

## 2. FSA Approvals Policy

This section sets out FSA's policy as it applies to the process of approval by the FSA, in accordance with Regulation (EC) Noes. 852/2004, 853/2004 and Regulation (EU) No 2017/625.

### 2.1 Approval Procedures

Article 148 of Regulation (EU) No 2017/625 provides that CAs:

- shall establish procedures for food business operators to follow when applying for the approval of their establishments in accordance with [Regulation \(EC\) No 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 the relevant 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 minced meat and meat preparations intended to be eaten less than thoroughly cooked. The FBO's food safety management system must be made available to the CA
- **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 the 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 the infrastructure and equipment requirements
- the FSA shall grant **full approval** if the establishment and food business complies with the relevant requirements of food law (infrastructure, equipment and operational requirements) and the establishment has been observed in operation

Where the above requirements are not met, approval cannot be granted, and the FSA will refuse approval or approval will be discontinued.

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

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**, following conditional approval or extended conditional approval, if:

- the establishment ceases operations
- a visit cannot be undertaken because the relevant activities are not in operation
- the FBO requests for the approval to be discontinued

In such cases conditional or extended conditional approval will cease to have effect.

This would not prevent the FBO from applying at another point in the future, but will mean that the FBO will have to submit a new application for approval.

In between each period of conditional/extended conditional approval the FSA, DAERA or DC 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 on whether to refuse, or grant extended conditional or full approval.

FBOs wishing to apply for approval by the FSA should apply using our [approvals service](#).

However, those applying for approval for activities that are supervised by DCs in FSA approved establishments should apply via the DC and follow their procedures.

Once a food business is approved by the FSA, it will be subject to official controls in accordance with Regulation (EU) 2017/625 such as [audits](#) and unannounced inspections.

## 2.2 Types of food business

Depending on the nature/operations of the food business, there are several specific requirements applicable when an approval visit/assessment is undertaken. These may include the following.

### 2.2.1 Seasonal operations

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 six months.

### 2.2.2 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 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.

### 2.2.3 Multiple FBOs using shared facilities

Examples would include where more than one FBO wishes:

- to use a single premises to operate separate food businesses at different times, such as FBO A operates 09:00-17:00 and FBO B operates 17:00-09:00
- to operate separate food businesses sharing certain facilities with neighbouring FBOs

Approval by the FSA may still be permitted. These situations will be assessed on a case by case basis.

### **2.2.3.1 Enforcement action at wholesale markets and other establishments using shared facilities**

Any enforcement action, for example due to non-hygienic operations or equipment deficiencies, may need to be taken against some or all parties by the FSA until the issues are resolved if this non-compliance would affect the undertakings of the other FBOs. This is owing to the joint use of the premises being a pre-condition to the individual approval, regardless of which party caused the problem in the first place. If, at a point in the future, the shared facilities are no longer available, for example the neighbouring FBO no longer wishes to make the facilities available, the approval must be reviewed, and consideration given to suspension or withdrawal. Where an FBO is able to meet the requirements of the legislation in their own right, the approval may be able to continue, or re-approval may be appropriate.

### **2.2.4 Mobile Slaughterhouses**

When assessing 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. However, these shared facilities will still be required to meet the necessary hygiene requirements for an approved slaughterhouse. As such, all mobile slaughterhouses will be required to comply with the same hygiene requirements as any static slaughterhouse.

### **2.2.5 Less than thoroughly cooked burgers**

The FSA Board is particularly interested in the enhanced risk that rare burgers present. As such they have required that the processing of burgers and minced meat intended to be consumed less than thoroughly cooked is considered as a separate approval activity.

## **2.3 Changes to circumstances**

### **2.3.1 General Requirements**

An FBO is legally required by Article 6(2) of Regulation (EC) No. 852/2004 to ensure that the FSA always has up-to-date information on establishments. The FBO can notify the FSA by email: [NIOperationalpolicy@food.gov.uk](mailto:NIOperationalpolicy@food.gov.uk) or telephone 0844 057 0302 of any significant change in activities and any closure of an existing establishment.

An establishment is defined in case law as an entity consisting of the following three parameters.

- the premises for which approval is requested
- the identity of the FBO (who is required to be compliant with food law within the food business under their control) including relevant contact and address details
- the activities for which approval is sought.

Approval is granted to the establishment and therefore a change to any of these parameters means that a new approval is required.

Changes in information including any significant change in activities and any closure will include the following:

- [change to approved curtilage](#)
- [re-structuring within the approved curtilage](#)
- introduction of a new product within the scope of their existing approval
- introduction of a new product that doesn't require approval
- [additional activities that require approval](#)
- [change of trading name](#)
- [change of FBO](#)
- [FBO moving to different premises](#)
- [closure of an approved establishment](#)
- [surrender of approval](#)
- [transfer to a different CA](#)
- [a new Duly Authorised Representative is appointed](#)

Where the FBO notifies the FSA of such changes, the FSA will consider whether the changes notified would require any alteration to the existing approval and may trigger some/all of the following actions:

- a visit to inspect the alterations
- an amended HACCP based food safety management system is required
- amended approval documentation to reflect changes
- further approval of the establishment

The requirement for reapproval will depend on the nature and extent of the changes, and the FBO will be informed of next steps and/or any other actions.

#### **2.3.1.1 Change to approved curtilage**

A notification to the FSA of changes to the approved curtilage will require the FBO to provide revised plans indicating the changes to the FSA. Once the full details of the change and accompanying plans are received, these will be acknowledged by the Operational Policy and Delivery Team and forwarded to the FSA authorised official.

An assessment will be made to ascertain if the changes are appropriate. The FSA authorised official will assess whether an onsite visit is also required in order to establish whether the changes are compliant with the relevant requirements of food law. If they are not compliant then appropriate enforcement will be taken.

If changes to the approved curtilage are identified at a later date and it is established that the FBO has not informed the FSA of these changes then enforcement action may be taken under Article 6 of Regulation (EC) No. 852/2004 in addition to any other hygiene enforcement action which may be required.

FBO should be advised that they cannot undertake approvable activities from this additional area until this significant change has been reflected within their existing approval. It is the FBO's responsibility to make sure that all such changes meet the respective requirements of food law.

#### **2.3.1.2 Restructuring within the approved curtilage**

Significant restructuring of the approved establishment will require the FBO to notify the FSA and provide revised plans indicating those changes. The FSA will make an assessment to ascertain if

the changes are appropriate. As part of this assessment, professional judgement will be used by the FSA authorised official to determine whether an on-site visit is also required.

Once acknowledged by the FSA, restructuring should not require further or additional approval but could trigger additional interventions. It is the FBO's responsibility to ensure that all such changes meet the respective requirements of food law.

### **2.3.1.3 Additional Activities**

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

The establishment's ability to undertake additional activities should be assessed following the same procedures as a new establishment which are set out in this document.

Current FBO compliance levels will be taken into consideration, and if the most recent FBO compliance 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 have undergone a subsequent audit in which they had obtained a 'Generally Satisfactory' or 'Good' outcome.

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 FSA is satisfied with the infrastructure, equipment and the FBO controls and will be determined on a case by case basis.

### **2.3.1.4 Change of trading name**

The approval document includes the details of the trading name. Where there is a change of trading name, the approval document needs to reflect this and the FBO will need to notify the FSA so that the details of the trading name can be updated on the list of approved food establishments.

The trading name is the name that the FBO wishes to be known to trade under. This cannot be a different incorporated company and is not to be confused with a change of ownership described in Change of FBO, which would warrant a re-assessment for approval.

The change of trading name does not affect any existing matters arising in relation to the establishment and its approval.

### **2.3.1.5 Change of FBO**

A change of FBO for an establishment will trigger the requirement for a new approval for that establishment should the new FBO wish to carry out activities that are subject to approval.

The new FBO must notify the FSA as soon as possible of the impending change of FBO at an establishment by means of an application so that an assessment can be carried out by the FSA promptly in order that the establishment may continue to operate subject to the outcome of the FSA's approval assessment. The application requires information on 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 FSA informed about significant changes to those details.

If the FBO has not changed the operation at the premises in any significant way and no deficiencies are identified at the first assessment visit, full approval may be granted at the first visit at the FSA's discretion.

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 the same way, i.e., the type of food production by the business and the food safety control arrangements of the business will remain the same.

The different situations where a change in FBO occurs between different business entities and whether a new approval is required, or the approval can be retained are detailed in the table below.

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 DC of this so the DC can take appropriate enforcement action.

Existing ownership (as per approval documentation)	Change of ownership (in each case assuming no other changes to the business)
Sole trader, Partnership, or incorporated company (e.g., Ltd, PLC, etc)	Different sole trader, partnership or incorporated company ownership
Sole trader or Partnership	Company incorporated (and registered), Sole trader or partnership becomes Director/s
Sole trader	Creation of a partnership where the sole trader remains one of the active partners
Partnership	Dissolved and one of the partners takes over sole ownership and becomes a sole trader
Incorporated company after administration	Company taken over from administrators by a different sole trader, partnership, or incorporated company
Sole trader, partnership, or incorporated company	Bankruptcy, insolvency or in liquidation (wound up/dissolved)

Table indicates if re-approval is required in a change of ownership scenario.

#### 2.3.1.5.1 Change of FBOs in wholesale markets

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.

#### **2.3.1.6 FBO moving to different premises**

If an FSA approved food business is relocating to a different address, the FBO will need to apply for a new approval at this new address. The FBO will be required to submit a new application and be granted approval prior to operations commencing in the new location.

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:

- the FBO of the business remains the same, and the activities remain substantially the same, when the establishment moves to a new location
- remaining with the same CA, for example, the FSA and in Northern Ireland. In order to ensure that the approval number remains unique and ensure adequate traceability of the product, the previous approval will need to be surrendered by the FBO prior to it being granted for the approval at the new address.

#### **2.3.1.7 Closure of an Approved Establishment**

Where an establishment has a break in operation or closure, the FBO is legally obliged to keep the FSA informed. These breaks are categorised by the FSA for operational purposes as follows:

##### **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 FSA informed about any significant changes to those details including any establishment moving to or from a seasonal pattern.

##### **Temporary closure**

When an FBO needs to temporarily halt operations due to renovation or development work at an establishment or due to a temporary downturn in trade, the FBO is obliged to keep the FSA informed about these significant changes to the operational pattern. Also refer to Change to approved curtilage and Restructuring within the approved curtilage sections.

##### **Long-term closure**

A closure of an establishment is classed as long-term by FSA when an FBO stops operations, which are not part of a pre-notified routine seasonal closure, with no immediate intention to recommence for at least six months or longer. The FBO is obliged to keep the FSA informed about this significant change to the operational pattern and must notify the FSA when they close

and before they plan to re-commence operations.

#### **2.3.1.7.1 Official Controls during a period of closure**

During non-operational periods, official controls undertaken by DAERA will continue, e.g., unannounced inspections, to verify that approved establishments comply with the relevant requirements of food law.

In the case of audits of FBO procedures, undertaken by DAERA, where the next scheduled audit falls within the closed period, the audit will be undertaken within three months of operations re-commencing or sooner if needed to make sure that at least one audit is conducted within each 12 month period.

#### **2.3.1.7.2 Pre-opening visit following a period of closure**

When an FBO intends to re-commence operation following a period of closure described above, the FBO needs to notify the FSA at least two weeks before operations are intended to re-commence. DAERA will undertake a pre-opening visit to the premises to check the establishment continues to meet all relevant structural and equipment requirements and other relevant requirements of food law, including the existence of a food safety management system based on HACCP principles.

Where established non-compliances have been identified, DAERA will inform the FSA and the establishment may be subject to a formal review of approval set out in the Review of approval section.

Where the FSA becomes aware of an establishment that has re-commenced without first notifying the FSA, appropriate enforcement action may be taken against the FBO with regard to their non-compliance with the relevant requirements of food law which may include failure to keep the FSA informed of significant changes and placing food on the market which has not been produced, processed or distributed in compliance with the Hygiene Regulations.

#### **2.3.1.7.3 Surrender of Approval**

Where the FBO of an FSA approved establishment wishes to surrender their approval, the FBO is required to notify the FSA in writing of their intent.

Once acknowledged by the FSA, the approval will cease to exist, and the use of the approval number will also come to an end. The establishment will be removed from the official list of approved food establishments.

It is an offence to resume activities or to apply an [identification mark](#) on any food for which approval is required without being reassessed for and granted a new approval by the FSA.

In the case of surrender of approval of a slaughterhouse or game handling establishment, DAERA will remove all [health marking](#) equipment from the premises.

Establishments undertaking activities requiring an authorisation (for example, a cutting plant removing SRM vertebral column from bovine carcasses, transport of warm meat etc.) will have these authorisations automatically revoked upon removal of the approval.

#### **2.3.1.8 Transfer of approval or registration responsibilities between authorities**

In the circumstances described below in the sections: From FSA to DC and From DC to FSA, close liaison between the FSA and DCs is essential. The FSA will undertake a separate, new



approval process where there is a new added activity being proposed that requires approval by the FSA. The FSA will notify the DC when they receive an application for approval, when they have issued conditional approval to an establishment, or when an approval application has been refused. The DC retains enforcement responsibility for the whole of an establishment until such time as conditional approval has been issued by the FSA. The DC will resume the enforcement responsibility from the FSA if the establishment is refused approval by the FSA following conditional or extended conditional approval. The DC will need to continue to undertake official controls and undertake any necessary enforcement action for the protection of public health and communicate this to the FSA.

FSA, DAERA and DCs will liaise with each other and provide details of the original applications, approval documentation, recent audit/inspection report and a copy of the enforcement programme, as appropriate. Joint visits by CAs should be arranged if considered necessary.

Agreement should be reached by the FBO, the FSA and the DC on the date of the transfer, if possible, to ensure there is no break in the approval or registration for the establishment.

Guidance on the exemptions from approval can be found in the [Approval of Establishments: Guidance for Local Authorities](#).

#### **2.3.1.8.1 From FSA to DC**

The FSA is responsible for the approval of slaughterhouses, cutting plants, game handling establishments, raw liquid milk processors and egg packing centres in Northern Ireland. Where the FBO, holding an approval granted by the FSA, wishes to surrender these elements of their approval but would like to retain other activities subject to approval, this establishment, and the approval requirement, will be transferred to the DC. In these circumstances, the FSA will notify the relevant DC accordingly.

In the case of FBOs deciding to limit their activities to meet the exemption criteria and surrendering the approval granted by the FSA, the establishment will remain subject to the Regulation (EC) No. 852/2004 and must therefore register with the DC as a food business prior to surrendering their approval. On surrender of the approval the establishment will be removed from the official list of approved food establishments.

#### **2.3.1.8.2 From DC to FSA**

If a DC approved establishment wishes to become a slaughterhouse, cutting plant, game handling establishment, raw liquid milk processor or egg packing centre, the approval requirement, will be transferred to the FSA, even though the establishment may continue to carry out activities for which the DC is responsible for undertaking hygiene official controls at the establishment.

An existing DC registered establishment may wish to change their business so that they are no longer exempt from approval, for example, under the retail exemption from approval and thus require approval by the FSA. For example, a registered retail butcher wishing to supply the fresh meat they cut to other retail/catering establishments to the extent that they can no longer avail of the retail exemption. This food business will require to be approved by the FSA as a cutting plant.

Existing DC registered establishments taking advantage of exemptions from approval and applying to undertake activities that are approved by the FSA, may be considered for full approval following the initial approval visit at the FSA's discretion. 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 outside of the exemptions from approval until approval or conditional approval is granted by the FSA.

#### **2.3.1.8.3 Approval number/code**

Approval documentation will have to be issued to the FBO where there is a transfer of CA responsibility for an establishment. A new FSA or DC approval number/code should be issued.

An establishment may be able to retain its previous approval number/code at the CA's discretion having regard to issues of risk, cost and proportionality.

#### **2.3.1.9 New Duly Authorised Representative is appointed**

An FBO should inform the FSA when they appoint a new [duly authorised representative](#) for the food business.