

Operational Policy for the  
Approval of Meat Establishments  
Undertaken by the  
Food Standards Agency  
and  
Food Standards Scotland

## UK Meat Establishment Approvals

### Operational Policy for Approvals Undertaken by the FSA and FSS

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## Background

1. This documents sets out the Food Standards Agency's (FSA) and Food Standards Scotland (FSS) implementation of the requirements of Regulation (EC) No 882/2004, for approving meat establishments under Regulation (EC) No 853/2004 in Britain and Northern Ireland (NI).
2. The EC Food Hygiene Regulations (“[Hygiene Regulations](#)”) have applied in all Member States from 1 January 2006. These regulations are:

- **Regulation (EC) No 178/2002<sup>1</sup> – General Food Law Regulation:**  
This regulation provides a framework for food and feed law in the EC and applies to Member States and food and feed business operators. It applies to all stages of production, processing and distribution of food and feed, but does not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption. The principal aim of the regulation is to protect public health and consumers' interests in relation to food.
- **Regulation (EC) No 882/2004<sup>2</sup> of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules:**  
This includes procedures to be followed concerning the approval of establishments as required under Regulation (EC) No 853/2004.
- **Regulation (EC) No 852/2004<sup>3</sup> of the European Parliament and of the Council on the hygiene of foodstuffs:**  
This sets out general hygiene rules that apply to all registered and approved food businesses including structural requirements and the implementation of procedures based on hazard analysis and critical control point (HACCP) principles. The regulation sets out objectives for “[good hygiene practices](#)” to protect consumers.
- **Regulation (EC) No 853/2004<sup>4</sup> of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin:**  
This includes requirements for businesses producing Products of Animal Origin (POAO) that apply in addition to those set out in Regulation (EC) No 852/2004, including the requirement for establishments to be approved.
- **Regulation (EC) No 854/2004<sup>5</sup> of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption:**  
This includes the specific requirement for inspection and auditing activities by the CA to be carried out in relation to establishments that require approval under Regulation (EC) No 853/2004.

<sup>1</sup> [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](#)

<sup>2</sup> [Regulation \(EC\) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules](#)

<sup>3</sup> [Regulation \(EC\) No 852/2004 on the hygiene of foodstuffs](#)

<sup>4</sup> [Regulation \(EC\) No 853/2004 laying down specific hygiene rules for food of animal origin](#)

<sup>5</sup> [Regulation \(EC\) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin](#)

3. As the Competent Authorities (CA) the FSA and FSS must establish procedures in accordance with the provisions of Article 31(2) of Regulation (EC) No 882/2004, for approving meat establishments under Regulation (EC) No 853/2004.
4. Regulation (EC) No 853/2004 requires that food business establishments handling food of animal origin which falls under the categories for which Annex III lays down requirements must, with some exceptions, be approved by the CA.
5. For the purposes of these regulations, in accordance with Article 2 and 3 of Regulation (EC) No 178/2002 the following definitions apply:

- **'food business'** 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'** means 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'** 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.
- **'food'** (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

6. Compliance with relevant requirements of Regulation (EC) No 853/2004 is required in addition to compliance with Regulation (EC) No 852/2004. However, registration under Article 6(2) of Regulation (EC) No 852/2004 is not required for establishments subject to approval.
7. Slaughterhouses, Cutting Plants and Game Handling Establishments require veterinary control in accordance with Article 4(7) of Regulation (EC) No 854/2004 and must be approved by the FSA in England, Wales and Northern Ireland and by FSS in Scotland.
8. Any co-located Cold store, Re-wrapping Establishment, Minced meat, Meat Preparations, Mechanically Separated Meat Establishment or Processing Plant are also approved by the FSA or FSS. When stand-alone, these establishments are approved by the relevant Local Authority (LA) in Britain or District Council (DC) in NI.
9. Food Business Operators can find further guidance on food hygiene and other regulations for the UK Meat Industry in the Meat Industry Guide<sup>6</sup>.
10. The Meat Industry Guide has been produced in consultation with meat industry representatives for use by UK food businesses involved in the slaughter, cutting and processing of fresh meat, and especially those subject to veterinary control by the FSA in England and Wales; FSS in Scotland or the Department of Agriculture and Rural Department (DARD) in Northern Ireland. It should be particularly helpful for prospective

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<sup>6</sup> <http://fsahome/how/meatpremieresources/Documents/MOC/mig.pdf>

food businesses seeking an approval to start such operations. It is also an important reference for enforcement officials.

11. The Meat Industry Guide provides non-binding advice on the legal requirements of the EU Food Hygiene Regulations and should be read in conjunction with the legislation itself (quoted in each chapter) with which businesses have to comply. The text should not be taken as an authoritative statement or interpretation of the law, as only the courts have this power.

## **Governance Arrangements**

12. Responsibility for the policy on approvals is held by the FSA Policy & Science Group for England, Wales and Northern Ireland, and by the FSS Directorate of Policy, Science and Evidence for Scotland. Policy oversight will be carried out at the appropriate level depending on the sensitivity or impact of the issue, with the FSA's Board or the FSS Board having clear sight of the operation of the approvals system, with the strategic involvement of the FSA or FSS's Chief Executive or the respective Board, if and when required.
13. Approval assessments and recommendations in England and Wales are provided by veterinary officials in the FSA field management structure. To achieve consistency of decision-making there is a single authorised official with clear accountability for approval decisions within the FSA's Operations Assurance Division. Similar roles exist in FSA NIs structure and an equivalent authorised official is responsible for FSA approval decisions in Northern Ireland. In Scotland approval assessments and recommendations are provided by a veterinary official in the FSS Operations Directorate. A single authorised official is then responsible for the decision-making.
14. There is a complete separation of functions between the officials involved in assessments, recommendations and decisions on approvals and the officials responsible for conducting the audits of approved meat establishments.
15. The authorised officials work in collaboration and base their decisions upon the recommendation and evidence presented by the veterinary official who conducted the approval assessment.

# Establishments Requiring Approval

## Type of Establishments

16. The meat establishments listed below are subject to Regulations (EC) No 852/2004 and (EC) No 853/2004 and must be approved by the Agency, in order to operate, unless they meet the exemption criteria in Regulation (EC) No 853/2004:

- a. **Slaughterhouses**
- b. **On Farm Slaughter facilities**
- c. **Game Handling Establishments**
- d. **Cutting Plants**
- e. **Meat Wholesale Markets**

These establishments are subject to official controls enforced and executed by the FSA in England and Wales; by FSS in Scotland; and by DARD Veterinary Service, Veterinary Public Health Programme (VS-VPHP) on behalf of the FSA in Northern Ireland.

17. In Britain, where establishments are co-located with an approved Slaughterhouse, Cutting Plant or Game Handling Establishment, then the following associated **meat** activities are also approved by the FSA/FSS. In the case of such establishments operating in a stand-alone capacity, they are approved by the LA:

- a. **Minced Meat Establishments**
- b. **Meat Preparations Establishments**
- c. **Mechanically Separated Meat Establishments**
- d. **Processing Plants** (Meat products, Rendered animal fats & greaves, Treated stomach, bladders & intestines, Gelatine and Collagen)
- e. **Cold Stores**
- f. **Re-wrapping Establishments**

18. Where an approved meat establishment, in Britain, is also handling other products of animal origin (POAO) the Agency, in liaison and agreement with the relevant LA, may approve all operations requiring approval under Regulation (EC) No 853/2004 undertake official controls. Such approvals will be determined on a case by case basis.

19. Where the removal of dual enforcement is not practical then in order to avoid the allocation of dual approval numbers to the co-located establishment by the FSA/FSS and LA, the FSA/FSS should issue the approval to the establishment as a whole. The approval covering letter should explain the areas of responsibility and a list of all activities in the establishment should be included in the approval letter. Activities that fall within Regulation (EC) No 852/2004 only, such as butcher's shops and where the establishment is also handling non-POAOs or the parts of the premises where these operations are carried out will be under the control of the LA and are not allocated an FSA/FSS approval number.

20. There is no requirement for veterinary control of meat **Cold stores** or **Re-wrapping establishments**, but EU Commission guidance advises that cold stores still require approval in so far as they are used for activities for which Annex III of Regulation (EC) No 853/2004 lays down requirements. LAs or DCs will be responsible for approving cold stores, unless they are co-located with a Slaughterhouse, Cutting Plant or Game Handling Establishment.

21. If a cold store intends to undertake re-wrapping, then it must be additionally approved as a re-wrapping establishment. In order to ensure traceability, the FBOs should not place on the market re-wrapped POAO unless the identification mark of the re-wrapping establishment is applied.
22. Where an approved establishment undertakes cold storage of brought – in products of animal origin, the approval document should reflect the cold storage activity in addition to all other activities undertaken within the establishment.
23. Establishments that cut raw meat exclusively for the manufacture of meat products, minced meat, meat preparations or mechanically separated meat, require approval in respect of their manufacturing activities. They also need to comply with the requirements of Annex III of Regulation 853/2004, including those relating to cutting plants. However, because they do not place the meat they cut on the market as fresh meat they will not require approval as a ‘cutting plant’ and therefore do not require veterinary control.
24. In Northern Ireland, District Councils (DCs) are responsible for official controls and the recommendation of approval to the FSA of meat product and edible co-product activities in co-located establishments.
25. The table at **Annexe A** shows the establishments in column one which must be approved under Regulation (EC) No 853/2004, to carry out the operations in column two.
26. Regulation (EC) No 853/2004 Annex I provides definitions of the terms applicable in fresh and processed meat establishments.
27. Since the adoption of Regulation (EC) No 853/2004, the European Commission has provided guidance<sup>7</sup> on the implementation of certain provisions of these regulations.
28. This guidance document has been established for information purposes only and has not been adopted or in any way approved by the European Commission. It is mainly directed at food businesses and competent authorities in the Member States, and aims to give guidance on the implementation of the food hygiene requirements and on related subjects. It is an evolving document and will be updated to take account of experiences and further information.

## **Exemptions from Approval**

29. Regulation (EC) No 853/2004 provides certain exemptions from approval. In terms of establishments for which the FSA/FSS may need to consider for approval the exemptions fall into the following basic categories:
  - a. **Retail Establishments**
  - b. **Poultry Slaughter and Cutting on Farm**
  - c. **Slaughter for Private Domestic Consumption**
  - d. **Wild Game**

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<sup>7</sup> [SANCO/1732/2008 Rev. 7 - Guidance document on the implementation of certain provisions of Regulation \(EC\) No 853/2004 on the hygiene of food of animal origin](http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_853-2004_en.pdf)  
[http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance\\_doc\\_853-2004\\_en.pdf](http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_853-2004_en.pdf)

30. Full details of these exemptions are provided in **Annexe B**, an extract from the Meat Industry Guide<sup>8</sup>. For retail establishments, the flow diagram in **Annexe C** can be used to determine if the operator qualifies for exemption from the need to be approved:
31. In addition to the exemptions stated above there are other situations where approval may not be required but will still require registration with the relevant LA or DC, these are detailed as follows:

#### ***Collection Centres and Tanneries***

1. Collection centres and Tanneries may supply raw material for the production of gelatine and collagen intended for human consumption. They are not subject to the requirements of Regulation (EC) No 852/2004, nor are they subject to approval under Regulation (EC) No 853/2004.
2. They are, however, specifically authorised by the relevant LA or DARD VPHU on behalf of the Agency in NI in accordance with Regulation (EC) No 853/2004 Annex III Section XIV (Gelatine) Chapter 1(5) and Section XV (Collagen) Chapter 1(5) and must also meet the other requirements of Annex III, Section XIV (Gelatine) and Section XV (Collagen) of Regulation 853/2004.

#### ***Farmers Markets***

3. Establishments producing POAO for supply to the final consumer at farmers' markets, or at other markets supplying the final consumer, are regarded as supplying the final consumer directly and on this basis the market can be treated as an extension of the producer's establishment. Therefore, producers supplying POAO are not subject to approval under Regulation 853/2004, subject to the following conditions:
  - a. There is no change of control of the POAO (e.g. farmer A cannot cut meat and supply it to farmer B to sell at the market); and
  - b. The operation does not involve supply other than to the final consumer. Suppliers to shops or restaurants would render the premises subject to approval unless they meet the exemption criteria in Regulation (EC) No 853/2004.
4. Producers supplying POAO at farmers' markets or other markets supplying the final consumer should be regarded as if they were supplying the final consumer directly, on the basis that the market can be regarded as an extension of the producer's establishment. Furthermore, such sales should be treated as other sales to the final consumer and are not limited to the "localised" sale criterion.

#### ***Production of Composite Products***

5. Production of food containing both products of plant origin and processed products of animal origin, known as 'Composite Products', is subject to Article 1(2) of Regulation 853/2004 which states that: "*Unless expressly indicated to the contrary, this Regulation shall not apply to food containing both products of plant origin and processed products of animal origin. However, processed products of animal origin used to prepare such food shall be obtained and handled in accordance with the requirements of this Regulation*".
6. Therefore a food business operator who:
  - a. **assembles** processed products of animal origin with products of plant origin

<sup>8</sup> [Link to FSA website - Guide to food hygiene and other regulations for the UK meat industry](http://www.food.gov.uk/business-industry/meat/guidehygienemeat)  
<http://www.food.gov.uk/business-industry/meat/guidehygienemeat>

does not need approval, even if that product is then further processed i.e. Regulation (EC) No 852/2004 would be appropriate to that operations

- b. further processing of a processed product of animal origin prior to **combining** it with food of plant origin would need approval under Regulation (EC) No 853/2004 for that processing. The subsequent assembling of the processed product of animal origin with product of plant origin does not need approval, even if that (combined) product is then further processed i.e. Regulation (EC) No 852/2004 would be appropriate to that operation
- c. assembles food of plant origin with **unprocessed** food of animal origin that is further processed together would need approval under Regulation (EC) No 853/2004

**Note** - The addition of a product of plant origin to a processed product of animal origin does not automatically mean that the resulting food would be a composite product. For example, cheese to which herbs are added or sausages to which garlic or soya are added must be performed under Regulation (EC) No 853/2004.

7. Annex III of the EC Guidance document on the implementation of the provision of Regulation (EC) No. 852/2004 gives an overview of the scope of this Regulation. However the list is not exhaustive and therefore purely indicative.

## Responsibilities of Food Business Operators

32. Regulation (EC) No 882/2004 obliges competent authorities to establish procedures for food business operators to follow when applying for approval under Regulation (EC) No 853/2004 to which both Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004 apply.
33. Article 6(2) of Regulation (EC) No 852/2004 requires food business operators (FBO) to notify the CA *“of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment”* and Article 6(3) of the same regulation states that *“food business operators shall ensure that establishments are approved by the CA, following at least one on-site visit, when approval is required.”*
34. This places the legal onus on the FBO to make sure that establishments which are subject to approval under Regulation (EC) No 853/2004 are approved by the CA before they commence trading.
35. An **“establishment”** is any unit of a food business and denotes both premises and the manner in which those premises are being used by the food business operator. The approval of an **“establishment”** applies to both the **“premises”** and the business operating at the premises and, therefore, it is the enterprise that must be approved.
36. To gain and retain approval, the FBO must meet all the requirements of the EC Food Hygiene Regulations<sup>9</sup> and other relevant legislation as required for the type of establishment. These particularly include (but this is not intended as a definitive list):

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<sup>9</sup> Regulations (EC) No 852/2004 and Regulation (EC) No 853/2004 and all other relevant requirements of “food law” (as defined in Article 3(1) of 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 on matter of food safety.

- **Regulation (EC) No 2073/2005<sup>10</sup> – Microbiological Criteria for Foodstuffs:**  
Microbiological criteria are set for products of animal origin including carcasses of cattle, sheep, pigs, goats and horses, broiler chickens and turkeys, and for minced meat, meat products, and meat preparations.
- **Commission Regulation (EC) No 2074/2005<sup>11</sup> laying down implementing measures for certain products under 853/2004 and for the organisation of official controls under 854/2004 and 882/2004, derogating from 852/2004 and amends 853/2004 and 854/2004:**  
This provides the implementing measures for certain food business obligations and food products included in the hygiene package.
- **Regulation (EC) 1099/2009<sup>12</sup> “The Protection of Animals at the time of Killing” (PATOK), came into force on the 1<sup>st</sup> January 2013.**  
In Scotland there are domestic implementing regulations; The Welfare of Animals at the time of Killing (Scotland) Regulations 2012. (WATOK).  
In Wales and Northern Ireland similar domestic regulations came into force in 2014. The Regulations are expected to come into force in England in 2015.
- **The Food Hygiene Regulations 2006<sup>13</sup> as amended\*:**  
Came into force on 11 January 2006 and gave effect to the provisions of the EC Food Hygiene Regulations and the implementing and transitional measures (including the EU Microbiological Criteria Regulation).
- **Regulation (EC) No 1069/2009<sup>14</sup> – Animal By-Product Controls:**  
Laying down health rules concerning animal by-products not intended for human consumption.

\* - National legislation is provided by a Statutory Instrument (SI) in England and Wales and the equivalent in Scotland and Northern Ireland.

37. Article 6(2) of Regulation (EC) No 852/2004 also requires the FBO to “*ensure that the CA always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment*” (refer to *Changes to an Approval* section). Not complying with this requirement is an offence under the domestic hygiene Regulations.

38. In the context of this article, a change of FBO constitutes a closure of an existing establishment’s approval.

<sup>10</sup> [Regulation \(EC\) No 2073/2005 on microbiological criteria for foodstuffs](#)

<sup>11</sup> [Regulation \(EC\) No 2074/2005 laying down implementing measures for certain products](#)

<sup>12</sup> [Regulation \(EC\) No 1099/2009 on the protection of animals at the time of killing](#)

<sup>13</sup> [Link to FSA website - Background to the 2006 food hygiene legislation](#). These have been replaced in England by the [Food Safety and Hygiene Regulations 2013](#)

<sup>14</sup> [Regulation \(EC\) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation \(EC\) No 1774/2002 \(Animal by-products Regulation\)](#)

# Approval Requirements

## Application for Approval

39. Following an enquiry from a prospective FBO the FSA/FSS will provide the applicant with an application form. Application forms are also available to download from the FSA website<sup>15</sup>.
40. An FBO can only make an application for approval for an establishment under their control and only for processes and/or activities that they intend to carry out.
41. The applicant must provide details of:
- the premises for which approval is requested;
  - the activities for which approval is sought; and
  - the identity of the FBO including relevant contact and address details.
42. Article 3 of Regulation (EC) No 178/2002 states “*‘food business operator’ means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control*”.

- A **natural person** is a human being, (as opposed to an artificial, legal or juristic person, i.e., an organization that the law treats for some purposes as if it were a person distinct from its members or owner).
- A **legal person** has a legal name and has rights, protections, privileges, responsibilities, and liabilities under law, just as natural persons (humans) do. Legal personality allows one or more natural persons to act as a single entity (a composite person - considered under law separately from its individual members or shareholders) for legal purposes.

43. The legislation allows for natural and legal persons to be FBOs therefore the CA requires the applicant to identify themselves (including the name of officers, address and proof of status) as either a:
- Sole trader or partnership (natural person/s) who is required to be compliant with food law.
  - Incorporated and registered company (legal person) which is required to be compliant with food law (even though the actions of the company are carried out by human hands).
  - Other business types such as cooperatives, registered charities and other specialised types of organisation will have to establish the natural or legal person who will have control and responsibility for the operation of the food business.
44. Applications for approval are required for new builds / start-up food businesses and are also required in the following circumstances:
- Registered establishments under Regulation (EC) No 852/2004 applying to undertake activities that are approved by the Agency.
  - Establishments approved under Regulation (EC) No 853/2004 by the LA or DC applying to undertake activities that are approved by the FSA/FSS (i.e.

<sup>15</sup> <http://www.food.gov.uk/enforcement/sectorrules/meatplantsprems>

Slaughterhouses, Cutting plants or Game Handling Establishments) to become co-located (refer to [Type of Establishments](#) section).

- c. Existing establishments approved by the FSA/FSS where the FBO is applying to undertake additional approvable activities.

45. In considering applications for approval, the FSA/FSS will consider any exemption that may be available to the applicant afforded by Article 1 of Regulation (EC) No 853/2004.

## Advisory Visits

46. The FSA/FSS may offer an advisory visit to those food business that have applied for approval prior to an approval visit. The aim of an advisory visit is to help FBOs identify any problems in the areas of structure and maintenance and food safety management to avoid any potential difficulties when the establishment is assessed for approval.

47. FBOs must be aware that there is a difference between an advisory visit and an approval visit. The FSA/FSS reaffirms that the FBO will not be able to undertake activities, that are approved by the FSA/FSS, until an approval visit has been carried out and a decision following such visit has been formally conveyed to the FBO.

**Note** - The FBO will not be able to undertake activities that are approved by the Agency, until approval or conditional approval is granted.

## Approval Procedures

48. Article 31(2) of Regulation (EC) No 882/2004 provides that competent authorities:

- a. 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
- b. on receipt of an application for approval, shall make an on-site visit
- c. 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

49. There is no obligation for a CA to grant an approval. By virtue of Article 31(2)(c) of Regulation (EC) 882/2004 an approval can only be granted where the FBO has demonstrated compliance with the relevant requirements of food law. Past compliance is a relevant factor and may be used as an indication of future levels of compliance.

Following an on-site visit:

- a. the CA may grant **conditional approval** if the establishment meets all the infrastructure and equipment requirements. The food business may not have a recognisable 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. In such cases, the FBOs food safety management system needs to be available to the CA but if the establishment is not operational, it will not be possible to assess how effectively this works in practice
- b. **full approval** shall only be granted where it appears from a new official control visit, which must be carried out within three months of conditional approval, that the establishment meets all structural and equipment requirements and other relevant requirements of food law, including the need to implement an effective food safety management system based on HACCP principles
- c. if clear progress has been made but the establishment and food business still does not meet all of the relevant requirements, **conditional approval may be extended**, but must not exceed a total of six months. In such cases the establishment must still meet all the infrastructure and equipment requirements
- d. the Agency shall grant **full approval** if the establishment and food business complies with all the relevant requirements of food law (infrastructure, equipment and operational requirements) and the establishment has been observed in operation

50. Where the above requirements are not met and approval cannot be granted the CA will refuse or discontinue approval.

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

52. Full approval subsequent to conditional approval will be **refused**:

- a. if, within the three months' conditional approval, insufficient progress has been made to meet the requirements in full and, in the judgement of the CA, 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
- b. 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

53. Approval will be **discontinued** if, following conditional approval and before consideration can be given to recommend full approval or prolong conditional approval the establishment ceases operations or a visit cannot be undertaken caused by the relevant activities not being in operation. In such cases conditional approval will cease to have effect.

54. The procedures detailed above are also shown in a flow diagram at **Annexe D**.

55. In between each period of conditional/extended conditional approval the CA may conduct unannounced visits to check the food business compliance with operational hygiene requirements. Evidence of non-compliance with these requirements may result in appropriate enforcement action and may be used as evidence in the final decision whether to grant or to refuse to grant full approval.

## Approval Visits & Assessments

56. On-site visits undertaken with a view to the approval of premises will be undertaken by a Veterinary Official. The Agency will make an appointment with the FBO or their duly authorised representative<sup>16</sup>. Following an approval visit the Agency will make an assessment of the compliance with the approval requirements for the premises and FBO controls.
57. Following conditional approval, measures must be taken by the FBO within the conditional approval period to remedy any operational or food safety management system deficiencies on a permanent basis. The initial conditional approval period of up to three months may only be extended for a further period if progress is made to remedy any deficiencies during the initial period and if, in the judgement of the Agency, there is evidence that the necessary work will be completed if a further period of conditional approval is granted. The total period of conditional approval cannot exceed six months; at the end of the conditional approval period, all aspects of compliance will be reassessed.
58. Although conditional approval may last up to three months or if extended up to a maximum of six months, assessment for full approval may be undertaken at any time after conditional approval has been granted.
59. Before full approval can be recommended, the food business must be observed in operation to verify that it meets all the requirements of food law, and other relevant legislation as required for the type of approval.
60. Where the slaughter of all species requiring approval cannot be reasonably seen on an approval visit professional judgement can be used. When the veterinary official reaches a point where they are satisfied with infrastructure, equipment and the FBO controls they should recommend approval, even if every species has not been observed in operation.
61. 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 CA will aim to conclude the approval process within one season even if it means that conditional approval will last for less than the allowed three or six months. However, where this is not practicable conditional approval may be split.
62. In these cases the veterinary official undertaking the assessment must satisfy themselves that:

### ***Seasonal Establishments***

- it is practical to split the approval across one or more seasons and any potential risk to public health is managed;
- measures will be taken by the FBO within the expected conditional approval period to remedy any operational or food safety management system deficiencies on a permanent basis; and
- full approval is achievable within three years.

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<sup>16</sup> a person who is given the authority to stand in the place of the FBO

63. Depending on the type of application for approval there are several specific requirements applicable when an approval visit/assessment is undertaken. These are as follows:

#### ***New builds / Start-up Food Businesses***

- 1.a If conditions are such that conditional approval cannot be recommended at the first inspection that inspection may be treated as an advisory visit and the operator given a reasonable period of time to achieve compliance before it is re-inspected.
- 1.b If conditions are such that approval is not achievable in a reasonable period of time the veterinary official must recommend refusal of approval.

**Note** - The FBO will not be able to operate until conditional approval is granted.

- 1.c If during an advisory visit conditions are such that conditional approval could be recommended that visit may be treated as an approval assessment visit with the agreement of the applicant. In Northern Ireland advisory visits are carried out by DARD Veterinary Service, Veterinary Public Health Unit Programme (VS-VPHUVPHP) on behalf of the Agency who are not able to recommend conditional approval as this is only carried out by a veterinary official.

#### ***Food Businesses Transferring from LA or DC Control***

- 2.a If conditions are such that conditional approval cannot be recommended at the first inspection of a registered establishment, applying to undertake activities that are approved by the FSA/FSS, that inspection may be treated as an advisory visit. The operator can then be given a reasonable period of time (but not exceeding six months) to achieve compliance before it is re-inspected. After such time the application is null and void and the FBO will need to re-apply if they wish to undertake the approvable activity in the future.
- 2.b If conditions are such that approval is not achievable within a six month period the veterinary official must recommend refusal of approval.

**Note** - The FBO will not be able to undertake activities approved by the FSA/FSS, until conditional approval is granted.

3. Until conditionally approved by the FSA/FSS, responsibility for enforcement action remains with the LA or DC. When assessing for approval the FSA/FSS, where possible in consultation with the relevant LA or DC, will consider whether any enforcement action for the protection of public health is needed and communicate this to the relevant LA or DC responsible official.
4. With the industrial nature of the processes and likelihood of daily damage to structure and equipment, it would be unreasonable to expect any already operating premises to have all infrastructure and/or equipment fully compliant without the need for maintenance. Where the FBO can demonstrate that infrastructure and/or equipment deficiencies have been identified and scheduled for repair in a way that manages any potential risk to public health, dependent on the nature and extent of the deficiency (i.e. minor / operational wear and tear), approval or conditional approval will be recommended.

5. Registered establishments under Regulation (EC) No 852/2004 taking advantage of the exemption criteria (refer to [Exemptions from Approval](#) section) and applying to undertake activities that are approved by the Agency, may be recommended for full approval following the initial approval visit. This can only be the case where the establishment and FBO controls have been observed in operation and complies with all the relevant requirements of food law (infrastructure, equipment and operational requirements) and any other relevant legislation as required for the type of approval.

**Note** - The FBO will not be able to undertake activities, that are approved by the FSA/FSS (in this case working outside of the exemption criteria), until approval or conditional approval is granted.

### ***Wholesale Markets***

6. 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.
7. Regulation (EC) No 854/2004 Chapter II Article 3(3) permits the allocation of secondary numbers to individual stalls. The common parts of wholesale meat markets must be approved as one establishment while individual stalls under the control of separate food business operators must be approved in their own right and receive an approval number consisting of the approval number for the common parts and a secondary number that is stall-specific.
8. Responsibility for complying with the Hygiene Regulations<sup>17</sup> rests with the landlord of the market for the general areas within the market and with the individual food business operators for the unit(s) that they operate. However, FBOs for individually approved units have a duty to ensure that the common area requirements, providing the pre-requisites for hygienic operation such as waste disposal and pest control, are in place.

### ***Multiple FBOs Operating from One Establishment***

9. Where more than one FBO wishes to use a single premise to operate separate food businesses at different times, for example FBO A operates 09:00-17:00 and FBO B operates 17:00-09:00, approval may still be permitted but these situations will be assessed on a case by case basis.
10. The FBO/s for the individual businesses requiring approval using one premise will need to demonstrate how they plan to manage any food safety risks adequately. When undertaking the assessment the Agency must be satisfied that infrastructure, equipment and the FBO controls are acceptable before approvals can be granted. The arrangements regarding the operating pattern and joint use of the premises will be included in the approval document as a precondition to the approval.
11. Where the arrangements are satisfactory, approval or conditional approval will be granted to each FBO individually with each FBO receiving their own approval number. Refer to [Allocation of Approval Number](#) section.

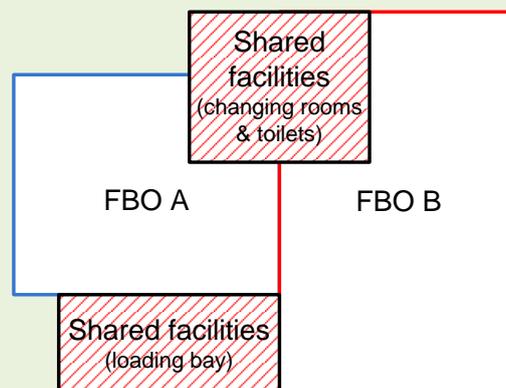
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<sup>17</sup> The Food Hygiene Regulations 2006 / Food Safety and Hygiene (England) Regulations 2013, Regulations (EC) No 852/2004 and Regulation (EC) No 853/2004 and all other relevant requirements of "food law" (as defined in Article 3(1) of Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures on matter of food safety.

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

### **Shared Facilities**

13. In the event that an FBO requiring approval to operate an establishment can only fully meet the requirements of the regulations by sharing certain facilities with a neighbouring FBO, approval may still be possible. These situations will be treated on a case by case basis but examples would include sharing facilities such as changing rooms, toilets, loading bays and chillers.
14. The FBO requiring approval using shared facilities will need to demonstrate how food safety risks are managed. When undertaking the assessment, the CA must be satisfied that infrastructure, equipment and the FBO controls are acceptable before approval can be granted. Shared facilities will be identified in the approval document and marked on the site plan.
15. An example site plan identifying the shared facilities:



16. Where the arrangements are satisfactory, approval or conditional approval will be granted on the basis that the facilities being shared remain available and the requirements of the regulations continue to be fulfilled.
17. If at a point in the future the sharing of facilities is no-longer possible, the approval will be reviewed. Also refer to [Review of Meat Establishments Approval with the view to Withdraw or Suspend](#) section. Where either FBO is able to become self sufficient in their own right, separate approval as an individual establishment can be sought.
18. When carrying out official controls, if the CA needs to take enforcement action, for example due to non-hygienic operations or equipment deficiencies, this may be taken against both parties. As the terms of the joint use of the shared facility are a precondition to the individual approval enforcement action must be taken against both parties regardless of which party caused the problem in the first place.

**Note** - The facilities which are to be shared must form part of an approved establishment. A registered establishment may share them but the relevant LA/DC is responsible for official controls. In the event enforcement action is required this will be undertaken by the relevant authority.

64. Where the facilities in a slaughterhouse are only suitable for a particular age, size or type of animal, conditions may be imposed by the CA on the approval to control actual or potential risk to public health or animal welfare. Any such conditions will be stated to the approval documentation.

## Granting or Refusing Approval

65. Following an approval visit a veterinary official makes an assessment of the compliance with the approval requirements for the establishment and FBO controls. The results of this assessment will be formally confirmed by means of a recommendation to an authorised official in the FSA Operations Assurance Division.

66. In England and Wales the authorised official in the Operations Assurance Division is responsible for making a decision on whether or not to grant approval or conditional approval of a food business including any subsequent additional activities at an existing approved establishment. Where approval cannot be granted the CA will refuse approval. In such cases, where the establishment is located in Wales the authorised official will discuss the formal recommendation, including supporting evidence with the FSA Wales Director.

67. In NI the authorised official is the Head of the Operational Policy and Delivery Team. In Scotland the authorised official is the FSS Director of Operations.

68. Approval assessment decisions must be notified to the FBO in writing in the form of an approval document which must include the following details:

- a. establishment for which approval is granted;
- b. identity of the FBO (refer to [Application for Approval](#) section);
- c. activities for which approval or conditional approval is granted or refused; and
- d. in the case of conditional approvals, examples of any deficiencies (but not an exhaustive list) regarding the establishment &/or FBO controls.

69. In the case of Wholesale markets separate approval documents must be issued for the market as a whole and for individual units within the market, which are approved establishments in their own right.

70. In the event that a decision to refuse to grant approval is made, the FBO must be given notice of the decision, the reason why the decision was made and a list of deficiencies that were noted at the time of the visit including the requirements of the legislation in relation to hygiene, structure, HACCP or other elements relevant to the type of approval being sought and show how the FBO has failed to satisfy those requirements. The FBO of an establishment that has been refused approval has the right to appeal as per the following requirements:

1. The Official Feed and Food Controls Regulations provide that, if approval is refused, the operator has one month\* to appeal to a Magistrates' Court (in England and Wales) or the Sheriff (in Scotland) or Court of Summary Jurisdiction (in Northern Ireland).
2. The time limit for lodging an appeal is one month from the date on which notice of the decision is served on the relevant person.
4. For matters under litigation, which is the case for establishments that have lodged an appeal, any communication relating to the appeal with either the FBO or their

legal representatives must be directed to the point of contact in FSA/FSS Legal Services.

5. Where the FBO lodges an appeal and the Magistrates' Court, the Sheriff or Court of Summary Jurisdiction overturns the CA's decision the CA must grant approval or conditional approval, in accordance with the courts' decision.

\* - *calendar month*

71. From the date on which notice of the decision to refuse approval is served on the relevant person the establishment must cease approvable activities regardless of whether an appeal is lodged.

## Approval Number / Identification Mark

### Allocation of Approval Number

72. On granting approval or conditional approval, Regulation (EC) No 854/2004 Chapter II Article 3(3) requires the CA to give each approved establishment an approval number. For wholesale markets, secondary numbers indicating units or groups of units may be added to the approval number. The approval number should be unique to the establishment/wholesale market and FBO.
73. The following numbering system for regional variations in allocating approval numbers, to establishments approved by the FSA/FSS, will apply:
- England 1000-1099, 2000-6999 & 8000-8999
  - Scotland 1100-1999
  - Wales 7000-7999
  - Northern Ireland 9000-9999
74. 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.
75. Article 5 of Regulation (EC) No 853/2004 requires that products of animal origin handled in establishments subject to approval are not placed on the market unless they have an identification mark (ID) or health mark, in accordance with Regulation (EC) No 854/2004.
76. Annex II, Section I B of Regulation (EC) No 853/2004 requires that the mark must indicate the approval number of the establishment. The requirements for the form of the ID mark are as follows:

#### **Identification Mark**

- The mark must be legible and indelible, and the characters easily decipherable. **It must be clearly displayed for the competent authorities.**
- The mark must indicate the name of the country in which the establishment is located – it may be written out in full or a two letter code used (UK for the United Kingdom).
- The mark must indicate the approval number of the establishment. If an establishment manufactures both food to which this Regulation applies and food to which it does not, the food business operator may apply the same identification mark to both types of food.
- When applied in an establishment located within the community, the mark must be oval in shape and include one of the two letter abbreviations allowed e.g. EC.

77. Where an establishment premise has been re-assessed for approval due to a change of FBO and approval is granted, generally a new approval number should be given. However, to have regard to issues of risk, cost and proportionality, a business may be

able to retain its approval number where, other than for the change of FBO, the business is to continue to operate from the same premises and in essentially the same way, i.e. the type of food production by the business and the food safety control arrangements of the business will remain essentially the same. Also refer to [Change of FBO](#) section.

78. If the FBO moves to a new premise the CA may allow the FBO to retain the same approval number which was provided to them for the establishment which they are vacating. This will be subject to remaining with the same CA and the same country. The FBO will also still be required to submit a new application and be granted approval prior to operations commencing in the new location (see paragraph 124). In order to ensure that the approval number remains unique the previous approval will need to be surrendered by the FBO prior to it being granted for the approval at the new address.
79. In addition to the above, re-allocation of an approval number would only be permissible where the FBO of the business remains the same, and the activities remain substantially the same, when the establishment moves to a new location.
80. Where an establishment is approved by the LA and the FBO is subsequently granted an approval by the FSA/FSS, due to the establishment becoming co-located, the FSA/FSS will issue a new approval number to the establishment as a whole. In order not to penalise FBOs in this situation, upon request, a reasonable period of time (but typically not exceeding the conditional approval period) will be given for the business to use up old packaging. The request will be dealt with on a case by case basis in conjunction with the LA.
81. With regard to traceability Regulation (EC) No 178/2002 Article 18(1) states “[The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.](#)” In the event that traceability is believed to be compromised due to fraudulent use of an identification mark (ID) or health mark the CA may issue a new approval number to the establishment. The original approval number will be removed from the official published lists, refer to [List of approved establishments in the UK](#) section, with the new number taking effect from a specified date.

## **Flexibility in the Use of Approval Numbers**

82. The practice of allowing products of animal origin (POAO) to bear an identification mark using an approval number other than that of the establishment of production or of processing is contrary to Regulation (EC) No 853/2004, Annex II, Section I, paragraphs 1 and 7: “[The identification mark must be applied before the product leaves the establishment](#)”; and “[The mark must indicate the approval number of the establishment](#)”.
83. The Recitals to Regulation (EC) No 853/2004 link the application of the identification mark explicitly to traceability, saying that it applies in addition to the requirements of Regulation (EC) No 178/2002. Recital 15 states that “[the traceability of food is an essential element in ensuring food safety](#)”.

84. The only flexibility that could be applied to this requirement would be in the event of a force majeure<sup>18</sup>.
85. Where FBOs, of establishments approved by the FSA/FSS, ask for permission for products to bear an approval number other than the one relating to the establishment where the product was manufactured or handled the request must be made in writing. This should include:
- a. the nature of the extraordinary event (flexible application of the legislation should not apply to address normal business risks);
  - b. the duration of the proposed alternative arrangements;
  - c. why alternative ID arrangements (e.g. sleeves or stick-on labels) cannot be made;
  - d. the alternative approval number being proposed as part of this request for flexibility;
  - e. how traceability will be maintained during the period of the alternative arrangements; and
  - f. any additional supervision arrangements needed to be made as products produced or handled during the period of alternative arrangements must be for the UK market only.
86. Consideration of the written request for flexibilities in extreme circumstances and a decision on whether or not to accept it will be undertaken by the authorised official responsible for making decisions on approvals.

## List of Approved Establishments in the UK

87. Article 31(2) of Regulation (EC) No 882/2004 provides that the competent authorities shall maintain up-to-date lists of approved establishments and make them available to other Member States and to the public. Although not specifically stated in the regulations, the list of establishments will be updated by the FSA at least monthly.
88. The requirements for the published lists of EU approved food establishments are detailed in SANCO/2179/2005 Revision 5<sup>19</sup>. Member States are required to publish lists of establishments which are granted approval or conditional approval under sixteen separate sections each corresponding to a different food sector. Each section requires the following details:
- a. the approval number;
  - b. name of establishment;
  - c. town/region<sup>20</sup>;
  - d. category of food establishments;
  - e. associated activities;
  - f. species; and
  - g. remarks
89. The published list of approved food establishments in the England, Wales and NI is available from the FSA website<sup>21</sup>. Establishments located in Scotland have their details published on the FSS website<sup>22</sup>.

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<sup>18</sup> “force majeure “: an extraordinary event beyond the control of the parties involved, for which no contingency arrangements could be made, such as war, flooding or fire

<sup>19</sup> [http://ec.europa.eu/food/food/biosafety/establishments/techspecs\\_en.pdf](http://ec.europa.eu/food/food/biosafety/establishments/techspecs_en.pdf)

<sup>20</sup> This will include the full address unless the FBO has opted out of having their full address details published

<sup>21</sup> <http://www.food.gov.uk/enforcement/sectorrules>

90. A list of approved establishments in other Member and European Economic Area States is available from the European Commission - Food and Feed Safety website<sup>23</sup>

## Review of Meat Establishments Approval with the view to Withdraw or Suspend

91. Approval of establishments must be kept under review by the CA including initiating action to withdraw or suspend the approval as described in Article 31(2)(e) of Regulation (EC) No 882/2004, extract below:

*“The CA shall keep the approval of establishments under review when carrying out official controls. If the CA identifies serious deficiencies or has to stop production at an establishment repeatedly and the feed or food business operator is not able to provide adequate guarantees regarding future production, the CA shall initiate procedures to withdraw the establishment’s approval. However, the CA may suspend an establishment’s approval if the feed or food business operator can guarantee that it will resolve deficiencies within a reasonable time”*

92. Interpretation of the terms “serious deficiency” or “repeated stoppage” mentioned in Article 31(2)(e) as the criteria that provide the basis for withdrawal of approval, has not been specified in the regulations. For consistency of approach, working definitions for these terms have been developed by the FSA and FSS and are detailed in **Annexe E**.
93. In the case of a wholesale market, Article 3(4)(c) of Regulation (EC) No 854/2004 allows the withdrawal or suspension of an approval in respect of certain units or groups within the market. In the event that 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 are able to become self sufficient in their own right separate approval as individual establishments can be sought.
94. Referrals for review may be identified as a result of either performance monitoring when carrying out official controls (compliance and enforcement) or as a result of local intelligence for example where the establishment has been non operational (long-term), major curtilage change/rebuild or acts of God<sup>24</sup> and/or where there is a strong likelihood that serious deficiencies will have developed.
95. Where a food business is referred for review of approval by those responsible for carrying out official controls and enforcement at the establishment or through local intelligence a preliminary review of the evidence presented will be undertaken by a veterinary official.
96. Where the preliminary evidence suggests that there may be serious deficiency or there has been repeated stoppage, the CA will:

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<sup>22</sup> <http://www.foodstandards.gov.scot/approved-premises-register-mar-2015>

<sup>23</sup> [Link to European Commission Food and Feed Safety website - List of Approved Establishments for other Member and European Economic Area States](#)

<sup>24</sup> “Act of God”: An event which is caused solely by the effect of nature or natural causes and without any interference by humans whatsoever.

- a. carry out an unannounced inspection of the establishment when production is taking place. This will not be possible where the establishment is not operating due to enforcement action or where the operator has voluntarily ceased to operate; and
  - b. undertake an assessment of the FBOs history of compliance with regulatory requirements at the approved establishment, the relevant history of enforcement and any prosecutions involving the FBO.
97. The Veterinary Official undertaking the review will assess whether serious deficiencies or evidence of repeated stoppage exists. Where either of these are present a formal recommendation including supporting evidence will be made to the authorised official responsible for making such decisions. Where the establishment is located in Wales the authorised official in the Operations Assurance Division will discuss the formal recommendation, including supporting evidence with the FSA Wales Director.
98. In Northern Ireland the Veterinary Official carrying out the review will discuss the outcome of such a review with the Head of Operational Policy and Delivery and the FSA NI Director.
99. The decision will be communicated in writing to the FBO that the CA is minded to withdraw the approval.
100. Where a “**minded to**” Notice of Review of Approval has been served the FBO may provide the CA, within 14 calendar days from the date of service, with any guarantees regarding future production and any guarantees that it will resolve the deficiencies within a reasonable<sup>25</sup> time.
101. Where the FBO does offer guarantees to the CA the guarantees will be considered as submitted and the CA is not obliged to seek further information from the FBO. The process for consideration of guarantees is described below and also shown in flow chart format at **Annexe F**:
- a. Where the FBOs guarantees regarding future production are not accepted the approval will be withdrawn.
  - b. Where the CA does accept that the FBOs guarantees mean that deficiencies will be permanently resolved **immediately** and that there will be no foreseeable future stoppages of production approval will continue.
  - c. Where the CA accepts that the guarantees mean that the deficiencies will be permanently resolved **within a reasonable time** and the situation will be such that, once the deficiencies have been resolved, there will be no foreseeable future stoppages of production the *approval will be suspended*. Where this is not the case approval will be withdrawn.
  - d. Where the FBO does not provide any guarantees approval will be withdrawn.
102. Suspension of approval will be lifted once the deficiencies are permanently resolved and the situation is such that there will be no foreseeable future stoppages of production. If this has not been undertaken **within a reasonable time** the approval will be withdrawn.
103. Where the FBO’s suspension has been lifted and the FBO returns to full operation such approval will remain under review when carrying out official controls and if the previously identified deficiencies or repeated stoppages of production recur the CA shall initiate procedures to withdraw said approval.

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<sup>25</sup> “Reasonable” would be relative to the nature and magnitude of the deficiencies present

104. The FBO has the right to appeal the decision to withdraw or suspend the approval as per the following requirements:

1. The Official Feed and Food Controls Regulations provide that, if approval is withdrawn or suspended, the operator has one month\* to appeal to a Magistrates' Court (in England and Wales) or the Sheriff (in Scotland) or Court of Summary Jurisdiction (in Northern Ireland).
2. The time limit for lodging an appeal is one month from the date on which notice of the decision is served on the relevant person.
3. For matters under litigation, which is the case for establishments that have lodged an appeal, any communication relating to the appeal with either the FBO or their legal representatives must be directed to the point of contact in FSA/FSS Legal Services.
4. Where the FBO lodges an appeal and the Magistrates' Court, the Sheriff or Court of Summary Jurisdiction overturns the CA's decision the CA must reinstate the approval or lift the approval suspension, in accordance with the courts' decision.

\* - *calendar month*

105. From the date on which notice of the decision to withdraw or suspend the approval is served on the relevant person the establishment must cease approvable activities regardless of whether an appeal is lodged.

## Changes to an Approval

### General Requirements

79. Article 6(2) of Regulation (EC) No 852/2004 states the FBO is to “*ensure that the competent authority always has up-to-date information on establishments, including by notifying, any significant change in activities and any closure of an existing establishment*”. Not complying with this requirement is an offence under the Food Hygiene Regulations 2006.
80. Where the FBO notifies the CA of such changes, consideration needs to be given as to whether a visit should be made to inspect the alterations and whether amended approval documentation is required. The amendment will depend on the extent of the changes, as follows:
- a. additional Activities
  - b. change to Approved Curtilage / Restructuring
  - c. change of FBO
  - d. change of name
  - e. closure of an Approved Establishment
  - f. surrender of Approval
  - g. transfer of Official Controls to LA

### Additional Activities

106. The FBO of a fully approved establishment wishing to undertake (an) additional activities requiring approval (as detailed in *Type of Establishments* section), must apply to the Agency for approval before carrying out the additional activity.
107. The approval procedures, stated in paragraphs 48 to 55, will be applied when assessing the additional activities for approval.
108. Professional judgement may be used, in the case of approving additional activities, to grant full approval in the first instance. This is only when the CA reaches a point where they are satisfied with infrastructure, equipment and the FBO controls. Examples include adding an approval (this is not an exhaustive list):
- a. to slaughter goats at an existing sheep approved slaughterhouse
  - b. to cut an additional meat type at an approved cutting plant already approved to cut two or more types of meat
  - c. for a minced meat establishment to an already approved meat preparations establishment
  - d. for the cold storage of meat
  - e. for the re-wrapping of meat

### Change to Approved Curtilage / Restructuring

109. Significant curtilage changes and/or restructuring within the approved curtilage will necessitate the FBO providing revised plans indicating the changes. An assessment will be made to ascertain if the changes are appropriate. As part of this assessment professional judgement will be used to determine whether an on-site visit is also required.

110. Once acknowledged by the CA, curtilage changes or restructuring should not require further or additional approval. It is the FBO's responsibility to make sure that all such changes meet the respective requirements of the Regulations.

**Note** - The FBO will not be able to undertake approvable activities in the areas subject to a curtilage change or restructuring until acknowledged by the CA.

## Change of FBO

111. The approval of an “[establishment](#)” applies to both the premises and the business operating at the premises. If an approved establishment changes FBO the food business will have to be assessed and granted a new approval under the new FBO.

112. On change of FBO an establishment can continue to operate under the existing approval for a short period of time, but not exceeding a maximum of **25 working days** after the change of FBO, until an approval assessment is carried out by the CA.

113. This provision is on condition that:

- a. the new FBO submits an application for a new approval that is received by the CA within **one calendar week** of the change of FBO.  
If no application is received within one week, the CA will formally notify the FBO that the approval is no longer in force and all approvable activity must cease with immediate effect. The relevant LA or DC will also be informed and requested to check that the establishment has stopped carrying out any activity subject to approval; and
- b. in order to safeguard public health, the new FBO must not change the operation at the premises in any significant way until a new approval is given, e.g. the new FBO must not change the type of animals slaughtered, nature of products produced / handled, and the HACCP based controls that have been subject to FSA/FSS audit.

114. The approval assessment will be undertaken as soon as possible and in all cases within **20 working days** of receiving an approval application from the new FBO. This timescale only starts once the change of FBO has occurred.

115. The FSA/FSS is prepared, on request by the FBO to carry out a pre change of FBO advisory visit, refer to [Advisory Visits](#) section. However, any views given at such a visit will in no way provide a guarantee as to the future approval status of the business.

116. The different situations where a change in FBO, between different business entities, requires a new approval or where the approval can be retained are detailed in **Annexe G**.

117. Article 6(2) of Regulation (EC) No 852/2004 requires the FBO to inform the CA when there is a change of FBO. This will be by means of an application form as detailed in [Application for Approval](#) section that includes the type of business entity, name of officers and relevant address/es of the FBO wishing to apply for approval. The FBO is then obliged to keep the CA informed about significant changes to those details.

118. Once received by the Agency the application will be assessed in the same way as a new establishment and if approval is granted may be subject to a new approval number. Also refer to [Allocation of Approval Number](#) section.
119. Where the CA becomes aware of a change of FBO at an establishment and the new FBO has failed to notify the change, the CA 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 CA will also inform the relevant LA/DC of this so that the LA/DC can take appropriate enforcement action.
120. 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.

## Change of Name

121. The approval document includes the details of the establishment and the identity of the FBO. Where there is a change of name in either of these areas, the approval document must reflect this.

**Note** – This is not to be confused with a change of FBO, which would warrant a re-assessment for approval. Refer to [Change of FBO](#) section.

122. The change of name does not affect any existing matters arising in relation to the establishment, which may be the subject of separate inspection or enforcement activity.

## FBO moving to Different Premises

123. If an approved food business relocates to a different address the FBO will need to apply for a new approval at this new address. The approval procedures, stated in paragraphs 48 to 55, will be applied when assessing the food business at the new address for approval.

## Closure of an Approved Establishment

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

### Seasonal closure

1. An establishment may operate to a seasonal pattern with routine breaks in operation. Notification of this pattern must be provided by the FBO as part of the application process by identifying the months when the FBO intends to operate the establishment. The FBO is then obliged to keep the Agency informed about any significant changes to those details including any establishment moving to or from a seasonal pattern. When an FBO intends to re-commence operation the Agency needs to be notified at least two weeks before operations are intended to re-commence.

### Temporary closure

2. When an FBO needs to temporarily halt operations due to renovation / development work at an establishment or due to a temporary downturn in trade the FBO is obliged to keep the Agency informed about these significant changes to the operational pattern. In these cases the FBO must notify the Agency at least two weeks before operations re-commence. Also refer to [Change to Approved Curtilage / Restructuring](#) section.

### Long-term closure

3. When an FBO stops operations with no immediate intention to recommence for at least six months or longer the closure is classed as long-term. The FBO is obliged to keep the Agency informed about this significant change to the operational pattern and must notify the Agency at least two weeks before operations re-commence.

**Note** – Temporary or long-term closures should not be confused with seasonal closures. Seasonal closures are pre-notified routine breaks in operation to a seasonal pattern.

125. During non-operational periods official controls undertaken by the CA will be partially suspended, with the exception of ad hoc controls as stated in Recital 13 of Regulation EC No 882/2004, until operations re-commence.

Recital 13 of Regulation EC No 882/2004 “*The frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control programmes or quality assurance programmes, where such programmes are designed to meet requirements of feed and food law, animal health and animal welfare rules. Ad hoc controls should be carried out in case of suspicion of non-compliance. Additionally ad hoc controls could be carried out at any time, even where there is no suspicion of non-compliance.*”

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

127. Following a period of closure the FBO must **not** start operations until the CA has been notified and undertaken a pre-opening visit. This visit is to assess that the

establishment meets all structural and equipment requirements and other relevant requirements of food law, including the existence of a food safety management system based on HACCP principles.

128. The FBO's food safety management system must be available at the visit but as the establishment will not be operational, it will not be possible to assess how effectively this works in practice. The effectiveness of the FBO's food safety management system will therefore be assessed at the first scheduled audit visit undertaken by the CA.
129. The process of pre-opening assessments is described below and also shown in flow chart format at **Annexe H**:
- a. where the pre-opening assessment results in the CA being confident that the requirements of food law are met the FBO will be notified that operations at the establishment **can re-commence**.
  - b. where the pre-opening assessment identifies serious deficiencies in meeting the requirements of food law the FBO may provide the CA with guarantees on how the deficiencies will be resolved on a permanent basis and within a reasonable time.
  - c. where the FBO provides adequate guarantees that the deficiencies will be resolved on a permanent basis and within a reasonable time the approval will remain but operations **cannot re-commence** until the deficiencies have been resolved.
  - d. where the FBO does not provide adequate guarantees or the timescale suggested for the deficiencies to be resolved is not reasonable the establishment **cannot re-commence** operations and the approval will be referred for formal review. Also refer to *Review of Meat Establishments Approval with the view to Withdraw or Suspend* section.
130. For consistency of approach, the working definition for the term “*serious deficiency*” used when assessing closed premises in advance of re-opening will be the same as that used in a formal review of approvals, as detailed in **Annexe E**.
131. Following the pre-opening assessment visit and when the CA is content that the establishment meets all of the relevant requirements of food law, the FBO will be notified that operations can re-commence.
132. In the event that the CA is not content for operations to re-commence, the FBO will be notified of the deficiencies and appropriate enforcement action will be taken until the deficiencies are resolved on a permanent basis or a formal review of approval has been undertaken.
133. Where the CA becomes aware of an establishment that has re-commenced operations without first notifying the CA and a pre-opening visit assessment has not been undertaken, the following measures will be taken:
- a. appropriate enforcement action will be taken to prevent FBO operating the establishment until a formal assessment of compliance has been undertaken or where deficiencies are identified such deficiencies have been rectified.
  - b. if food has been placed on the market prior to a formal assessment the CA's action regarding withdraw/recall of food will be risk-based and proportionate. However, food not yet placed on the market will be detained until the FBO has been notified that operation can re-commence.

134. If an establishment ceases to operate as food business the approval granted to it will no longer have effect. The CA will monitor establishments which have ceased operating and not informed the CA of their future plans. If the FBO does not confirm the surrender of their approval in writing within six months of the establishment ceasing operations then the CA will write to the FBO to confirm their approval no longer has effect and the establishment will be removed from the published list of approved meat establishments.

## **Surrender of Approval**

135. Where the FBO, of an establishment under their control, holding an approval, granted by the FSA/FSS, wishes to surrender that approval, the FBO is required to provide formal notice.

136. Once acknowledged by the CA, 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.

137. It would be an offence to resume activities subject to Regulation (EC) No 852/2004 or Regulation (EC) No 853/2004 at the establishment, before the FBO is granted approval or conditional approval or registered as appropriate by the relevant CA.

138. As set out in Regulation (EC) No 854/2004, where health marking carcasses of domestic ungulates, farmed game mammals other than lagomorphs, and large wild game, at Slaughterhouses and/or Game Handling Establishments is carried out, health marking equipment will be retrieved. In establishments where ID marks are applied, following surrender, the FBO should be advised that it would be an offence to apply the ID Mark on any surplus labels or packaging.

139. Establishments undertaking activities that require an authorisation (e.g. a cutting plant removing SRM vertebral column from bovine carcasses) which is based on the establishment holding an approval, the authorisation will automatically be revoked with the removal of the approval.

## **Transfer of Official Controls to LA**

140. As detailed in [Establishments Requiring Approval](#) section, the FSA and FSS are the CA's responsible for the approval of meat establishments and associated activities when co-located with an approved Slaughterhouse, Cutting Plant or Game Handling Establishment.

141. Where the FBO, holding an approval granted by the FSA/FSS, wishes to surrender the Slaughterhouse, Cutting Plant and/or Game Handling Establishment elements of their approval but wishes to retain stand-alone activities, this establishment, and the approval requirement, will be transferred to the LA or DC. In these circumstances the FSA/FSS will notify the relevant LA/DC accordingly. As the FSA/FSS had already approved the standalone activity, the LA/DC may not have to undertake a separate re-approval. This is provided that it is satisfied that the establishment can continue to meet all the requirements of the Regulations, and that the establishment's food safety management system is adequate to cover the stand alone activity.

142. In the case of FBOs deciding to limit their activities to meet the exemption criteria and surrendering the approval granted by the FSA/FSS, the establishment will remain subject to the Regulation (EC) No 852/2004 and must therefore register with the LA or 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.

## Type of Establishments that require approval by FSA/FSS

| Establishments:  | Activities / Operation for which establishment may be approved:  |
|--|--|
| Slaughterhouse (Red Meat)  | <b>Slaughter and/or Dressing of Domestic Ungulates:</b> <ul style="list-style-type: none"> <li>• Cattle (Bovine)</li> <li>• Calves (Bovine)</li> <li>• Bison</li> <li>• Water buffalo</li> <li>• Sheep (Ovine)</li> <li>• Goats (Caprine)</li> <li>• Pigs (Porcine)</li> <li>• Domestic Soliped / Equidae (horses)</li> </ul> <b>Slaughter and/or Dressing of Farmed Game:</b> <ul style="list-style-type: none"> <li>• Farmed land mammals (other than domestic ungulates)</li> <li>• Farmed Deer</li> <li>• Farmed Wild Boar</li> <li>• Ratites (Ostrich, rhea &amp; emu)</li> </ul> |
| Slaughterhouse (White Meat)  | <b>Slaughter and/or Dressing of Farmed Birds &amp; Lagomorphs:</b> <ul style="list-style-type: none"> <li>• Domestic Fowls (Chickens, hens &amp; broilers)</li> <li>• Turkey</li> <li>• Duck</li> <li>• Geese</li> <li>• Guinea fowl</li> <li>• Quail</li> <li>• Pigeon</li> <li>• Ratites (Ostrich, rhea &amp; emu)</li> <li>• Lagomorphs (rabbits, hares and rodents)</li> </ul>   |
| Game Handling establishment  | <b>Dressing &amp; cutting of:</b> <ul style="list-style-type: none"> <li>• Large wild game (e.g. wild deer &amp; feral wild boar)</li> <li>• Small wild game in-feather (e.g. pheasants, pigeons &amp; grouse)</li> <li>• Small wild game in-fur (e.g. rabbits, hares &amp; rodents)</li> </ul>  |
| Cutting Plant (Refer to Slaughterhouses and Game Handling establishment for definitions of species groups) | <b>Cutting of meat from:</b> <ul style="list-style-type: none"> <li>• Domestic ungulates</li> <li>• Farmed birds &amp; lagomorphs</li> <li>• Large wild game</li> <li>• Small wild game</li> <li>• Farmed game</li> </ul>  |
| Authorised On Farm Slaughter facilities  | <b>Slaughter at the place of origin of:</b> <ul style="list-style-type: none"> <li>• Domestic Fowls (Chickens, hens &amp; broilers)</li> <li>• Turkey</li> <li>• Duck</li> <li>• Geese</li> <li>• Guinea fowl</li> <li>• Quail</li> <li>• Pigeon</li> <li>• Ratites (Ostrich, rhea &amp; emu)</li> <li>• Farmed Deer</li> <li>• Farmed Wild Boar</li> <li>• Bison</li> </ul>   |
| Minced meat  | <ul style="list-style-type: none"> <li>• Production of minced meat</li> </ul>  |

| <b>Establishments:</b>   | <b>Activities / Operation for which establishment may be approved:</b>   |
|--|--|
| establishment*   |  |
| Meat preparations establishment*   | <ul style="list-style-type: none"> <li>• Production of meat preparations</li> </ul>  |
| Mechanically separated meat establishment*                                   | <ul style="list-style-type: none"> <li>• Production of mechanically separated meat</li> </ul>                              |
| Processing Plant*  | <b>Processing of:</b>  |
|  | <ul style="list-style-type: none"> <li>• Meat products (<i>to be cooked before eating</i>)</li> </ul>                      |
|  | <ul style="list-style-type: none"> <li>• Ready to eat meat products</li> </ul>   |
|  | <ul style="list-style-type: none"> <li>• Rendered animal fats and greaves</li> </ul>                                       |
|  | <ul style="list-style-type: none"> <li>• Treated stomach, bladders, intestines</li> </ul>                                  |
|  | <ul style="list-style-type: none"> <li>• Gelatine</li> </ul>   |
|  | <ul style="list-style-type: none"> <li>• Collagen</li> </ul>   |
|  | <ul style="list-style-type: none"> <li>• Raw milk</li> </ul>   |
|  | <ul style="list-style-type: none"> <li>• Dairy products</li> </ul>   |
|  | <ul style="list-style-type: none"> <li>• Egg products</li> </ul>   |
|  | <ul style="list-style-type: none"> <li>• Fishery products</li> </ul>   |
| <ul style="list-style-type: none"> <li>• Frogs' legs &amp; Snails</li> </ul> |  |
| Factory vessel*  | <ul style="list-style-type: none"> <li>• Processing of fishery products (on board)</li> </ul>                              |
| Freezing vessel*   | <ul style="list-style-type: none"> <li>• Freezing of fishery products (on board)</li> </ul>                                |
| Fresh fishery products plant*  | <ul style="list-style-type: none"> <li>• Handling of unprocessed fishery products</li> </ul>                               |
| Auction hall*  | <ul style="list-style-type: none"> <li>• Storing and displaying of fishery products</li> </ul>                             |
| Authorised Collection centre*  | <ul style="list-style-type: none"> <li>• Collection of Raw milk</li> </ul>   |
| Dispatch centre*   | <ul style="list-style-type: none"> <li>• Reception, conditioning, wrapping and packing of Live bivalve molluscs</li> </ul> |
| Purification centre*   | <ul style="list-style-type: none"> <li>• Purification of Live bivalve molluscs</li> </ul>                                  |
| Packing centre*  | <ul style="list-style-type: none"> <li>• Packing of eggs</li> </ul>  |
| Liquid egg plant*  | <ul style="list-style-type: none"> <li>• Handling of unprocessed egg contents</li> </ul>                                   |
| Cold Store*  | <ul style="list-style-type: none"> <li>• Storage of POAO (fresh or processed)</li> </ul>                                   |
| Re-wrapping/re-packaging establishments*                                     | <ul style="list-style-type: none"> <li>• Re-wrapping and/or repackaging of POAO (fresh or processed)</li> </ul>            |
| Wholesale market   | <ul style="list-style-type: none"> <li>• Shared common installations and sections where foodstuffs are sold</li> </ul>     |

\* Standalone establishments of these types of operation are approved by Food Authorities i.e. Local Authorities or District Councils.

## Exemption Criteria – Extract from MIG

### A - RETAIL ESTABLISHMENTS

The exemption is for retail establishments that supply food of animal origin to the final consumer, or supply other retail establishments (including caterers) on a 'marginal, localised and restricted basis (853/2004 Article 1 Scope point 5).

Recital 13 of Regulation 853/2004 interprets marginal as a small part of the establishment's business, but subsequent EU Commission guidance provides that it may also be interpreted as a small amount of food of animal origin in absolute terms. Following consultation, the UK is interpreting the terms marginal, localised and restricted in relation to meat as follows:

▪ **Marginal:** *supply of food of animal origin:*

(i) *up to a quarter of the business in terms of food; or*

(ii) *in relation to: fresh or processed meat, (but not wild game meat) up to 2 tonnes a week, subject to the establishment having a genuine retail outlet supplying the final consumer with part of its production of meat;*

**and**

▪ **Localised:** *supply of food of animal origin within the supplying establishment's own county plus the greater of either the neighbouring county or counties or 50 km/30 miles from the boundary of the supplying establishment's county;*

**and**

▪ **Restricted:** *supply of food of animal origin is limited to certain types of products or establishments. In the meat sector, the restrictions are in relation to the amounts of meat supplied and the requirement for a 'genuine' retail outlet (see 'marginal' above).*

**Notes:** Up to a quarter of the business in terms of food "should be calculated by measuring the amount (either by weight or volume) of food of animal origin supplied to other food business establishments (including caterers) against the entire supply in terms of food (this includes food of any type, e.g. drink, biscuits etc).

2 tonnes could be averaged over any 12 month period.

Both the above criteria must not be used simultaneously at an establishment. It is either the 25% **or** the 2 tonne rule (for establishments that only handle meat).

Supply to a final consumer can include mail order and internet sales. Retail establishments attached to approved establishments under veterinary control do not require approval.

### RETAIL EXEMPTION EXAMPLES:

A butcher supplying retailers (e.g. butchers shops, restaurants, pubs) as well as final consumers from his own premises, may be exempt from approval as a cutting plant if the wholesale element of the business is 'marginal, localised and restricted' exemption (see 'A' above). For example:

- A butcher cutting 12 tonnes a week, supplying 3 tonnes to caterers and 9 tonnes to the final consumer, would be exempt from approval because the 3 tonnes does not exceed a quarter of his production.
- A butcher cutting 3 tonnes a week, of which up to 2 tonnes goes to caterers, would be exempt because, although it is 70% of his production, it doesn't exceed 2 tonnes.

### B - POULTRY SLAUGHTER AND CUTTING ON FARM

There is an exemption for producers supplying small quantities of meat from poultry and lagomorphs slaughtered on the farm directly to the final consumer and to local retail establishments directly supplying the final consumer (853/2004 Article 1 point 3d amended by Regulation 2076/2005 Article 3).

Producers must be registered and comply with Regulation 852/2004 and the labelling and record keeping requirements of Schedule 5 of the Food Hygiene Regulations (England) 2006 or equivalent legislation in Scotland, Wales and Northern Ireland. Following consultation, the UK is interpreting the terms small and local as follows:

▪ **'Small'** *supply is interpreted as (i) under 10,000 birds or lagomorphs; or (ii) producers annually slaughtering over 10,000 birds or lagomorphs who are members of an appropriate assurance scheme and who either (a) dry pluck by hand or (b) slaughter for 40 days per year or less;*

**and**

- **'Local'** supply is interpreted as being the same as 'localised' – see 'A' above; additionally anywhere within the UK in the two weeks preceding Christmas or Easter and for geese, Michaelmas (late September).

#### **C - SLAUGHTER FOR PRIVATE DOMESTIC CONSUMPTION – HOME SLAUGHTER OF LIVESTOCK**

When slaughter of a livestock animal is carried out by its owner on their property for their own personal consumption or that of members of their immediate family living there and the meat is not placed on the market (whether free of charge or not), such activity is exempt from both 852/2004 and 853/2004, although the Food Safety Act (or in NI the Food Safety Order) will apply. However, the EU TSE Regulations apply wherever a TSE susceptible animal (i.e cattle, sheep and goat) is slaughtered (**including home slaughter**). Animal Welfare Regulations also apply wherever livestock is slaughtered. It should be noted that home slaughter is likely to carry a greater human health risk than slaughter that takes place in approved premises.

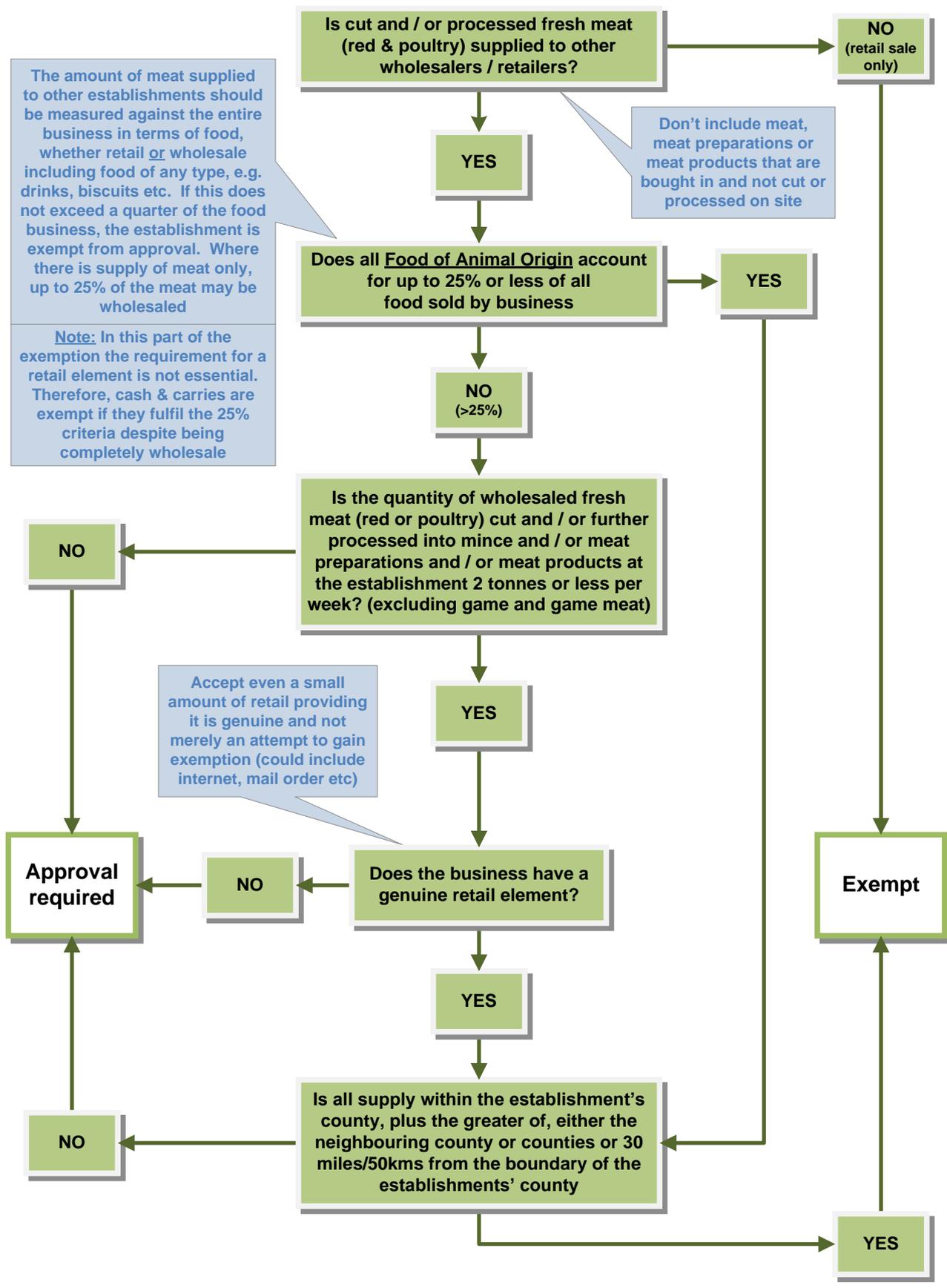
#### **D - WILD GAME**

There is an exemption for primary producers (individual hunters or shooting estates) supplying small quantities of wild game carcasses in fur/feather directly to the final consumer and to local retail establishments directly supplying the final consumer (*853/2004 Article 1 point 3c*).

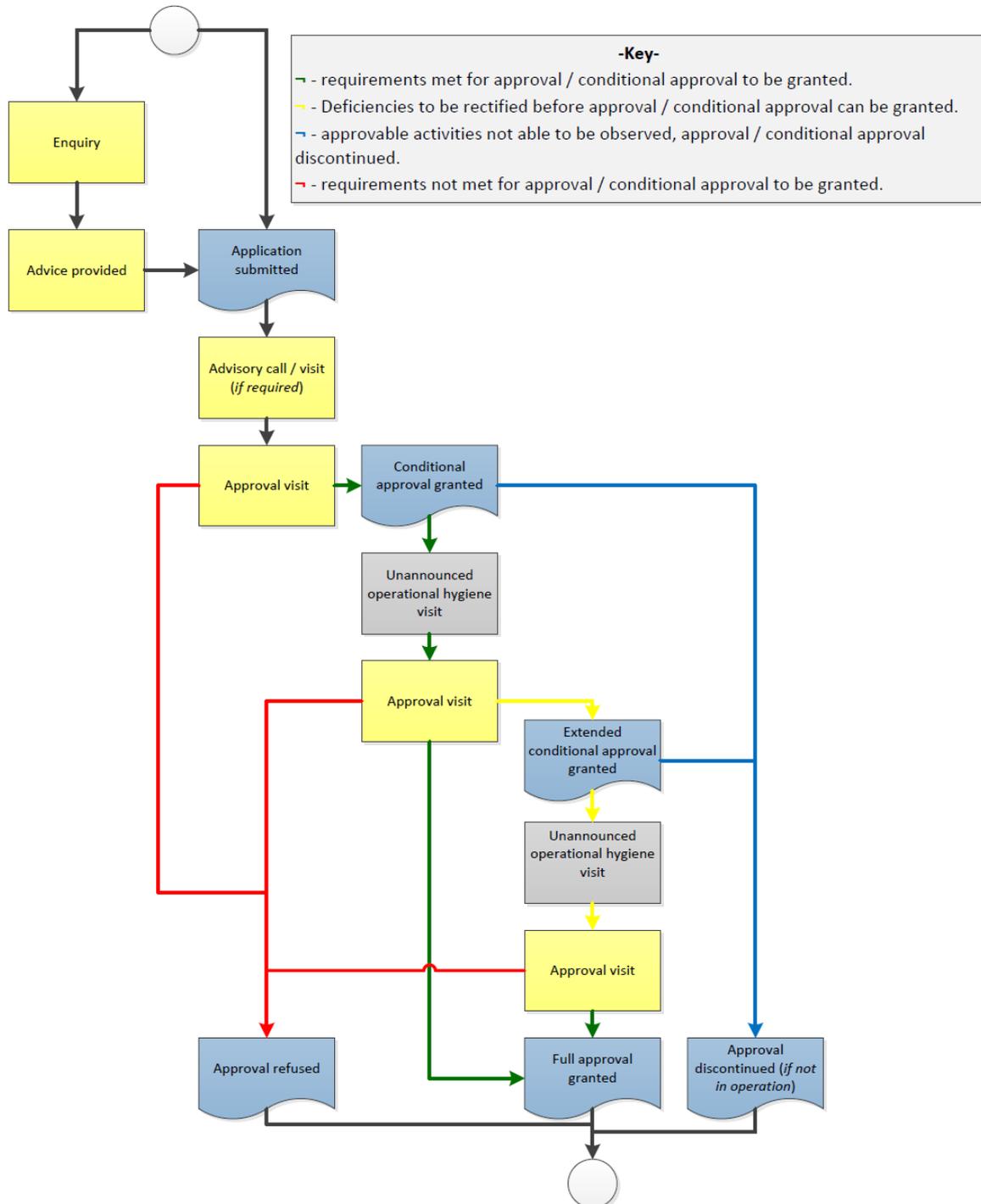
There is also an exemption for hunters and active members of a hunting party supplying small quantities of wild game meat directly to the final consumer and to local retailers directly supplying the final consumer. The meat must be prepared by an individual who has played an active part in the shoot, such as a beater, so the exemption is available to shooting estates. (*853/2004 Article 1 point 3e*).

## **Annexe C**

### **Exemption Criteria – Flow Diagram**



# Approval Process – Decision Flow Diagram



### Interpretation of the Criteria for Suspension / Withdrawal of Approval

Working definitions for the terms Serious Deficiency and Repeated Stoppage:

#### SERIOUS DEFICIENCY

##### General indicator of serious deficiency

Actual or potential risk to public health/animal welfare

**Likely issues** – (this is not an exhaustive listing and some or all elements may be present and to a varying degree)

##### Structure

- Major structural deficiency – e.g. capacity/layout of plant renders it not fit for use
- Poor maintenance preventing effective cleaning

##### Contamination

- Extensive and frequent contamination of carcasses or products
- Failure to control contamination from any source
- Visibly contaminated product without action from FBO
- Inadequate separation between products of different risk categories

##### Temperature control

- Inadequate temperature control

##### Pest control

- Serious rodent infestation

##### Water

- Inadequate supply of potable water

##### Animal welfare

- Abuse of animal welfare

##### Food safety management system

- Poor management attitude & commitment
- Inadequate HACCP good hygiene practices (commonly known as pre-requisite programme)
- Failure of HACCP based controls

##### Traceability

- Inadequate traceability procedures

#### REPEATED<sup>26</sup> STOPPAGE

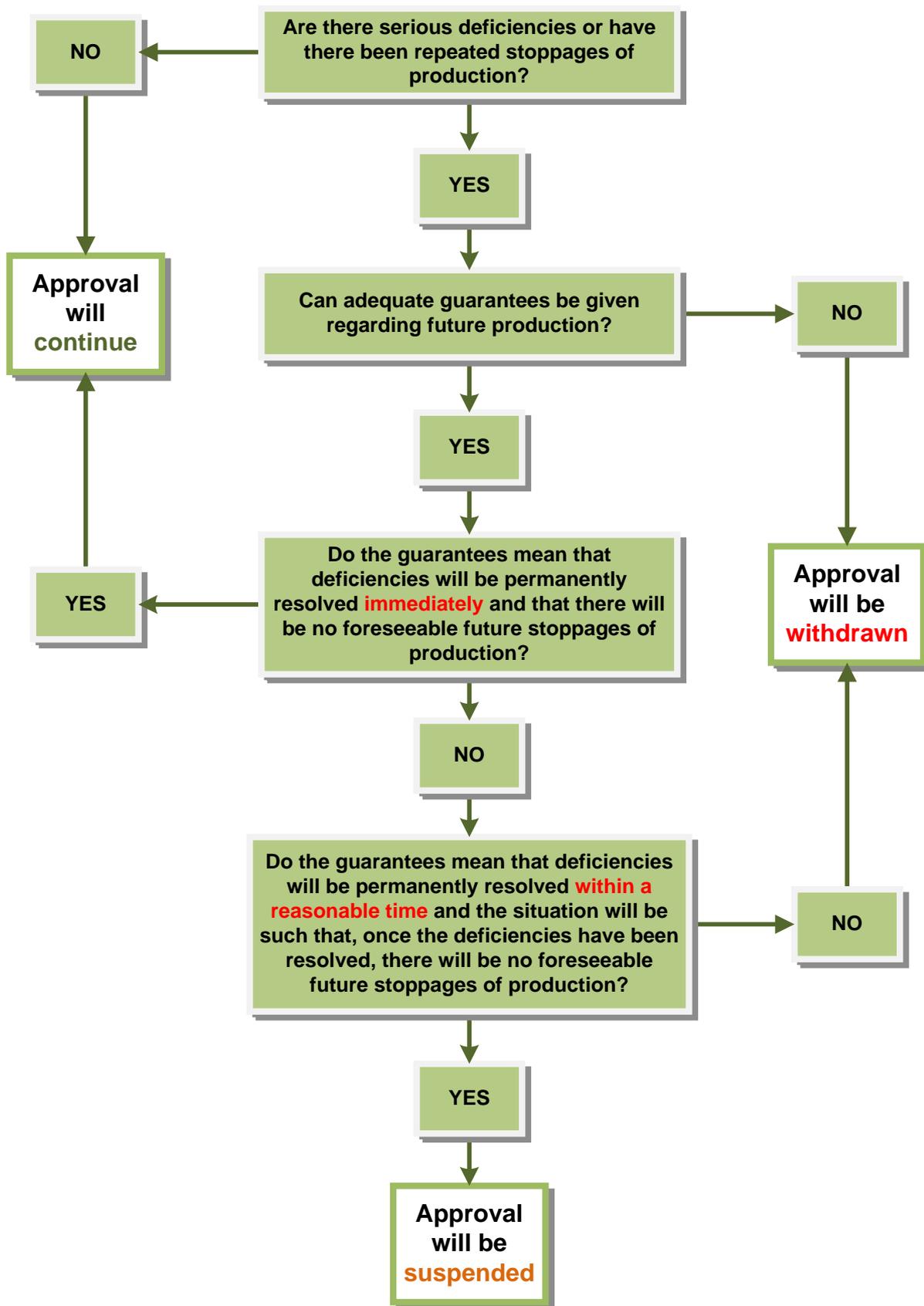
Production has to be stopped repeatedly through official intervention in order to ensure food safety.

**Likely issue** - failure of the FBO to take corrective actions despite advice/notification

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<sup>26</sup> Dictionary definition of “repeated” is “recurring again and again”

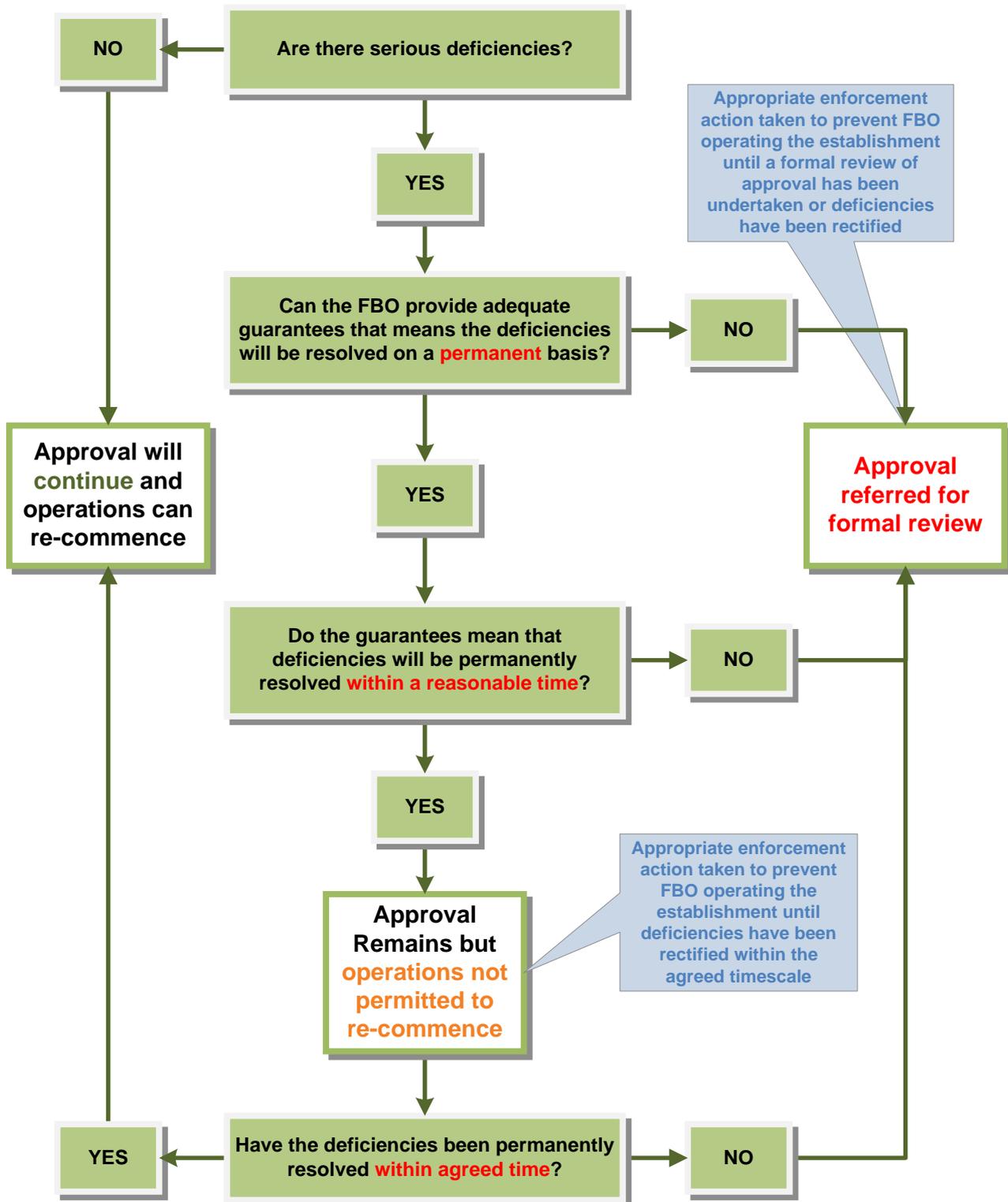
### Review of Approval – Decision Flow Chart



## Change of FBO

|  | Existing FBO<br>(as per approval<br>documentation)  | Change of FBO<br>(in each case assuming no<br>other changes to the<br>business)  | Approval<br>status | Comments   | New<br>approval<br>required |
|--|---|--|--------------------|--|-----------------------------|
| 1  | Sole trader,<br>Partnership or<br>incorporated<br>company ( <i>e.g. Ltd,<br/>PLC, etc</i> ) | Different sole trader,<br>partnership or incorporated<br>company takes over<br>ownership   | Expires            | Discontinuation of<br>operator/s   | Yes                         |
| 2  | Sole trader or<br>Partnership   | Company incorporated ( <i>and<br/>registered</i> ), Sole trader or<br>partner/s becomes<br>Director/s  | Expires            | Creation of a<br>Company so the<br>company is<br>responsible not the<br>individual/s | Yes                         |
| 3  | Sole trader   | Creation of a partnership<br>where the sole trader is one<br>of the partners   | Retained           | Continuation of<br>operator  | No                          |
| 4  | Partnership   | Dissolved and one of the<br>partners takes over sole<br>ownership and becomes a<br>sole trader   | Retained           | Continuation of<br>operator  | No                          |
| 5  | Partnership   | New partner joins or a<br>partner leaves ( <i>also refer to<br/>dissolved partnership</i> ) as long<br>as there is a continuation of<br>at least one partner | Retained           | Continuation of<br>operator/s  | No                          |
| 6  | Incorporated<br>company   | Company goes into<br>administration and is being<br>run as a going concern by<br>the administrators.   | Retained           | Continuation of<br>operator/s  | No                          |
| 7  | Incorporated<br>company in<br>administration  | Company taken over from<br>administrators by a different<br>sole trader, partnership or<br>incorporated company  | Expires            | Discontinuation of<br>operator/s   | Yes                         |
| 8  | Sole trader,<br>Partnership or<br>Incorporated<br>company                                   | Bankruptcy, insolvency or in<br>liquidation ( <i>wound up /<br/>dissolved</i> )  | Expires            | Discontinuation of<br>operator/s,<br>approval expires                                | N/A                         |
| <p>Other business types such as cooperatives, registered charities and other specialised types of organisation will be treated on a case by case basis to identify the change in natural person or legal person required to be compliant with food law within the food business under their control.</p> |   |  |                    |  |                             |

# Re-commence Operations Following Closure – Decision Flow Chart



## Glossary

Definitions and abbreviations used in this document:

|                                 |   |
|---------------------------------|---|
| <b>Animal by-products (ABP)</b> | Parts of animal which are not intended for human consumption  |
| <b>Audit</b>                    | A systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives   |
| <b>Carcase</b>                  | The body of an animal after slaughter and dressing  |
| <b>Cold store</b>               | Cold Store is not defined in the Hygiene Regulations. 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 |
| <b>Collagen</b>                 | The protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant requirements of this Regulation  |
| <b>CA</b>                       | The central authority of a Member competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country  |
| <b>Composite products</b>       | This is the term generally used for food containing both products of plant origin and processed products of animal origin as indicated in Article 1.2 of Regulation (EC) No. 853/2004   |
| <b>Cutting plant</b>            | An establishment used for boning and/or cutting up meat   |
| <b>Dairy products</b>           | Processed products resulting from the processing of raw milk or from the further processing of such processed products  |
| <b>DARD</b>                     | Department of Agriculture and Rural Development   |
| <b>DC</b>                       | District Council  |
| <b>Dispatch centre</b>          | Any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs fit for human consumption  |
| <b>Domestic ungulates</b>       | Domestic bovine (including Bubalus and Bison species), porcine, ovine and caprine animals, and domestic solipeds  |
| <b>EC</b>                       | European Commission   |

|   |  |
|---|--|
| <b>Edible co-products</b>                                       | <p>Parts of animals that are unsuitable for human consumption when they are produced at the slaughterhouse, but which can later be processed for use in human food, e.g. hides and skins processed into gelatine and collagen, sheep intestines processed into sausage casings, and stomach (omental) fat processed into lard.</p> <p>In order to be considered as an edible co-product, the product should not have been at any stage considered or handled as Animal By-product and must have been handled and stored in accordance with the Hygiene Regulations. Edible co-products must be handled in accordance with the food hygiene legislation at all stages of their production. At no point should they come into contact with or be categorised as animal by-product. If this happens they should immediately be removed from the human food chain and down-graded to animal by-product</p> |
| <b>Egg products</b>   | Processed products resulting from the processing of eggs, or of various components or mixtures of eggs, or from the further processing of such processed products  |
| <b>Establishment (Also refer to definition of a “Premises”)</b> | Any unit of a food business. An “ <i>establishment</i> ” does not simply mean “ <i>premises</i> ”, but is directly linked to the food business occupying the premises (establishment denotes both premises and the manner in which those premises are being used by the food business operator)  |
| <b>EU</b>   | European Union   |
| <b>Factory vessel</b>   | Any vessel on board which fishery products undergo one or more of the following operations followed by wrapping or packaging and, if necessary, chilling or freezing: filleting, slicing, skinning, shelling, shucking, mincing or processing  |
| <b>Farmed game</b>  | Farmed ratites and farmed land mammals other than Domestic ungulates   |
| <b>Final consumer</b>   | The ultimate consumer of a foodstuff who will not use the food as part of any food business activity or operation  |
| <b>Food business</b>  | 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  |
| <b>Food business operator (FBO)</b>                             | The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control   |
| <b>Food (or foodstuff)</b>                                      | Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans   |
| <b>Food law</b>   | 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   |
| <b>FOAO</b>   | Food of Animal Origin  |

|   |  |
|---|--|
| <b>Freezer vessel</b>                       | Any vessel on board which freezing of fishery products is carried out, where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins and, where necessary, followed by wrapping or packaging   |
| <b>Fresh meat</b>                           | Meat 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  |
| <b>FSA</b>                                  | Food Standards Agency (CA for food safety in England, Wales and Northern Ireland )   |
| <b>FSS</b>                                  | Food Standards Scotland (as from 1 April 2015 FSS is the CA for food safety in Scotland)   |
| <b>Game handling establishment</b>          | Any establishment in which game and game meat obtained after hunting are prepared for placing on the market  |
| <b>Gelatine</b>                             | Natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals   |
| <b>Greaves</b>                              | The protein containing residue of rendering, after partial separation of fat and water   |
| <b>HACCP</b>                                | Hazard Analysis and Critical Control Point (food safety management system)   |
| <b>Hazard</b>                               | a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect  |
| <b>Health mark</b>                          | A mark indicating that, when it was applied, official controls had been carried out in accordance with Regulations (EC) No 854/2004  |
| <b>Hygiene (in respect to food hygiene)</b> | The measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use   |
| <b>Identification mark (ID)</b>             | A mark indicating that a POAO has been produced in an approved establishment in accordance with legal requirements   |
| <b>Inspection</b>                           | 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 |
| <b>LA</b>                                   | Local Authority  |
| <b>Lagomorphs</b>                           | Rabbits, hares and (edible) rodents  |
| <b>Large wild game</b>                      | Wild land mammals living freely in the wild that do not fall within the definition of small wild game  |
| <b>LBM</b> s                                | Live bivalve molluscs. 'Bivalve molluscs' means filter-feeding lamellibranch molluscs  |
| <b>Liquid egg</b>                           | Unprocessed egg contents after removal of the shell  |
| <b>Meat</b>                                 | Edible parts of an animal, including blood:  |

- Domestic ungulates: bovine, ovine, caprine & domestic solipeds;
- Poultry: farmed birds
- Lagomorphs: rabbits, hares and rodents
- Large wild game: wild land mammals
- Small wild game: wild games birds and lagomorphs
- Farmed game: farmed ratites and farmed land mammals

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| <b>Meat preparations</b>                    | Fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasoning or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus eliminate the characteristics of fresh meat  |
| <b>Meat products</b>                        | 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  |
| <b>Mechanically separated meat (or MSM)</b> | 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   |
| <b>MIG</b>                                  | Guide to food hygiene and other regulations for the UK meat industry (commonly known as the Meat Industry Guide)  |
| <b>Minced meat</b>                          | Boned meat that has been minced into fragments and contains less than 1% salt   |
| <b>Member State</b>                         | A state that is party to treaties of the EU and has thereby undertaken the privileges and obligations that EU membership entails  |
| <b>Non-compliance</b>                       | Non-compliance with feed or food law, and with the rules for the protection of animal health and welfare  |
| <b>Offal</b>                                | Fresh meat other than that of the carcass, including viscera and blood  |
| <b>Official controls</b>                    | Any form of control that the CA performs for the verification of compliance with feed and food law, animal health and animal welfare rules  |
| <b>Packaging</b>                            | The placing of one or more wrapped foodstuffs in a second container, and the latter container itself  |
| <b>Packing centre</b>                       | An establishment where eggs are graded by quality and weight  |
| <b>Placing on the market</b>                | 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   |
| <b>POAO</b>                                 | Product of Animal Origin means: <ul style="list-style-type: none"> <li>• Food of animal origin, including honey and blood;</li> <li>• Live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption; and</li> <li>• Other animals destined to be prepared with a view to being supplied live to the final consumer</li> </ul> |
| <b>Poultry</b>                              | Farmed birds, including birds that are not considered as domestic but which are farmed as domestic animals, with the exception of ratites.  |
| <b>Premises</b>                             | Includes any place, any vehicle, stall or moveable structure and, for   |

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| <b>(Also refer to definition of an “establishment”)</b> | such purposes as may be specified in an order made by the Ministers, any ship or aircraft of a description so specified in Part 1 (3) of the Food Safety Act 1990 / the Food Safety (Northern Ireland) Order 1991 <sup>27</sup>  |
| <b>Primary production</b>                               | The production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter, it also includes fishing and harvesting of wild products   |
| <b>Primary products</b>                                 | Products of primary production including products of the soil, of stock farming, hunting and fishing. Primary products include <i>amongst other things</i> : <ul style="list-style-type: none"> <li>• Products of plant origin: grains, fruits, vegetables, herbs etc</li> <li>• Products of animal origin: eggs, raw milk, honey, fishery products, LBMs</li> <li>• Products harvested from the wild either from plant or animal origin, e.g. mushrooms, berries, snails etc</li> </ul> |
| <b>Processed fishery products</b>                       | Processed products resulting from the processing of fishery products or from the further processing of such processed products   |
| <b>Processed products</b>                               | 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   |
| <b>Processing plant</b>                                 | An establishment where POAO are either treated, processed (heating, smoking, curing etc) and wrapped or undergoes one or more of those handling activities   |
| <b>Purification centre</b>                              | An establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption  |
| <b>Raw milk</b>   | Milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40 °C or undergone any treatment that has an equivalent effect   |
| <b>Ready-to-eat food</b>                                | Food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing  |
| <b>Rendered animal fat</b>                              | Fat derived from rendering meat, including bones, and intended for human consumption   |
| <b>Retail</b>   | The 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  |
| <b>Risk</b>   | A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard   |
| <b>Re-packaging establishment</b>                       | 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.  |
| <b>Re-wrapping establishment</b>                        | An establishment that unwraps the initial wrapping or initial container, which is in direct contact with the product and then re-wraps the products  |

<sup>27</sup> [Food Safety Act 1990 / Food Safety \(Northern Ireland\) Order 1991](#)

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| <b>Slaughterhouse</b>                                    | An establishment used for slaughtering and dressing animals, the meat of which is intended for human consumption  |
| <b>Small wild game</b>                                   | Wild game birds and lagomorphs living freely in the wild  |
| <b>Stages of production, processing and distribution</b> | 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   |
| <b>Traceability</b>                                      | 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  |
| <b>Treated stomachs, bladders and intestines</b>         | 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   |
| <b>Unit</b>  | A single undivided entity or whole  |
| <b>Unprocessed products</b>                              | Foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed   |
| <b>Verification</b>                                      | Checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled  |
| <b>Viscera</b>   | The organs of the thoracic, abdominal and pelvic cavities, as well as the trachea and oesophagus and, in birds, the crop  |
| <b>VS-VPHU</b>   | Veterinary Service, Veterinary Public Health Unit   |
| <b>Wholesale market</b>                                  | A food business that includes several separate units which share common installations and sections where foodstuffs are sold to food business operator  |
| <b>Wild game</b>   | Means: <ul style="list-style-type: none"> <li>– wild ungulates and lagomorphs, as well as other land mammals that are hunted for human consumption and are considered to be wild game under the applicable law in the Member State concerned, including mammals living in enclosed territory under conditions of freedom similar to those of wild game;</li> </ul> and <ul style="list-style-type: none"> <li>– wild birds that are hunted for human consumption</li> </ul> |
| <b>Wrapping</b>  | 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)   |