

# **Approval of food establishments in Northern Ireland: governance arrangements and approvals policy**

## **Approval of food establishments in Northern Ireland policy: summary**

This document sets out the governance, policy and other arrangements for the approval of food establishments by the Food Standards Agency (FSA) in Northern Ireland.

Issued August 2022

### **Purpose**

This document sets out the governance, policy and other arrangements for the approval of food establishments by the Food Standards Agency (FSA) in Northern Ireland in accordance with Regulation (EC) No. 853/2004. This includes FSA's implementation of the requirements of Regulation (EU) 2017/625 as they apply to the process of approval in Northern Ireland.

The reader should always refer to the relevant legislation referenced in this document. The use of the term approval throughout this document refers to approval in accordance with Regulation (EC) No. 853/2004 only.

### **Who is this document for?**

This document is for the FSA, Department of Agriculture, Environment and Rural Affairs, Veterinary Public Health Programme (DAERA VPHP), Department of Agriculture, Environment and Rural Affairs, Agri-food Inspection Branch (DAERA AfIB) and District Councils (DCs). The information in this document may be of interest to food business operators.

### **Which UK countries does this document apply to?**

Northern Ireland.

### **Key words**

- FSA approvals
- food law, monitoring and controls
- hygiene and food safety
- meat, livestock, eggs and dairy.

### **Review**

The next scheduled review date for this document is July 2024.

# Approvals of food establishments in Northern Ireland: Introduction

Sets out the FSA approvals of food establishments in Northern Ireland, and the implementation of relevant obligations in Regulation (EU) 2017/625. Procedures for food business operators to follow when applying under Regulation (EC) No.853/2004.

This document sets out:

- the governance, policy and other arrangements for FSA approvals of food establishments in Northern Ireland
- the FSA's implementation of relevant obligations contained in Regulation (EU) 2017/625
- procedures for food business operators (FBOs) to follow when applying for approval under Regulation (EC) No. 853/2004

More detailed arrangements will be covered in FSA standard operating procedures (SOPs) and the Manual for Official Controls as deemed necessary.

## 1.1 Approval responsibilities

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 subject to approval under [Regulation \(EC\) No. 853/2004](#).

Any co-located [cold store](#), [re-wrapping/repacking activities](#), [minced meat](#), [meat preparations](#), [mechanically separated meat activities](#) or [processing plant](#) are also approved by the FSA. When not connected with the above FSA establishments, these activities are approved by the relevant DC.

## 1.2 Delivery of Official Controls at approved establishments:

FSA approved establishments, are subject to [official controls](#) enforced and executed by DAERA VPHP (in slaughterhouses, cutting plants, and game handling establishments) and DAERA AfIB (in raw liquid milk processors and egg packing centres) on behalf of the FSA.

DCs are responsible for the delivery of official controls at the premises that they approved.

The term '[integrated establishment](#)' is applied to FSA approved establishments in Northern Ireland that require hygiene official controls to be undertaken by both DAERA (on the behalf of the FSA) and the DC within a common curtilage, for example, a cutting plant and a fishery products processor within the same FSA approved establishment.

A more detailed description of the division of responsibilities between DCs and the FSA can be found in the Food Law Practice Guidance for Northern Ireland - [2.13.1 Division of responsibilities between local authorities and FSA](#).

As the [competent authority](#) (CA), the FSA must establish procedures in accordance with the provisions of [Regulation \(EU\) 2017/625](#), for approving these establishments under Regulation (EC) No. 853/2004.

## 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)	Approval status	Comments	Re-approval required
Sole trader, Partnership, or incorporated company (e.g., Ltd, PLC, etc)	Different sole trader, partnership or incorporated company takes over ownership	Expires	Discontinuation of operator/s	Yes
Sole trader or Partnership	Company incorporated (and registered), Sole trader or partner/s becomes Director/s	Expires	Creation of a new Company	Yes
Sole trader	Creation of a partnership where the sole trader remains one of the active partners	Retained	Continuation of operator	No
Partnership	Dissolved and one of the partners takes over sole ownership and becomes a sole trader	Retained	Continuation of operator	No



Existing ownership (asper approval documentation)	Change of ownership (in each case assuming no other changes to the business)	Approval status	Comments	Re-approval required
Incorporated company after administration	Company taken over from administrators by a different sole trader, partnership, or incorporated company	Expires	Discontinuation of operator/s	Yes
Sole trader, partnership, or incorporated company	Bankruptcy, insolvency or in liquidation (wound up/dissolved)	Expires	Discontinuation of operator/s, approval expires	N/A

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.

## **3. Governance arrangements**

This section looks into the governance arrangements of the approvals for food establishment.

Responsibility for approvals policy and the operational delivery of approvals in FSA approved establishments in Northern Ireland is held by the Operational Policy and Delivery Team.

For England and Wales, the operational delivery of approvals of FSA approved establishments is the responsibility of the Approvals and Registration Team, [approvals@food.gov.uk](mailto:approvals@food.gov.uk).

The oversight of policy and operational delivery on approvals is carried out at an appropriate level as described below with the strategic involvement of the FSA's Chief Executive or the FSA's Board, when required.

### **3.1 Decision making- FSA approved establishments:**

Article 148 of Regulation (EU) 2017/625 places obligations on the FSA as a CA to carry out an on-site visit upon receipt of an application for approval from a food business operator and to make a decision on whether to grant conditional or full approval in compliance with Article 148. If conditional or full approval cannot be granted the FSA will refuse approval, or the approval is discontinued.

The FSA is also required by Article 148 to keep the approval of establishments under review when carrying out official controls. Article 138 of Regulation (EU) 2017/625 places obligations on the FSA to undertake actions, including the option of suspension or withdrawal of the approval of the establishment, in the event of established non-compliance, when deemed appropriate, to ensure compliance with the rules referred to in Article 1(2) of Regulation (EU) No 2017/625 in respect to food hygiene and safety.

#### **3.1.1 Granting conditional and full approval:**

In Northern Ireland, decisions on approval pursuant to Article 148(3) (approval) and Article 148(4) of Regulation (EU) 2017/625 (conditional approval and full approval) have been delegated to the following people:

- [FSA authorised officials](#) who are authorised to conduct the on-site visit under Article 148 of Regulation (EU) No 2017/625
- Head of Operational Policy and Delivery in Northern Ireland who is also an FSA authorised official and can conduct the on-site visit under Article 148 of Regulation (EU) No 2017/625
- Head of Food Safety Policy and Delivery and equivalent Grade 6 posts in NI.

FSA authorised officials, will routinely make the decisions to grant conditional or full approval in accordance with Article 148 of Regulation (EU) No 2017/625. However, the authorised officials may discuss a proposed decision with other delegated decision makers noted above or with the NI Approvals Panel if they consider this necessary before making their decision following an on-site visit.

Decisions on approval can also be made by a Senior Civil Servant of the FSA.

When a decision to either refuse, suspend or withdraw approval is being considered by the FSA authorised official, the authorised official will follow the process set out below.

#### **3.1.2 Refusal**

When a decision to refuse approval is being considered by the FSA authorised official, the official will have the ability to discuss with or refer the approval decision to the Head of Food Safety Policy and Delivery, Director for Regulatory Compliance, People and NI, the Deputy Director in NI or the NI Approvals panel as appropriate.

The FSA authorised official will ensure discussions with other decision makers are recorded and retained.

### **3.1.3 Suspension or withdrawal**

In the event of established non-compliance, the FSA shall take any measure deemed appropriate to ensure compliance with the rules referred to in Article 1(2) of Regulation (EU) 2017/625 in respect to food hygiene and safety. Such actions may result in the suspension or withdrawal of the approval of the establishment, but until the process is completed, the appropriate official controls and relevant risk-based enforcement action will continue as set out in Review of approval.

When an FSA authorised official is considering a decision to suspend or withdraw an approval, the proposed decision must be referred to the NI Approval Panel. The outcome of NI Approval Panel's recommendation will be passed to a Senior Civil Servant as decisions pursuant to Article 138(2)(j) of Regulation (EU) 2017/625 (suspension or withdrawal of approval) in the event of established non-compliance must be made by a Senior Civil Servant.

For Northern Ireland, the Senior Civil Servant will be the Deputy Director in NI or Director for Regulatory Compliance, People and NI.

The name and signature of the decision maker who makes each decision on an approval will be recorded on the documentation detailing the decision that is issued to the FBO.

#### **3.1.3.1 Wholesale market**

In the case of a wholesale market, Article 138 of Regulation (EU) 2017/625 allows the withdrawal or suspension of an approval in respect of certain units or groups within the market. If the common parts of a wholesale market have the approval withdrawn or suspended, the individually approved units are not able to operate as the approval of the common parts facilities is a precondition to their approval. Where the units can become self-sufficient, separate approval as individual establishments may be sought.

### **3.1.4 FSA authorised officials**

FSA authorises officials to conduct the on-site visits required under Article 148 of Regulation (EU) 2017/625 as part of the assessment of whether food business operators have demonstrated that they comply with the relevant requirements of food law and therefore approval can be granted by the FSA.

Slaughterhouses, cutting plants and game handling establishments subject to approval under Regulation (EC) No. 853/2004 require official veterinarian control. Therefore, the approval assessments including the on-site visit are provided by FSA authorised officials who are [official veterinarians](#).

In raw liquid milk processors and egg packing centres, subject to approval under Regulation (EC) No 853/2004, the approval assessments including the on-site visits are undertaken by FSA authorised officials that are not necessarily official veterinarians.

All FSA authorised officials will have the required technical knowledge. FSA authorised officials must have regard to the governance, policy and other arrangements for approvals set out in this document, and SOPs developed for the processes and administration of FSA approvals in Northern Ireland.

### **3.1.5 District council recommendations (integrated establishments)**

[DC authorised officers](#) who conduct on-site visits to integrated establishments to carry out approval assessments will recommend the decisions to grant conditional or full approval in compliance with Article 148 of Regulation (EU) No 2017/625 to the FSA. DC authorised officers will have ability to discuss a proposed decision with the FSA if they consider this necessary before making their recommendation to the FSA following an on-site visit.

When considering a recommendation to the FSA to either refuse, suspend or withdraw approval, the officer must firstly discuss the recommendation with the FSA. The DC authorised officer will ensure discussions with the FSA are recorded and retained. An appropriate FSA decision maker will be appointed to consider the DC's recommendation and will follow the procedures as outlined in this Governance section for FSA authorised officials.

When a recommendation to suspend or withdraw an approval is being considered, the FSA decision maker must refer recommendation to the NI Approval Panel and the procedures set out in the section NI Approval Panel should be followed.

The name and signature of the FSA's decision maker who makes an approval decision in response to a recommendation of approval from a DC will be recorded on the documentation detailing the decision that is issued to the FBO.

### **3.1.6 NI Approvals Panel**

The NI Approvals Panel may be convened by the FSA authorised official responsible for the on-site visit to assist in their deliberations or by an appointed FSA decision maker to consider a DC's recommendation. The panel must always be convened when a decision to suspend or withdraw an approval is being considered.

This panel in NI should comprise as a minimum, of:

- FSA authorised official or DC authorised officer who conducted the on-site visit under Article 148 of Regulation (EU) 2017/625
- Head of Food Safety Policy or equivalent Grade 6 post in NI
- The Deputy Director in NI or Director for Regulatory Compliance, People & NI

Other optional attendees:

- Head of Operational Policy and Delivery in Northern Ireland
- DAERA representatives
- District Council representatives
- Representative from FSA Operations with the relevant technical knowledge and qualifications in relation to Approvals.

The Operational Policy and Delivery executive support officers will schedule the Panel to discuss the evidence and any other relevant issues and will provide the secretariat for the NI Approvals Panel, ensuring the evidence provided by the FSA authorised official or DC authorised officer who conducted the on-site visit, minutes of any meeting and their recommendations are recorded and retained.

## **3.2 Review of approval**

The FSA is required by Article 148(5) of Regulation (EU) 2017/625 to keep the approval of establishments under review when carrying out official controls.

The enforcing authorities (DAERA/DCs) will inform the FSA of any FSA approved establishments where established non-compliance has been identified, in order to trigger a review of approval.



The requirement for a review of approval may be identified:

- when carrying out official controls
- as a result of local intelligence: for example, where the establishment has been non-operational or has undertaken a major curtilage change or rebuild
- when an event, such as flooding or fire, has occurred where there is a strong likelihood that serious non-compliance with food law will have developed

### **3.2.1 Established non-compliance**

There is no detailed definition of established non-compliance in EU food law. However, the DAERA/DC will take into account of the nature of the non-compliance being observed and the operator's past record with regard to compliance with the rules referred to in Article 1(2) of Regulation (EU) 2017/625 in respect to food hygiene and safety.

The non-compliance may include poor hygienic production, poor infrastructure, facilities and maintenance, ineffective food safety management system and any other recognised non-compliance of a serious nature. The established non-compliance may provide a potential or actual risk to public health.

Throughout the review of approval process, the appropriate official controls and relevant risk-based enforcement action will continue to be carried out in parallel, to ensure public health is not compromised and to secure FBO compliance.

Where a food business is referred for review of approval, a preliminary review of the evidence presented will be undertaken by an FSA authorised official. Where considered necessary, the FSA authorised official may choose to arrange for an unannounced inspection to corroborate the evidence presented and assess current compliance.

The findings of the FSA authorised official's review of the evidence (including any evidence from an unannounced inspection), together with any steps the FBO is required to take to rectify compliance, will be communicated to the FBO in a timely matter and will be confirmed in writing.

The FBO will also be informed of any further steps that will be taken by the FSA or DAERA/DC in writing and may include the following:

- relevant risk-based enforcement action
- increased frequency of official controls
- consideration of suspension or withdrawal approval by the FSA

The FSA authorised officer will liaise with DAERA, and the DC as appropriate, when conducting a review of approval process at an establishment.

Should the FSA authorised official consider that their recommendation is likely to lead to a suspension or withdrawal of approval, they must refer this to the NI Approval Panel.

The NI Approval Panel will be convened to consider whether deficiencies that are found at the establishment are sufficient to demonstrate that the FBO's food safety management system is ineffective to control hazards, and if so, to determine whether the approval should be suspended or withdrawn based on the individual circumstances of the case.

The NI Approval Panel's decision to suspend or withdraw an approval in the event of established non-compliance must be ratified by a Senior Civil Servant.

## **3.3 Right of appeal**



Regulation 12 of The Official Feed and Food Controls Regulations (Northern Ireland) 2009 provides that any person who is aggrieved by a decision of the CA taken in respect of an establishment subject to approval under Article 4(2) of Regulation (EC) No. 853/2004 in accordance with

- Article 148(3) of Regulation (EU) 2017/625 (approval)
- Article 148(4) of Regulation (EU) 2017/625 (conditional approval and full approval)
- Article 138(2)(j) of Regulation (EU) 2017/625 (suspension or withdrawal of approval)

may appeal to a court of summary jurisdiction.

The operator has one calendar month to appeal from the date on which notice of the decision is served on the relevant person.

The procedure on an appeal to a court of summary jurisdiction shall be by way of notice under Part VII of the Magistrates' Courts (Northern Ireland) Order 1981.

The FBO does not have the right to continue to operate under appeal. Therefore, the FBO will be required to cease operations requiring approval once the approval has been refused, suspended or withdrawn and this has been deemed to have been served.

Where the FBO lodges an appeal and the court of summary jurisdiction overturns the FSA's decision, the FSA will reinstate the approval or lift the approval suspension, in accordance with the court's decision.

## **3.4 Administration of approvals**

The administration of and secretariat for approvals carried out by the FSA in Northern Ireland is the responsibility of the executive support officers in the Operational Policy and Delivery Team. Approval decisions will be effective from the date indicated and recorded on the approval documentation issued by the executive support officers in the Operational Policy and Delivery Team.

On receipt of an application, executive support officers will process the administration of the application. Throughout the application process the FSA authorised official and executive support officers will liaise with DAERA (and DCs if required) and will follow the processes and procedures in this guidance and in the relevant SOPs.

Executive support officers will maintain, and update SOPs developed for the processes and administration of FSA approvals in Northern Ireland. The SOPs should be followed where possible and any deviations and the reasons for them recorded.

### **3.4.1 Approval number**

On granting full approval or conditional approval the FSA will give each new approved establishment an approval number.

The following numbering system for Northern Ireland in allocating approval numbers, to establishments approved by the FSA will apply:

- Meat: 9300 series
- Egg packing centre [\(footnote 1\)](#): 9700 series
- Raw liquid milk processors: 9900 series

There are some instances whereby FSA approved establishments do not follow this format, for example, NI 001 M, AA 123, or AA 321 FE. The establishments with a different format of approval code were initially approved by DCs or DAERA and issued a DC or DAERA approval code before then transferring to FSA for approval, please see section Transfer of approval responsibilities between CAs for more information.

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. 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.

1. Egg packing centres: the approval number and the egg packing centre approval number can differ.

## **Approval of food establishments in Northern Ireland policy: glossary**

Definitions and abbreviations used in this guidance explained in full.

Definitions and abbreviations used in this guidance. Unless the legislation is stated within the given definition, this is an FSA interpretation of the term. Some definitions provide a legal reference in 'quote marks' and further FSA interpretation of the legislation is provided thereafter.

### **AfIB**

Agri-food Inspection Branch, Department of Agriculture, Environment and Rural Affairs.

### **Audit**

Defined in Article 3 (30) of Regulation (EU) 2017/625 as 'a systematic and independent examination to determine whether activities and the related results of such activities comply with planned arrangements and whether these arrangements are applied effectively and are suitable to achieve the objectives'.

### **Authorised officer**

Defined in the Food Hygiene Regulations (Northern Ireland) 2006 as 'in relation to an enforcement authority, means any person (whether or not an officer of the authority) who is authorised by them in writing, either generally or specially, to act in matters arising under the Hygiene Regulations'. In the context of this guidance, the CA is the DCs.

### **Cold store**

Cold Store is not defined in food law. For the purposes of approval, the FSA considers a cold store to be a wholesale establishment, not forming an integral part of a slaughterhouse, cutting plant or game handling establishment, used for the storage under temperature controlled conditions of POAO intended for sale for human consumption.

## **Competent Authority**

Has the meaning as defined in Article 3(3)(a) of Regulation (EU) 2017/625 to include ‘the central authorities of a Member State responsible for the organisation of official controls and of other official activities, in accordance with this Regulation and the rules referred to in Article 1(2);’

## **Cutting plant**

Defined in Annex I, point 1.17 of Regulation (EC) No 853/2004 as ‘an establishment used for boning and/or cutting up meat’

## **DAERA**

Department of Agriculture, Environment and Rural Affairs

## **DAERA AfIB**

Department of Agriculture, Environment and Rural Affairs, Agri-food Inspection Branch

## **DAERA VPHP**

Department of Agriculture, Environment and Rural Affairs Veterinary Public Health Programme

## **DC**

District Council

## **Duly authorised representatives**

Duly authorised representative is a person who is given the authority to stand in the place of the FBO in certain circumstances.

## **EC**

European Commission

## **EU**

European Union

## **Egg packing centre**

Packing centre is defined in Annex I, point 5.4 of Regulation (EC) No 853/2004 to mean ‘an establishment where eggs are graded by quality and weight.’

## **Establishment**

Article 2(c) of Regulation (EC) No. 852/2004 defines an establishment as 'means any unit of a food business'.

## **Food business**

Defined by Article 3(2) of Regulation (EC) No. 178/2002 as 'means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing, and distribution of food'.

## **Food business operator (FBO)**

Defined by Article 3(3) of Regulation (EC) No. 178/2002 as 'the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control'.

## **Food law**

'food law' as defined in Article 3, point 1 of Regulation 178/2002 means 'the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals'.

## **Fresh meat**

Fresh Meat is defined as Annex 1, point 1.10 as 'that has not undergone any preserving process other than chilling, freezing or quick-freezing, including meat that is vacuum-wrapped or wrapped in a controlled atmosphere'.

## **FSA**

Food Standards Agency (FSA) The central competent authority for food safety in England, Wales, and Northern Ireland.

## **Game handling establishment**

'Game-handling establishment' is defined as 'any establishment in which game and game meat obtained after hunting are prepared for placing on the market' in Regulation (EC) No 853/2004.

## **HACCP**

Hazard Analysis and Critical Control Point (food safety management system)

## **Hazard**

A biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect.

## **Health mark**

A mark indicating that, when it was applied, official controls had been carried out in accordance with Regulation (EU) 2019/627. Health marks are only applied by the CA, under the supervision of an official veterinarian in slaughterhouses and game handling establishments. Their application to the carcasses of domestic ungulates, farmed game mammals (with the exception of lagomorphs) and large wild game demonstrates that they have been deemed fit for human consumption.

## **Hygiene regulations**

The Food Hygiene Regulations (Northern Ireland) 2006, regulation 2 defines “the Hygiene Regulations” means these Regulations and the Community Regulations’. The Community Regulations are listed in The Food Hygiene Regulations (Northern Ireland) 2006.

## **Identification mark**

A mark indicating that a POAO has been produced in an approved establishment in accordance with legal requirements.

## **Inspection**

The examination of establishments, animals and food, of their processing, of food business, of their management and productions systems, including finished product testing and feeding practices, and of their origin and destination of production inputs and outputs, in order to verify that all these items conform to legal requirements.

## **Integrated establishments**

The term ‘integrated establishment’ is applied to FSA approved establishments in Northern Ireland that require hygiene official controls to be undertaken by both DAERA (on the behalf of the FSA) and the DC within a common curtilage, e.g., a cutting plant and a fishery products processor within the same approved establishment.

## **Raw liquid milk processors**

An establishment pasteurising and or processing raw liquid milk to produce liquid dairy products.

## **Meat preparations**

Defined in Regulation (EC) No 853/2004 Annex I, Point 1.15 as ‘fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat.’

## **Meat products**

Meat products ‘means processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat’ as defined in Point 7.1, Annex I of Regulation (EC)

No 853/2004.

## **Mechanically separated meat (for MSM)**

“Mechanically separated meat’ or ‘MSM’ is defined in Point 1.14, Annex I of Regulation (EC) No 853/2004 as ‘the product obtained by removing meat from flesh bearing bones after boning or from poultry carcasses, using mechanical means resulting in the loss or modification of the muscle fibre structure’.

## **Minced meat**

Regulation (EC) No 853/2004, Annex I, Point 1.13 defines ‘Minced meat’ as ‘boned meat that has been minced into fragments and contains less than 1% salt’.

## **Member state**

A state that is party to treaties of the EU and has thereby undertaken the privileges and obligations that EU membership entails.

## **Official controls**

As defined by Article 2(1) of Regulation (EU) 2017/625 to mean ‘activities performed by the competent authorities, or by the delegated bodies or the natural persons to which certain official control tasks have been delegated in accordance with Regulation (EU) 2017/625 in order to verify compliance by the operators and that animals or goods meet the requirements laid down in the rules referred to in Article 1(2) of (EU) 2017/625, including for the issuance of an official certificate or official attestation’.

## **Official Veterinarian**

Regulation (EU) 2017/625, Article 3 (32) defines ‘official veterinarian means a veterinarian appointed by a competent authority, either as staff or otherwise, and appropriately qualified to perform official controls and other official activities in accordance with this Regulation and the relevant rules referred to in Article 1(2)’ of Regulation (EU) 2017/625.

## **Placing on the market**

Regulation (EC) No 178/2004, Article 3, point 8 defines ‘placing on the market’ means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves’.

## **Premises (also refer to definition of an 'establishment')**

The Food Safety (Northern Ireland) Order 1991, Regulation 2 defines “premises” as ‘includes any place, any vehicle, stall or moveable structure and, for such purposes as may be specified in an order, any ship or aircraft of a description so specified’.

## **Processed product**

Defined by Article 2 (1)(o) of Regulation (EC) No. 852/2004 as 'foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics'.

## **Processing plant**

An establishment where POAO are either treated, processed (heating, smoking, curing etc) and wrapped or undergoes one or more of those handling activities.

## **Products of animal origin (POAO)**

Defined by Annex I of Regulation (EC) No. 853/2004 as 'Products of animal origin means:

- food of animal origin, including honey and blood
- live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption
- other animals destined to be prepared with a view to being supplied live to the final consumer'

## **Regulation (EC) No. 178/2002**

Regulation (EC) No.178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

## **Regulation (EC) No. 852/2004**

Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

## **Regulation (EC) No. 853/2004**

Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin

## **Regulation (EC) No. 2017/625**

Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 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

## **Retail**

Defined in Article 3(7) of Regulation (EC) No. 178/2002 as 'handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets'.

## **Risk**

A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

## **Re-packaging establishment**

An establishment which removes wrapped foodstuffs from a second container and re-packages them without removing the initial wrapping which is in direct contact with the product.

## **Re-wrapping establishment**

An establishment that unwraps the initial wrapping or initial container, which is in direct contact with the product and then re-wraps the products.

## **Slaughterhouses**

In Regulation (EC) 853/2004, Annex I, Point 1.16. 'Slaughterhouse' means an establishment used for slaughtering and dressing animals, the meat of which is intended for human consumption'.

## **Stages of production, processing and distribution**

Any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed.

## **Traceability**

Regulation (EC) No 178/2002, Article 3 (15) defines "traceability' means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution'

## **Treated stomachs, bladders and intestines**

Regulation (EC) No 853/2004, Annex I, Point 7.9. 'Treated stomachs, bladders and intestines means stomachs, bladders and intestines that have been submitted to a treatment such as salting, heating or drying after they have been obtained and after cleaning'.

## **Unit**

A single undivided entity or whole.

## **Unprocessed products**

Defined by Article 2 (1)(n) of Regulation (EC) No. 852/2004 as 'foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, cut, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep frozen or thawed'.

## **Verification**



Checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled.

## **Wholesale market**

Defined by Annex I of Regulation (EC) No. 853/2004 as 'a food business that includes several separate units which share common installations and sections where foodstuffs are sold to food business operators'.

## **Wrapping**

The placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself. (Therefore, re-wrapping means the replacement of initial wrapping or initial container, which is in direct contact with the product.)

[Yn ôl i'r brig](#)