



Approval of establishments - Guidance for local authority authorised officers

March 2016

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Contact telephone 0207 276 8180

Summary

Intended audience:	For the use of Local Food Authority (LA) ¹ Authorised Officers (AOs).
Reginal coverage	UK.
Purpose:	This guidance is intended to help LA officers with the interpretation and implementation of the relevant legislation and regulations as they apply to approved establishments.
Legal status:	Guidance to provide interpretation and implementation of EC Regulation.
Key words	<ul style="list-style-type: none"> • Approvals • Dairy products • Fish and shellfish • Food law, monitoring and controls • Hygiene and food safety • Meat and livestock
Review date	December 2016

Revision history

This guidance follows the Government [Code of Practice on Guidance](#). If you believe this guidance breaches the Code for any reason, please let us know by emailing betterregulation@foodstandards.gsi.gov.uk. If you have any comments on the guidance itself, please call us using the contact number on page 2 or complete our ongoing [Guidance survey](#): <https://www.surveymonkey.com/s/55QQDCG>

Revision No.	Revision date	Purpose of revision and paragraph number	Revised by
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¹ For the purpose of this document LAs include DCs in Northern Ireland unless otherwise indicated to the contrary.

2		Update legal references Clarification of advice on FSA Policy	Nick Laverty
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Glossary

Definitions and Abbreviations used in this guidance

Animal by-products	Parts of animal which are not intended for human consumption.
Assurance Schemes	Voluntary systems which verify, through regular independent inspections, that farmers and growers are meeting certain stated standards of production. The scope of assured food schemes covers both primary production and processes covering the rest of the food chain as far as retail sale. Production standards are set by the assurance scheme and vary across different schemes, generally covering food safety and traceability, animal welfare and environmental protection. Members of a particular scheme can use the scheme's logo on their produce, and/or use a specific claim, to advertise to consumers that the product has been produced to these standards.
Audit	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.
Authorised officer (AO)	In relation to an enforcement authority, any person (whether or not an officer of the Authority) who is authorised by the Food Authority in writing, either generally or specifically, to act in matters arising under the Food Safety and Hygiene (England) Regulations 2013 and the Food Hygiene Regulations 2006 in Scotland, Wales and Northern Ireland .
Cold store	A wholesale establishment used for the storage under temperature controlled conditions of POAO intended for sale for human consumption.
Collection centre	An establishment where raw milk is collected and where it may be cooled and filtered.
Competent authority	The central authority of a Member State 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.
Composite products	This is the term generally used for food containing both products of plant origin and <u>processed</u> products of animal origin as indicated in Article 1.2 of Regulation (EC) No.

853/2004².

DARD(QAB) Department of Agriculture and Rural Development (Quality Assurance Branch)

DC District Council

Dispatch centre 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.

Edible co-products 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.

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.

EC European Community (when named in European Regulations)

Establishment (Also refer to definition of a "Premises") Any unit of a food business - **Note:** *"establishment" does not simply mean "premises", but is directly linked to the business occupying the establishment ("establishment denotes both premises and the manner in which those premises are being used by the food business operator)"*³

² Definition of composite products in Commission Decision 2007/275/EC:

a foodstuff intended for human consumption that contains both processed products of animal origin and products of plant origin and includes those where the processing of primary product is an integral part of the production of the final product

³ Allan Rich Seafoods v Lincoln Magistrates' Court:

<http://www.bailii.org/ew/cases/EWHC/Admin/2009/3391.html>

<http://www.bailii.org/ew/cases/EWHC/Admin/2010/1232.html>

Factory vessel	Any vessel on which fishery products undergo one or more of the following operations followed by packaging, namely, filleting, slicing, skinning, mincing, freezing or processing but does not include a fishing vessel in which only shrimps and molluscs are cooked on board or a fishing vessel on board which only freezing is carried out.
Final consumer	The ultimate consumer of a foodstuff who will not use the food as part of any food business activity or operation.
Food Authority	As defined in the Food Safety Act section 5 ⁴
Food business	Any undertaking whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food.
Food business operator (FBO)	The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.
FSA	Abbreviation for the Food Standards Agency
Greaves	The protein-containing residue of rendering, after partial separation of fat and water.
HACCP	Hazard Analysis and Critical Control Point (food safety management system)
Health Mark	A mark indicating that, when it was applied, official controls had been carried out in accordance with Regulation (EC) No. 854/2004. Note: Health marks are only applied to meat carcasses. ID marks are used for other POAO.
Identification Mark (ID)	A mark indicating that a POAO has been produced in an approved establishment in accordance with legal requirements
Inspection	The examination of establishments, animals and food, of their processing, of food business, of their management and productions systems, including finished product testing and feeding practices, and of their origin and destination of production inputs and outputs, in order to verify that all these

⁴ <http://www.legislation.gov.uk/ukpga/1990>

items conform to legal requirements.

LA	Local Authority
Lagomorphs	Rabbits, hares and (edible) rodents.
LBM	Live bivalve molluscs
Meat	Edible parts of the following animals, including blood: <ul style="list-style-type: none">• Domestic ungulates: bovine, porcine, ovine, caprine and domestic solipeds;• Poultry: farmed birds;• Lagomorphs: rabbits, hares and rodents;• Large wild game: wild land mammals;• Small wild game: wild game birds and lagomorphs; and• Farmed game: farmed ratites and farmed land mammals
Meat preparations	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 to eliminate the characteristics of fresh meat.
Meat products	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.
Mechanically separated meat (or MSM)	The product obtained by removing meat from flesh-bearing bones after boning or from poultry carcasses, using mechanical means resulting in the loss or modification of the muscle fibre structure.
Minced meat	Boned meat that has been minced into fragments and contains less than 1% salt.
Official controls	Any form of control that the competent authority or the European Union performs for the verification of compliance with feed and food law, animal health and animal welfare rules.
Packaging	The placing of one or more wrapped foodstuffs in a second container, and the latter container itself.

Premises
(Also refer to definition of an “establishment”)

Includes any place, any vehicle, stall or moveable structure and, for such purposes as may be specified in an order made by the Ministers, any ship or aircraft of a description so specified.⁵

POAO

Product of animal origin means:

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

Primary production

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.

Primary products

Products of primary production including products of the soil, of stock farming, hunting and fishing. Primary products include *amongst other things*:

- Products of plant origin: grains, fruits, vegetables, herbs etc.;
- Products of animal origin: eggs, raw milk, honey, fishery products, LBMs; and
- Products harvested from the wild either from plant or animal origin, e.g. mushrooms, berries, snails etc.

Processing establishment

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

Processed products

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.

Purification

An establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to

⁵ Part 1 (3) of the Food Safety Act 1990 and Part 1(2) of the Food Safety (Northern Ireland) Order 1991

Centre	reduce contamination to make them fit for human consumption.
RAN	Remedial Action Notice
Re-wrapping establishment	An establishment that unwraps the initial wrapping or initial container, which is in direct contact with the product and then re-wraps the products.
Re-packaging establishment	An establishment which removes wrapped foodstuffs from a second container and re-packages them without removing the initial wrapping which is in direct contact with the product
Unit	A single undivided or whole entity
Unprocessed products	Foodstuffs that have not undergone processing, and includes products that have been divided, sliced, boned, cut, minced, chilled, thawed, frozen etc.
Wholesale market	A food business that includes several separate units which share common installations and sections where foodstuffs are sold to food business operator.
Wrapping	Placing of foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself.

Intended Audience

This guidance is for the use of Local Food Authority (LA)⁶ Authorised Officers (AOs) in the UK in relation to the approval of food business establishments that handle products of animal origin (POAO). **These guidance notes cover separate but equivalent regulations in all four countries of the UK.**

The guidance is intended to help LAs, but it does not provide authoritative interpretations of the law and is not a substitute for an understanding of the legal requirements. This should be read in conjunction with the legislation and European Guidance.

⁶ For the purpose of this document LAs include DCs in Northern Ireland unless otherwise indicated to the contrary.

Purpose of Guidance

This guidance is intended to help LA officers with the interpretation and implementation of the relevant legislation and regulations as they apply to approved establishments.

Legal Status

This guidance has been produced to explain the legal requirements of;

- General EU Food Law
- The EU Food Hygiene Regulations (“the Hygiene Regulations”) which have applied in all Member States from 1 January 2006.
- Official Controls Legislation
- Domestic food safety and hygiene legislation

In relation to the approval of establishments.

- **Regulation (EC) No 178/2002⁷ – General Food Law Regulation:**

The regulation provides a framework for food and feed law in EU Member States and imposes both on Member States and on 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.

- **Commission Implementing Regulation (EU) 931/2011⁸:**

Enhancing the traceability requirements in Regulation 178/2002 specifically for POAO

- **Regulation (EC) No 852/2004⁹ 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

⁷ 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

⁸ Commission Implementing Regulation (EU) No 931/2011 on the traceability requirements set by Regulation (EC) No 178/2002

⁹ Regulation (EC) No 852/2004 on the hygiene of foodstuffs

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 853/2004¹⁰ 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 852/2004, including the requirement for establishments to be approved.

- **Regulation (EC) No 854/2004¹¹ 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 competent authority to be carried out in relation to establishments, which require approval under Regulation 853/2004.

- **Regulation (EC) No 882/2004¹² 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 853/2004.

- **Regulation (EC) 2073/2005¹³ on microbiological criteria for foodstuffs:**

This Regulation complements the food hygiene legislation and applies to all food businesses involved in the production and handling of food. It sets out some testing requirements for certain types of food. Competent Authorities must verify that FBOs are compliant with these requirements. Separate FSA guidance on the microbiological criteria Regulation is available¹⁴

Domestic Legislation

The Food Safety Act (1990)

The Food Safety and Hygiene (England) Regulations 2013

The Food Hygiene (Northern Ireland) Regulations 2006

¹⁰ Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin

¹¹ Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin

¹² 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

¹³ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

¹⁴ <https://www.food.gov.uk/sites/default/files/multimedia/pdfs/eceguidmicrobiolcriteria.pdf>

The Food Hygiene (Scotland) Regulations 2006
The Food Hygiene (Wales) Regulations 2006

Approval of Establishments

1. Regulation (EC) No 853/2004 requires that food business establishments handling food of animal origin that fall under the categories for which Annex III lays down requirements must, with some limited exceptions, be approved by the competent authority. Compliance with relevant requirements of Regulation 853/2004 is required in addition to full compliance with Regulation (EC) No. 852/2004. **Registration** under Article 6(2) of Regulation (EC) No. 852/2004 is **not** required for establishments that are subject to approval.

Categories of food establishments that require approval

2. The following establishments in column 2 must be approved under Regulation (EC) No. 853/2004 by **LAs**, to carry out the operations in column 3 unless specifically exempted from the Regulations:

(1) Product	(2) Establishment	(3) Operation for which establishment may be approved
<p>Meat</p> <p>(approved in accordance with Annex III, Section V)</p>	<p>Minced meat, meat preparations and mechanically separated meat</p> <p><i>(see table footnote)</i></p>	<p>Producing minced meat, meat preparations and/or mechanically separated meat</p>
<p>Meat</p> <p>(approved in accordance with Annex III, Section VI)</p>	<p>Meat products</p> <p><i>(see table footnote)</i></p>	<p>Production of meat products</p>

(1) Product	(2) Establishment	(3) Operation for which establishment may be approved
Meat (approved in accordance with Annex III, Section XII)	Rendered animal fats and greaves <i>(see table footnote)</i>	Intermediate storage of rendered animal fats and greaves
Meat (approved in accordance with Annex III, Section XIII)	Treated stomachs, bladders and intestines (Processing Plant)	Processing of treated stomachs, bladders and intestines
Meat¹⁵ (authorised in accordance with Annex III, Section XIV) (Note: these establishments require authorisation rather than approval)	Gelatine (Collection Centre/Tannery) <i>(see table footnote)</i>	Processing of gelatine
Meat¹⁶ (authorised in accordance with Annex III, Section XV) (Note: these establishments require authorisation rather than approval)	Collagen (Collection Centre/Tannery) <i>(see table footnote)</i>	Processing of collagen
Live bivalve molluscs(LBM) (approved in accordance with Annex III, Section VII)	Dispatch centre	Reception, conditioning, washing, cleaning, grading, wrapping and packaging of LBMs
	Purification centre	Purification of LBMs in tanks fed by clean seawater for the time necessary to reduce contamination to make them fit for

¹⁵ DARD (on behalf of the FSA in NI) authorise collection centres for raw material for the production of gelatine and collagen intended for human consumption in NI.

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(1) Product	(2) Establishment	(3) Operation for which establishment may be approved
		human consumption
Fishery products (approved in accordance with Annex III, Section VIII)	Factory vessel	Filleting, slicing, skinning, shelling, shucking, mincing or processing of fishery products on board
	Freezing vessel	Freezing of fishery products after bleeding, heading, gutting, and removal of fins and, where necessary, followed by wrapping or packaging.
	Processing plant	Processing of fishery products
	Fresh fishery products plant	Handling of unprocessed fishery products that have not undergone any treatment to ensure preservation other than chilling
	Auction hall	Storing and displaying of fishery products for auction sale
	Wholesale market	Establishment that includes separate sub-units operating independently as wholesalers, but sharing common facilities

(1) Product	(2) Establishment	(3) Operation for which establishment may be approved
Raw milk and dairy products¹⁷ (approved in accordance with Annex III, Section IX)	Collection centre	Collection of raw milk where it is cooled and filtered.
	Processing plant	Treating, processing and/or wrapping of dairy products (milk or any milk-based product)
Eggs and egg products (approved in accordance with Annex III, Section X)	Packing centre ¹⁸	Packing and grading of eggs by quality and weight ¹⁹
	Processing plant	Processing of egg products
	Liquid egg plant	Handling of unprocessed egg contents after removal of shell
POAO	Cold store (<i>see table footnote</i>)	Storage of products of animal origin
POAO	Wholesale market	Establishment that includes separate sub-units operating independently as wholesalers, but sharing common facilities
POAO	Re-wrapping establishment and/or Re-packaging (<i>see table footnote</i>)	Re-wrapping and/or re-packaging of products of animal origin
FOOTNOTE: Approved by the FSA if situated on the same site as a slaughterhouse, cutting plant or game		

¹⁷ FSA in NI approves liquid milk processing establishments and integrated liquid milk/dairy product establishments.

¹⁸ FSA in NI approves egg packing centres.

¹⁹ <http://animalhealth.defra.gov.uk/egg-and-milk/eggs/marketingsegs.html>

(1) Product	(2) Establishment	(3) Operation for which establishment may be approved
	handling establishment, otherwise approved by LAs	

Cutting meat for use in meat products and preparations

- 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. The Approval granted will need to reflect the final product or products being sold; for example, meat products. If such establishments are stand alone (i.e. not co-located with an FSA approved Establishment), approval will therefore fall to the LA.

Re-wrapping & Re-packaging Establishments

- Regulation 853/2004 Annex II Section I: A. 2.** "... when a product's packaging **and/or** wrapping is removed or it is further processed in another establishment, a new mark must be applied to the product. In such cases, the new mark must indicate the approval number of the establishment where these operations take place.

5. Re-wrapping establishments unwrap POAO that were wrapped in another establishment, and further handle them before rewrapping them. Since re-wrapping establishments handle exposed POAO that are covered by Annex III of Regulation (EC) No. 853/2004, they fall within the scope of Article 4, paragraph 2 of the Regulation. Approval is therefore required.

Re-packaging, where the outer packaging²⁰ (including approval number) of bulk packaging is removed also requires approval. FBOs must have full traceability systems in place in accordance with the requirements in Regulation 178/2002 and 931/2011.

6. In order to ensure traceability, FBOs should not place on the market POAO if its packaging and/or wrapping has been removed or if its further processed in re-wrapping establishments, unless the identification mark of the re-wrapping establishment is applied.

NOTE: rewrapping and re-packaging of composite products does not require approval.

Cold stores

7. There is no requirement for veterinary control of cold stores and LAs are responsible for enforcement except where cold stores are co-located with approved establishments under veterinary control such as slaughterhouses, cutting plants or game handling establishments.
8. EU guidance advises that cold stores require approval in so far as they are used in relation to activities for which Annex III of Regulation 853/2004 lays down requirements. However, Article 1, paragraph 5(b), exempts colds stores operated by genuine retail outlets and cold stores that are involved in **wholesale** operations which are physically limited to transport or storage, these do not need to be approved but remain subject to the temperature requirements in Regulation 853/2004. This means that unless they are exempt, stand alone cold stores used for the storage of POAO **must be approved**.

Cold stores which are not engaged in any form of retail activity to the final consumer themselves should not be considered as exempt under a retail exemption as wholesalers. Guidance from the EU Commission states:

²⁰ See definitions for wrapping and packaging in the Glossary

In the context of food hygiene, retail [as defined in regulation (EC) NO 178/2002] should generally have a more limited meaning as follows: “activities involving direct sale or supply of food of animal origin to the final consumer”.

The activity of selling POAO to other establishments (approved establishments, retail establishments, catering establishments) means that the FBOs which do this are not limited to storage and transport. Activities limited to storage or transport refer to cold storage by an FBO of their own products.

9. POAO should be handled in approved establishments up to the point it reaches a **genuine** retail establishment with supply to the final consumer, or a point at which an exemption applies (e.g. no specific temperature requirements, composite products see below).
10. The Registration of a cold store (Article 6 of Regulation (EC) 852/2004) is required if that cold store is exempt from approval. Stand alone cold stores supplying the final consumer exclusively (i.e. retail) or supplying the final consumer and, on a “marginal, localised and restricted” basis, other retail establishments (including caterers) are exempt from approval.
11. Therefore cold stores engaged in the following activities would need approval under Regulation 853/2004:
 - the storage of unprocessed POAO which has been brought in from other establishments for the supply to further establishments;
 - the storage of processed, or partly processed POAO brought in from other establishments to be supplied to other establishments for use as an ingredient in other products.
 - Storage of POAO (which may be packaged and ready for retail sale) but which are sold to retailers, caterers or to other food businesses but not as part of a logistical distribution chain for a given retailer.
12. Under no circumstances must a cold store undertake any other activity for which it is not approved. It should, however, be noted that the freezing of POAO is not a processing action and, therefore, cold stores undertaking blast freezing of foods can carry out this activity under their cold store approval.
13. There is no requirement to apply a new ID mark on product unless its packaging and/or wrapping is removed or it is further processed in another establishment, in which case the new mark must indicate the approval number of the establishment where these operations take place (853/2004, Annex II, Section I, A, 2). Therefore cold stores that only keep product for storage purposes need not apply their ID mark onto the product. The FBO

could consider including their ID mark on paperwork associated with POAO that they supply to other establishments to assist traceability and in this case, the ID mark should be in the appropriate format (see paragraph 64).

14. If a cold store intends to undertake re-wrapping (**see section on Re-wrapping**), then it must be additionally approved as a re-wrapping centre and apply its own ID mark to any POAO it rewraps and/or repacks. Cold stores that do not have additional approval as a re-wrapping centre must not undertake re-wrapping of damaged products nor apply the manufacturer's identification mark. If products are found to be damaged upon delivery or during handling, they should either be returned to the manufacturer or disposed of as food waste as per Chapter VI of Regulation (EC) 852/2004.

Where cold stores wish to operate with a view to carrying out additional activities which are subject to approval (for example re-wrapping) or are registered but wish to be able to carry out activities subject to approval part of the time, they should discuss an application for approval with the LA. See paragraph 39 for more details.

Collection centres and tanneries supplying raw material for the production of gelatine and collagen intended for human consumption

15. 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 852/2004, nor are they subject to approval under Regulation 853/2004. They will, however, need to be specifically authorised by the relevant LA or the FSA in NI in accordance with Annex III, Section XIV, Chapter 1(5) of Regulation 853/2004 (gelatine) and Section XV, Chapter 1(5) of Regulation 853/2004 (collagen).

What are the Exemptions from Approval?

16. The relevant exemptions from the requirements for approval under Regulation 853/2004 fall into three categories:

Direct supply of small quantities of primary products;
regulation 853/2004, article 1(3)(c),(d) and (e)

Article 1(3)(c) exempts:

“the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer”

In general terms, the notion of “small quantities” should be broad enough to allow *amongst other things*:

- Farmers to sell primary products directly to the final consumer e.g. farm gate sales or sales at local markets. This exemption also covers sales to local retail shops and local restaurants directly supplying the final consumer with the exception of raw drinking milk and eggs (see below).
- Fishermen who harvest live shellfish products and fishery products such as crabs and lobsters to deliver directly to the final consumer or to local retail shops for direct sale to the final consumer and to local restaurants.

The expression “small quantities” is not defined in Regulations, the FSA, therefore, suggest the following as maximum amounts, which could be considered as small quantity for individual products of animal origin:

Products	Maximum amounts
Milk	Up to 24 pints of raw drinking milk ²¹ per day (approximately 14 litres)
Eggs	Less than 360 eggs (i.e. less than one full case) per week. <i>Note: This exemption only applies to the producer supplying directly to the final consumer from the farm and farmers’ markets and door to door. If the producer sells the eggs, for example, to local shops, restaurants or bakeries, they must first be graded as Class A; and, therefore, the premises must</i>

²¹ Not applicable in Scotland

	<i>also be approved and authorised as a packing centre for that activity²².</i>
Fishery products	Up to 25 tonnes in a calendar year
Live Bivalve Molluscs	Up to 25 tonnes in a calendar year, but subject to maximum limits for individual species as set out below: <ul style="list-style-type: none"> • Cockles - 25 tonnes • Oysters - 5 tonnes • King Scallops - 5 tonnes • Queen Scallops - 10 tonnes • Mussels - 20 tonnes • Other LBMs - 10 tonnes • Marine Gastropods - 20 tonnes

Article 1(3)(d) (also refer to Schedule 5 of the Food Safety and Hygiene (England) Regulations 2013 and the equivalent Food Hygiene Regulations 2006 in Scotland, Wales and Northern Ireland) exempts²³:

“the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail

²² For further details on production and marketing of eggs visit Defra website at <http://archive.defra.gov.uk/corporate/policy/opengov/complain/inspect/emicode.pdf>

²³ Also refer to Schedule 5 of the Food Safety and Hygiene (England) Regulations 2013 and the equivalent Food Hygiene Regulations 2006 in Scotland, Wales and Northern Ireland)

establishments directly supplying such meat to the final consumer as fresh meat”.

Note: although exempt from approval, FBOs carrying out on-farm slaughter of poultry and lagomorphs must still comply with the requirements in Schedule 5 of the domestic regulations.

The exemption applies to producers of poultry i.e. farmed birds (except ratites (ostriches and emus)) or lagomorphs (i.e. rabbits, hares and rodents) who slaughter their own animals on the farm of production (i.e. animals raised by that producer, on the farm in question), as long as only *small quantities* of meat are supplied.

“Small quantities” is not defined in the legislation, but the FSA’s interpretation is that producers such as the following should benefit from the exemption:

- producers annually slaughtering under 10,000 birds or lagomorphs; or
- producers annually slaughtering over 10,000 birds or lagomorphs who are members of an appropriate assurance scheme* and who either dry pluck by hand or slaughter for 40 days per year or less.

The limit of 10,000 birds or lagomorphs in the first category should not be applied absolutely. Annual fluctuations in slaughtering around the 10,000 level are acceptable provided that annual slaughtering are typically no more than 10,000. The limit of 10,000 should be applied to the total number of poultry or lagomorphs slaughtered. For example a producer slaughtering 6,000 chickens and 2,000 turkeys would be exempt, while another slaughtering 6,000 chickens and 6,000 turkeys or slaughtering 6,000 chickens and 6,000 rabbits would not be exempt.

Although there is no limit to the number of birds or lagomorphs that producers in the second category may slaughter, the FSA anticipates that the restrictions will limit production to relatively small quantities. The purpose of the restrictions on those slaughtering over 10,000 is to allow the exemption to apply only to those producers where the assessed public health risk is likely to be low.

*In judging whether an assurance scheme is appropriate, regard should be had as to whether the scheme has requirements that at least meet the minimum legal requirements in relation to food safety and hygiene and whether it has independent verification arrangements.

Where can the meat be sold?

Meat produced under this exemption may be supplied:

- (i) direct to the final consumer; or
- (ii) direct to local retail establishments directly supplying such meat to the final consumer.

In the first category, direct supply to the final consumer would include mail order, internet sales, farmers markets, as long as the supply is *direct* to the consumer. Such supplies are not necessarily limited to meat in the form of fresh meat. They could be in the form of minced meat and, meat products or meat preparations.

In the second category, the supply must be direct to local retail establishments (in the form of fresh meat, minced meat, meat preparations or meat products*), and could include the supply by the producer to restaurants or other catering establishments. The retail establishments supplied must be *local*. 'Local' supply is interpreted as being the same as 'localised' (see **Annex 3, A.3.4.5.1 of the Food Law Practice Guidance**) and, in addition, anywhere within the UK in the two weeks preceding Christmas and Easter and (for geese) Michaelmas (late September).

*although Regulation 853/2004 refers to fresh meat, a transitional derogation is in place, which means that this supply is not limited to fresh meat. The derogation is currently provided, until 31st December 2016 by virtue of Article 2 of Commission Regulation 1079/2013. Refer also to recital 8 of that regulation for more detail

Article 1(3)(e) exempts:

“hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.”

There is an exemption for primary producers (individual hunters and/ 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.

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 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.

For more information: see the separate 'Wild Game Guide' available at:
www.food.gov.uk/foodindustry/guidancenotes/meatregsguid/wildgameguidance

17. "Direct supply" to a final consumer can be via mail order or internet sales as well as by delivery or collection. The final consumer does not have to be local to the primary producer, however retail establishments supplied must be. Requirements in respect of those producers benefiting from the exemption afforded by Article 1(3)(d) are set out in Regulation 33/ Schedule 5 to the Food Safety and Hygiene (England) Regulations 2013, as amended; and the equivalent 2006 regulations in Scotland, Wales and Northern Ireland.

Retail exemptions: Regulation 853/2004, Article 1(5)

18. The effect of the Article 1(5) is that, in general, Regulation 853/2004 does not apply to retail. The Regulation does, however, apply to retail if food of animal origin is supplied to another establishment, unless the activities in Article 1(5)(b)(i) or (ii) are undertaken (see below)

Article 3(7) of Regulation 178/2002 defines retail as follows:

'retail' means 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.'

Regulation 853/2004, Article 1(5)(b)(i) and (ii) states that:

"However, this Regulation shall apply to retail when operations are carried out with a view to the supply of food of animal origin to another establishment, unless:

(i) the operations consist only of storage or transport, in which case the specific temperature requirements laid down in Annex III shall nevertheless apply; or

(ii) the supply of food of animal origin from the retail establishment is to other retail establishments only and, in accordance with national law, is a marginal, localised and restricted activity.”

19. ‘Wholesale outlets’ are included in the definition of ‘retail’; the broader terms “wholesale”, “wholesale activities” or similar are not used and LAs should bear in mind this distinction. An example would be an establishment supplying its customers on a “cash and carry” basis is included in the retail exemption, as long as an element of that supply is to the final consumer, as defined.
20. Although a ‘wholesale outlet’ may be considered to be ‘retail’ as defined in Regulation 178/2002, approval may nonetheless be required depending on the specific activities undertaken. If POAO for which Annex III of Regulation 853/2004 lays down requirements are handled, and these products are not supplied to the final consumer exclusively, or are not supplied to other retail establishments on a “marginal, localised and restricted” basis, approval would be required.
21. Marginal, localised and restricted are interpreted as follows and all three criteria must be met for the establishment to be exempt:

- **“marginal”:**
 - Where the POAO wholesaled to other retailers/caterers is up to a quarter of the establishment’s annual turnover in terms of food OR;
 - In relation to meat (fresh or processed, excluding wild game meat) up to 2 tonnes a week; subject to the establishment concerned having a genuine retail element to its operation

2 tonnes could be averaged over any 12 month period.

If either applies, the establishment will be exempt from approval under regulation 853/2004, provided it also meets the localised and restricted criteria.

Note:

For meat, either of the measures of marginal is available, however both must not be used simultaneously at an establishment. It is either the 25% or the 2 tonne rule

(for establishments that only handle meat). For other POAO, only the 25% criterion applies.

Up to a quarter of the business in terms of food “should be calculated by measuring the amount (either by sales, 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.).

- **“localised”**: as sales within the establishment’s own county plus the greater of either the neighbouring county or counties or 30 miles/50km from the supplying establishment’s county boundary;

Note: Producers of rare breed meats who satisfy the ‘marginal’ and ‘restricted’ requirements of the retail exemption may be unable to find sufficient ‘localised’ customers in order to maintain the viable sale of a particular rare breed meat in the UK. In these exceptional circumstances, the interpretation of “localised” may be extended to the whole of the UK in agreement with the competent authority in advance, in cases where the geographical distribution of certain rare farmed or rare game animals would otherwise significantly restrict the national supply or where a traditional, or high value product could not find a sufficient and/or specialist market on a local basis as defined above. In NI, “localised” may include neighbouring counties of Northern Ireland and the Republic of Ireland.

- **“restricted”**: *is described in Recital 13 of Regulation 853/2004 as ‘concerning only certain types of products or establishments’.* Having to list establishments and products is seen as bureaucratic and a potential barrier to trade and there are, in any case, other legal requirements for the traceability of food products. In relation to the meat sector, LAs should interpret ‘restricted’ as set out in the Food Law Practice Guidance (PG) Annex 5, Paragraph A.5.4.2. In respect of other products of animal origin, LAs should consider whether the supply is in some way restricted in relation to either:
 - The products being supplied by product category as referenced in Regulation 853/2004 (e.g. dairy products, fishery products etc.), or;
 - The type of retail establishment supplying the products, and/or;
 - The type of retail establishment(s) being supplied with the products

For example, the restricted criterion may not apply where a retailer is supplying a wide range of different POAO commodities (e.g. dairy, fishery products and live bivalve molluscs) to other retailers

Specifically, in relation to:

- **meat** the restrictions are in relation to the amounts of meat supplied and the requirement for a 'genuine retail element' (see 'marginal' above);
- **wild game and wild game meat**, the supply is subject to the game having been examined by a trained person, and for large game, being accompanied by a declaration stating that no abnormalities were observed either before or after shooting.

Note: Supply to a final consumer can include mail order and internet sales.

Cold stores – retail exemptions

22. If a stand-alone cold store has supply to the final consumer and can therefore be considered a retail establishment it may be exempt from approval. This is the case where:
- Supply is exclusively to the final consumer
 - There is supply to the final consumer, and POAO are also supplied to other retailers and caterers only (i.e. not to approved establishments) on a marginal localised and restricted basis.

Retail logistical chain

23. Where a cold store can be considered purely as part of the logistical chain for a specific retailer or caterer and is only used as part of their storage and transport operation (e.g. retailers' distribution centres), the cold store can be considered as exempt from approval. This exemption is only applicable where that supply remains dedicated to a specific retail outlet, such that the POAO under cold storage are all essentially under the ownership of that retail/catering outlet. Where supply is also to other establishments, purchasing POAO from the cold store, the exemption no longer applies.
24. Cold stores which are part of the logistical chain for retailers such as retailers' distribution centres are not subject to the temperature control requirements for products of animal origin in Regulation (EC) No. 853/2004.
25. Food retail shops and their distribution centres are within the scope of other legislation on temperature controls, specifically, the requirements of Annex II of Regulation (EC) No. 852/2004 and the national temperature control rules in

Schedule 4 of the Food Safety and Hygiene (England) Regulations 2013 and the Food Hygiene Regulations 2006 in Scotland, Wales and Northern Ireland.

Supply of food of animal origin by the producer to the final consumer at farmers' markets

26. Establishments producing POAO for supply to the final consumer at farmers' markets, or at other markets supplying the final consumer (i.e. establishments that produce and retail their own products), are not subject to approval under Regulation 853/2004. This is subject to the following conditions:
- 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);
 - It does not involve supply to other than the final consumer. Supply to shops or restaurants from the market stall would render the production establishment subject to approval if supply was above the marginal or local or restricted limits.
27. 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 criteria.

Multiple premises constituting a single establishment (Satellite Operations)

28. There may be circumstances where authorised officers wish to consider separate sites and/or locations as part of a wider establishment and therefore a 'single (retail) establishment' for the purposes of registration under Regulation (EC) No. 852/2004 and for risk rating in accordance with section 5.6 of the Food Law Code of Practice. This flexibility may only be applied where the main focus of the establishment's activities is that of a retail business (i.e. the business must involve the supply of food direct to the final consumer). LAs should consider such businesses on a case by case basis to ensure that all three of the following criteria are satisfied:

- a) The operation is under a single ‘controlling mind’, i.e. there is one natural or legal person who is responsible for the implementation of food safety management procedures; and
- b) a single food safety management system covers all stages and units of the operation within the wider establishment; and
- c) all the activities undertaken at the various locations or units within the ‘wider’ establishment are within close enough proximity that it can be reasonably expected that the single controlling mind can effectively manage the food safety management controls at all sites.

If these criteria are met and at the discretion of the LA, the sites may be considered as the same establishment and therefore subject to registration, rather than approval.²⁴

Please also see section 3.2.5 of the FSA Code of Practice and section 3.2.4 of the FSA Practice Guidance.

(iii) “Composite Products”

29. **Article 1(2) of Regulation 853/2004:** Food Containing Both Products of Plant Origin and Processed Products of Animal Origin, *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”

30. Thus a food business operator who:

- Merely **assembles** processed products of animal origin with products of plant origin does not need approval as it is a composite product, even if that product is then further processed-i.e. Regulation (EC) No. 852/2004 would be appropriate to that operation or those operations;
- Further processes a processed product of animal origin prior to **combining** it with food of plant origin would need approval under Regulation (EC) No. 853/2004. Because processing is carried out on a

²⁴ This position is not in place in Northern Ireland. Please contact FSANI using contact details in Annex 2 if you would like more information

POAO not on a product containing both POAO and non-POAO and therefore the food undergoing processing is not considered to be a composite product. 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;

- Assembles food of plant origin with **unprocessed** food of animal origin which is further processed together would need approval under Regulation (EC) No. 853/2004 as it is not considered to be a composite product.
31. The addition of a product of plant origin to a processed product animal origin does not automatically mean that the resulting food would be a composite product. For example, manufacture of cheese to which herbs are then added or sausages to which garlic or soya are added would fall within Regulation (EC) No. 853/2004.
32. 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.²⁵

Cold Stores which only store composite products are exempt from approval

33. Cold stores which are exclusively engaged in the storage and distribution of composite products do not need approval, and only need to be registered under Regulation 852/2004.
34. Exemptions from Approval based on retail activity may also apply as described above.

Slaughter for private domestic consumption

35. 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, such activity falls out of

²⁵http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_853-2004_en.pdf

the scope of both Regulation (EC) No. 852/2004 and Regulation (EC) No. 853/2004. Further information can be found on the FSA's website at:

<https://www.food.gov.uk/business-industry/guidancenotes/meatregsguid/home-slaughter-livestock> for England, Scotland, Wales and Northern Ireland.

Responsibilities of Food Business Operators

36. Article 6(2) of Regulation (EC) No. 852/2004 places the legal onus on food business operators to ensure that establishments under their control which are subject to approval under Regulation (EC) No. 853/2004 are approved by the competent authority **before they commence trading**. Regulation (EC) No. 882/2004 obliges competent authorities to establish procedures for food business operators to follow when applying for approval. These procedures for handling applications for approval, being administered by LAs are set out in the statutory Food Law Code of Practice.²⁶
37. Article 6(2) also requires the FBO 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 Safety and Hygiene (England) Regulations 2013 and the Food Hygiene Regulations 2006 in Scotland, Wales and Northern Ireland.
38. In the context of this article, a change of FBO constitutes a significant change which should be notified to the competent authority.

Approvals Procedure

Application for approval

39. Following an enquiry from a prospective FBO, the LA should provide applicants with an application form. A template of an “Application for Approval” form can be found at section 3.3.4 of the Food Law Practice Guidance. Although the content of this document should be regarded as the minimum

²⁶ <http://www.food.gov.uk/enforcement/enforcework/foodlawcop/copenland/>

<http://www.food.gov.uk/enforcement/enforcework/foodlawcop/copni/>

<http://www.food.gov.uk/enforcement/enforcework/foodlawcop/copscotland/>

<http://www.food.gov.uk/enforcement/enforcework/foodlawcop/codepracticewales/>

required, LAs may adapt them as necessary to meet local requirements. All applications for approval should be dealt with promptly.

40. Applications for approval of establishments should only be accepted from FBOs that intend to engage in activities for which approval would be required in accordance with Regulation (EC) No. 853/2004. This might include FBOs who wish to include an additional activity or activities which they will only carry out part of the time, but nevertheless part of their operations will be subject to Regulation 853/2004 and approval should be granted before the activities commence. Under no circumstances should approval be granted to an establishment which is not subject to approval under Regulation (EC) No. 853/2004, i.e. is not carrying out any activities that require approval.
41. LAs should ensure that the FBO supplies all relevant information before an application for approval is determined. The information may be obtained from the FBO in documentation supplied with the application or during the subsequent on-site visit to the establishment as required by Article 31(2)(b) of Regulation (EC) No. 882/2004. It is the matter for the LA to decide at which stage of the application this information should be provided.
42. The applicant must provide details of:
 - the establishment for which approval is requested;
 - the identity of the FBO including relevant contact and address details; and
 - the activities for which approval is sought
43. **Article 3 of Regulation (EC) No 178/2002** defines “*food business operator*’ as the **natural** or **legal** persons responsible for ensuring that the requirements of food law are met within the food business under their control”.

A **natural person** is a human being, (as opposed to an artificial, legal or juristic person, i.e., an organisation that the law treats for some purposes as if it were a person distinct from its members or owner).

A **legal person** has a legal name and has rights, protections, privileges, responsibilities, and liabilities under law, just as natural persons (see above) 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.

44. The legislation allows for natural and legal persons to be the FBO therefore LAs must require the applicant to identify themselves (including the name of officers, address and proof of status) as 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); *or*
 - Other business types such as cooperatives, registered charities and other specialised types of organisation. These will be treated on a case by case basis to identify the natural person or legal person required to be compliant with food law within the food business under their control.
45. In considering applications for approval, LAs should ensure that they fully consider any exemption that may be afforded to the applicant by Article 1 of Regulation (EC) No. 853/2004.
46. Applications for approval must be sought for new build/start-up establishments and are also required in the following circumstances:
- Registered establishments under Regulation (EC) No. 852/2004 applying to undertake activities that require approval;
 - Establishments approved under Regulation (EC) No. 853/2004 by the LA applying to undertake additional activities
 - Establishments approved under Regulation (EC) No. 853/2004 by the LA applying to undertake additional activities that require approval by FSA, i.e. “co-located”²⁷ establishments;
 - Change of food business operator – see paragraphs 113 - 120.

Advisory visits

47. LAs may wish to offer advisory visits to those establishments that have applied for approval prior to an approval visit. The aim of the advisory visit will be to help FBOs identify any problems in the areas of structure and

²⁷ In NI, dual enforcement establishments are referred to as “integrated establishments”

maintenance; and food safety management, so as to avoid any potential difficulties when the establishment is formally assessed for approval.

48. LAs need to make the FBO aware of the differences between an advisory and an approval visit.

Approval Requirements

49. On-site visits undertaken with a view to the approval of an establishment may only be undertaken by AOs of the LA who have a detailed knowledge of enforcement in approved establishments, the risks associated with the particular operation and the technologies utilised. See Chapter 4 (Qualifications and Experience) of the FSA Code of Practice for information on qualifications and competence.
50. To gain approval, establishments will have to fully meet the requirements of Regulations (EC) No 852/2004 and (EC) No. 853/2004 and other requirements of food law relevant to the type of establishment. LAs should ensure that they and the FBO follow these procedures as appropriate. Any deviation from these procedures should be recorded and retained by the LA. The requirements for approval fall into three broad categories based on **Article 31.2(d) of Regulation 882/2004**:

INFRASTRUCTURE AND EQUIPMENT

i. Structure of premises/equipment/layout;

OTHER RELEVANT REQUIREMENTS OF FOOD LAW

ii. Prerequisites* - applicable to all food establishments, for example:

- FBO's procedures for maintaining environmental hygiene including the management and disposal of waste animal by-products;
- Traceability including Food Chain Information;
- Training and supervision

iii. **HACCP based food safety management system** - specific to individual establishments:

- FBO to demonstrate compliance with the requirements of Article 5 of Regulation (EC) No 852/2004.

Approval of establishments

51. Certain approvals procedures are set out in Article 31.2 of the Official Controls Regulation (EC) No. 882/2004, with provision for further procedures to be established by national competent authorities. An overview of the approval process is set out in a flow chart at **Annex 1**. LAs should note that new establishments requiring approval will not be able to operate until they have been granted “conditional approval”. It follows that operational standards cannot be observed at the time of the first visit and a second and possibly subsequent visits will be necessary.
52. LAs must not permit establishments to operate (in a manner that requires approval) until approval or conditional approval has been granted.
53. LAs should bear in mind that an FBO can only make an application for approval of a premises under their control; the decision whether or not to grant conditional approval to an establishment which does not fully comply rests with the LA. ‘Conditional approval’ should not be given unless/until the relevant requirements of the legislation have been met such as those requirements for infrastructure and equipment (see table below). Full approval should not be given unless/until all relevant requirements of the legislation have been met and the FBO demonstrates that the operational controls are in place and they are fully compliant.

For a new establishment, in all circumstances conditional approval should be granted prior to full approval being granted. This is because it will be impossible for the FBO to demonstrate that the food safety management system is valid and to verify its effectiveness.

54. Granting ‘full’ approval for a new start up establishment at the first visit is not applicable. A new establishment has not had the opportunity to demonstrate their HACCP based food safety management procedures as they could not operate until approval is granted. However there might occasions when an LA may consider granting full approval without the need for conditional approval, for example (not exhaustive):
 - Where there is a change of ownership, but the controlling mind, staff, operations and equipment are sufficiently the same that the LA has seen the HACCP-based approach in operation already
 - Where an FBO is already operating but due to an exemption from approval, they are currently registered with the LA. The FBO already

meets the requirements in 852/2004 and the specific requirements in 853/2004 and the LA has seen the HACCP-based approach in operation already. The FBO moves beyond the exemption requirements, for example supply is no longer localised, or supply to an approved establishment is added to the activities

This decision is at the discretion of LA authorised officers when considering the application for approval and when carrying out the on-site approval visit.

55. Following approval visits for a new establishment, the options available to the AO are as set out below:

<p>1st visit</p>	<p>If compliant with infrastructure and equipment requirements, grant conditional approval.</p> <p>At this stage the establishment may not have a fully implemented HACCP based food safety management, 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 documented food safety management system needs to be made available but if the establishment is not operational, it will not be possible to assess how effectively this works in practice.</p> <p>While compliance with all the requirements of food law cannot be demonstrated before operations start, the officer carrying out the approval visit should be able to gain some confidence on the prospective FBO's ability to comply and decide if conditional approval is appropriate. An assessment of proposed methods of operation, staff training arrangements, cleaning procedures, etc. i.e. all the pre-requisites for HACCP principles implementation which should be assessed at the time of the approval to inform this</p>	<p>If not compliant with infrastructure and equipment requirements refuse application.</p>
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	<p>decision.</p> <p>Ultimately the decision to grant conditional approval is a professional judgement on the part of the officer carrying out the approval but compliance with these requirements must be assessed as part of making that decision.</p>	
<p>2nd visit within three months of conditional approval</p>	<p>If compliant with operational requirements and compliance with infrastructure and equipment requirements are maintained, grant full approval.</p>	<p>If not:</p> <ul style="list-style-type: none"> ● refuse application: or ● extend conditional approval for a further three months, if adequate progress has been made and the infrastructure and equipment requirements continue to be complied with. <p>Note: conditional approval cannot last longer than six months</p>
<p>3rd visit-at end of six months from conditional approval</p>	<p>If fully compliant, grant full approval</p>	<p>If not, <u>refuse approval</u></p>

Note: Model forms for FBO Applications for Approval, granting and refusing approvals can be found in the FSA Practice Guidance Annex 9 and here: <http://www.food.gov.uk/enforcement/approved-premises-official-controls>

Refusal to issue approval

56. An approval can be refused at any time in the approval assessment process as detailed below:
- Approval can be **refused** if there are structural or equipment deficiencies at the initial approval visit or if the prospective FBO has no proposed HACCP-based food safety management system or it is deemed inappropriate to protect consumer health.
 - Full approval subsequent to conditional approval can be **refused**:
 - a. if, within the three months of conditional approval, insufficient progress has been made to meet the requirements in full and, in the judgement of the AO, there is insufficient evidence to demonstrate that the necessary work will be completed if a further period of conditional approval is granted, conditional approval can be refused by the LA
 - b. if, at the end of the six month period there is insufficient compliance with structural, equipment and/or operational requirements and/or other relevant requirements of food law, including the implementation of an effective food safety management system based on HACCP principles.
57. 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 and the LA should notify the FBO.
58. Where an AO considers it possible that an establishment's approval may have to be refused, he/she should keep a record of the reasons of these decisions on the establishment's record file. Templates for model forms including refusal to approve can be found in Annex 9 of the FSA Practice Guidance.
59. The FBO must be given written notice of the decision to approve or refuse approval; the reason why the decision was made; 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 should also be provided with information on rights of appeal.

60. The applicant has the right to appeal to the relevant Court against the refusal of an approval or conditional approval. Rights of appeal are subject to the Official Feed and Food Controls (England) Regulations 2009 (as amended), and parallel Regulations in Scotland, Wales and Northern Ireland. From the date on which the notice of the decision is served on the relevant person the establishment cannot continue operating whilst the appeal is being determined.

Approval of seasonal establishments

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 Competent Authority 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 AO undertaking the assessment must satisfy themselves that:
- It is practical to split the approval across one or more seasons and any potential risk to public health is managed;
 - Measures will be taken by the FBO within the expected conditional approval period to remedy any operational or food safety management system deficiencies on a permanent basis; and
 - Full approval is achievable within three years.

Approval number/identification mark (ID)

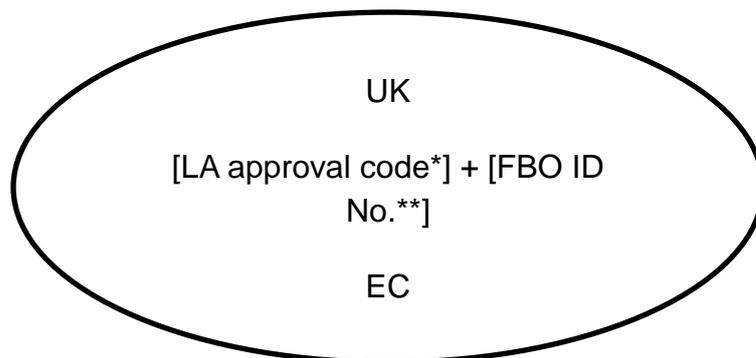
63. Article 5 of Regulation (EC) No 853/2004 requires that products of animal origin handled in establishments subject to approval are not placed on the market unless they bear an identification mark (ID) or health mark (health marks do not apply to LA enforced establishments), applied in accordance with Regulation (EC) No. 854/2004.
64. 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 EU, the mark must be oval in shape and include one of the permitted two letter abbreviations. In the UK this is EC.

Example Identification Marks

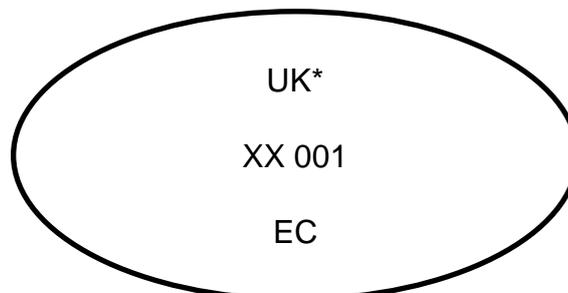
Format:



* The unique code given to each LA is the prefix of the approval number

** The Unique approval number given to the FBO once approved by the Authority

For example:



* Could be written as UK or United Kingdom

65. LA must give a unique approval number to each food business establishment it approves, or conditionally approves, in accordance with Article 3(3) of Regulation (EC) No. 854/2004. This approval should be a unique three digit number. The approval number should form part of the approval code consisting of the LA's two-letter code followed by the approval number. Although, in principle, LAs should use this protocol, there are exceptions to this rule. LAs may allow FBOs to retain an approval code that had been allocated by the FSA at the establishment for a transitional period, provided that traceability is not compromised in any way. This would avoid the need for businesses to change their packaging, labelling, etc., thereby avoiding any potential cost implications. However, LAs are advised to consider phasing these out over a period of six months, by which time such businesses should have used up all existing stocks of pre-printed labelling materials. Transfer of approval number from one LA to another should not be permitted, unless this is due to unforeseen circumstances such as changes to LA boundaries, or force majeure (see paragraph 78 for details). Under certain circumstances an approval number can be retained where an FBO moves to a new establishment in the same authority area (see paragraph 73 for details).
66. The approval code should be incorporated into an identification mark which approved establishments are required to apply to their relevant products, as appropriate. LAs should agree an identification mark with each establishment it approves which (a) incorporates the approval code it has allocated, and (b) meets the requirement of Annex II, Section I B of Regulation (EC) No. 853/2004. (see Practice Guidance, Section 5, Chapter 5.1 for example of identification marks)
67. Annex II Section I Part C of Regulation 853/2004 also sets out other requirements for the application of the ID Mark and the methods of marking applicable to different product types. Where an ID is not applied to the product itself (including the wrapping and/or packaging), for example if it is applied to paperwork for POAO carried in bulk containers (e.g. liquid egg, fishery products etc.), the mark on the paperwork must still meet requirements for the form of the mark in the Regulation, including being in an oval shape.
68. An exception to this is in relation to eggs, where an identification mark is not necessary on **packs of eggs** when a packing centre code is applied in accordance with Part A of Annex XIV to Council Regulation (EC) No. 1234/2007²⁸ on marketing standards for eggs and poultry meat. However an LA (or FSA in NI) approval number must still be allocated and, some FBOs

²⁸<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:299:0001:0001:EN:PDF>

may choose to use that LA allocated approval number on commercial documentation.

69. Where a premises has been re-assessed for approval due to a change of ownership 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 Food Business Operator* section, paragraphs 113-118.
70. In order to avoid the allocation of dual approval numbers to the co-located establishment by FSA and LA, the FSA 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.
71. Where an establishment is approved by the LA and the FBO is subsequently granted an approval by the FSA, due to the establishment becoming co-located, the FSA will issue a new approval number to the establishment as a whole. In order not to penalise FBOs in this situation, upon request, a reasonable period of time (but 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.
72. An approval number is not transferable. For example, if an establishment ceases to operate and the approval is surrendered or withdrawn, the approval is no longer in existence at that premises. If the FBO then intends to move to a new establishment, that establishment would have to be given a new approval number, unless they apply to the LA to retain the approval number when moving to a new premises in the same LA area (see below).

Moving premises within the same authority area – retaining approval numbers

73. If a FBO of an approved establishment moves from their existing premises to a new one, LAs may allow the FBO to retain the same approval number which was provided to them for the establishment which they are vacating. The operation at the new premises will be subject to a new approval including application for approval, a site visit and assessment of compliance with the requirements of the legislation. The FBO must have been granted approval prior to operations commencing in the new location. Where this move is within the same Authority boundary, the LA may allow the FBO to retain its existing approval number. In order to ensure that the approval numbers

remain unique to a single establishment, the approval must first be surrendered by the FBO and operations at the existing premises must cease. The same number can then be re-issued to the FBO at the new premises, if approval is deemed to be appropriate.

74. 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.

If an FBO of a LA approved establishment moves to another LA area, the approval number cannot be retained.

Handling business request for flexibility in the use of approval numbers

75. There will be occasions where FBOs ask LAs to permit products to bear an approval number other than the one relating to the establishment where the product was manufactured or handled.
76. The FSA's view is that the practice of allowing 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 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*”.
77. The Recitals to Regulation 853/2004 link the application of the identification mark explicitly to traceability, saying that it applies in addition to the requirements of Regulation 178/2002. Recital 15 states that “*the traceability of food is an essential element of food safety*”.
78. The only flexibility that could be applied to this requirement would be in the event of a *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).
79. If a FBO approaches a LA for consideration of extreme circumstances, such a decision **can be only** made through the FSA's single contact point, which is listed at **Annex 2**. The LA should clearly make the case in writing for:
- the nature of the extraordinary event (flexible application of the legislation should not apply to address normal business risks);

- the duration of the proposed alternative arrangements (maximum duration should not exceed the time required to print new labels or 6 months as a maximum);
- why alternative ID arrangements (e.g. sleeves or sticky labels) cannot be made;
- to indicate the alternative approval number being proposed as part of this request for flexibility;
- how traceability will be maintained during the period of the alternative arrangements; and
- any additional supervision arrangements needed to be made as products produced or handled during the period of alternative arrangements should for the UK market only.

Notifying the FSA of approvals

80. In addition to notifying the FBO, **LAs must also notify the FSA²⁹** of any establishment to which they grant approval or conditional approval. Details required are as follows:
- the approval number;
 - name of establishment;
 - address;
 - category of food establishments;
 - all approved activities;
 - associated activities;
 - species; and
 - remarks

Note: as of XXXX 2015 full address details for all approved establishments will be published on the FSA website unless the FBO specifically chooses to opt out. The wish to opt out should be made to LAs at the time of application and LAs should notify the FSA where an approved establishment wishes to opt out. The FSA model application form for approval includes an option to opt out of publication of the publication of full addresses. See the Practice Guidance for details.

²⁹ For England it should be send to approvals@foodstandards.gsi.gov.uk; and for the rest of the UK notifications must be sent to the relevant contacts detailed at Annex 2.

81. These details are based on the specification set out by the European Commission on the layout of the list of approved food establishments. Further information on the technical specification can be found on the European Commission's website at: http://ec.europa.eu/food/food/biosafety/establishments/techspecs_en.pdf. Details of the establishments are then updated on the FSA's website which can be found at: <http://www.food.gov.uk/enforcement/sectorrules>

[Notifications of new approvals and updates to approvals must be sent to:](#)

England: approvals@foodstandards.gsi.gov.uk

Wales: lasupportwales@foodstandards.gsi.gov.uk

NI: executive.Support@foodstandards.gsi.gov.uk

Scotland: enforcement@fss.scot

Types of approvals

Wholesale markets

82. Wholesale markets must be allocated an overall approval number for the establishment that constitutes the common parts, with secondary numbers as a suffix to that number indicating the approval of individual units within the market. 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.
83. Responsibility for complying with the Hygiene Regulations³⁰ rests with the landlord or responsible tenant of the market for the general areas within the market and individual food business operators for the unit(s) which they operate. However, FBOs for individual approved units have a duty to ensure that adequate common parts facilities are in place as a prerequisite to them operating, e.g. waste disposal, potable water supply, hot water etc.
84. The LA has the right to withdraw/suspend approval/conditional approval and in the case of a wholesale market, article 3(c) of Regulation (EC) No.

³⁰ The Food Safety and Hygiene Regulations (England) 2013 and the Food Hygiene Regulations 2006 for Scotland, Wales and Northern Ireland, Regulations 852/2004 and Regulation 853/2004 and all other relevant requirements of "food law" (as defined in Article 3.1 of Regulation (EC) 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.

854/2004 allows the LA to withdraw or suspend approval/conditional approval in respect of the general areas and certain units within the market.

Multiple FBOs operating from one establishment

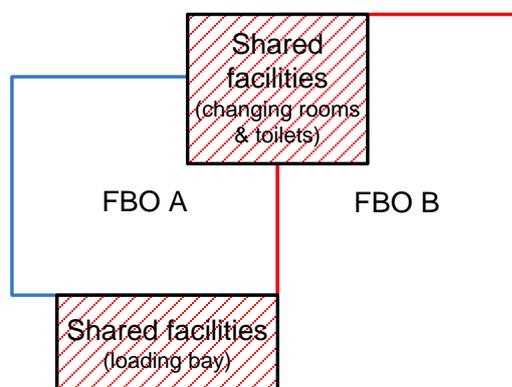
85. Where more than one FBO wishes to use a single premise to operate separate food businesses at different times, for example FBO A operates 09:00-17:00 and FBO B operates 17:00-09:00, approval may still be permitted but these situations will be assessed on a case by case basis. In this case both the FBOs will require separate approvals.
86. The FBO/s for the individual businesses requiring approval using one premises will need to demonstrate how they plan to manage any food safety risks adequately. When undertaking the assessment the LA must satisfy themselves that infrastructure, equipment and the FBO controls are acceptable before the 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.
87. Where this is achieved approval or conditional approval will be granted to each FBO individually with each FBO receiving their own approval number. Refer to *Approval Number/Identification Mark (ID)* section, paragraphs 63-72.
88. In the event that the competent authority, when carrying out official controls, needs to take enforcement action, for example due to non-hygienic operations or equipment deficiencies, this may need to be taken against both parties until the issues are resolved. This is owing to the joint use of the premises being a precondition to the individual approval, regardless of which party caused the problem in the first place.

Shared facilities

89. 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 chiller capacity.
90. The FBO requiring approval using shared facilities will need to demonstrate how food safety risks are managed. When undertaking the assessment, the LA must satisfy themselves 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.

91. An example site plan identifying the shared facilities:



92. Where this is achieved 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.
93. If at a point in the future the shared facilities are no-longer available i.e. the neighbouring FBO no-longer wishes to make the facilities available, the approval must be reviewed with the view to suspending the approval. Also refer to *Review of Establishment with the view to Suspension or Withdrawal of an Approval* section, paragraphs 139-148. Where the FBO is able to become self sufficient in their own right, separate approval as an individual establishment can be sought.
94. As in the scenario above (see paragraph 88), in the event that the competent authority, when carrying out official controls, needs to take enforcement action for example due to non-hygienic operations or equipment deficiencies, this may need to be taken against both parties until the issues are resolved. This is owing to the shared facility being a precondition to the individual approvals and will be regardless of which party caused the problem in the first place.

Note - The facilities which are to be shared may form part of an approved or registered establishment where either the FSA or relevant LA is responsible for official controls. In the event enforcement action is required this will be undertaken by the relevant authority.

Division of enforcement responsibilities

95. Responsibility for monitoring and verifying compliance with the Regulations and enforcement of it is divided. The division of responsibility is summarised below:

In GB

96. Responsibility rests with LAs for the approval of, and enforcement in establishments subject to approval under Regulation 853/2004, which do not fall to the FSA.
97. The FSA is responsible for approving meat products, minced meat, meat preparations, mechanically separated meat plants, cold stores or edible co-products plants that are co-located with an approved slaughterhouse, cutting plant or game handling establishment.
98. Where an approved meat establishment subject to veterinary control, in **Great Britain**, is also handling other POAO the **FSA or FSS**, in liaison with the relevant LA, **may approve** all operations requiring approval under Regulation (EC) No 853/2004 that are co-located. Such approvals will be determined on a case by case basis.
99. Where there are some elements of dual enforcement required, the LA must reach agreement with the FSA's Field Veterinary Leader (or Senior Veterinary Advisor in NI; or FSS Head of Approvals in Scotland) as to the split of enforcement responsibilities and refer to this in their approval recommendation for inclusion in the approval document. If you would like to contact the FSA or FSS with regard to a possible transfer of enforcement responsibility, or if you are unsure who is the appropriate FVL to discuss a case with (for England and Wales), please contact the FSA at the following email address for England and Wales:

approvals@foodstandards.gsi.gov.uk

for Northern Ireland:

executive.support@foodstandards.gsi.gov.uk

and for Food Standards Scotland:

approvals@fss.scot

100. The term "co-located establishments" should only be applied to establishments that require approval within a common curtilage, e.g. a slaughterhouse and processing plant. Any business subject only to the

requirements of Regulation (EC) No 853/2004 fall to the LA e.g. a **retail** butcher's shop attached to a slaughterhouse (refer to *Exemption from Approval* section, paragraph 16) and where the establishment is also handling non-POAOs.

See also paragraph 138 with regard to transfer of official controls to the FSA

In Northern Ireland

101. District Councils (DCs) are responsible for the approval of, and enforcement of standalone approved establishments where control does not fall to FSA NI.
102. In approved establishments, that are integrated establishments, DCs are responsible for the approval and enforcement in relation to those parts of the establishment producing meat products, edible coproducts, dairy or egg products.
103. The FSA in NI is responsible for the approval of meat establishments where control falls to an official veterinarian. DARD Veterinary Public Health Unit (VPHU) is responsible for enforcement in such establishments once approved. Such meat establishments include slaughterhouses, game handling establishments, cutting plants, and co-located establishments including cold stores or those establishments where minced meat, meat preparations and mechanically separated meat, are also produced.
104. DARD (VPHU) will on behalf of the FSA execute and enforce the relevant provisions of the Hygiene Regulations at Collection Centres and Tanneries supplying raw material for the production of gelatine and collagen intended for human consumption.
105. The FSA in NI is responsible for the approval of establishments and enforcement at liquid milk processing establishments and egg packing establishments. DARD Agri – Food Inspection Branch (AfIB) is responsible for enforcement in such establishments once approved.

Changes to approvals

General requirements

106. FBOs are required to notify the relevant LA of any significant changes in activities in existing establishments. **Regulation (EC) No. 852/2004, article 6.2.** FBOs should be reminded of this during all programmed interventions. LAs may also wish to consider including this in approval documentation and/or correspondence with FBOs so that the FBOs' obligations are clear.
107. Where the FBO notifies the LA of such changes, AOs need to consider whether a visit should be made to inspect the alterations and whether an amended HACCP based food safety management system is required. This will depend on the extent of the changes, such as:
- Proposed additional activities and changes to activities
 - Change to approved curtilage/re-structuring
 - Change of ownership
 - Change of name
 - Closure of an approved establishment
 - Surrender of approval

Additional activities

108. If a FBO, of an approved establishment wishes to undertake additional approvable activities (as detailed in *Categories of Food Establishments* section, paragraph 5), the FBO must apply to the relevant LA for approval before commencing the operation of that additional activity.
109. The establishment's ability to undertake additional activities should be assessed following the same procedures as a new establishment.
110. Professional judgement should be used, in the case of approving additional activities, to decide to grant full approval in the first instance. This is only appropriate when the AO reaches a point where they are satisfied with infrastructure, equipment and the FBO controls. For example, adding an approval for a minced meat establishment to an already approved meat preparations establishment. A revised approval document will still need to be issued to reflect changes in the approval.

Change to approved curtilage / restructuring

111. A notification to the LA of significant curtilage changes and/or restructuring to the approved establishment will require the FBO to provide revised plans indicating those changes. A LA assessment should be made to ascertain if the

changes are appropriate. As part of this assessment professional judgement should be used to determine whether an on-site visit is also required.

112. Once acknowledged by the LA, curtilage changes or restructuring should not require further or additional approval. It is the FBO's responsibility to ensure 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 LA.

Change of food business operator

113. The approval of an "establishment" applies to both the premises and the business operating at the premises. An approved establishment cannot change ownership and retain the exiting approval. If premises used for an approved establishment changes ownership, the new establishment will have to be assessed and granted a new approval before it can operate. Carrying out activities which require approval in an establishment which is not approved is an offence.
114. Article 6(2) of Regulation (EC) No 852/2004 requires the FBO to inform the competent authority when there is a change of FBO. This will be by means of an application form as detailed in *Application for Approval* section, paragraphs 33-40, which includes the type of business entity, name of officers and relevant address of the FBO wishing to apply for approval. The FBO is then obliged to keep the LA informed about significant changes to those details.
115. **Annex 3** provides clarification of what the FSA would regard as a change of FBO in different business set-ups. The key issue is whether there has been a change in the "controlling mind" of the business. For example, when a member of a partnership leaves, it does not necessarily trigger a new approval if the remaining members of the partnership continue the business. However, if the partners sold the business to a sole trader who was not in the partnership, then this would constitute a change of FBO.
116. Once an application is received, the LA should assess the application in the same way as a new establishment and if approval is granted may be subject to a new approval number. Also refer to Approval Number/Identification Mark (ID) section, paragraphs 55-63.

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

117. Where the LA becomes aware of a change of FBO that continues placing food on the market without seeking a new approval after the change of operator, the LA action regarding withdraw/recall of such food should be risk-based and proportionate. However, food not yet placed on the market should be detained until the new FBO has been able to gain approval.
118. In the case of wholesale markets the following principles may apply:
- The overall approval for the market (common parts) will be treated in the same way as an individual premises ownership change. Therefore the change in FBO would necessitate a re-approval and there might be a need for a new approval number to be granted for the wholesale market. The individual units within the market do not need to be individually re-approved, however if the markets approval number is changed, the units can be re-allocated a new corresponding number using the new market approval number (for common areas of the market).
 - 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 prerequisite 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 ownership, this will be treated in the same way as an individual premises ownership change.

Change of trading name

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

Note – This is not to be confused with a change of ownership, which would warrant a re-assessment for approval. Refer to *Change of Food Business*

Operator section, paragraphs 102-107.

120. 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.

Closure of an LA approved establishment

121. Where an establishment has a break in operation or closure the FBO is obliged to keep the LA informed. The following is the **FSA's policy** on dealing with closure of an establishment. LAs may wish to follow the FSA's procedure or use alternative approaches in line with your enforcement policy.

Summary of FSA policy on closure of an establishment

122. Where an establishment has a break in operation or closure the FBO is obliged to keep the FSA informed. These breaks are categorised as follows:

Seasonal closure

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

Temporary closure

When an FBO needs to temporarily halt operations due to renovation / development work at an establishment or due to a temporary downturn in trade the FBO is obliged to keep the FSA informed about these significant changes to the operational pattern. In these cases the FBO must notify the LA at least two weeks before operations re-commence. Also refer to *Change to Approved*

Curtilage / Restructuring section, paragraphs 100-101.

Long-term closure

When an FBO stops operations with no immediate intention to recommence for at least 6 months or longer the closure is classed as long-term. The FBO is obliged to keep the FSA informed about this significant change to the operational pattern and must notify the FSA at least two weeks before operations re-commence.

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

123. During non-operational periods official controls undertaken by the FSA should 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.

124. Recital 13 of Regulation EC No 882/2004 state that:

*“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.”*

125. Following a period of closures the FBO must **not** start operations until the LA 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.

126. The FBOs 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 visit undertaken by the FSA.

127. The process of pre-opening assessments is described below:

- Where the pre-opening assessment results in the FSA being confident that the requirements of food law are met the FBO will be notified that operations at the establishment **can re-commence**.
 - Where the pre-opening assessment identifies serious deficiencies in meeting the requirements of food law the FBO may provide the FSA with guarantees on how the deficiencies will be resolved on a permanent basis and within a reasonable³¹ time.
 - 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.
 - 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, paragraphs 128-137 for establishments handling meat.
128. 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 the Review of Establishment with a View to Suspension/Withdrawal of Approval section, paragraphs 128-137.
129. Following the pre-opening assessment visit and when the FSA is content that the establishment meets all of the relevant requirements of food law, the FBO will be notified that operations can re-commence.
130. In the event that the FSA 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.
131. Where the FSA becomes aware of an establishment that has re-commenced operations without first notifying the FSA and a pre-opening visit assessment has not been undertaken, the following measures will be taken:
- Appropriate enforcement action will be taken to prevent FBO operating the establishment until a formal assessment of compliance has been

³¹ “Reasonable” would be relative to the nature and magnitude of the deficiencies present

undertaken or where deficiencies are identified such deficiencies have been rectified.

- If food has been placed on the market prior to a formal assessment the LA's action regarding withdraw/recall of food will be risk-based and proportionate. However, food not yet placed on the market can be detained under Regulation 10 of the Food Safety and Hygiene (England) Regulations 2013 until the FBO has been notified that operation can recommence.
- If on further investigation and examination, the FSA deems the food has not been produced in accordance with the Hygiene Regulations, they can certify the food as such using Regulation 29 of the Food Safety and Hygiene (England) Regulations 2013 (Regulation 27 in the equivalent 2006 Regulations).

Surrender of approval

132. Where the FBO of an establishment under their control, holding an approval granted by the LA, wishes to surrender that approval, the FBO is required to provide formal notice under Article 6(2) of Regulation (EC) 852/2004.
133. Once acknowledged by the LA, the approval will cease to exist and the use of the approval number will also come to an end. The LA must notify the FSA accordingly. Upon notification by the LA of the surrender, the establishment will be removed from the official list of approved establishments maintained by the FSA.
134. 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 competent authority.
135. Following the surrender, the FBO should be advised that it would be an offence to apply the ID Mark on any food or to resume activities for which approval is required without being reassessed for and granted a new approval.

Transfer of official controls from the FSA to LA

136. As detailed in Categories of Food Establishment section, following paragraph 2, the FSA is the competent authority responsible for the approval of meat establishments and associated activities when co-located with an approved slaughterhouse, cutting plant or game handling establishment.
137. Where the FBO holding an approval granted by the FSA wishes to surrender the slaughterhouse, cutting plant and/or game handling establishment

element of their approval but wishes to retain stand-alone approved activities, the establishment will be transferred to the LA. In these circumstances the FSA will notify the relevant LA accordingly. As the FSA had already approved the standalone activity, the LA may not have to undertake a separate re-approval however an LA approval number will be required (see para 59). 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 or activities subject to approval.

There may also be instances where FBOs approved by the LA will cease activities requiring approval or move within exemption limits which mean they need to be registered with the LA.

In the case of FBOs:

- deciding to limit their activities to meet the exemption criteria and surrendering the approval granted by the FSA; or
- losing their right to operate through withdrawal or suspension or refusal or approval but deciding to limit their activities to meet the exemption criteria, the establishment will remain subject to the Regulation (EC) No 852/2004 and must therefore register with the LA as a Food Business prior to surrendering their approval. On surrender of the approval the establishment will be removed from the official list of FSA approved establishments.

Transfer of official controls from LA to FSA

138. There may be occasions where an FBO under LA jurisdiction wishes to carry out activity which is subject to approval by the FSA. Examples of this are:

- A registered FBO operating within the limits of an exemption, who wishes to expand e.g. a retail butcher wishing to supply over 2 tonnes to other retail/catering establishments
- An approved Establishment under LA jurisdiction (e.g. fishery products), who also wishes to cut and sell fresh meat to other establishments

In both scenarios, the LA should contact the FSA approvals team to arrange a joint visit with the FSA. If the FBO is already operating in a way that requires FSA approval, any enforcement action remains the responsibility of the LA, until approval has been granted.

In the second scenario, transfer of responsibility for enforcement of all approved activity co-located with cutting and/or slaughter to the FSA will be considered on a case-by case basis. All such cases should be referred to the FSA for consideration. See also paragraphs 88-89.

Formal enforcement: Withdrawal and suspension of approval

Review with a view to suspension or withdrawal of an approval

139. Article 31(2)(e) of Regulation (EC) No. 882/2004 requires the competent authority to keep the approval of establishments under review. It states that:

“the competent authority shall keep the approval of establishment under review when carrying out official controls. If the competent authority 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 competent authority shall initiate procedures to withdraw the establishment’s approval. However, the competent authority may suspend and establishment’s approval if the feed or food business operator can guarantee that it will resolve deficiencies within a reasonable time.”

140. An interpretation of the terms “serious deficiency” mentioned in the above **Article** that provide the basis for withdrawal of approval has not been specified in the regulations. For consistency of approach, working definitions for “serious deficiency” have been developed by the FSA and are detailed below:

General indicator of serious deficiency

Actual or potential risk to public health

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
- poor maintenance preventing effective cleaning

Contamination

- contamination of 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

Food safety management system

- Poor management attitude and commitment
- Inadequate HACCP based food safety management system or good hygiene practices (commonly known as pre-requisite programme)
- Failure of HACCP based controls
- Inadequate traceability procedures and observance

141. 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 prerequisite to their approval. Where the individual units within the market are able to become self sufficient in their own right, separate approval as an individual establishment can be sought.
142. Review of approval may be triggered as a result of carrying out routine 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 (e.g. flooding) and/or where there is a strong likelihood that serious deficiencies will have developed.

Note: The LA should monitor establishments which have ceased operating and not informed them 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 LA should write to the FBO to confirm their approval no longer has effect and the establishment will be removed from the published list of approved establishments.

143. Where the preliminary evidence suggests that there may be serious deficiencies the AO should:

- 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
- Undertake an assessment of the FBO's history of compliance with regulatory requirements at the approved establishment, the relevant history of enforcement and any prosecutions involving the FBO.

144. Where the AO undertaking the review decides serious deficiency exists, the procedure at **Annex 4** should be followed.

145. The provisional decision to withdraw the approval must be communicated in writing to the FBO. The FBO must provide the LA with any guarantees that it will resolve the deficiencies within a reasonable³² time (the FSA recommends 'a reasonable time' as being within 14 calendar days from the date of issue of the letter to the FBO).

146. The process for consideration of guarantees is described below:

- Where the FBOs guarantees regarding future production are not accepted the approval will be withdrawn.
- Where the LA does accept that the FBOs guarantees mean that serious deficiencies will be permanently resolved **immediately** and that there will be no foreseeable future stoppages of production approval will continue.
- Where the LA accepts that the guarantees mean that the serious deficiencies will be permanently resolved **within a reasonable time** and the situation will be such that, once the serious deficiencies have been resolved, there will be no foreseeable future deficiencies serious enough to warrant stoppages of production, the *approval will be suspended*. Where this is not the case approval will be withdrawn.

³² "Reasonable" would be relative to the nature and magnitude of the deficiencies present

- Where the FBO does not provide guarantees approval will be **withdrawn**.
147. Suspension of approval will be lifted in writing by the LA, once the serious deficiencies are permanently resolved and the situation is such that there will be no foreseeable cause for future stoppages of production. If this has not been undertaken **within a reasonable time** the approval will be withdrawn.
148. The FBO has the right to appeal to a relevant Court against the decision to withdraw or suspend an approval or conditional approval. Rights of appeal are governed by the Official Feed and Food Controls Regulations 2009 (as amended), and parallel Regulations in Scotland, Wales and Northern Ireland. From the date on which the notice of the decision is served on the relevant person the establishment cannot continue operating whilst the appeal is being determined.

Model forms for the suspension and withdrawal of approvals can be found in Annex 9 of the FSA Practice Guidance.

Transfer of establishment to local authority following refusal, suspension, or withdrawal by the FSA

149. There will be occasions when the FSA decides to refuse, suspend or withdraw approval of an establishment under Regulation (EC) 853/2004 or identifies establishments undertaking activities for which approval from the FSA is required but, has not been granted. Although the FSA is the competent authority responsible for the approval of certain categories of establishments, where approval is refused, suspended or withdrawn, or activities are carried out without the necessary approval, enforcement responsibility immediately falls to the relevant LA (see also para 145).
150. The Food Law Code of Practice gives the LA enforcement responsibility in establishments engaged in activities that require approval, but that are not approved.³³ Therefore the offence of carrying out an activity that requires approval without first obtaining approval is enforced by the LA.
151. In cases concerning refusal, suspension or withdrawal of approval, the FSA will forward a copy of the refusal, suspension or withdrawal letter to the

³³ Section 3.3.2 of the FSA Food Law Code of Practice

relevant LA. The LA will also be provided with any supporting documents, which would have been taken into account when the decision to refuse, suspend or withdraw the establishment's approval was being considered:

- summary of deficiencies;
- [if applicable] enforcement programme at the establishment;
- photographic evidence of deficiencies found;
- [if available] summary report of any meeting with the FBO;
- [if available], plan detailing the boundaries and extent of the approved establishment

152. Following the notification of refusal, suspension or withdrawal by the FSA, and as the establishment now falls within the remit of the LA, it will need to ensure that the FBO either ceases the activity requiring approval or limits his/her trading to meet the exemption criteria (**at Annex 5**), and operates under Regulation 852/2004. LAs are encouraged to arrange a visit to such establishments as soon as possible to confirm that the establishment has indeed stopped carrying out any activity or activities that require approval under Regulation 853/2004, or that their current operation is restricted to only meet the requirement of an exempt activity (by nature or scale). LAs should consider organising a joint visit with FSA staff where appropriate to facilitate an effective transfer. LAs should continue to monitor such establishments to ensure ongoing compliance with the exemption criteria.

153. If, at the visit to check that the FBO has ceased activities that require approval, there is evidence that business has not ceased these activities or reduced throughput below the exemption threshold, LAs should consider taking the following enforcement actions, and in line with the LA's own enforcement policy:

- all products that have been produced without approval on the premises could be certified using Regulation 29 of The Food Safety and Hygiene (England) Regulations 2013 (and Regulation 27 in equivalent 2006 Regulations in Scotland, Wales and Northern Ireland) as not being produced, processed or distributed in accordance with the Regulations. Food certified in this way is then treated for the purposes of Section 9 of the Food Safety Act 1990/ Article 8 of the Food Safety (Northern Ireland) Order as failing to comply with food safety requirements and should be dealt with accordingly;
- serve a Remedial Action Notice under Regulation 9 of The Food Safety and Hygiene (England) Regulations 2013 (equivalent legislation in Scotland, Wales and Northern Ireland)

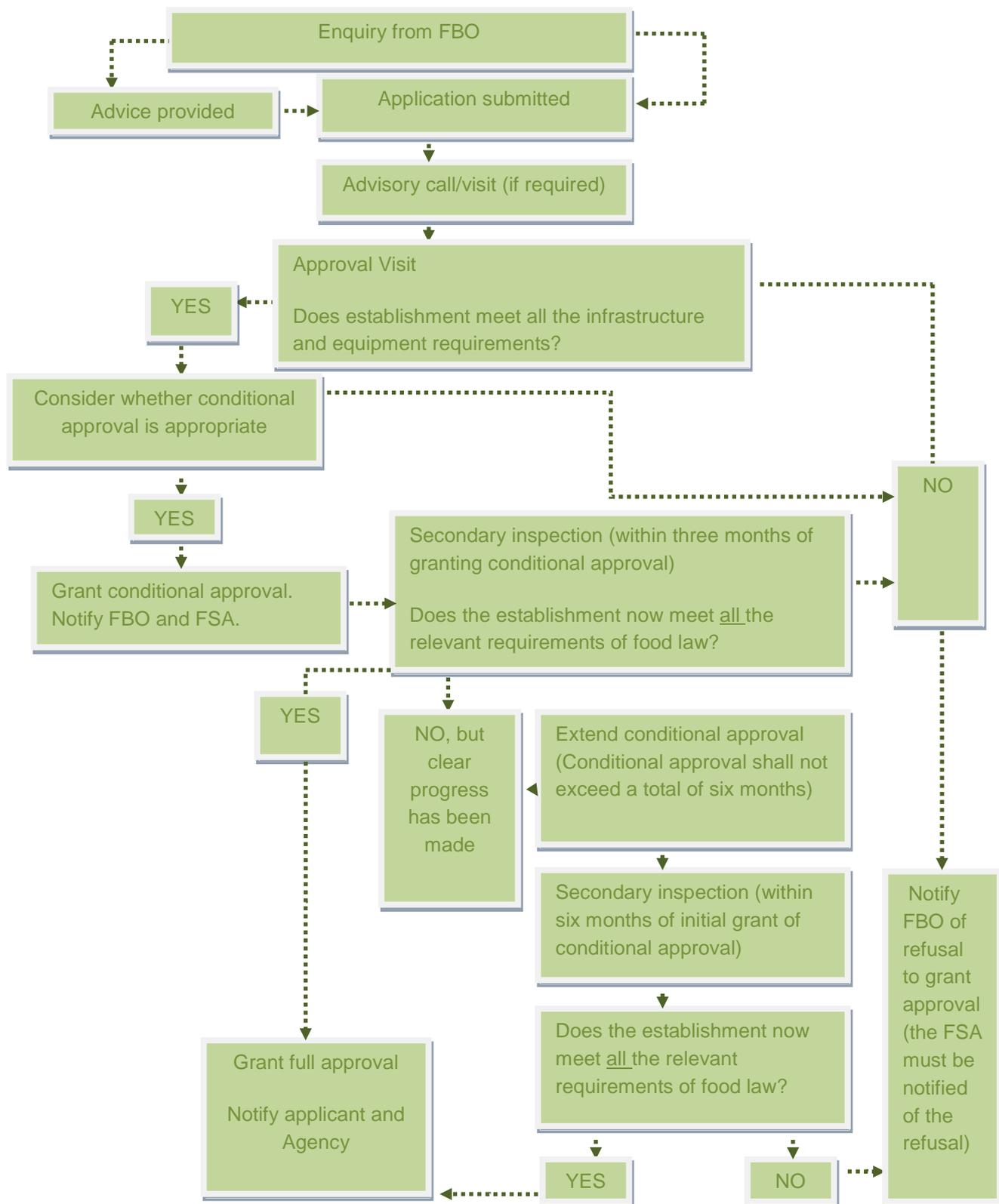
- Consideration should also be given to reporting this as an incident to the FSA incidents team, for example where there is a serious hazard or national distribution of food.
154. If the FBO still continues to carry out activities that require approval without approval, after the LA has taken action detailed above, the FBO will be guilty of an offence and could be prosecuted. Irrespective of the above enforcement actions, the operator has one month to appeal against the FSA's decision to refuse, withdraw or suspend its approval from the date that decision is made.
155. If the operator wishes to submit a new application for approval, it should be made clear that until such an approval is granted, the establishment legally cannot carry out the activity requiring approval above the exemption threshold.

Premises subject to approval operating without approval

156. Where an FBO is operating and carrying out activities subject to approval but is not approved, the enforcement responsibility lies with the LA. This includes FBOs carrying out activities which are subject to FSA approval (e.g. slaughter, cutting) but where conditional or full approval has not been granted by the FSA. Until such a time as they are approved, the FSA has no jurisdiction for enforcement.

NOTE: LAs can consider the use of RANs for premises which are subject to approval, but which are not yet approved. Regulation 9 of the Food Safety & Hygiene (England) Regulations 2013 states that RANs can be served "...in respect of an establishment that Article 4(2) of Regulation 853/2004 requires to be approved..."

APPROVAL PROCESS FLOW CHART FOR A NEW ESTABLISHMENT - ANNEX 1



CONTACT DETAILS FOR INFORMATION ON APPROVED
ESTABLISHMENT ACROSS THE UK:

ANNEX 2

Country	Contact(s)	Tel/Email	Address
England	Chris Rowswell	020 7276 8180 Chris.rowswell@foodstandards.gsi.gov.uk	Floor 1B, Aviation House, 125 Kingsway, London, WC2B 6NH <u>Location map:</u> http://www.food.gov.uk/multi-media/bigimages/aviation.jpg
	Nick Laverty	020 7276 8371 nicholas.laverty@foodstandards.gsi.gov.uk	
Scotland	Lorna Murray	Lorna.murray@fss.scot	Food Standards Scotland Pilgrim House (4 th Floor) Old Ford Road Aberdeen AB11 5RL
	Doreen Tawse	Doreen.tawse@fss.scot	
Wales	Delyth Murray-Lines	02920678927 Delyth.murray-lines@foodstandards.gsi.gov.uk	Food Standards Agency Wales 11th Floor Southgate House Wood Street Cardiff CF10 1EW <u>Location map:</u> http://www.food.gov.uk/multi-media/bigimages/welshmap.jpg
Northern Ireland	Ruth Moreno	028 9041 7756 ruth.moreno@foodstandards.gsi.gov.uk	10A-10C Clarendon Road Belfast BT1 3GB <u>Location map:</u> http://www.food.gov.uk/multi-media/bigimages/nimap.jpg
	Executive Support Unit	028 9041 7700 executive.support@foodstandards.gsi.gov.uk	

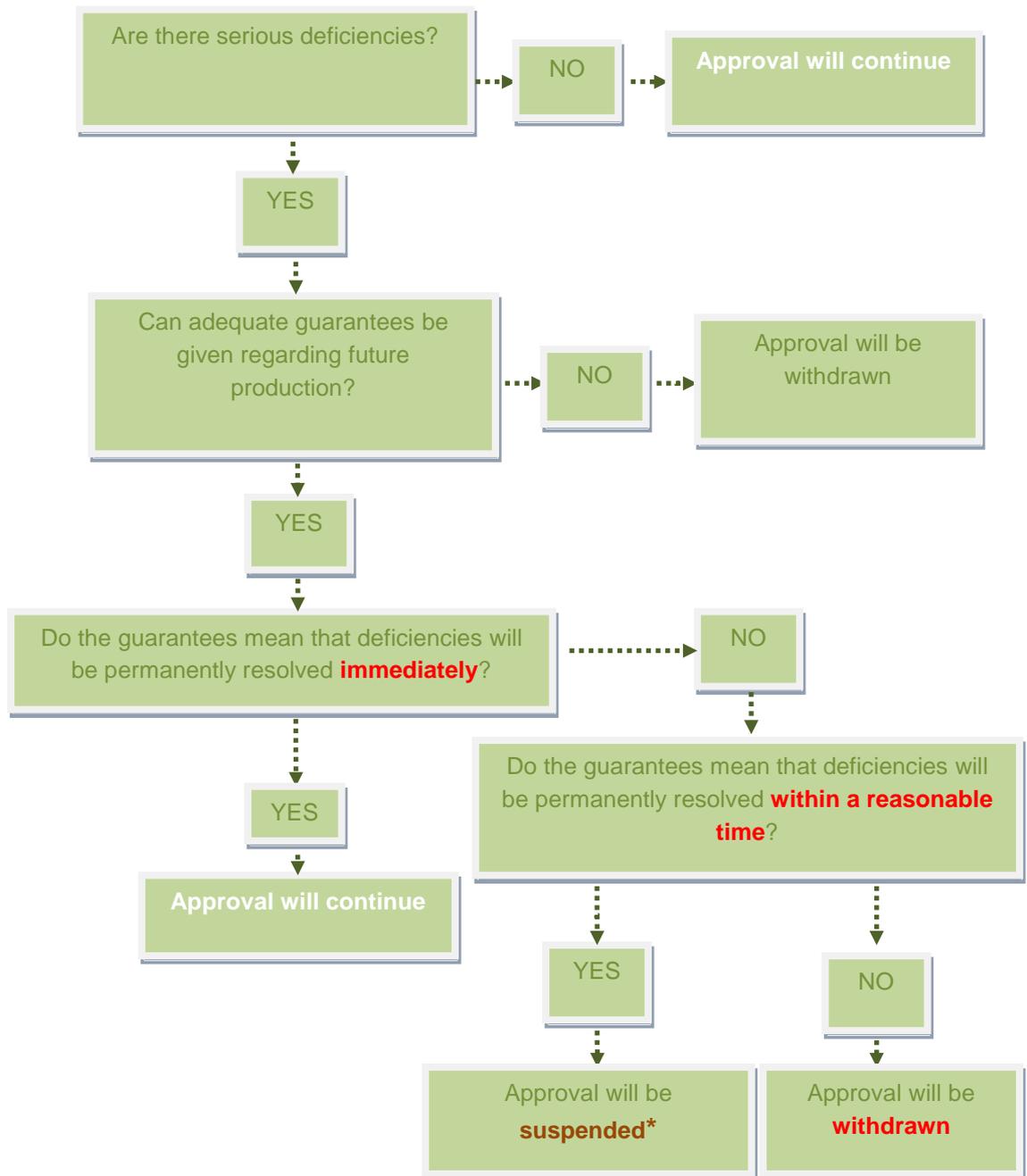
	Existing Ownership (as per approval documentation)	Change of Ownership (in each case assuming no other changes to the business)	Approval status	Comments	Re-approval required
1	Sole trader, Partnership or incorporated company (e.g. Ltd, PLC, etc)	Different sole trader, partnership or incorporated company takes over ownership	Expires	Discontinuation of operator/s	Yes
2	Sole trader or Partnership	Company incorporated (and registered), Sole trader or partner/s becomes Director/s	Expires	Creation of a new Company	Yes
3	Sole trader	Creation of a partnership where the sole trader remains one of the active partners	Retained	Continuation of operator	No
4	Partnership	Dissolved and one of the partners takes over sole ownership and becomes a sole trader	Retained	Continuation of operator	No
5	Partnership	New partner joins or a partner leaves (also refer to dissolved partnership) as long as there is a continuation of at least one partner	Retained	Continuation of operator/s	No
6	Incorporated company in administration	Company goes into administration and is being run as a going concern by the administrators.	Retained	Continuation of operator/s	No

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

Other business types such as cooperatives, registered charities and other specialised types of organisation will need to 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.

Review of approval - decision flow chart ANNEX 4

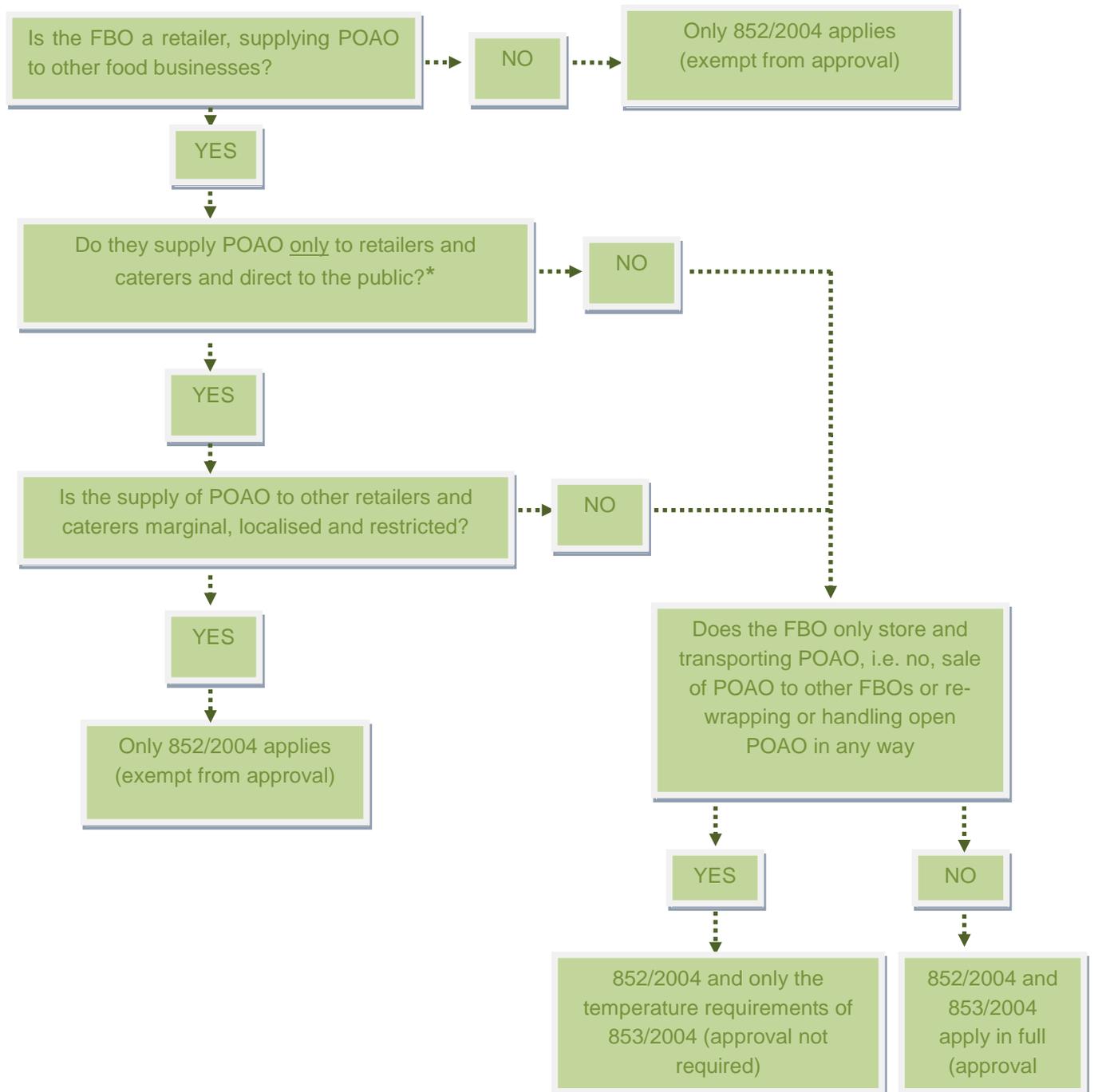
In considering whether suspension or withdrawal is the most appropriate action in a particular case, LA should consider the following process:



* **Note:** suspension can only be invoked where the FBO can satisfy the LA that acceptable corrective action will be taken. The FSA's opinion is that a very high standard of proof is needed, including evidence that the remedial work can be adequately financed.

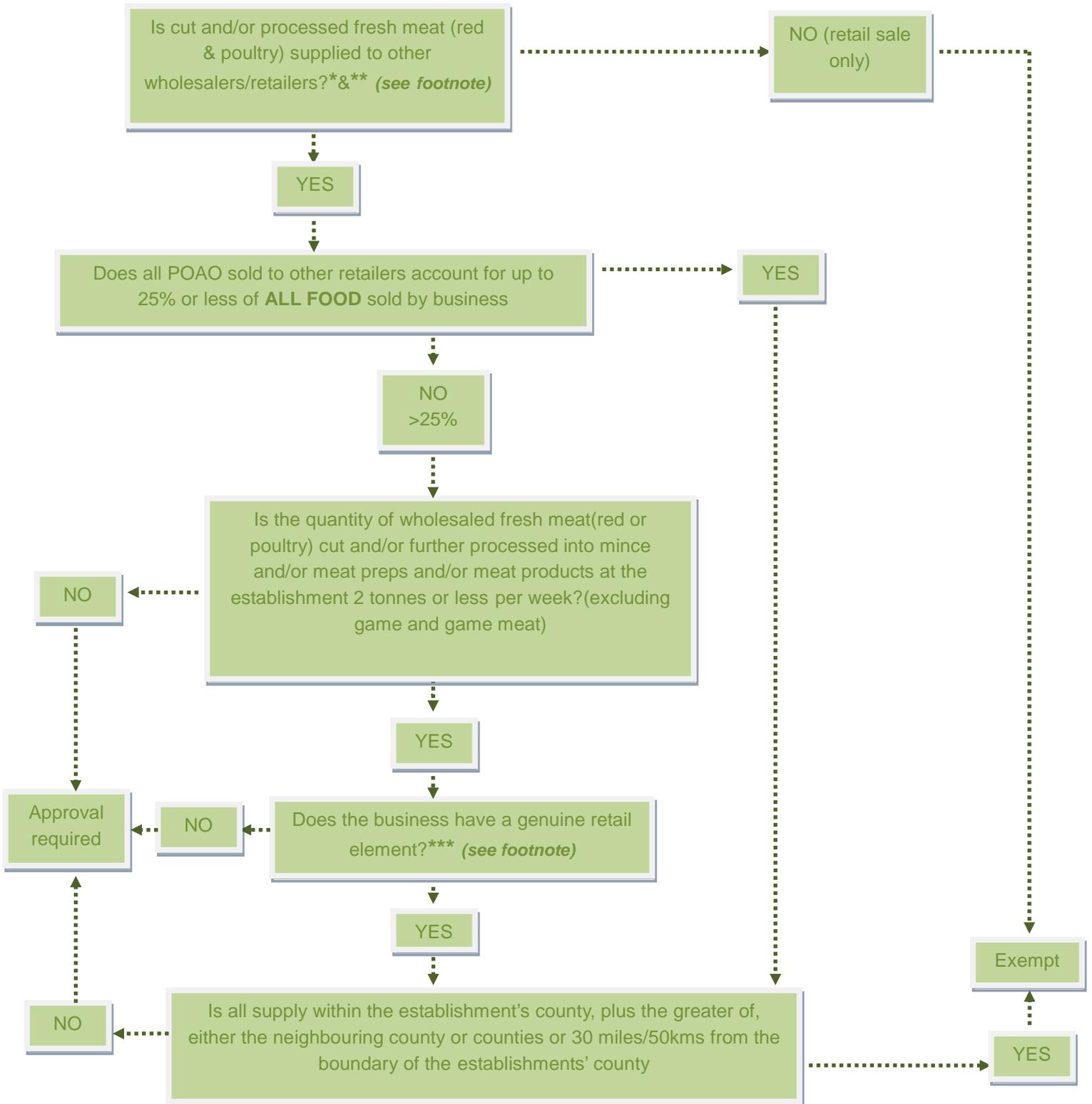
Exemption criteria flowchart: all POAO (except meat)

ANNEX 5



***Note:** Retailers can include wholesalers, but not any establishment approved under 853/2004, including other wholesalers who may be approved.

Exemption flowchart: MEAT



Footnote:

*The amount of meat supplied to other establishments should be measured against the entire business in terms of food, whether retail or wholesale including food of any type, e.g. drinks, biscuits etc. If this does not exceed a quarter of the food business, the establishment is exempt from approval. Where there is supply of meat only, up to 25% of the meat may be wholesaled.

** Don't include meat, meat preparations or meat products that are bought in and not cut or processed on site.

*** Accept even a small amount of retail providing it is genuine and not merely an attempt to gain exemption (could include internet, mail order etc)