

Manual for Official Controls Amendment 110

Chapter 13 Approval of Establishments

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1. Introduction

1.1

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

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

1.2 Type of establishments and activities

The meat establishments listed below are subject to assimilated Regulation (EC) 852/2004 and Regulation 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

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- Meat Preparations Establishments
- Mechanically Separated Meat Establishments
- Processing Plants (Meat products, Rendered animal fats and greaves, Treated stomach, bladders and 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 Regulation 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

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comply with the requirements of Annex III of Regulation 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.

The types of activities requiring approval are provided in Annex 1.

1.3 Governance and decision making

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 Excellence Team (OAE).

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 Operations Assurance and Excellence, FSA Legal, Head of Veterinary Audit, 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. In the absence of the Head of Operations Assurance and Excellence decisions may be made by an alternative SCS in the Operations Division.

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.

1.4 Exemptions from approval

Regulation 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

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

Full details of these exemptions are provided in **Annex 2**. For retail establishments, the flow diagram in **Annex 3** can be used to determine if the operator qualifies for exemption from the need to be approved.

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2. Application process

- 2.1 Applications for approval
- 2.2 Past compliance history
- 2.3 Advisory visits
- 2.4 Approval procedure
- 2.5 Approval assessment and visits
- 2.6 Allocation of approval number
- 2.7 Seasonal establishments
- 2.8 Wholesale markets
- 2.9 Food businesses transferring from LA control
- 2.10 Multiple FBOs operating from one premises
- 2.11 Shared facilities
- 2.12 Mobile slaughterhouses

2.1 Applications for approval

Application forms are available to download from the [FSA website](#). 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
- The identity of the FBO including relevant contact and address details
- **Updated:** [For establishments which have previously been refused approval or had approval withdrawn, the FSA will also require details

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of how the non-compliances leading to the refusal/withdrawal have been rectified.]

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 organisation 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.

2.2 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

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- 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 Service Delivery Partners 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

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

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

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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 consider 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.

2.3 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.

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More [advice on the cost and the type of guidance](#) which is available in an advisory visit can be found on our website.

2.4 Approval Procedure

Article 148 of assimilated (EU) Regulation 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 Regulation 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

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- 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.

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2.5 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.

2.6 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:

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- 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.

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2.7 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
- Full approval is achievable within two years

2.8 Wholesale Markets

Wholesale markets are defined in Regulation 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.

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2.9 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 retained Regulation 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 been 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.

2.10 Multiple FBOs operating from one premises

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.

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

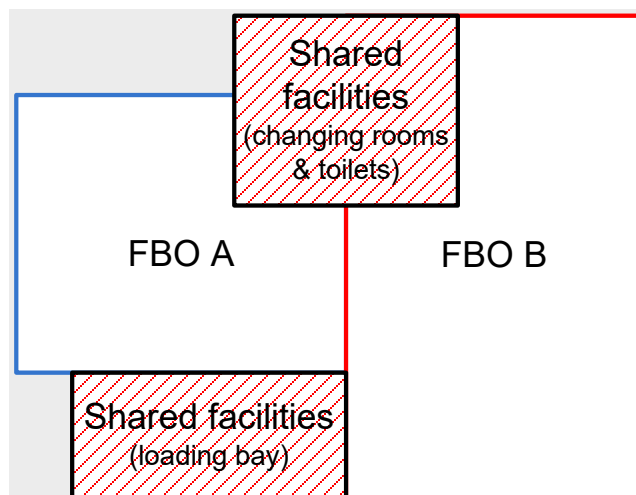
When carrying out official controls, if the CA needs to take enforcement action, for example due to non-hygienic operations or equipment deficiencies, this may be taken against both parties. As the terms of the joint use of the establishment are a precondition to the individual approval enforcement action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

2.11 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.

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If at a point in the future the sharing of facilities is no-longer possible, the approval will be reviewed. Also refer to Chapter 13, Section 4 **Review of Meat Establishments Approval with the view to Withdraw or Suspend** section and Chapter 13, Section 3.3 Changes to Curtilage.

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.

2.12 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.

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3. Significant changes

- 3.1 Significant changes
- 3.2 Additional activities
- 3.3 Changes to curtilage
- 3.4 Changes of food business operator
- 3.5 FBO moving to a new premises
- 3.6 Seasonal closure
- 3.7 Temporary closure
- 3.8 Long term closure

3.1 Significant Changes

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 852/2004. **Not complying with this requirement is an offence under domestic food hygiene regulations.**

3.2 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

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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

If an establishment is conducting activities for which they are not approved appropriate enforcement should be taken and the FBO be directed to the [Food.Gov page](#) on which they can apply for additional activities and species.

[Applying for approval of a meat or food establishment by the FSA | Food Standards Agency](#)

3.3 Changes of curtilage

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 assess 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.

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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).

3.4 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, 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 Chapter 13 Section 2.3 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 Chapter 13 **Annex 5**.

Article 6(2) of Regulation 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 Chapter 13 Section 2.6 Allocation of Approval Number section.

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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.
- If 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 can 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.

3.5 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.

3.6 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.

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3.7 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.

3.8 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 re-commence.

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 operations 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.

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4. 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 Regulation 2017/625.

The process the Agency will follow when reviewing approval is detailed in the enforcement chapter (Chapter 7 Section 6).

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5. Annexes

Note: Some of these pages can only be accessed by FSA staff on FSA devices.

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| Annexe 1 | <u>List of activities subject to approval or additional authorisation</u> |
| Annexe 2 | <u>Exemption Criteria</u> |
| Annexe 3 | <u>Exemption flow chart</u> |
| Annexe 4 | <u>Relevant Offences</u> |
| Annexe 5 | <u>Change of FBO</u> |