Manual for Official Controls: Amendment 103 Chapter 1 Introduction

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1. Background and Functions

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- 1.3 Contacts

1.1 Food Standards Agency

1.1.1 Food Standards Agency remit

The Food Standards Agency (FSA) is an independent Government body, established in 2000 to protect public health and consumer interests in relation to food.

The FSA is the national authority responsible for food safety and food hygiene across England, Wales and Northern Ireland.

FSA's remit includes:

- negotiations on behalf of England, Wales and Northern Ireland by legal experts and policy officials to ensure that retained EU law reflects the interests of consumers
- providing FBOs responsible for placing unsafe food on the market with appropriate advice to withdraw or recall it and working with other enforcement authorities to take appropriate action
- ensuring good food hygiene, through various initiatives delivered in partnership with Local Authorities (LAs)
- ensuring minimum standards of meat hygiene are maintained within approved slaughterhouses and meat establishments throughout Great Britain. In Northern Ireland, this role is carried out by the Department of Agriculture Environment and Rural Affairs (DAERA)

This guidance manual, the Manual for Official Controls (MOC), contains details of the tasks, responsibilities and duties FSA staff and veterinary contractors undertake in approved meat establishments.

This version of the Manual for Official Controls has been updated to take account of new EU Official Control requirements which came into effect on the 14 December 2019. It is important that FSA Authorised Officers, FSA and LA staff implement the legislation as set out in this manual.

Guidance on some aspects of the new Official Control package has not yet been introduced as these require more consideration. The FSA is working on this and as guidance is finalised it will be communicated to staff and included within the MOC. In the meantime, staff must continue to undertake official controls as outlined within the MOC.

The FSA's website is www.food.gov.uk.

1.2 Food Standards Agency Operations (meat hygiene)

1.2.1 Principal functions

The principal functions of FSA staff working in approved meat establishments are listed in the table below together with the Government department that holds the policy lead.

Function	Policy lead
Provision of meat inspection and health marking	FSA
Enforcement of food safety and hygiene legislation in approved slaughterhouses, cutting plants and game handling establishments, together with co-located plants, processing minced meat, meat preparations, mechanically separated meat and meat products.	FSA
Enforcement of controls over Specified Risk Material (SRM) and other animal by-products (ABP)	FSA, (TSE) Defra and Welsh Government
Enforcement of welfare at slaughter regulations	Defra and Welsh Government
Collection and despatch of samples for statutory veterinary medicines residue testing and testing of suspect cases	Defra, Veterinary Medicines Directorate (VMD)
Collection and despatch of sheep and goat brain stem samples for the testing of Transmissible Spongiform Encephalopathy (TSE)	Defra and Welsh Government
Supervision of Bovine Spongiform Encephalopathy (BSE) testing	Defra and Welsh Government
Collection and despatch of samples for examination and testing for some notifiable diseases	Defra, Animal and Plant Health Agency (APHA)

Provision of export certification when required by the importing authority or by retained EU regulations

Inspection of imported meat in approved premises

Provision of services to British Cattle Movement Service
(BCMS) for the Cattle Tracing System

Provision of other services on a repayment basis to other Service Level Agreement customers

Policy lead

Defra / APHA

Defra / APHA

Payments (Rural Payments Agency)

Other customers

1.3 Contacts

FSA teams:

Corporate Support Unit York Transactions Team (Tel: 01904 232177)

Approvals and Registrations (Tel: 01904 232060)

SLA and Contracts (Tel: 01904 232093)

FSA Helpline (Tel: 020 7276 8000)

Data and Performance

MOC Guidance Team

National Food Crime Unit (Tel: 0207 276 8787)

Throughput (Tel: 01904 232209)

Food Incidents Team (Tel: 020 7276 8448)

Imported Food Team

Other:

Department for Environment, Food and Rural Affairs

Animal and Plant Health Agency (APHA)

Find a relevant APHA regional office (Tel: 03000 200 301)

Local authorities:

Find a relevant LA office

Companies House (Tel: 0870 33 33 636)

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2. Relationships with Other Bodies

- 2.1 Introduction
- 2.2 Defra
- 2.3 Animal and Plant Health Agency
- 2.4 Local Authorities
- 2.5 Meat industry

2.1 Introduction

2.1.1 Stakeholders and customers

The FSA has many stakeholders and customers, primarily consumers and the public, but also including:

- other government departments and agencies
- health ministers in England, Scotland and Wales
- meat industry
- halal, kosher and religious slaughter groups
- staff and their professional / representative organisations
- Local authorities (LAs)
- farming industry
- animal welfare organisations
- competent authorities of other countries
- European Commission (EC)
- DAERA / Veterinary Public Health Unit (VPHU)

2.1.2 Service standards

Our approach to customers and stakeholders, including Food Business Operators (FBOs) and their staff, must be:

- courteous
- professional
- considerate

patient

FSA officials must always make a clear distinction between statutory requirements and recommendations of best practice. All advice and enforcement action should be proportionate and comply with the Enforcement Policy in Meat Plants.

Reference: For additional information see chapter 7 on 'Enforcement'.

2.2 Defra

2.2.1 Responsibility

Defra are the central competent authority for animal health and animal welfare legislation in England.

2.2.2 Defra executive agencies

FSA Operations carries out work on behalf of the following Defra Executive Agencies:

- Rural Payments Agency (RPA), which incorporates BCMS for cattle identification matters
- VMD for medicinal residues
- APHA for animal welfare, identification and disease control and monitoring

2.2.3 Work on behalf of Defra

The work that FSA undertake on behalf of Defra and its agencies is outlined in this chapter at section 1.2.

2.2.4 Contact information

Defra can be contacted via their website.

2.3 Animal and Plant Health Agency

2.3.1 Background

FSA Operations works closely with APHA on matters relating to animal welfare and disease control.

2.3.2 Contact information

More information on the <u>operational responsibilities and structure of APHA</u> can be found via their website.

2.4 Local Authorities

2.4.1 LA purpose

LAs provide services directly to local communities. These services include trading standards and environmental health.

2.4.2 LA Animal Health Enforcement Officers

County Councils, Unitary Authorities, Metropolitan Borough Councils and London Boroughs are responsible for the enforcement of legislation relating to the health and welfare of farmed animals. The Trading Standards departments within these authorities usually provide this service, but this is dependent on the individual structure of each authority.

LA Animal Health Officers are responsible for the enforcement of legislation related to the health and welfare of animals on farms and during transport. The legislation covers animal identification, animal movements, disease control, animal welfare, animal by-products, bio-security and contingency planning.

LA Food Officers may visit food premises and have right of entry.

2.4.3 LA Food Enforcement Officers

LA Environmental Health Officers are responsible for enforcement of all food safety and hygiene legislation in all registered and approved food establishments, except for slaughterhouses, cutting plants and game handling establishments requiring approval by the FSA and those approved meat processing plants colocated to slaughter, cutting and game handling premises.

LA's Trading Standards Officers are also responsible for all food standards enforcement, animal health and animal welfare in transport provisions.

Food establishments falling within the remit of the LA range from major national manufacturers to stand-alone cold-stores where the FSA is not present.

LA Food Enforcement Officers are also responsible for the prevention of illegal slaughter outside approved establishments, and for investigating food complaints from consumers.

2.4.4 FSA and LAs

Our officials work closely with LAs, particularly animal health Officers, Trading Standards Officers (TSOs) and Environmental Health Officers (EHOs). LA officers deal specifically with:

- welfare of animals in transit
- · confirmation of validity of cattle passports
- processing of animal by-products
- animal identification
- movement and documentation relating to animals
- bio-security
- beef labelling requirements
- · durability marking of food
- complaints from the general public relating to physical, chemical and microbiological contamination of meat
- issues relating to meat hygiene outside approved establishments

2.4.5 Relationships

Effective communication between FSA staff and LA enforcement officers is essential. Communication can:

- identify local risks, consumer complaints and concerns
- promote understanding of individual pressures and priorities
- facilitate successful enforcement activities that make the most effective use of local resource

2.4.6 Means of communication

Local communication channels between FSA officials and the LA officers must be maintained, for example:

- proactive and informal communication when LA enforcement officers are attending slaughterhouses
- maintaining ongoing discussions in relation to referrals or areas of common interest
- inviting FSA staff to LA regional meetings where appropriate, to discuss LA priorities and issues; FSA staff attending LA regional meetings where resource allows, and contribute to discussions
- considering possible joint local training opportunities, and sharing of information

2.4.7 Partnership working

Effective partnership working by the FSA and LAs will help achieve enforcement objectives and will ensure they are resourced effectively.

The FSA should always provide LAs with referral information at the earliest opportunity.

LAs should respond to the referrals at the earliest opportunity or advise when and how they will be able to respond. Where LAs are unable to respond straight away, the LA should offer advice to FSA staff on any immediate action (e.g. appropriate evidence gathering) required to ensure future enforcement action is successful.

LAs should proactively advise FSA staff on the outcomes of any non-compliance detected at a slaughterhouse and explain why such an enforcement approach has been taken.

2.4.8 LA food complaints

Periodically LAs receive complaints from consumers and retailers about meat, meat products / meat preparations / MSM produced in approved establishments.

In order that the matter is investigated, the LA should refer the complaint to Corporate Support Unit (CSU) at York.

CSU will assign an appropriate officer at the establishment concerned to investigate. The assigned officer will be provided with a Food Complaint Investigation Report for completion.

Once the investigation is concluded and the form completed by the assigned officer, it must be returned to CSU and any physical evidence handed back to the LA officer who referred the matter (observing all security and continuity of evidence issues).

2.5 Meat industry

2.5.1 Liaison with industry

As well as day-to-day dealings with FBOs, the FSA also liaises with industry representatives through their respective organisations.

3. Communication and Guidance

- 3.1 Lines of communication
- 3.2 Manuals and guides
- 3.3 Daybook
- 3.4 Official notebooks
- 3.5 Operations staff personal conduct
- 3.6 Authorisation documents
- 3.7 Modern Slavery & Human Trafficking (MSHT)

3.1 Lines of communication

3.1.1 Communication procedure

All staff follow a standard set of procedures when dealing with communications and queries. These procedures allow FSA Operations staff to work efficiently and effectively. There are situations where the lines of communication are different to those detailed here and are outlined in the relevant instructions.

3.1.2 Summary

The table below summarises the point of contact for technical advice, and also provides points of contact where non-technical advice is required.

Note: In Urgent Improvement Necessary establishments, technical matters should be discussed by the Field Veterinary Co-ordinator (FVC) and the contractor's Technical Manager (TM). The FVL should be involved in these discussions when necessary.

Advice required by **Technical Advice** Non-Technical Advice given by given by MHI OV Inspection Team Leader (ITL) cOV FVC (following their Refer to their contractor's TM contractors' procedure via their TM) eOV **FVC** ITL **FVC** FVL Operations Manager (OM) / Head of Operational Delivery (HOD) **FVC** Area Manager (AM) / OM ITL AM FVC OM / HOD **FVL** HOD OM

3.1.3 FBOs seeking advice

FBOs should be made aware that they should ask for advice in the first instance from their OV.

3.1.4 Technical advice for OMs / HODs

AMs / OMs / HODs should always seek technical veterinary advice from the FVC / FVL and / or FSA legal when making decisions relating to application or enforcement of official controls.

3.1.5 Internal Communication of Non-compliance reporting

When reporting an incident regarding any consignment arriving at the premises, which does not comply with the Regulations, the Authorised Officer (AO) must complete an Internal Communication of Non-Compliance Report (ENF 11/22).

Records of AO reports are monitored in York. This analysis allows the premises regularly dispatching non-conforming product to be identified and enables follow-up action to be initiated.

Reference: See chapter 9 on 'Forms'.

3.1.6 Liaison with other Authorities

There will be occasions where it will be necessary for the OV to contact other authorities, such as APHA, LAs, the Environment Agency etc. For ease of reference, the OV should be aware of their local points of contact.

The 'Farm to Fork' wall poster was issued to all FSA facilities in slaughterhouses may be used to record contact details for each Authority.

Reference: See Annex 1 for an example of the poster.

3.2 Manuals and guides

3.2.1 Manual for Official Controls

The MOC provides details of the tasks, responsibilities and duties FSA staff and veterinary contractors undertake in approved meat establishments.

Volume 1 contains detail of the official controls and forms.

Volume 2 contains relevant legislation.

The manual includes guidance for staff on:

- inspection
- · verification and audit
- health marking
- decision making and actions to be taken following official controls
- enforcement
- · sampling procedures
- monitoring and surveillance programmes

Note:

- 1. The OV is responsible for ensuring that all members of the team read and understand the instructions and is also responsible for making the FBO aware of any changes to the manual.
- 2. All staff must be aware of and follow the instructions in the manual unless there is good reason to depart from it. Where the guidance in the MOC is departed from the rationale for this should be clearly recorded.

3.2.2 User identifies requirement for MOC amendment

Users of the MOC may identify areas of the manual where they feel that an amendment to existing instructions is warranted. In this case, they should email the Guidance Team, providing full details of their suggestion for improvement or amendment.

The Guidance Team will evaluate the suggestion and commission to the relevant Portfolio Group.

3.3 Daybook

3.3.1 Daybook maintenance

An official daybook must be maintained by FSA staff at each approved establishment. The day and date of operation must be entered by the AO on arrival at the premises. All operational staff should contribute to the daybook when necessary. The daybook is the property of the FSA and must remain under official control at all times. The daybook should not be used in place of other operational records or to needlessly duplicate information recorded elsewhere.

After completion of the day's entries, the AO or Inspection Team Leader (ITL) should enter their signature then rule a line across the page, immediately below the signature. This is to prevent further, non-contemporaneous, entries being made.

3.3.2 Daybook access

All FSA operational staff must have ready access to the daybook. The OV should inform the FBO that they are entitled to read and make entries in the daybook and reasonable access should be provided.

3.3.3 Daybook security

The Daybook is FSA property and needs to remain under the control of the FSA or its SDP at all times. It is a requirement that the AO ensures that the Daybook is appropriately secured in a lockable storage unit where provided and available. In establishments where it has not been possible to provide a lockable storage unit, it may be appropriate to make local arrangements to keep the Daybook as secure as possible in an alternative location with the agreement of the local management team including the FVC. Those establishments should inform CBI to record them on a central record.

Evidence recorded contemporaneously in a Daybook, such as records of conversations with FBOs and accounts given by different AOs, is often essential evidence in a case and scanned copies of such entries are often used as exhibits. The defence is entitled to see the best evidence (the original version) of the Daybook to ensure the version being exhibited correlates to the original and has not been changed or added to. Therefore, it is vital that the security of the Daybook is maintained so any evidence within, is retained in its original form to comply with the Criminal Procedures and Investigations Act 1996 (CPIA). [See MOC Chapter 7, Section 2.5 for further guidance on gathering and preserving evidence in accordance with CPIA].

3.3.4 Other daybook functions

The daybook should be used to:

- record the health mark number(s) issued to or used by operational staff
- record the serial numbers of seals applied
- record the start and end times of regulatory duties
- record the time of the first kill and last carcase inspected each day,
 together with any relevant comments; inspection teams may choose to
 record specific times for each species slaughtered at their establishment
- create a daily record of significant incidents, events or actions which occur at the establishment
- · record specific actions taken by the FSA
- provide a means of communication between members of the operational team
- record details of non-compliances or offences that may become a source of evidence for legal proceedings
- · record details of enforcement action taken by operational staff
- record verbal technical advice given by Veterinary colleagues or management to all AOs or other operational staff

Note: Contemporaneous notes should be recorded in your personal official notebook where access to the daybook is not readily available. These notes need not be transcribed into the daybook although a reference to their existence may be made.

Reference: See topic 3.4 on 'Official notebooks' in this section for additional information.

3.3.5 Arrival and departure

For health and safety purposes all members of the FSA team and their visitors must print their name, designation and time of arrival and departure at the establishment. If necessary, extend the vertical lines by ruling down. After all expected staff have arrived, the ITL should rule across the daybook page leaving four blank lines to accommodate other FSA officials who may visit the establishment.

Note: These entries must be signed by the team member or visitor at the time of departure from the premises.

3.3.6 Use and recording of stamps

It is very important that Health Marks (HMs) are controlled to prevent fraudulent use. All stamps used by FSA staff working in approved establishments must be kept in secure storage when not in use and be recorded in the daybook when issued and returned.

3.3.7 Health mark stamp

All members of staff using a HM stamp must record:

- the number of the HM and the time of issue
- the time stamps are returned to storage

3.3.8 Guidance on daybook entries

All entries in the daybook may be disclosed, for example, to the FBO, and must be professional and courteous. The daybook is an open document, and it may be used as evidence in court.

Entries in the daybook:

- must not be written in offensive language
- must not be derogatory about any individuals
- · must adhere to the facts
- must state professional opinions that the author is prepared to defend in court if necessary
- must not be used to record disagreements within the team
- must not be used to record criticism of any FSA staff or policy

Daybook entries must be:

- indelible (in ink or ballpoint pen, not pencil)
- relevant
- factual
- legible
- concise
- unambiguous
- written in clear English
- contemporaneous
- signed with the person's name (not just initialled

dated

3.3.9 Record of incidents

The format to be used to record incidents should include:

- time of the incident
- description of the incident
- action taken, including details of evidence collected and held under official control and advice given
- names of FSA and FBO staff involved

3.3.10 Retention

In accordance with FSA retention policy, all daybooks should be securely retained for a period of 6 years prior to disposal.

Older daybooks should not be sent for disposal without the approval of the OM / HOD.

3.4 Official notebooks

3.4.1 Official notebook use

These are to be used for recording contemporaneous notes where the daybook is not readily available; for example, where an incident occurs in the lairage that requires facts to be recorded immediately or where the OV is making notes at a meeting with the FBO.

The use of the notebook is not to replace the plant daybook for recording of dayto-day activities and is only to be used for recording factual information, which may need to be presented in court at a subsequent prosecution.

3.4.2 Reference to notebook entries

Where information is recorded in an official notebook, this need not be transcribed into the daybook; however, an entry should be made in the daybook referring to the fact that notes have been taken.

3.4.3 Important points

The notebook may be inspected in court and the following guidance must be adhered to maintain validity:

record name on front cover, designation and date started

- make all entries with ink or ballpoint pen
- include only original entries and do not copy notes from elsewhere
- record the date and time at commencement of an entry, and upon completion
- enter the notes at the time 'the offence' is witnessed or as soon as possible afterwards whilst the facts are fresh in the memory

Note: Include names of other FSA staff present at the time

- if making alterations, strike a pen through the words and make the correction, initialling in left hand column; **notes must not be erased**
- do not remove pages from the notebook
- sign and date each entry at the base of each page
- do not use the notebook for any purpose not connected with your official duties.

The notebook may have to be produced in court and read by all parties so entries must be relevant, factual, legible, concise, and written in plain English.

3.4.4 Security

You are responsible for ensuring the security of your notebook and producing it in court. Further notebooks are available from CSU on return of your completed notebook.

3.4.5 Return of all notebooks

Notebooks remain the property of the FSA and must be returned prior to leaving the FSA or when requesting a further notebook.

3.4.6 Storage of completed notebooks

Completed notebooks which have been returned as above will be stored and may be required for evidence in the future.

3.5 Operations staff personal conduct

3.5.1 Staff conduct

All staff should adopt, maintain and demonstrate best practice in the course of their duties and conduct themselves in a professional way at all times.

The FSA takes incidents of bullying and harassment very seriously. Information, including policies and other resources, can be found on the FSA Intranet <u>Bullying</u>

<u>and Harassment</u> pages. **N.B.** These pages can only be accessed by FSA staff on FSA devices.

3.5.2 Health and safety

All employees will remain aware of their legal obligations and take seriously the responsibility for their own health and safety and that of other persons who may be affected by their acts or omissions. Information, including policies and other resources can be found on the FSA Intranet Health, safety and wellbeing pages.

N.B. These pages can only be accessed by FSA staff on FSA devices.

3.5.3 Personal Standards

Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.

Reference: Regulation (EC) 852/2004 Annex II Chapter VIII.

3.5.4 Personal hygiene

FSA staff are to:

- · wear white, clean protective clothing when handling exposed meat
- wear hairnets (and beard snoods if appropriate) to cover the hair of the head and where necessary the neck
- wear clean waterproof footwear
- wear designated waterproof footwear and lairage coats when working in dirty areas or with livestock
- not wear watches, jewellery (except plain wedding rings), aftershaves and perfumes in production areas

3.5.5 Operational hygiene

When working in an approved establishment, FSA staff must:

- keep personal equipment clean and change protective clothing as necessary
- use the proper hygiene facilities at all times and in such a way that there is no risk of contamination of meat
- wash contaminated aprons in the apron wash facilities
- · use a dedicated hygiene facility

- wash hands, or gloves, whenever they become soiled, and always after handling detained or rejected product
- use a rubber glove over a chain mail glove to reduce the risk of cross contamination
- use blue, food safe, waterproof dressings to protect cuts
 Note: some FBOs may require that dressings are also metal detectable.

3.5.6 Health status

FSA staff handling food or entering any food-handling area in any capacity where there is any likelihood of direct or indirect contamination must not be:

- · suffering from a disease likely to be transmitted through food
- a carrier of a disease likely to be transmitted through food
- afflicted, for example, with infected wounds, skin infections, sores or diarrhoea.

3.6 Authorisation documents

3.6.1 OA / MHI title

The (EU) 2017/625 official control package uses the title of Official Auxiliaries (OAs) for Meat Hygiene Inspection (MHI) staff.

MHIs can continue to use the title of MHI except when participating in enforcement action, when the title Official Auxiliary must be used. Authorisation certificates will also use the title Official Auxiliary.

3.6.2 Authorisation documents

FSA staff are issued with authorisation documents depending on their designations, together with photo ID cards for some staff.

There is a legal requirement that AOs must produce a "duly authenticated document showing authorisation" when requested to utilise their powers of entry etc.

Authorisation documents are now issued electronically as a pdf document. AOs have options of how they produce such a document if requested and this may be:

 By downloading the pdf document onto their phone and saving it, to be accessed if or when requested,

• By downloading the pdf document and printing it off as a hard copy, to be produced if or when requested.

AOs must have access to their authorisations document in hard copy or electronic form whilst engaged in official duties and be prepared to produce them on request. AOs must also ensure they possess all relevant authorisations for the type of establishment where they work and activities which they are performing.

When ceasing to work on behalf of the FSA, authorisation documents and letters of confirmation must be returned to their line manager.

Any lost or found authorisation documents must be reported to CSU.

3.6.3 Devolved administrations and other government departments

The FSA does not directly authorise officers for functions that are the policy area of Defra or the Welsh Government (except animal welfare). The FSA receives a delegated authority letter, that authorises its staff as "inspectors" / "persons" to act on their behalf. The general authorisation document provided, reflects the officer's authority to act on behalf of both the FSA and those other government departments.

3.6.4 Powers of entry

Authorisation documents provide evidence of the legislation under which they may act. This includes the officer's power to enter approved establishments at all reasonable hours to identify contraventions of the legislation under which they are authorised and for the performance of all statutory duties.

3.6.5 Action without authorisation

All officers acting on behalf of the FSA must never take enforcement action where they have not been appropriately authorised, as such action would not be valid.

If officers are in any doubt as to whether they are appropriately authorised, they should seek technical advice as detailed in the topic 'Lines of Communication' previously in this section.

3.7 Modern Slavery & Human Trafficking (MSHT)

Issues of MSHT as defined in the Modern Slavery Act 2015 may be encountered during the operation of food businesses. The indications of such offending taking place may be subtle, but present non the less.

Incidents of suspected MSHT may impact on the FBO, by way of criminal investigation; the consumer, by way of untrained/unqualified staff being involved in the production process and importantly the Potential Victim of Trafficking (PVoT).

Concerns and suspicions of MSHT incidents that do not cause food hazards should be reported to MSHCU Food Crime inbox immediately, or alternatively:

- your local Police force
- Modern Slavery Helpline (Tel: 08000 121 700)
- the Gangmasters and Labour Abuse Authority (Tel: 0800 432 0804)

MSHT incidents which have a direct cause of food hazards should be reported immediately to the Incidents Team.

In identifying signs of MSHT, consideration should be given to the following factors:

- FBO staff who live on site. This accommodation may be located within the FBO's premises or externally in temporary accommodation such as caravans, out houses and vehicles, or even just mattresses located in a room.
- FBO staff who appear to have been subject to physical violence or show fear when in the presence of management, allowing the management to answer questions directed at staff.
- FBO staff who are not in possession of their identity documents as they are held by a third party or are not receiving any wage for their work.
- FBO staff who are not allowed to leave the workplace and have little to no contact with the outside world including friends or family.
- FBO staff who do not appear to have access to health care, clean clothing or food and water.
- FBO staff who appear to be juveniles under the age of 18, working full time and living with persons who are not members of their family.
- FBO staff who are dropped off and collected for work always in the same way, especially at unusual times.
- FBO staff who are in a situation of dependence, maybe unfamiliar with the local language or show signs of control, which may include psychological control, (for example, through religion, witchcraft, juju).
- FBO staff who have no contract of employment and are unable to negotiate their working conditions, working excessively long hours, with little to no days off, do not have the correct protective clothing, training or professional knowledge to conduct their job.

• FBO staff who appear to be distrustful of authorities and act as if instructed by a third party.

4. Process Overview: FSA Approval of Establishments

4.1 Process overview

4.1 Process overview

4.1.1 Approval of meat establishments

Competent Authorities may grant approval to establishments handling, preparing or producing products of animal origin for which requirements are laid down in REUL 853/2004.

Under the food hygiene legislation, meat plants require approval unless they benefit from specific exemptions.

4.1.2 Type of establishments

The meat establishments listed below are subject to REUL 852/2004 and REUL 853/2004 and must be approved by the Agency, in order to operate, unless they meet the exemption criteria:

- Slaughterhouses
- On Farm Slaughter facilities
- Game Handling Establishments
- Cutting Plants
- Meat Wholesale Markets

These establishments are subject to official controls enforced and executed by the FSA in England and Wales

In England and Wales where establishments are co-located with an approved Slaughterhouse, Cutting Plant or Game Handling Establishment, then the following associated **meat** activities are also approved by the FSA. In the case of such establishments operating in a stand-alone capacity, they are approved by the LA:

- Minced Meat Establishments
- Meat Preparations Establishments

- Mechanically Separated Meat Establishments
- Processing Plants (Meat products, Rendered animal fats & greaves,
 Treated stomach, bladders & intestines, Gelatine and Collagen)
- Cold Stores
- Re-wrapping / re packaging establishments

Where an approved meat establishment in England and Wales is also handling other products of animal origin (OPOAO) the Agency, in liaison and agreement with the relevant LA, may approve all operations requiring approval under REUL 853/2004 and undertake official controls. Such approvals which remove the need for dual enforcement by the FSA and LA will be determined on a case by case basis.

In order to provide a recommendation for approval for the processing of other products of animal origin (such as fishery; egg; dairy; processing) the Field Veterinary Leader needs to gain agreement, from the Veterinary Audit Lead in Operations Assurance and the Head of Delivery responsible for the Approvals process, that the FSA has an appropriate level of local knowledge to be able to deliver Official Controls for the activity. The FSA will for instance need to consider the complexity of the activity, the level of throughput and previous compliance level of the FBO. If the FSA is not content to deliver the Official Controls for this additional activity, the responsibility will default back to the LA.

Where an approved establishment undertakes cold storage of brought – in products of animal origin, the approval document should reflect the cold storage activity in addition to all other activities undertaken within the establishment.

Establishments that cut raw meat exclusively for the manufacture of meat products, minced meat, meat preparations or mechanically separated meat, require approval in respect of their manufacturing activities. They also need to comply with the requirements of Annex III of REUL 853/2004, including those relating to cutting plants. However, because they do not place the meat they cut on the market as fresh meat they will not require approval as a 'cutting plant' and therefore do not require veterinary control.

4.1.3 Governance

Approval assessments and recommendations in England and Wales are provided by veterinary officials in the FSA field management structure. Decisions on approval are made by a Senior Civil Servant. In the absence of a suitable Senior Civil Servant, decisions may be delegated to an AO within the Operational Assurance and Transformation Team (OAT).

The official responsible for decisions may convene a panel to assist in their deliberations. The panel will consist of, or a representative of; the Head of OAT, FSA Legal, and the veterinary official making the recommendation. The panel will typically be convened in cases which may result in a refusal to grant approval or a withdrawal of approval.

There is a separation of functions between the officials involved in assessments, recommendations and decisions on approvals and the officials responsible for conducting the audits of approved meat establishments.

The authorised officials work in collaboration and base their decisions upon the recommendation and evidence presented by the veterinary official who conducted the approval assessment, together with other relevant information available, such as the outcomes of recent official controls.

4.1.4 Exemptions from approval

Regulation (EC) No 853/2004 provides certain exemptions from approval. In terms of establishments for which the FSA may need to consider for approval the exemptions fall into the following basic categories:

- Retail Establishments
- Poultry Slaughter and Cutting on Farm
- Slaughter for Private Domestic Consumption
- Wild Game

Full details of these exemptions are provided in **Annex 6**. For retail establishments, the flow diagram in **Annex 7** can be used to determine if the operator qualifies for exemption from the need to be approved.

4.1.5 Advisory visits

The FSA offers advisory visits to those food businesses that have applied for approval prior to an approval visit. The aim of an advisory visit is to help FBOs identify any problems in the areas of structure and maintenance and food safety

management to avoid any potential difficulties when the establishment is assessed for approval. The FSA will apply a fully recoverable charge for all advisory visits.FBOs must be aware that there is a difference between an advisory visit and an approval visit.

The FSA reaffirms that the FBO will not be able to undertake activities, that are approved by the FSA, until an approval visit has been carried out and a decision following such visit has been formally conveyed to the FBO.

More <u>advice on the cost and the type of guidance</u> which is available in an advisory visit can be found on our website.

4.1.6 Applications for approval

Application forms are also available to download from the <u>FSA website</u>. An FBO can only make an application for approval for an establishment under their control and only for processes and/or activities that they intend to carry out.

The applicant must provide details of:

- the premises for which approval is requested;
- · the activities and species for which approval is sought; and
- the identity of the FBO including relevant contact and address details.

A food business operator means the **natural** or **legal** persons responsible for ensuring that the requirements of food law are met within the food business under their control.

- A natural person is a human being, (as opposed to an artificial, legal or juristic person, i.e., an organization that the law treats for some purposes as if it were a person distinct from its members or owner).
- A legal person has a legal name and has rights, protections, privileges, responsibilities, and liabilities under law, just as natural persons (humans)
 do. Legal personality allows one or more natural persons to act as a single

entity (a composite person - considered under law separately from its individual members or shareholders) for legal purposes.

4.1.7 Past Compliance History

The FSA will take into account past compliance with the requirements of food law, animal health and animal welfare rules as a relevant factor and this may be used as an indicator of likely future compliance with the requirements of food law. This will include past compliance by the applicant and any relevant person.

In assessing compliance with the requirements of food law, the FSA will use the following criteria, as relevant:

- The potential consequences for the objective of achieving a high level of consumer protection with regards to food safety and food hygiene;
- Potential consequences for legitimate business;
- The culpability of the applicant and whether any contraventions were the result of deliberate acts;
- Whether any prior warnings, advice and/or guidance have been provided and the response to this¹;
- Whether the applicant record demonstrates repeated failures of infrastructure, procedures or management controls;
- Whether the applicant has been reticent in explaining circumstances, has been uncooperative or abusive to FSA staff and those from its contractual services providers, for example, OVs provided by Eville & Jones or DAERA;
- Whether the applicant has previously had an application for approval refused or conditional approval not extended, full approval refused, or either conditional or full approval withdrawn, and the circumstances in each case;
- Whether the applicant has been convicted of a relevant offence;
- Whether there has been a failure to disclose any relevant offences;
- Repeated significant and / or numerous non-compliances continuing without regard to warnings or advice.

¹ This could include a reference to any Day Book or enforcement programme entries made that evidence advice/guidance given.

Applicants are also required to disclose in their application any relevant conviction against themselves or other relevant persons. 'Relevant person' is the person applying for the approval and any person connected to the applicant and includes:

For companies:

- the company itself
- the officers of the company (a director, manager, secretary or other similar officer)
- other companies, when the officers of the company were officers of that other company when they were convicted.

For partnerships and limited liability partnerships (LLP):

- the individual partners
- · the individual partners in the limited liability partnership
- partners within a partnership or limited liability partnership that have either been convicted of a relevant offence themselves, or who held a position as a partner, or partner in another LLP or corporate body when it was convicted of a relevant offence

For individuals:

- the individual
- companies for which the individual is an officer (a director, manager, secretary or other similar officer)
- partnerships and limited liability partnerships that the individual is a partner of

Offences that are relevant are set out in Annex 4. The FSA must take into account the terms of the Rehabilitation of Offenders Act 1974 and the applicant does not need to disclose 'spent convictions' covered by that Act. The Act applies only where an individual has been convicted of an offence. However, where the person convicted is a corporate body, the FSA should have regard to whether the conviction would have been spent if it had been committed by an individual and should normally treat the corporate body in the same way.

If during checks the FSA discovers a relevant conviction against the applicant which has not been disclosed, the FSA may refuse the application or the FSA may contact the applicant which will delay the decision to approve or otherwise.

Refusal of approval would normally be appropriate for offences that demonstrate a deliberate disregard for the requirements of food law, animal health and animal

welfare rules, for example where there are repeated convictions, (or deliberately making false or misleading statements).

If it thinks it right to do so, the FSA may still decide to grant conditional approval or full approval even though an applicant has demonstrated a poor record of compliance with regulatory requirements such as being convicted of a relevant offence.

4.1.8 Approval procedure

Article 148 of REUL 2017/625 provides that competent authorities;

- shall establish procedures for food business operators to follow when applying for the approval of their establishments in accordance with REUL 852/2004
- on receipt of an application for approval, shall make an on-site visit
- shall approve an establishment for the activities concerned only if the food business operator has demonstrated that it complies with the relevant requirements of food law

Following an on-site visit:

- the FSA may grant conditional approval if the establishment meets all the infrastructure and equipment requirements. The food business may not have a fully developed and documented HACCP based procedures but the planned method of operation must not constitute a risk to public health and there must be adequate provision to control any such risks that have been identified. This is particularly so for high risk food items such as ready to eat meat products and minced meat/burger intended to be eaten less than thoroughly cooked. The FBOs food safety management system needs to be available to the FSA.
- full approval shall only be granted where it appears from a new official
 control visit, which must be carried out within three months of conditional
 approval, that the establishment meets all structural and equipment
 requirements and other relevant requirements of food law, including the
 need to implement an effective food safety management system based on
 HACCP principles

- if clear progress has been made but the establishment and food business still does not meet all of the relevant requirements, conditional approval may be extended, but must not exceed a total of six months. In such cases the establishment must still meet all the infrastructure and equipment requirements
- the Agency shall grant full approval if the establishment and food business complies with all the relevant requirements of food law (infrastructure, equipment and operational requirements) and the establishment has been observed in operation

Full approval subsequent to conditional approval will be refused:

- if, within the three months' conditional approval, insufficient progress has been made to meet the requirements in full and, in the judgement of the FSA, there is insufficient evidence to demonstrate that the necessary work will be completed if a further period of conditional approval is granted, conditional approval will cease to have effect
- if, at the end of the six months period there is insufficient compliance with structural, equipment or operational requirements and other relevant requirements of food law, including the implementation of an effective food safety management system based on HACCP principles

Approval will be **discontinued** if, following conditional approval and before consideration can be given to recommend full approval or prolong conditional approval the establishment ceases operations or a visit cannot be undertaken caused by the relevant activities not being in operation. In such cases conditional approval will cease to have effect.

In between each period of conditional/extended conditional approval the FSA may conduct unannounced visits to check the food business compliance with operational hygiene requirements. Evidence of non-compliance with these requirements may result in appropriate enforcement action and may be used as evidence in the final decision whether to grant or to refuse to grant full approval

In the event that a decision to refuse to grant approval is made, the FBO must be given notice of the decision, the reason why the decision was made and a list of deficiencies that were noted at the time of the visit, including the requirements of the legislation in relation to hygiene, structure, HACCP or other elements relevant to the type of approval being sought and show how the FBO has failed to satisfy those requirements. The FBO of an establishment that has been refused approval has the right to appeal. From the date on which notice of the decision to refuse approval is served on the relevant person, the establishment must cease approvable activities regardless of whether an appeal is logged.

4.1.9 Approval assessments and visits

On-site visits undertaken with a view to the approval of premises will be undertaken by a Veterinary Official. The Agency will make an appointment with the FBO or their duly authorised representative. Following an approval visit the Agency will make an assessment of the compliance with the approval requirements for the premises and FBO controls.

Following conditional approval, measures must be taken by the FBO within the conditional approval period to remedy any operational or food safety management system deficiencies on a permanent basis. The initial conditional approval period of up to three months may only be extended for a further period if progress is made to remedy any deficiencies during the initial period and if, in the judgement of the Agency, there is evidence that the necessary work will be completed if a further period of conditional approval is granted. The total period of conditional approval cannot exceed six months; at the end of the conditional approval period, all aspects of compliance will be reassessed.

Although conditional approval may last up to three months or if extended up to a maximum of six months, assessment for full approval may be undertaken at any time after conditional approval has been granted.

Before full approval can be recommended, the food business must be observed in operation to verify that it meets all the requirements of food law, and other relevant legislation as required for the type of approval.

Where the slaughter of all species requiring approval cannot be reasonably seen on an approval visit professional judgement can be used. When the veterinary official reaches a point where they are satisfied with infrastructure, equipment and the FBO controls they should recommend approval, even if every species has not been observed in operation.

4.1.10 Seasonal Establishments

In the case of establishments operating a seasonal pattern, conditional approval may be split into two or more periods as long as the combined period does not exceed six months. Wherever possible the FSA will aim to conclude the approval process within one season even if it means that conditional approval will last for less than the allowed three or six months. However, where this is not practicable conditional approval may be split.

In these cases the veterinary official undertaking the assessment must satisfy themselves that:

- It is practical to split the approval across one or more seasons and any potential risk to public health is managed;
- Measures will be taken by the FBO within the expected conditional approval period to remedy any operational or food safety management system deficiencies on a permanent basis; and
- Full approval is achievable within two years

4.1.11 Allocation of approval number

On granting approval or conditional approval the FSA will give each approved establishment an approval number. For wholesale markets, secondary numbers indicating units or groups of units may be added to the approval number. The approval number should be unique to the establishment / wholesale market and FBO during the period they are approved.

The following numbering system for regional variations in allocating approval numbers, to establishments approved by the FSA / FSS, will apply:

- England 1000-1099, 2000-6999 & 8000-8999
- Scotland 1100-1999
- Wales 7000-7999
- Northern Ireland 9000-9999

In the case of individual units at wholesale markets, the approval number will consist of the approval number for the common parts and a secondary number that is stall-specific. The secondary number allocation is applied to help overcome problems with enforcement, traceability and differing standards of compliance between the different FBOs operating within the wholesale market.

Where an establishment premise has been re-assessed for approval due to a change of FBO and approval is granted, generally a new approval number should be given. However, to have regard to issues of risk, cost and proportionality, a business may be able to retain its approval number where, other than for the change of FBO, the business is to continue to operate from the same premises and in essentially the same way, i.e. the type of food production by the business and the food safety control arrangements of the business will remain essentially the same.

If the FBO moves to a new premise the FSA may allow the FBO to retain the same approval number which was provided to them for the establishment which they are vacating. This will be subject to remaining with the same CA and the same country. The FBO will also still be required to submit a new application and be granted approval prior to operations commencing in the new location. In order to ensure that the approval number remains unique the previous approval will need to be surrendered by the FBO prior to it being granted for the approval at the new address.

In addition to the above, re-allocation of an approval number would only be permissible where the FBO of the business remains the same, and the activities remain substantially the same, when the establishment moves to a new location.

Where an establishment is approved in England or Wales by the LA and the FBO is subsequently granted an approval by the FSA, due to the establishment becoming co-located, the FSA will issue a new approval number to the establishment as a whole. In order not to penalise FBOs in this situation, upon

request, a reasonable period of time (but typically not exceeding the conditional approval period) will be given for the business to use up old packaging. The request will be dealt with on a case by case basis in conjunction with the LA.

4.1.12 Food businesses transferring from LA control

Until conditionally approved by the FSA, responsibility for enforcement action remains with the LA. When assessing for approval the FSA, where possible in consultation with the relevant LA will consider whether any enforcement action for the protection of public health is needed and communicate this to the relevant LA.

With the industrial nature of the processes and likelihood of daily damage to structure and equipment, it would be unreasonable to expect any already operating premises to have all infrastructure and/or equipment fully compliant without the need for maintenance. Where the FBO can demonstrate that infrastructure and/or equipment deficiencies have been identified and scheduled for repair in a way that manages any potential risk to public health, dependent on the nature and extent of the deficiency (i.e. minor / operational wear and tear), approval or conditional approval may be recommended.

Registered establishments under Regulation (EC) No 852/2004 taking advantage of the exemption criteria and applying to undertake activities that are approved by the Agency, may be recommended for full approval following the initial approval visit. This can only be the case where the establishment and FBO controls have be observed in operation and complies with all the relevant requirements of food law (infrastructure, equipment and operational requirements) and any other relevant legislation as required for the type of approval.

The FBO will not be able to undertake activities, that are approved by the FSA (in this case working outside of the exemption criteria), until approval or conditional approval is granted.

4.1.13 Wholesale Markets

Wholesale markets are defined in Regulation (EC) No 853/2004 Annex I as food businesses that include several separate units which share common installations and sections (such as access corridors, loading bays, changing rooms, toilet facilities and water supply etc) where foodstuffs are sold to food business operators.

The common parts of wholesale meat markets must be approved as one establishment while individual stalls under the control of separate food business operators must be approved in their own right and receive an approval number consisting of the approval number for the common parts and a secondary number that is stall-specific.

Responsibility for complying with the Hygiene Regulations rests with the landlord of the market for the general areas within the market and with the individual food business operators for the unit(s) that they operate. However, FBOs for individually approved units have a duty to ensure that the common area requirements, providing the pre-requisites for hygienic operation such as waste disposal and pest control, are in place.

4.1.14 Multiple FBOs operating from one establishment

Where more than one FBO wishes to use a single premise to operate separate food businesses at different times, for example FBO A operates 09:00-17:00 and FBO B operates 17:00-09:00, approval may still be permitted but these situations will be assessed on a case by case basis.

The FBO/s for the individual businesses requiring approval using one premise will need to demonstrate how they plan to manage any food safety risks adequately. When undertaking the assessment the Agency must be satisfied that infrastructure, equipment and the FBO controls are acceptable before approvals can be granted. The arrangements regarding the operating pattern and joint use of the premises will be included in the approval document as a precondition to the approval.

Where the arrangements are satisfactory, approval or conditional approval will be granted to each FBO individually with each FBO receiving their own approval number.

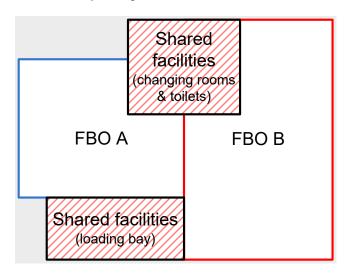
When carrying out official controls, if the CA needs to take enforcement action, for example due to non-hygienic operations or equipment deficiencies, this may be taken against both parties. As the terms of the joint use of the establishment are a precondition to the individual approval enforcement action must be taken against both parties regardless of which party caused the problem in the first place.

4.1.15 Shared facilities

In the event that an FBO requiring approval to operate an establishment can only fully meet the requirements of the regulations by sharing certain facilities with a neighbouring FBO, approval may still be possible. These situations will be treated on a case by case basis but examples would include sharing facilities such as changing rooms, toilets, loading bays and chillers.

The FBO requiring approval using shared facilities will need to demonstrate how food safety risks are managed. When undertaking the assessment, the CA must be satisfied that infrastructure, equipment and the FBO controls are acceptable before approval can be granted. Shared facilities will be identified in the approval document and marked on the site plan

An example layout of shared facilities



Where the arrangements are satisfactory, approval or conditional approval will be granted on the basis that the facilities being shared remain available and the requirements of the regulations continue to be fulfilled.

If at a point in the future the sharing of facilities is no-longer possible, the approval will be reviewed. Also refer to **Review of Meat Establishments Approval with the view to Withdraw or Suspend** section. Where either FBO is able to become self-sufficient in their own right, separate approval as an individual establishment can be sought.

When carrying out official controls, if the CA needs to take enforcement action, for example due to non-hygienic operations or equipment deficiencies, this will be taken against the party responsible for ensuring compliance. If both parties are responsible, enforcement may be taken against both.

The facilities which are to be shared will form part of the approved establishment but they may be shared with a registered establishment. If enforcement action is required on the shared facilities this will be undertaken by the FSA if the operator responsible for the non-compliance is carrying out operations in relation to a slaughterhouse, a cutting plant or a game handling establishment, or by the LA in other cases where so empowered and by agreement.

4.1.16 Mobile slaughterhouses

When considering applications from FBOs seeking to operate a mobile slaughterhouse the FSA may consider permitting the use of shared facilities. The mobile slaughter unit may utilise facilities such as toilets, changing rooms and chillers with an approved or registered food business. These shared facilities will still be required to meet the necessary hygiene requirements for an approved

slaughterhouse, and, all mobile slaughterhouses will be required to comply with the same hygiene requirements as any static slaughterhouse.

4.1.17 Review of approval with a view to withdraw or suspend

Where non-compliances have been established the FSA will take appropriate measures to ensure the operator concerned remedies the non-compliance and prevents further occurrences of such non-compliance. When deciding what measures to take, the FSA shall take account of the nature of that non-compliance and the operator's past record with regard to compliance' Article 138 (1)(b) of (REUL) Regulation 2017/625.

Article 138(2) then goes onto state, 'When acting in accordance with paragraph 1 of this Article, competent authorities shall take any measure they deem appropriate to ensure compliance with the rules referred to in Article 1(2), including, but not limited, to the following -

'order the suspension or withdrawal of the registration or approval of the establishment, plant, holding or means of transport concerned, of the authorisation of a transporter or of the certificate of competence of the driver'.

Where the evidence suggests that there may be major or critical non-compliances the FSA will request guarantees over future production from the FBO. The guarantees should be a clear undertaking of action by an FBO to remedy the non-compliances which have been communicated to the FBO. There must be clear evidence of the intended action, the timescale for implementation and the expected outcome.

In the case of a wholesale market, Article 138 (EU) No 2017/625 allows the withdrawal or suspension of an approval in respect of certain units or groups within the market. In the event that the common parts of a wholesale market have the approval withdrawn or suspended, the individually approved units are not able to operate as the approval of the common parts facilities is a precondition to their approval. Where the units are able to become self-sufficient in their own right, separate approval as individual establishments can be sought.

Referrals for review may be identified as a result of either performance monitoring when carrying out official controls (compliance and enforcement) or as a result of local intelligence for example where the establishment has been non-operational (long-term), major curtilage change/rebuild or acts of God and/or where there is a strong likelihood that non compliances will have developed.

Where a food business is referred for review of approval by those responsible for carrying out official controls and enforcement at the establishment or through local

intelligence, a preliminary review of the evidence presented will be undertaken by a veterinary official.

Where the preliminary evidence suggests a non-compliance may still be present or there has been repeated stoppages, the FSA will write to the FBO detailing the evidence indicating non-compliances and provide the FBO with a timescale to provide adequate guarantees over future production and the resolution of these non-compliances. During this period the FSA's audit cycle of the food business will be suspended.

Where the preliminary evidence from a source other than an audit report suggests a potential non-compliance, the Field Veterinary Officer may choose to conduct an unannounced inspection and assess whether non-compliances are present. If evidence is found these will be communicated to the FBO as above.

Upon response from the FBO the FSA will conduct an unannounced inspection of the establishment when production is taking place and consider the adequacy of the guarantees provided by the FBO.

A recommendation will then be submitted by the veterinary official conducting the unannounced inspection to a SCS decision maker.

- Where the FBOs guarantees regarding future production are not accepted as adequate the approval will be withdrawn.
- Where the CA does accept that the FBOs guarantees mean that noncompliances will be resolved and there will be no foreseeable future stoppages of production, approval will continue. The next FSA audit will be arranged within three months.
- Where the CA accepts that the guarantees mean that the non-compliances
 will be permanently resolved within a reasonable time and the situation
 will be such that, once the non-compliances have been resolved, there will
 be no foreseeable future stoppages of production, the approval will be
 suspended.

Suspension of approval will be lifted once the non-compliances are resolved and the situation is such that there will be no foreseeable future stoppages of production. If this has not been undertaken **within a reasonable time** the approval will be withdrawn.

Where the FBO's suspension has been lifted and the FBO returns to full operation, such approval will remain under review when carrying out official controls and if the previously identified non-compliances or repeated stoppages of production recur the FSA shall initiate procedures to withdraw approval.

From the date on which notice of the decision to withdraw or suspend the approval is served on the relevant person, the establishment must cease approvable activities regardless of whether an appeal is logged.

4.1.18 Additional Activities

The FBO of a fully approved establishment wishing to undertake additional activities requiring approval must apply to the FSA for approval before carrying out the additional activity.

The usual approval procedures will be applied when assessing the additional activities for approval.

If a fully approved establishment's most recent audit has the outcome 'Improvement Necessary' or 'Urgent Improvement Necessary' the FSA will not consider any applications for further activities or species until such time as the FBO has demonstrated sufficient improvement to exit the Improvement Necessary or Urgent Improvement Necessary status during a subsequent audit.

Professional judgement may be used, in the case of approving additional activities, to grant full approval in the first instance. This is only when the CA reaches a point where they are satisfied with infrastructure, equipment and the FBO controls. Examples include adding an approval (this is not an exhaustive list):

- to slaughter goats at an existing sheep approved slaughterhouse
- to cut an additional meat type at an approved cutting plant already approved to cut two or more types of meat
- for a minced meat establishment to an already approved meat preparations establishment
- · for the cold storage of meat
- for the re-wrapping / repackaging of meat

4.1.19 Change to curtilage of approved establishment

The FSA must be informed of any significant change to food business operations, such as additional activities, changes to the approved curtilage, change of FBO, the closure of an establishment or surrender of approval. This is to ensure the FSA always has up-to-date information on establishments in compliance with Article 6(2) of Regulation (EC) No 852/2004. **Not complying with this requirement is an offence under the Food Hygiene Regulations 2013.**

The agreed curtilage is the area which has been assessed by the FSA as compliant with EU hygiene and animal welfare regulations and is delineated on the approval document by a red boundary. If a FBO changes the area in which

they operate which could be in the form of an extension or utilising a room previously not included in the curtilage they need to inform the FSA of this. A failure to notify the FSA should result in appropriate enforcement action being taken.

Once the FBO notifies the FSA of changes to the area they are using, the FSA Approvals and registration team will acknowledge the change on the revised site plan provided by the FBO and will notify Field Operations. Field Operations can then asses the extent of the change and if necessary visit the premises to verify the changes have not resulted in non-compliances.

Once the FBO has notified the FSA of such changes they are entitled to use the new area as soon as they are content it complies with their regulatory requirements towards food safety and/or animal welfare.

If the FSA later find non-compliances in the new area then appropriate action will be taken following the current hierarchy of enforcement (which can vary between verbal advice, notices being issued or could ultimately lead to withdrawal of approval or prosecution).

4.1.20 Change of Food business operator

The approval of an "establishment" applies to both the premises and the business operating at the premises. If an approved establishment changes FBO the food business will have to be assessed and granted a new approval under the new FBO.

The approval assessment will be undertaken as soon as possible and in all cases within **20 working days** of receiving an approval application from the new FBO. Therefore, in order to allow a business to carry on operating without a break in trade the FSA, upon receipt of a new application made ahead of the date of change of FBO, will conduct a new approval assessment in the immediate run up to the effective date of change. Conditionally approval may be granted to the new FBO if the premise meet the infrastructure and equipment requirements. The new FBO should therefore ensure the FSA is provided sufficient notice (at least 20 working days) of the change of FBO.

The FSA is prepared, on request by the FBO to carry out a pre change of FBO advisory visit, refer to Advisory Visits section. However, any views given at such a visit will in no way provide a guarantee as to the future approval status of the business.

The different situations where a change in FBO, between different business entities, requires a new approval or where the approval can be retained are detailed in **Annex 5**.

Article 6(2) of Regulation (EC) No 852/2004 requires the FBO to inform the FSA when there is a change of FBO. This will be by means of an application form as detailed in Application for Approval section that includes the type of business entity, name of officers and relevant address/es of the FBO wishing to apply for approval. The FBO is then obliged to keep the CA informed about significant changes to those details.

Once received by the Agency the application will be assessed in the same way as a new establishment and if approval is granted may be subject to a new approval number. Also refer to Allocation of Approval Number section.

Where the FSA becomes aware of a change of FBO at an establishment and the new FBO has failed to notify the change, the FSA will inform the FBO that the food business is no longer approved and must not undertake activities that require approval until a new approval has been issued. The FSA will also inform the relevant LA of this so that the LA can take appropriate enforcement action.

In the case of wholesale markets the following principles apply:

- The market overall approval (common parts) will be treated in the same way as an individual establishment FBO change but the individual units within the market do not need to be individually re-approved and can transfer over under the new market (common parts) approval.
- In the event that the common parts of a wholesale market are not granted approval, the individually approved units are not able to operate as the approval of the common parts facilities is a precondition to their approval.
 Where the units are able to become self-sufficient in their own right separate approval as an individual establishment can be sought.

If an individual unit of a wholesale market changes FBO, this will be treated in the same way as an individual establishment FBO change.

4.1.21 FBO moving to a new premise

If an approved food business relocates to a different address the FBO will need to apply for a new approval at this new address. The approval procedures will be applied when assessing the food business at the new address for approval.

4.1.22 Seasonal closure

An establishment may operate to a seasonal pattern with routine breaks in operation. Notification of this pattern must be provided by the FBO as part of the application process by identifying the months when the FBO intends to operate the establishment. The FBO is then obliged to keep the Agency informed about any significant changes to those details including any establishment moving to or

from a seasonal pattern. When an FBO intends to re-commence operation the Agency should be notified at least two weeks before operations are intended to re-commence. This is so an inspection can be arranged to check the premises are still compliant.

4.1.23 Temporary closure

When an FBO needs to temporarily halt operations due to renovation / development work at an establishment or due to a temporary downturn in trade the FBO is obliged to keep the Agency informed about these significant changes to the operational pattern. In these cases the FBO should notify the Agency at least two weeks before operations re-commence.

4.1.24 Long term closure

When an FBO stops operations with no immediate intention to recommence for at least six months or longer the closure is classed as long-term. The FBO is obliged to keep the Agency informed about this significant change to the operational pattern and should notify the Agency at least two weeks before operations recommence.

Following a period of closure the FBO must notify the CA before operations recommence. Keeping the CA informed of significant changes is a regulatory requirement which allows the CA to ensure it has up to date information. This notification allows the CA to plan a visit to the premises to check the establishment continues to meet all structural and equipment requirements and other relevant requirements of food law, including the existence of a food safety management system based on HACCP principles.

If there are major or critical non-compliances which indicate the establishment is a serious risk to public health or animal welfare appropriate enforcement action should be taken and the establishment could be subject to a formal review of approval.

Where the FSA becomes aware of an establishment that has re-commenced o without first notifying the FSA appropriate enforcement action will be taken in regard to their failure to keep the FSA informed of significant changes.

The FSA will monitor establishments which have ceased operating and not informed the FSA of their future plans. If the FBO does not confirm the surrender of their approval in writing within six months of the establishment ceasing operations then the FSA will write to the FBO to confirm their approval no longer has effect and the establishment will be removed from the published list of approved meat establishments.

5. Annexes

N.B. These pages can only be accessed by FSA staff on FSA devices.

Annex 1a Sample Farm to Fork poster (England)

Annex 1b Sample Farm to Fork poster (Wales)

Annex 2 <u>Checklist</u>

Annex 3 Glossary of abbreviations

Annex 4 Relevant Offences

Annex 5 Change of FBO

Annex 6 <u>Exemption Criteria</u>

Annex 7 <u>Exemption flow chart</u>