

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.

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.