

Chapter 1

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1. Background and functions

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1.1 Food Standards Scotland

1.1.1 Food Standards Scotland remit

Food Standards Scotland (FSS) replaced the Food Standards Agency Scotland from 1 April 2015.

FSS is the competent authority responsible for food and feed safety and food hygiene across Scotland.

FSS structure can be found [here](#).

FSS's remit includes:

- negotiations on behalf of Scotland by legal experts and policy officials to ensure that retained EU law reflects the interests of Scottish consumers
- removing unsafe food from sale, in conjunction with other enforcement organisations
- ensuring good food hygiene, through various initiatives delivered in partnership with Local Authorities (LAs)
- ensuring meat hygiene in approved slaughterhouses and other meat establishments throughout Scotland
- approval of establishments that require veterinary oversight
- function as an assessment Centre for the delivery of qualifications, such as slaughterer's Qualification Certificates, leading to Certificates of Competence.

This guidance manual, the Scottish Manual for Official Controls (SMOC), contains details of the tasks, responsibilities and duties FSS staff undertake in approved meat establishments.

The FSS website is www.foodstandards.gov.scot and the SMOC is published there.

1.2 Food Standards Scotland Operations (meat hygiene)

1.2.1 Principle function

The principal functions of the FSS staff working in approved meat establishments are listed in the table below, highlighting other responsible Government departments that may hold the Policy lead.

Function	Policy lead
Provision of meat inspection and health marking	FSS
Enforcement of Food Hygiene Regulations in approved slaughterhouses, game handling establishments (GHEs), cutting plants and minced meat, meat preparations and meat products premises which are collocated with cutting plants, slaughterhouses or GHEs.	FSS
Enforcement of controls over Specified Risk Material (SRM) and other animal by-products	FSS, Scottish Government, Defra
Reporting of animal welfare on farm incidents identified at the abattoir	FSS, APHA (Animal and Plant Health Agency)
Reporting of animal welfare in transport incidents identified at the abattoir	Scottish Government, LA, FSS
Enforcement of animal welfare incidents originating at abattoir level	FSS
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 TSEs	Defra
Supervision of BSE testing	Defra
Collection and despatch of samples for examination and testing for some notifiable diseases	Defra, APHA
Provision of export certification when required by the importing authority or by European Union (EU) regulations	FSS, Defra, APHA
Inspection of imported meat in approved premises	FSS, Defra, APHA
Provision of services to British Cattle Movement Service (BCMS) and ScotEID for the Cattle Tracing System	Defra, SG

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Provision of other services on a repayment basis to other Service Level Agreement customers	Other customers
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1.3 Contact page

Ops Approvals and Registrations	T: 01224 285368 Email: Approvals@fss.scot
Ops SLA and Contracts	T: 01224 285190 Email: Operations@fss.scot
Ops Technical Co-ordination Team	Email: Operations@fss.scot
FSS Throughput	Email: Operations@fss.scot
Find a relevant APHA regional office	Website: http://www.gov.scot/Topics/farmingrural/Agriculture/animal-welfare/News/8377#a4
Find a relevant LA office	Website: Find your local council - GOV.UK (www.gov.uk)
Companies House	T: 0303 1234 500 Website: https://www.gov.uk/government/organisations/companies-house
Food Standards Agency - Operations	Email: business.support@foodstandards.gov.uk

2. Relationship with other bodies

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[2.4 Local Authorities \(LAs\)](#)

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2.1 Introduction

2.1.1 Stakeholders and customers

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

- other government departments and agencies
- health ministers in Scotland, Wales and England
- meat industry bodies (e.g. Scottish Association of Meat Wholesalers - SAMW)
- Muslim, kosher and other religious slaughter groups
- staff and their professional organisations
- Local Authorities
- farming industry (e.g. National Farmers Union Scotland)
- Animal welfare organisations
- European Commission (EC)
- Department of Agriculture, Environment and Rural Affairs (NI)/ 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

FSS 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.

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

2.2 Scottish Government

2.2.1 Responsibility

Scottish Government Animal Health and Welfare Division is the competent authority for animal health and animal welfare legislation in Scotland.

2.2.2 Executive agencies

FSS Operational Delivery Division carries out work on behalf of the following Defra Executive Agencies:

- Rural Payments Agency (RPA), which incorporates British Cattle Movement Service (BCMS) for cattle identification matters
- Veterinary Medicines Directorate (VMD) for medicinal residues
- Animal and Plant Health Agency (APHA) for animal welfare, identification and disease control and monitoring

2.3 Animal and Plant Health Agency

2.3.1 Background

FSS Operations works closely with APHA (an Executive Agency of Defra) on matters relating to animal welfare and disease reporting and control.

2.4 Local Authorities

2.4.1 Local Authorities purpose

Local Authorities (LAs) provide services directly to the local communities. These services include trading standards and environmental health.

2.4.2 LA Animal Health Enforcement Officers

LAs are responsible for the enforcement of legislation relating to the health and welfare of farmed animals. The Trading Standards and/or Environmental Health services

within these authorities usually provides this service, but this is dependent on the individual structure of each authority.

LA Animal Health and Welfare 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 Food Enforcement Officers are responsible for enforcement of food standards in all food establishments. They are also responsible for food law/food hygiene inspections in LA registered and approved businesses.

Food establishments falling within the remit of the LA range from major national manufacturers to stand-alone cold-stores.

These officers are also responsible for the prevention of illegal slaughter outside approved establishments from the food safety perspective and for investigating food complaints from consumers linked to establishments under their remit.

2.4.4 FSS and LAs

FSS officials are required to liaise with LA Animal Health and Food Standards Enforcement Officers, usually within the Trading Standards Department, about:

- welfare of animals in transit
- confirmation of validity of cattle passports
- processing of animal by-products
- identification of animals
- movements and documentation of animals
- bio-security
- 'use by' date marking and other food standards matters
- food incidents investigations, joint unannounced visits to approved food premises and matters related to the transfer of approved premises from LAs to FSS and vice versa.

2.4.5 FSS and Environmental Health Officers (EHOs)

FSS officials liaise with Environmental Health Officers (EHOs) about:

- complaints from the general public relating to physical and chemical contamination of meat
- issues relating to meat hygiene outside approved establishments

2.4.6 Relationships

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

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

2.4.7 Means of communication

Local Government Regulation (LGR) and FSS recommend that local communication channels be maintained, for example:

- proactive and informal communication when the LA enforcement officers are attending slaughterhouses or GHEs.
- maintaining on-going discussions in relation to referrals or areas of common interest
- inviting FSS staff to LA regional meetings where appropriate, to discuss priorities and issues. Where staffing allows, FSS may attend, for example, the Animal Health and Welfare Strategy Group and Animal Health and Welfare Local Panels.
- considering possible joint local training opportunities, and sharing of information.

2.4.8 Partnership working

Effective partnership working by FSS and LAs will help achieve enforcement objectives and will also be resource effective.

FSS should always provide the LA with any referral information at the earliest opportunity.

The LA should respond to the referrals at the earliest opportunity or advise when and how they will be able to respond. Where the LA is unable to respond straight away, they should offer advice to the FSS staff on any immediate action required to ensure future enforcement action can be successful.

The LA should proactively advise FSS staff, and vice versa, on the outcomes of any non-compliance detected within the slaughterhouse, and explain why such an enforcement approach has been taken.

2.4.9 LA Food Complaints

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

In order that the matter is investigated, the LA should refer the complaint to FSS Operations.

FSS Operations will assign an appropriate officer at the establishment concerned to investigate.

2.5 Meat industry

2.5.1 Liaison with industry

Apart from routine business with FBOs, FSS also liaises with industry customers through their representative organisations.

2.5.2 The Partnership Working Group

The Partnership Working Group (PWG) is a core group of key UK wide meat stakeholders, of which the Head of Operational Delivery for FSS is a member. The group's main purpose is to identify opportunities for efficiencies both in the discharge of FBO responsibilities and delivery of FSA/FSS official control duties in approved meat establishments. It will also consider the operational impact of implementing legislative or policy changes and contribute views to the development of policy affecting the meat sector.

2.5.3 Scottish Meat Industry Forum

The Scottish Meat Industry Forum (SMIF) is a core group of Scottish meat industry stakeholders and includes representatives from the Scottish meat industry and FSS Operations and Policy. It's primarily role is to act as a consultative body for FSS with the industry. It provides updates on FSS initiatives and creates a forum for the meat industry to update FSS on matters of mutual interest.

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 certificate](#)

3.1 Lines of communication

3.1.1 Communication procedure

All field staff should follow a standard set of procedures when dealing with communications and queries. These procedures allow the FSS Operations to work efficiently and effectively. There are situations where the lines of communication are different to those detailed here, however these exemptions from the general rules will be outlined in 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.

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Advice required by	Technical Advice given by	Non-Technical/ Business Advice given by
Meat Hygiene Inspector	Official Veterinarian	Field Operations Coordinator
Official Veterinarian	Veterinary Advisor	Operations Manager
Field Operations Coordinator	Veterinary Advisor	Operations Manager
Veterinary Advisor	Head Veterinarian	Operations Manager/ Head of Field Operations
Operations Manager	Veterinary Advisor/ Head Veterinarian	Head of Field Operations

3.1.3 FBOs seeking advice

FBOs should be made aware to ask for advice in the first instance from their Official Veterinarian (OV).

3.1.4 OV to OV non-compliance reporting

When reporting an incident regarding any consignment arriving at the premises, which does not comply with the Regulations, the OV must complete a Non-Compliance Report (ENF 11/22). OV sending the report from one site to another should copy operations@fss.scot.

Records of OV to OV reports are monitored by the area Veterinary Advisors. This analysis allows the premises regularly dispatching non-conforming product to be identified and enables follow-up action to be initiated.

3.1.5 Liaison with other authorities

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

3.2 Manuals and guides

3.2.1 Scottish Manual for Official Controls

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

Link to the SMOC can be accessed from: SCOTS laptops

<http://sgsharepoint16/sites/FSS/ops/Shared%20Documents/SMOC/SMOC/Home%20page.pdf>

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Volume 1 contains details of the Official Controls and forms (FSS forms only available through access from the SCOTS laptops)

Volume 2 contains relevant legislation.

The manual includes guidance for staff on a range of activities, such as:

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

The OV is responsible for ensuring that all members of the team read and understand the instructions and for informing the FBO of any significant changes to the manual.

Note: All staff must be aware of any updates to the manual and should sign off the SMOC amendment form in [Annex 2](#) to provide evidence of this.

The Action/Information log is to enable AOs to keep track of any action or information note that is released. It can be found in [Annex 3](#), must be printed and accompany any Action/Information note release. Both are to be filed in the plant.

All field staff must read and understand the Action/information note and sign the log accordingly.

3.2.2 User-identified SMOC changes

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

The FSS Operations Team will evaluate the suggestion and consider commissioning to the relevant Portfolio Lead.

3.3 Daybook

3.3.1 Daybook maintenance

An official daybook must be maintained by the FSS staff at each approved establishment with routine FSS attendance (i.e. SHs and AGHEs) The date of operation must be entered by the Authorised Officer (AO) on arrival at the premises.

All operational staff should utilise the daybook when necessary. The daybook is the property of FSS 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 OV 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 FSS 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 Other daybook functions

The daybook should be used to:

- record the start and end times of regulatory duties
- record the health mark number(s) used by operational staff
- record the serial numbers of seals applied along with date and time of application and/or their removal
- record the time of the first kill and last carcass inspected each day, along 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 certain specific actions taken by FSS
- provide a means of communication between members of the operational team
- record significant details of non-compliances or offences that may become a source of evidence for legal proceedings
- record any significant verbal technical advice given by veterinary colleagues or management to OVs 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 should be made.

Reference: See topic [3.4 on 'Official notebooks'](#) in this section for additional information.

3.3.4 Arrival and departure

For health and safety purposes all members of the FSS 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. These entries must be signed by the team member or visitor at the time of departure from the premises.

3.3.5 Use and recording of stamps

It is very important that Health Marks (HMs) are controlled to prevent fraudulent use. All stamps used by FSS 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.

3.3.6 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.

3.3.7 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 subject to Freedom of Information requests 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 FSS 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 (not just initialled - plus printed name if signature is illegible)
- dated

3.3.8 Record of events

The format to be used to record any significant event should include:

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

3.3.9 Retention

In accordance with FSS retention policy, all daybooks should be securely retained at plant for a period of 3 years prior to being sent to Pilgrim House for further storage.

The daybook must be retained for a total of 6 years prior to secure disposal.

3.4 Official notebooks

3.4.1 Official notebook use:

These are issued to all new field staff upon enrolment and 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.

The use of the notebook is not to replace the plant daybook for recording of day-to-day activities and is only to be used for recording factual information, which may need to be presented 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 FSS staff present at the time, for corroboration.

- make alterations by striking once the pen through the words, writing the correction, and 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 out 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 FSS Admin Team - adminteam@fss.scot on return of your completed notebook. The detailed procedure can be found in Chapter 7 on Enforcement.

3.4.5 Return of all notebooks

Notebooks remain the property of FSS and must be returned to FSS prior to leaving employment or upon completion.

3.4.6 Storage of completed notebooks

Completed notebooks which have been returned as above will be stored by FSS, as 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 Operations Professional Standard can be found [here](#).

3.5.2 Personal and professional 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.

Regulation: Regulation No. 852/2004, Annex II, Chapter VIII.

3.5.3 Personal hygiene

FSS staff is to:

- wear white, clean protective clothing when handling exposed meat or any product
- wear hairnets (and beard snoods if appropriate) to cover the hair of the head and where necessary the face and 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), heavy make-up, aftershaves and perfumes in production areas.

3.5.4 Operational hygiene

When working in an approved establishment, FSS 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.

3.5.5 Health status

FSS staff handling food or entering any food handling area in any capacity where there is the 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 certificates

3.6.1 OA or MHI title

Regulation No. 2017/625 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 certificates

FSS staff is issued with authorisation certifications depending on their designations, along with photo ID cards.

Staff must sign the authorisation documentation, carry them whilst engaged in official duties, and be prepared to produce them on request. Staff are responsible for ensuring they possess all relevant authorisations for the establishment where they work.

When ceasing to work on behalf of the FSS, staff must return all authorisation certificates and letters of confirmation to their OM. Any lost or found authorisation certificates or ID cards must be reported to FSS Admin Team Mailbox at adminteam@fss.scot.

3.6.3 Electronic Records

All FSS staff and contractors have a responsibility to manage the electronic records we create, receive and hold on behalf of FSS and across all records and document management repositories.

FSS IT Systems:

Access to IT systems and FSS data shall only be granted to personnel with the right level of security clearance who need to use the system or data to perform their job function. Systems and applications available for staff in plants to use are:

- The Operations Workflow System (OWS) – A corporate system to record and report official controls data.
- SCOTS - It is the name of the Scottish Government IT network also hosting FSS. Any issues using SCOTS should be reported through the iFix Web Portal. Staff will be asked to provide details about themselves, including PC asset number (the blue label on the laptop), User ID, location and a brief description of the fault or issue. Staff can also report any issues by telephone to the Scottish Government IT Corporate Services desk on 0131 244 8500.

- SharePoint – FSS corporate browser-based collaboration and document management platform where FSS official policies, guidance, instructions and documents are stored.
- eRDM - document management platform where FSS official policies, guidance, instructions and documents are stored.
- Microsoft Outlook – Secure email environment for transmission of information.

Always think about Security:

- Do not leave any official FSS information unattended in FSS or FBO offices, at home or areas accessible to the members of the public.
- Do not send any confidential, personal, or commercially sensitive data over unencrypted portable storage devices, and think carefully before sending them in an email.
- Do not send any FSS official information or communication through a personal email account.

FSS IT Contact Details:

Email: FSS-IT@fss.scot

Tel: 01224 285121/5126

3.6.4 Powers of entry

Authorisations give the holder the powers to enter approved establishments within their authority and must be produced upon request. This power of entry exists at all reasonable hours and is for the purposes of ascertaining contraventions of provisions of the legislation for which they are authorised and the performance of statutory duties.

Regulation: The Official Feed and Food Controls (Scotland) Regulations 2009.

3.6.5 Action without authorisation

Do not take any enforcement action for which you have not been authorised, as such action is not valid.

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

4. Process overview: FSS approval of establishments

[4.1 Background](#)

[4.2 Legislation](#)

[4.3 Requirement for approval: Retained Regulation No. 2017/625](#)

[4.4 Meat establishments requiring approval](#)

[4.5 Separation of functions](#)

[4.6 Approval assessments](#)

4.1 Background

4.1.1 Approval of meat establishments

Competent authorities for food safety are responsible for the approval process of establishments handling, preparing or producing products of animal origin which are subject to requirements laid down in Regulation No. 853/2004.

Under the food hygiene legislation (see following page), meat establishments require approval- unless they benefit from specific exemptions, as detailed in the Approved Establishments Scottish National Protocol, available at:

https://www.foodstandards.gov.scot/downloads/Approved_establishments_working_group_-_2019_-_Scottish_National_Protocol_Update_-_January_2020.pdf

4.1.2 Approvals operational policy

The Society of Chief Officers of Environmental Health in Scotland (SoCOEHS) and the SFELC Approved Establishment Working Group proposed that a Joint Approval Process Model be implemented identifying the relationship between and respective roles of FSS and LAs in the context of the approval process. The 'Approved Establishments Scottish National Protocol' (SNP) applies to all approved establishments (both by LA and FSS) with FSS having the responsibility of approval and enforcement, as described in Regulation No. 853/2004 and Food Hygiene (Scotland) Regulations 2006 (as amended).

4.1.3 Purpose of this guidance

The information and guidance provided by the SNP is intended to provide:

- a broad overview of the type of Approvals work undertaken by FSS
- instances where interaction and exchange of information between Field Operations and the FSS Approvals team is required
- instances where Field Operations personnel may be requested to carry out visits to establishments whilst those establishments are operating under Conditional Approval

4.2 Legislation

4.2.1 Food Hygiene legislation

From the 1st of January 2021, the EC Food Hygiene Regulations are being applied in the UK as Retained Regulations. The main regulations are:

- Regulation No. 178/2002 – general Food Law regulation
- Regulation No. 2017/625 – on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products
- Regulation No. 852/2004 – on the hygiene of foodstuffs
- Regulation No. 853/2004 – laying down specific hygiene rules for food of animal origin.

4.3 Requirement for approval: Regulation No. 2017/625

4.3.1 Article 148(1)

Article 148 of Regulation No. 2017/625 requires that:

- competent authorities shall establish procedures for feed and food business operators to follow when applying for the approval of their establishments in accordance with Regulations No. 852/2004 and 853/2004
- upon receipt of an application for approval, the competent authority (in this context, the FSS) shall make an on-site visit
- the CA (FSS) 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

- the competent authority may grant conditional approval if it appears that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new official control visit to the establishment, carried out within three months of granting conditional approval, that the establishment meets the other relevant requirements of feed or food law. If clear progress has been made but the establishment still does not meet all of the relevant requirements, the competent authority may prolong conditional approval. However, conditional approval shall not exceed a total of six months.
- the competent authority shall keep the approval of establishments under review when carrying out official controls.

Note: The application process for Approval of Meat Establishments is available on the FSS website:

<https://www.foodstandards.gov.scot/business-and-industry/safety-and-regulation/approval-of-meat-plants>

4.4 Separations of functions

4.4.1 Governance arrangements

Responsibility for the policy on approvals is retained by the FSS's Regulatory Policy Branch.

The process of granting approvals is an operational delivery matter and is the responsibility of FSS's Operational Delivery Division, more specifically the Veterinary Branch.

4.5 Approval assessments

4.5.1 Application received

Once the application form and relevant supplementary documentation is completed and submitted through the [online form](#), as per [approvals process requirements](#), a notification will be received by the Approvals Team on Approvals@fss.scot. The necessary on-site visit(s) and approval assessments are carried out by a trained approvals officer, usually a Veterinary Auditor.

4.5.2 Obligation to grant approval

There is no obligation on FSS to grant approval to an establishment. An approval will only be granted where the FBO has demonstrated compliance with the relevant requirements of food law.

Reference: Regulation No 2017/625, Title VIII, Chapter II, Article 148 (3).

4.5.3 Initial on-site visit: conditional approval

Following submission of a validated HACCP-based Food Safety Management Systems by the future FBO, an assessment of the documentation will take place. If satisfactory, an on-site visit by an approvals officer will be scheduled and conditional approval may be recommended and granted if the establishment meets all the structure and equipment requirements.

Conditional approval will be refused if there are concerning structural or equipment deficiencies at the initial approval visit.

The result of the initial on-site visit (granting or refusal of conditional approval) will be notified in writing to the FBO, and copies of the letter will be sent to the relevant Operational Delivery Division managers and respective LA. Where conditional approval is granted, the notification will include details of relevant requirements of food law which must be met in order for the establishment to gain full approval.

4.5.4 Extended conditional approval

Conditional approval is granted for a period of three months. Within that three month period, a new official control visit will be conducted by an approvals officer. Where clear progress has been made but the establishment and food business still does not meet all relevant requirements of food law, the period of conditional approval may be extended. The total period of conditional approval may not exceed six months. In between the announced approval visits, FSS can also conduct unannounced inter-approval visits. If findings from any inspections during the approval period are concerning, recommendation to refuse approval should be submitted.

4.5.5 Full approval

Full approval will be granted where evidence from a new official controls visit shows that the establishment complies with all the relevant requirements of food law and all activities have been observed.

Note: In the event that extended conditional approval was granted, the approvals officer will arrange a further on-site official control visit, within the over-riding 6 month period, with a views for full approval or refusal of approval.

4.5.6 Approval assessment report

Following each of their announced inspections, the approvals officer will produce an assessment report and, ideally, a photographic report.

In addition to assessing the adequacy of structure and equipment, the approvals officer will:

- measure levels of compliance of every system

- identify any deficiencies
- record significant areas which may be pertinent to the delivery of Official Controls once the establishment has gained full approval

4.5.7 Significant areas pertinent to the delivery of official controls

Significant areas which may be pertinent include:

- whether there are other FBOs operating within the same building and sharing some facilities (shared facilities)
- time/ area separation of activities
- whether separate authorisations are required (for example, VC removal, warm meat transportation)
- whether there are areas of the establishment covered by another competent authority (for example, retail counter, dairy/ fish processing)

4.5.8 New establishment

On receipt of an application form requesting approval of an establishment, the FSS Approvals Executive will provide a copy to the Veterinary team. At the point of granting conditional approval, a copy of the approvals officer assessment report and the Conditional Approval letter are sent to the same recipients as stated in [section 4.6.3](#).

At this point in time, the OM will consider operational matters which need to be organised before the establishment begins production.

5. Field operations involvement: post conditional approval

[5.1 Inter-approval visits](#)

[5.2 Notification of changes in activities](#)

5.1 Inter-approval visits

During each period of conditional approval (initial conditional approval and where applicable, extended conditional approval), the Audit team may ask for an unannounced inter-approval inspection to be conducted in establishments with no routine veterinary attendance, such as cutting plants. These can be conducted by any trained approvals officer or experienced OV.

Inter-approval inspections should normally be undertaken around 4 to 6 weeks after the conditional approval/ extended conditional approval has been granted but may be earlier if the approvals officer has indicated a specific reason that an earlier visit is required.

The purpose of the inter-approval inspection will be to:

- provide information regarding the FBO operational hygiene practices at the establishment
- assist the FBO in progressing towards achievement of compliance in advance of the next approval assessment

This is an important opportunity for the approvals officer to observe the establishment in operation.

During the visit, the approvals officer should, in particular, review those areas where the approval assessment report contains a column requesting inter-approval comments. The approvals officer may also wish to highlight any other issues which are relevant to the FBO's progression towards achievement of compliance in advance of the next approval assessment.

Once the Approval report is completed, the approvals officer should submit it to the Approvals team: approvals@fss.scot

Note: The approvals officer should take appropriate enforcement action if the need for this is identified during the course of their visit. Ideally, every visit should also produce a photographic report for the decision maker/s.

5.1.1 Copy of approval assessment report

The Approvals team will provide the VAs with a copy of the approval assessment report.

5.2 Notification of changes in activities

5.2.1 FBO duty to notify significant changes in activities

Article 6(2) of Regulation No 852/2004 states that the FBO is to 'ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment'. Not complying with this requirement is an offence under the Food Hygiene Regulations 2006 (as amended).

5.2.2 Amendment to approval documentation

Where the FBO notifies FSS of such changes, consideration needs to be given as to whether a visit should be made to inspect the alterations/ changes to activities and whether amended approval documentation is required.

Amendment to the approval documentation will depend on the extent of the changes. The following sub-paragraphs detail the types of changes which may require such amendment.

Note: Any member of the inspection or FSS Management Team should be alert to the fact that, if they are informed or become aware of any change which has the potential to affect the approval status of an establishment, they must ensure that the Approvals team is advised immediately.

5.2.3 Additional activities

The FBO should notify FSS by way of an application form for any additional activities they wish to undertake. Undertaking approvable activities without first gaining approval is a contravention of Regulation No. 853/2004 Article 4(3).

On receipt of an application form, the Approvals team will arrange for an approvals officer to contact the FBO and arrange an approval assessment.

If any member of the inspection or FSS management team at the establishment becomes aware that the FBO wishes to undertake additional activities, please notify the Approvals team immediately, who will provide the FBO with details on how to make an application.

5.2.4 Change to approved curtilage/ restructuring

The original approval letter sent to the FBO will be accompanied by a site plan detailing the approved area in which the approved activities may be undertaken. The inspection

team at the establishment should be familiar with the detail of the approval letter and site plan and ensure all information FSS holds matches reality.

If any member of the inspection at the establishment or FSS management team becomes aware that the FBO wishes to operate outside of the approved area or changed the designation of some of the areas and did not notify FSS, they should inform the Approvals team immediately.

The FBO will be asked to produce a revised site plan, detailing the new area in which they wish to operate. An approvals officer will then make an assessment. If the new layout is acceptable then the Approvals team will acknowledge the establishment's new curtilage/ layout and issue a letter to that effect. The Approvals team may utilise the site OV to gather further information on the suitability of the changes made to the curtilage.

5.2.5 Change of FBO

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 need to be assessed and if appropriate, granted a new approval under the new FBO.

Guidance on identifying changes of FBO has been published on the FSS website at:

<https://www.foodstandards.gov.scot/business-and-industry/safety-and-regulation/approval-of-meat-plants/change-of-food-business-operator>

5.2.6 Temporary closure of an approved establishment

FBOs are required to keep FSS informed of periods of closure.

Reference: For further guidance on periods of closure see Chapter 4 on 'Audit, HACCP based procedures and verifying operator's own checks'.

Once advised of this, the Approvals team will update the Establishments Database to indicate the temporary or seasonal closure. This information will assist other teams within FSS; for example, FSS Revenue Accounting will be aware that no throughput details will be required for the period in question.

If the FBO informs the inspection team or FSS management team at the establishment of a period of closure, please immediately notify the Approvals team of the information by email.

Once an establishment plans to re-open after a period of closure, please follow the guidance found in chapter 4 on 'Audit, HACCP based procedures and verifying operator's own checks', part 1, section 1.

5.2.7 Surrender of Approval

If the establishment is closing permanently, then FSS needs confirmation of surrender of Approval from the FBO, in writing.

Note: If the FBO does not surrender the approval, then the only alternative action available to FSS to remove the approval is to conduct a formal 'Review of Approval' which may lead to suspension or withdrawal.

If any member of the inspection or FSS management team at the establishment becomes aware of its intended permanent closure, please request that the FBO contacts the Approvals team (by email or letter) to provide confirmation of the surrender of approval.

5.2.8 Transfer of official controls

Where an FBO holding an approval granted by FSS wishes to surrender the slaughterhouse, cutting plant and/ or game handling establishment element(s) of their approval, but wishes to retain stand-alone activities, the establishment and the approval requirement can be transferred to the LA if that change meets the requirements of the Scottish National Protocol for Approvals.

In the case of an FBO electing to limit their activities to meet the exemption criteria and surrendering the approval granted by FSS, the establishment will remain subject to the provisions of Regulation No. 852/2004 and must therefore register with the LA as a food business prior to surrendering their approval.

If any member of the inspection or FSS management team at the establishment becomes aware of either scenario as detailed above, please ask the FBO to confirm the details to the Approvals team (by email or letter).

The Approvals and Certifications team will then liaise with the LA over the transfer of responsibility.

6. Annexes

- Annex 1** **Glossary of abbreviations**
- Annex 2** **SMOC Amendment Log**
- Annex 3** **SMOC Action/Information Note Log**