.2.3 Examples of how to describe risk

Some more examples using the 'X, Y, Z' model are set out below:

High risk

- the risk that carcases with faecal contamination are produced [X], because
 the FBO does not have adequate systems in place to prevent dirty livestock
 from being slaughtered [Y], resulting in consumers getting food poisoning
 [Z]' Public Health Risk
- 'the risk that lairaged animals cannot lie down, stand up or turnaround without difficulty [X], because the FBO has used untrained staff without the necessary knowledge and experience to lairage animals [Y], resulting in animals being overcrowded and experiencing avoidable suffering [Z]' – Animal Welfare Risk

Low risk

- 'the risk that wrapped and packaged meat will become cross contaminated from contact with a wall with a cracked tile [X], because the FBO has not implemented an adequate maintenance programme to replace broken tiles that cannot be effectively cleaned [Y], resulting in the potential for consumers getting food poisoning [Z]' – Public Health Risk
- 'the risk that wrapped vacuum packed meat will become contaminated from contact with used packaging and from other environmental contamination

[X], because the wrapped meat is removed from a non-waxed box, that is not easy to clean, re- labelled and replaced in the same box [Y], resulting in the potential for consumers getting food poisoning [Z]' – Public Health Risk

5.3 Risk assessment: Defining impact and likelihood

5.3.1 Categorising impact

Impact can be categorised as:

- 1 = minor risk, technical breach with minimal or no implications
- 2 = moderate risk
- 3 = major risk
- 4 = catastrophic risk

5.3.2 Rate the impact

- Assess and describe the 'Reasonably Foreseeable Worst Case Impact' (RFWCI) for the event, but not the 'worst possible case scenario'.
- Rate the impact: 1 for a minor impact and 4 for a catastrophic impact.
- It is **not** a requirement to foresee bizarre events or acts of God.
- It **is**, however, a requirement to understand that many risks are 'reasonably foreseeable' through a pro-active approach to risk management.

5.3.3 Scoring the impact

The impact rating will be determined by:

- · the species of meat being processed
- the bacteria associated with that type of meat
- the intended customers of the FBO
- whether the customers are part of a vulnerable group

5.3.4 Categorising likelihood

Likelihood can be defined and categorised as:

- 1 = unlikely do not expect to happen
- 2 = possible may occur occasionally
- 3 = likely will probably occur
- 4 = has happened or is almost certain to occur

5.3.5 Likelihood factors

- Has the event occurred, or could it occur at any moment?
- Intensity (speed of the line, pressure by management for operatives to do the job, operative being paid per carcase and not by time).
- Numbers of staff (for example, volume of staff to train, competencies, turnover).
- Duration (how long does the activity take, does it require a long concentration span?).
- Accident, incidents, near misses (past history of the FBO).
- Supervision of staff.
- Environment, age of equipment, ventilation, maintenance.
- Complexity of operation multi species.

5.3.6 Recording likelihood data

When describing the likelihood factors, the account must be backed up with objective evidence. The likelihood should describe an unambiguous data driven account.

Gather and retain suitable evidence to demonstrate that the likelihood factors have been accurately considered.

5.3.7 Assessing likelihood

Impact and likelihood are treated as independent variables when undertaking a risk assessment.

Care should be taken to ensure that once the RFWC impact has been considered, you **do not** assess the likelihood of the RFWC factor (Z), for example, food poisoning and death occurring in consumers.

It is the likelihood of the risk being realised (X) that must be assessed, for example, assess the likelihood of carcases becoming contaminated within the plant that could potentially lead to the RFWC (Z) factor.

5.3.8 Rating likelihood

- Look at the likelihood data for the risk.
- Check that the data is related to the concern [X] and not the impact [Z].
- Rate the likelihood.

5.3.9 Risk matrix

The risk score is a multiple of the reasonably foreseeable worst case impact and likelihood factors that prevail at the specific plant in question resulting from the food safety management systems the FBO has in place.

7	Almost Certain	4				
hoo	Likely	3				
Likelihood	Possible	2	G	GA	AR	R
	Unlikely	1				
			1	2	3	4
			Minor	Moderate	Major	Catastrophic
				lmp	act	

G	Green
GA	Green / Amber
AR	Amber / Red
R	Red

Trend	
Unknown; baseline to be	-
established	
Situation Worsening; risk	R
increasing	
Situation Stable; risk	Α
unchanged	
Situation Improving; risk	G
decreasing	

5.3.10 Trend

Assigning a trend allows you to indicate whether the risk is increasing, unchanged or decreasing, even where the overall score on the matrix remains the same.

For example, where an overall score is 4x4=16, the FBO may have taken some corrective action to improve the process and initial indications suggest that this has started to work. In this case the trend could change to demonstrate an improving status, even though the overall risk score may still remain unchanged.

All risks in the red (R) and amber red (AR) zone should have appropriate countermeasures by the competent authority to manage both the likelihood and impact with actions by the FBO to address both.

5.4 Recording procedure

5.4.1 Recording requirements for risks scoring 4 to 16 (ENF 11/5)

All contraventions must be recorded on the Enforcement Programme, (ENF 11/5).

Reference: See chapter 9 on 'Forms' for ENF 11/5.

Where the assessed risk scores medium to high, between 4 and 16, the OV should progress the matter through the hierarchy in the normal manner, gathering evidence at the time the offence is identified.

Reference: See topic 2.6 on 'Gathering and preserving evidence' for additional information.

5.4.2 Exception reporting requirements: low risks scoring 1 to 3 (ENF 11/29)

Where it has been determined that the risk posed is low, with a score between 1 and 3, the:

- non-compliance must be recorded on the Enforcement Programme (ENF 11/5), evidence of the low likelihood factors must be retained, to justify the low-risk assessment
- the rationale for not escalating the non-compliance, perceived to be low risk, must also be recorded on the 'Risk Assessment For Enforcement Form' (ENF 11/29)

The assessment which details the appropriate evidence and backs up the likelihood factors will act as 'tangible' evidence of the decision making process that:

- justifies the reason for not progressing the non-compliance
- provides a rationale for colleagues to ensure a consistency of approach

Non-compliance should always be brought to the attention of the FBO. However, where there is no justification in escalating the issue, an entry should also be made in the 'Completion Date' column of the ENF 11/5.

Note: All issues identified as a low-risk (1-3) must be re-assessed at successive audit frequencies to identify any changes to the likelihood factors and at monthly frequencies in slaughterhouses.

Where the likelihood factors remain the same, record this in your contemporaneous pocket book or in the plant day book.

Note: Where the likelihood factors have changed and the risk has increased, the non-compliance must be re-entered on the Enforcement Programme (ENF 11/5), evidence must be gathered and the issue progressed through the hierarchy in the usual manner.

For example, an isolated maintenance issue that has no major impact on public health should be pointed out to the FBO and recorded on the ENF 11/5. Where the risk assessment results in a low-risk score, the matter can be recorded on the ENF 11/29 and closed off by cross referencing the ENF 11/29 with the Completion Date column in the ENF 11/5.

Where the unresolved maintenance issue becomes more serious or where other minor maintenance issues emerge that individually may not pose a major risk to public health, but cumulatively may lead to the deterioration in the fabric of the building, this will be indicative of a failure by the FBO to have in place and implement a suitable maintenance programme.

In such circumstances, it would be reasonable for all these matters to be reentered on the Enforcement Programme ENF 11/5 and escalated through to compliance.

Reference: (EC) 852/2004, Annex II, Chapter I, Para 1.

Other non-compliances that may constitute a low risk might include:

minor cleaning issues in non-production areas

- ABP transit bins that have been colour coded but not labelled appropriately with the category of ABP
- operatives not wearing the appropriate PPE (for example, snoods) in boxed meat areas
- other low risk issues the FBO has identified themselves through effective
 monitoring systems, that have not been rectified immediately, but for which
 the risk is being managed and a plan exists for the matter to be resolved
 and the appropriate improvements to their process is being implemented

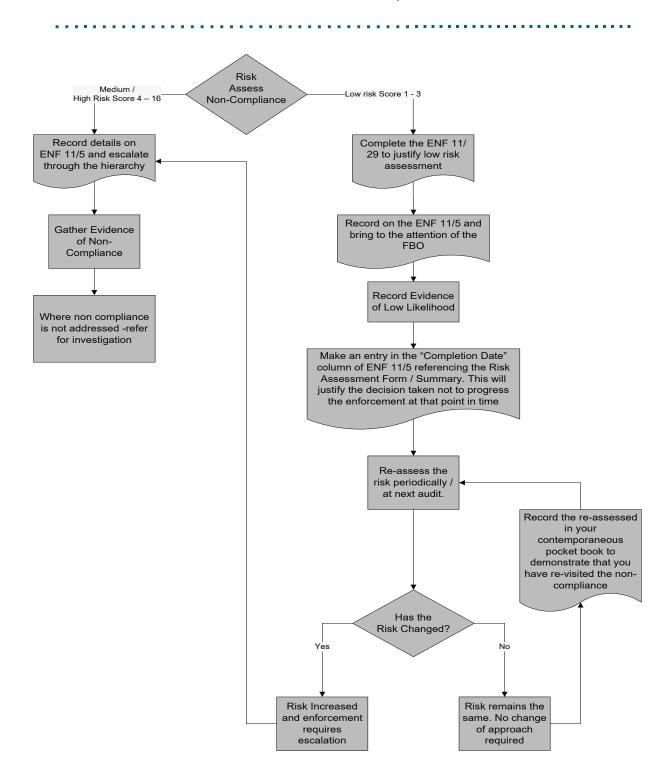
Reference: See chapter 9 on 'Forms' for ENF 11/29.

5.4.3 Audit

An audit trail must be established to demonstrate that the FSA is managing risk appropriately. Veterinary Auditors will review the risk assessment to satisfy themselves it provides the appropriate assurance and ensure the quality of documentation by monitoring the effective recording of evidence for low risk issues.

5.4.4 Risk assessment process

The flowchart below outlines the steps in the risk assessment process.



5.4.5 Reporting considerations 1: proactive risk assessment

An initial risk assessment should be undertaken when the potential risk is first identified. Where the risk is then realised because the event has occurred, a further assessment will need to be undertaken.

It is important that initial risk assessments are not undertaken in hindsight and that all potential risks are identified.

5.4.6 Reporting considerations 2: frequency v likelihood

The likelihood rating for non-compliances should not be scored low after the risk has already been realised.

Do not confuse **frequency** with **likelihood** and score the risk low because the event has only occurred infrequently.

If an event could happen at any time, or has already occurred, the likelihood score must be **high**.

The frequency with which an event occurs is academic, once it has happened.

5.4.7 Reporting considerations 3: FSA controls not a likelihood factor!

The likelihood of an event occurring should not result in a low score, when the FSA has an inspection point at a specific stage in the process that is able to identify a problem.

The presence of an FSA inspection point should not be used to mitigate the risk score.

The likelihood of an event occurring will not be affected by the presence of the FSA Operations Group. It is the FBOs systems and controls that are being assessed to determine the likelihood factor [Y], not the presence of the FSA carrying out an inspection checks at a particular point in the process.

5.4.8 Other factors to be considered

The FSA has identified certain high level outcomes that are to be achieved:

- · to limit food borne illness caused by meat
- to detect and control animal diseases
- to achieve high standards of animal welfare in approved establishments
- to facilitate the international trade of animal products
- meat entering the food chain is free from SRM

- animals intended for the food chain are tested for BSE / TSE where BSE testing is required
- meat from all animals tested for BSE / TSE does not enter the food chain unless tested negative
- meat from over age animals does not enter the food chain
- evidence of deliberate fraud

Where such contraventions are identified, that compromise these outcomes, the overall risk (reputational / business / public health / animal welfare) to the organisation will be high. As such these matters should always be recorded on the ENF 11-5 and progressed through the hierarchy.

5.4.9 ENF 11/29 risk assessment form

It is important that the FSA can objectively assess the consistency of risk assessments. To ensure consistency of approach, the Risk Assessment Form (ENF 11/29):

- must contain valid data
- must demonstrate the data can be tested and is true
- must be consistent and appropriate (for example, the impact is reasonably foreseeable, the likelihood is of the risk being realised)
- must demonstrate competent authority controls are proportionate to the risks

6. Intervention Protocol

6.1	Introduction
6.2	Strategic aims
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6.9	Medium risk establishments: Improvement necessary
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6.1 Introduction

This document provides guidance to HODs, OMs, FVLs, FVCs, Service Delivery Managers, and frontline teams on:

- Monitoring performance of approved meat establishments; and
- Action that should be taken in the event that an FBO does not put in place measures to raise levels of compliance with legal requirements.

FBOs can access this protocol.

6.2 Strategic aims

The goal of the Intervention Protocol is to safeguard consumers and improve public health by improving overall business compliance through:

- Targeting high impact intervention where risks to public health exist
- Seeking prompt compliance in high risk areas of non-compliance and targeting intervention.
- Provide a graduated and proportionate response to legislative noncompliance ensuring advisory and deterrent elements, along with the escalation of sanctions, where necessary, based on the level of noncompliance risk at individual establishments.

6.3 Background

As part of the intervention protocol, we want to ensure that all FBOs of approved meat establishments are complying with legal requirements and are taking responsibility for the production of safe meat. FSA resources and attention will be directed to non-compliant FBO establishments utilising non-compliances identified during official control activities outlined below:

- results of FBO audits
- findings from unannounced inspections (for example, routine or investigating complaints)
- establishment level inspection and audit findings (serious deficiencies or where evidence of repeated stoppage exists)

The protocol also brings in a process for recommending the appropriate withdrawal of approval as the ultimate sanction for poor performance by FBOs,

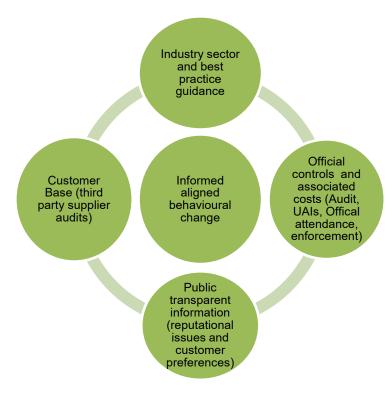
whilst taking an open and transparent approach to informing FBOs about what we are doing and why, in accordance with risk-based assessment methodology.

It will provide operational staff with clarity on when to act and what action to take. However, the FSA must take action quickly in the event of serious FBO non-compliances / or persistently contravening the regulations. Where a FBO fails to put in place the necessary measures leading to significant public health, animal health and welfare improvement, FSA officials will review their approval status where evidence exists indicating the presence of major or critical non-compliances. This could lead to their approval being withdrawn or suspended.

By gathering high quality evidence at the earliest stage via audits, unannounced inspections and regular official control activities, prompt intervention will be taken with the right enforcement actions.

Openness is one of the core principles of the FSA and underpins our strategic outcome that consumers and customers should have the information and understanding they need to make informed choices. Evidence suggests that consumer confidence and purchasing choice can also be a powerful incentive to drive up the standards of businesses.

Advice and education that can be applied will often secure sustained compliance as well as delivering a more cost-effective enforcement regime. Voluntary compliance is likely to be more sustainable in the long term than formal enforcement action as outlined in the following illustration:



6.4 Summary of risk rating

Actions taken by official staff will be driven by findings from audits, unannounced inspections and other official control activities. The FSA will use results from inspections and audit of FBOs to support informed tactical actions. Using these, we will

- escalate where necessary quickly the enforcement activity for high risk and/or persistent non-compliances; and
- Identify and prioritise criteria to assess risk-based planning and delivery of official controls.

Educational approaches should be considered at low and medium risk establishments and <u>FSA training materials</u> are available.

The table below presents a summary of tactical information on required actions, using the audit outcomes as a guide to plant level characteristics of compliance.

Compliance Category	FBO status	Intervention
Serious Risk	Approval will be formally reviewed if	intervention
Urgent Improvement	the outcome of Official Controls indicate the major or critical non-	Serious Risk category is the trigger for a formal review of approval.
Necessary (2 month audit category) Successive outcomes of Improvement Necessary	compliances are open	The FVL will conduct a preliminary examination of the results of official controls/local intelligence and identify the major and or critical non-compliances which have been evidenced and cross referenced with the Corrective Actions Report to see if they remain open.
		Where the critical/major non-compliances remain open The HOD will issue a letter to the FBO setting out the serious deficiencies which have been identified and providing the FBO with an opportunity to provide adequate guarantees over future production. The time provided for response to be commensurate with the major/critical non-compliances. FBO to be removed from audit cycle pending the response.
		FVL conducts an assessment visit once response is received/timescale for response elapses and makes recommendation whether to withdraw or suspend the approval or to allow the approval to remain if they are content the major and or critical non-compliances are resolved.
Medium risk	Major non compliances identified for which improvement is required by the time of the next full audit	Monitor via unannounced inspections (UAIs) in cutting plants and routine attendance in slaughterhouses and follow up audit visits. Advice FBO on educational

Improvement Necessary (3 month audit category)		programmes aimed at improving compliance (FSA training package). Establishment will move into the serious risk category if they are unable to improve sufficiently by the time of the next audit.
Low Risk Good / Generally Satisfactory (12 – 18 month audit category)	Compliant	Monitor via UAIs in Cutting Plants and routine attendance in slaughterhouses and follow up visits. Advice FBO on educational programs aimed at improving compliance (FSA training package) where conditions are deteriorating during interim audit period. Reasonable timelines to correct deficiencies.

6.5 Approvals

Approval of establishments must be kept under review by the competent authority whilst carrying out official controls (Article 148 of Regulation (EU) No 2017/625). This regulation also includes the requirement to include initiating action to withdraw or suspend the approval in certain circumstances (Article 138).

The process for a review of approval leading to a suspension or withdrawal is detailed in the FSA Operational Policy for the Approval of Food Establishments.

In this intervention protocol the FSA is strengthening the links between official control activities, enforcement, and review of approvals. Audit is a useful tool for risk-profiling premises. Having good quality audits / UAIs, and good quality enforcement action, will ensure that the right evidence is available to review approval, where there are concerns around non-compliance, repeated stoppages and/or deficiencies.

Activities / enforcement / approvals cycle



6.6 Identification for review of approval

Drawing on findings from the carrying out of official controls, or as a result of local intelligence, FVLs will have responsibility for initially assessing whether to undertake the process to initiate a review of approval in accordance with this protocol. Other matters which trigger a review of approvals are outlined in the

approvals policy, for example, fire. HODs have an overarching responsibility to make sure that appropriate action is being taken.

6.7 Additional controls

Past experience has demonstrated that introducing additional controls may provide an effective incentive to the FBO and deliver improvements in compliance. The HOD should consider whether additional official controls are required (up until satisfactory compliance is achieved), taking advice from the FVL / Coordinator. For example, an additional AO may be brought in to focus upon enforcement and hygienic production and practice, allowing the resident AO to continue to carry out daily duties. It will also ensure that public health risks are safeguarded ahead of any such review.

Charges for the cost of these additional controls may be made towards the FBO.

The HOD has ultimate responsibility for determining where additional controls should be put in place. The HOD should inform the FBO in writing prior to additional controls being introduced, explaining reasons for this action and that charges for these additional controls will be passed onto the FBO. Any changes to resourcing (for example, requirement for a second OV) should be communicated to the contract Area Veterinary Manager (AVM) and to the Head Office for the contract supplier in advance, in the normal way.

The Statement of Resources must also be amended by FSA Service Delivery Managers to reflect changes to resourcing.

When reviewing corrective actions taken by the FBO the following considerations must be taken into account:

- confirm what actions were taken and why, the appropriateness of the actions
- review any records that demonstrate the effectiveness of the corrective actions
- observation the changes; a follow-up inspection may be needed to confirm that the corrective action has been completed and is effective

Once appropriate action has been taken to address non-compliances, the additional resource should be removed and this made clear to the FBO, backed up by evidence from the FSA enforcement programme demonstrating improving conditions, Adjustments can then be made to the Statement of Resources.

The HOD should inform the FBO where normal resourcing is being re-established, drawing on advice from the FVL / Coordinator, with formal confirmation provided in writing. The contract supplier should be advised on any changes.

6.8 Low risk establishments

Low risk establishments will have audit outcomes of Good and Generally Satisfactory, with audit frequencies of 12 and 18 months (18 months for slaughterhouses only).

All premises must have at least one interim UAI. Field Veterinary Leaders should monitor the results of all UAIs and ensure enforcement action and/or official control activities are escalated accordingly and as per the Intervention Protocol.

The FSA reserves the right to carry out an early audit if the results of UAI or other enforcement action indicates compliance has significantly deteriorated since the last 'Good' or 'Generally Satisfactory' audit outcome.

Compliance Category	FBO status	Intervention
Low Risk	Compliant	Monitor via UAIs and follow up visit.
Good / Generally Satisfactory (18 and 12 month audit frequencies)		Advise FBO on educational programs aimed at improving compliance (FSA training package) any minor non-compliances with reasonable timelines to correct deficiencies in line with the FSA enforcement policy.

6.9 Medium risk establishments: Improvement necessary

Establishments entering into the 'Improvement Necessary' audit outcome will be subject to a further full audit within 3 months. In addition to this they will also receive a partial audit during that three-month period. This action is designed to drive up improvement in lower compliance premises by linking audit outcomes to follow-up action.

A letter will be sent to the FBO accompanying the audit outcomes report explaining the need for improvement and encouraging the FBO to look at their most recent audit report and/or UAI report (where applicable) and in particular the

Corrective Action Report and Enforcement Programme. These should identify key areas where the FBO needs to take action or make improvements. The FBO will be advised that a failure to exit the Improvement Necessary outcome by the time of their next full audit will result in a review of approval. See Annex 7.

Improvement Necessary establishments will be those which are exhibiting major non-compliances that are likely to compromise public health (including food safety), animal health and welfare, or which may lead to the production and handling of unsafe food if remedial action is not taken.

There is a role for the FSA as a regulator to work with FBOs to facilitate compliance. The key to a successful working relationship is communication. There is nowhere that this is more important than in relation to guiding the FBO on compliance with legal requirements.

Improvement Necessary premises have the following audit outcome profile:

Audit outcome	Definition	Non-compliance threshold
Improvement necessary	Major non-compliances identified at audit and/or non-compliances during the audit period not always responded to and corrected promptly.	3-6 majors during audit or during audit period No critical during audit period

The FBO will be required to tactically address non-compliance concerns over the next audit period.

Compliance Category	FBO status	Intervention
Medium risk	Major non-	Monitor via UAIs and follow up visits. Advise
	compliances	FBO on educational programs aimed at
Improvement	identified for	improving compliance (FSA training package)
Necessary	which	
	improvement	Establishment will move into the serious risk
	is required by	category if they are unable to improve
	the time of	sufficiently to exit the 'Improvement
	the next full	Necessary' status by the time of the next audit
	audit	

Medium risk establishments should be identified utilising official control activities and dealt with in order of non-compliance, for example, by prioritising premises which are demonstrating significant enforcement.

6.10 Serious risk establishments: Urgent improvement necessary

In line with audit outcomes, establishments can be identified as Urgent Improvement Necessary based on the severity and quantity of non-compliances.

Urgent Improvement establishments may have a critical non-compliance where the contravention poses an imminent and serious risk to public health (including food safety), animal health and welfare and/or multiple major non-compliances (as per MOC guidance) which are 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.

Audit outcome	Definition	Non-compliance threshold
Urgent Improvement necessary Successive outcomes of Improvement Necessary	Multiple major non-compliances or a critical non-compliance identified during audit visit, interim audit period or from the results of other official controls such as Unannounced Inspections. Official intervention required to ensure public health safeguards.	1 critical or >6 major non-compliances during audit or during audit period 3-6 majors during successive audits

Urgent Improvement Necessary interventions and procedures are of paramount importance and the FSA needs to escalate enforcement activity quickly to influence food business perceptions around risk and consequences of noncompliance.

6.11 Approach to FBOs identified as Serious Risk Establishments and support to frontline teams

Following an audit which places an establishment in Urgent Improvement Necessary or keeps them in Improvement Necessary, notification will be sent to the FBO by the Head of Delivery, this is to emphasis the seriousness of the FBOs current position following audit. The wording is provided at Annex 8. This letter will inform the FBO that they will now be subject to a formal review of approval if the Agency is not content the major/critical non-compliances identified in the audit are still resolved.

As a starting point, the FBO has a responsibility to operate in compliance with the regulations and should be encouraged to look at their most recent audit report and/or UAI report (where applicable) and in particular the Corrective Action Report and Enforcement Programme. An FBO may determine other ways of achieving compliance with the law as these may be equally valid.

The FVL will now have the responsibility to conduct a formal review of approval. The Corrective Action report and Enforcement Programme will be key in identifying the outstanding major/critical non-compliances.

Where the trigger point is identified from the outcome of an audit the review will initially be a desk top exercise considering the results of official controls to identify which major/critical non-compliances appear to be unresolved.

Where the trigger point is identified by the outcome of other intelligence the FVL will either conduct a similar desk top exercise or arrange an unannounced assessment to establish if major/critical non-compliances are present.

A letter identifying the issues found during the desk top exercise or the FVL visit will be drafted by the FVL on behalf of the HOD. This letter will explain to the FBO that they now have an opportunity to provide adequate guarantees over future production and will provide the timescale for which they need to provide these guarantees.

The HOD will then review the letter and if in agreement that a review of approval is now appropriate will send the letter to the Approval and Registration Team to issue the letter in the HOD's name and to update Establishment & People to show the establishment is no to be removed from the audit cycle.

HODs should also consider and authorise any additional controls recommended by the FVL, and/or UAIs within the interim audit period.

Any interim unannounced inspection should check the FBO is making progress against any agreed timescales. Any issues or concern over action being taken should be raised with the contract AVM in the first instance, as appropriate, or with the Field Veterinarian in the case of standalone cutting plants.

Following receipt of the FBOs guarantees the FVL should then visit the premises to verify the adequacy of the guarantees provided by the FBO.

The guarantee will be a clear undertaking of action by an FBO to permanently remedy the major/critical non-compliances which have made that FBO subject to this review. There must be clear evidence of the intended action, the timescale for implementation and the expected outcome.

Where the FVL is not content the major/critical non-compliances have been permanently resolved or the guarantees have not yet taken full effect a recommendation to withdraw or suspend the approval respectively will be made to the Head of Regulatory Delivery and Operational Transformation.

6.12 Dealing with adverse behaviour by the FBO

It is appreciated that, whilst many FBOs will respond positively and will want to put in place measures for improvement, others may react in a negative way. There is a wealth of <u>resources available on Digital Workplace on avoiding confrontation or aggression in the workplace</u>, including a code of conduct, and what to do when an incident happens.

6.13 Time recording

Cutting plant inspections by AOs should be coded to 'NOTH' (other non-chargeable time), although it should be remembered that if enforcement is necessary as a result of the visit (or subsequent visits) that this is chargeable to the FBO and should be coded to 'INSP' (official controls – inspection). Time spent on additional controls should also be recorded to 'INSP'.

At slaughterhouses, OV activities will typically form part of the normal official control duties and time should be recorded to 'INSP' (or other time-codes) as per guidance in the MOC. This should be time-coded to 'INSP'.

6.14 Routine monitoring

HODs should review action taken at establishments within their areas at their Operations Management Team meetings, drawing on advice from their FVLs.

Trends of compliance are monitored at a national level at the Field Management Group meeting. This includes a review of latest audit scores and changes to establishments that are identified as Serious Risk Establishments.

6.15 Support available

FVLs / Coordinators will ensure that support is in place for frontline teams and will liaise with the contract AVMs and AOs working at establishments identified as Serious Risk Establishments to ensure a consistent approach is taken.

The Head of Field Operations will offer guidance and support to the HOD and staff, as will legal and veterinary and technical colleagues.

Staff in the Operations Assurance Division's Delivery Assurance Team will issue relevant letters to FBOs and will also provide performance management information on activities in relation to Serious Risk Establishments.

The Operations Assurance Division's Business Support Team may also be called upon to provide administrative support to FVLs in the production of evidence packs.

The Operations Assurance Division's Approvals and Registrations Team will receive the review of approvals from the FVL and compile a submission to the Operations Head Veterinarian. This submission will provide a background to the case, referencing the FVL report and accompanying evidence.

6.16 Routine publication of audits and naming Urgent Improvement Necessary establishments on FSA website

The FSA publishes <u>results of FBO audits</u> on the FSA website.

If an FBO is not satisfied with a score awarded in any section of the audit report, the FBO does have the right of appeal against the outcome of the audit. Any appeals must be made in writing within 14 calendar days of receiving an audit report. There is a form to complete and the process is explained in the letter issued to the FBO, accompanying the FBO audit report.

Chapter 4 on 'Audit, HACCP Based Procedures and Verifying Operators Own Checks', sets out the appeal procedure. We will not publish an audit report on the FSA website until after an appeal process has been undertaken and the audit has been finalised. Necessary FSA interventions will continue during the appeal period.

6.17 Flowcharts

The process flowchart is available at Annex 11.

6.18 Review

These guidelines will be kept under review yearly and will be updated as required.

7. Annexes

Annex 1	Examples of enforcement of the EC Hygiene Regulations
Annex 2	Enforcement policy (Food.gov access click here)
Annex 3	Enforcement Concordat
Annex 4a	Template for HIN compliance letter
Annex 4b	Template for HIN/RAN cancel letter
Annex 5	Flow diagram: The treatment of animals, meat and food unsuitable for the human food chain
Annex 6	Supporting evidence photographic report template
Annex 7	Intervention Protocol - Improvement Necessary Outcome letter advising the FBO of the need to exit this status by the time of their next audit
Annex 8	Intervention Protocol - Serious Risk Category letter to FBO advising a review of approval may now take place
Annex 9	Intervention Protocol - Action letter to FBO providing an opportunity to provide guarantees over future production
Annex 10	Intervention Protocol - FVL Review of Approval Report
Annex 11	Intervention Protocol – Process flowchart
Annex 12	Chronos User Guide
Annex 13	Timestamp Camera App Guide