Guidance for local authority authorised officers on the approval of establishments
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**Glossary**

Definitions and Abbreviations used in this guidance

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<tr>
<th>Term</th>
<th>Definition/Explanation</th>
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<tbody>
<tr>
<td><strong>Agency</strong></td>
<td>Abbreviation for Food Standards Agency</td>
</tr>
<tr>
<td><strong>Animal by-products</strong></td>
<td>Parts of animal which are not intended for human consumption.</td>
</tr>
<tr>
<td><strong>Assurance Schemes</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Audit</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Authorised officer (AO)</strong></td>
<td>In relation to an enforcement authority, any person (whether or not an officer of the Authority) who is authorised by the Local Authority or District Council in writing, either generally or specifically, to act in matters arising under the Food Hygiene Regulations 2006.</td>
</tr>
<tr>
<td><strong>Cold store</strong></td>
<td>A wholesale establishment used for the storage under temperature controlled conditions of POAO intended for sale for human consumption.</td>
</tr>
<tr>
<td><strong>Collection centre</strong></td>
<td>An establishment where raw milk is collected and where it may be cooled and filtered.</td>
</tr>
<tr>
<td><strong>Competent authority</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Composite products</strong></td>
<td>This is the term generally used for food containing both products of plant origin and processed products of animal origin as indicated in Article 1.2 of Regulation (EC) No. 853/2004.</td>
</tr>
<tr>
<td><strong>DARD(QAB)</strong></td>
<td>Department of Agriculture and Rural Development (Quality Assurance Branch)</td>
</tr>
<tr>
<td><strong>DC</strong></td>
<td>District Council in NI</td>
</tr>
<tr>
<td><strong>Desinewed</strong></td>
<td>Also known at 'mechanically desinewed meat', Baader meat, 3mm</td>
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</tbody>
</table>
Meat

meat. See the FSA’s letter of 7 September 2010 to Heads of Environmental Health Services in England, Directors of Trading Standards, etc. Ref: ENF/E/10/032

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 Commission

Establishment

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”)

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 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.

Greaves

The protein-containing residue of rendering, after partial separation

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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 Regulations (EC) No. 854/2004.

**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 items conform to legal requirements.

**LA**
Local Authority

**Lagomorphs**
Rabbits, hares and (edible) rodents.

**LBMs**
Live bivalve molluscs

**Meat**
Edible parts of the following animals, including blood:
- Domestic ungulates: bovine, ovine, caprine and domestic solipeds;
- Poultry: farmed birds
- Lagomorphs: rabbits, hares and rodents
- Large wild game: wild land mammals
- Small wild game: wild games birds and lagomorphs
- Farmed game: farmed ratities 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 carcases, 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 Community 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.²

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, LBM
- 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 Centre
An establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption.

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.

Unit
A single undivided entity or whole

Unprocessed products
Foodstuffs that have not undergone processing, and includes products that have been divided, sliced, boned, cut, minced, chilled,
<table>
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<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>thawed, frozen etc</td>
<td></td>
</tr>
<tr>
<td>Wholesale market</td>
<td>A food business that includes several separate units which share common installations and sections where foodstuffs are sold to food business operator.</td>
</tr>
<tr>
<td>Wrapping</td>
<td>Placing of foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself.</td>
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Introduction

1. This guidance is for the use of Local Food Authority (LA)\(^3\) 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 parallel regulations in all four countries of the UK.

2. 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.

Background

3. The EC Food Hygiene Regulations (“the Regulations”) have applied in all Member States from 1 January 2006. These regulations are:

- **Regulation (EC) No 178/2002\(^4\) – General Food Law Regulation:**
  The regulation provides a framework for food and feed law in the EC 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.

  This sets out general hygiene rules that apply to all registered and approved food businesses including structural requirements and the implementation of procedures based on hazard analysis and critical control point (HACCP) principles. The regulation sets out objectives for “good hygiene practices” to protect consumers.

  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.


\(^3\) For the purpose of this document LAs include DCs in Northern Ireland unless otherwise indicated to the contrary.

\(^4\) 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

\(^5\) Regulation (EC) No 852/2004 on the hygiene of foodstuffs

\(^6\) Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin

\(^7\) Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin
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 882/2004 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.

### Approval of Establishments

4. 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

5. 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:

<table>
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<tr>
<th>(1)Product</th>
<th>(2)Establishment</th>
<th>(3)Operation for which establishment may be approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meat (approved in accordance with Annex III, Section V)</td>
<td>Minced meat, meat preparations and mechanically separated meat (see table footnote)</td>
<td>Producing minced meat, meat preparations and mechanically separated meat</td>
</tr>
<tr>
<td>Meat (approved in accordance with Annex III, Section VI)</td>
<td>Meat products (see table footnote)</td>
<td>Production of meat products</td>
</tr>
<tr>
<td>Meat (approved in accordance with Annex III, Section XII)</td>
<td>Rendered animal fats and greaves (see table footnote)</td>
<td>Intermediate storage of rendered animal fats and greaves</td>
</tr>
<tr>
<td>Meat (approved in accordance with Annex III, Section XIII)</td>
<td>Treated stomachs, bladders and intestines (Processing Plant)</td>
<td>Processing of treated stomachs, bladders and intestines</td>
</tr>
<tr>
<td>Meat³</td>
<td>Gelatine</td>
<td>Processing of gelatine</td>
</tr>
</tbody>
</table>

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³ 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
<table>
<thead>
<tr>
<th>(1)Product</th>
<th>(2)Establishment</th>
<th>(3)Operation for which establishment may be approved</th>
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<tbody>
<tr>
<td>(authorised in accordance with Annex III, Section XIV) (Note: these establishments require authorisation rather than approval)</td>
<td>Collection Centre/Tannery (see table footnote)</td>
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<tr>
<td>Meat¹⁰</td>
<td>Collagen (Collection Centre/Tannery (see table footnote))</td>
<td>Processing of collagen</td>
</tr>
<tr>
<td>(authorised in accordance with Annex III, Section XV) (Note: these establishments require authorisation rather than approval)</td>
<td>Dispatch centre</td>
<td>Reception, conditioning, washing, cleaning, grading, wrapping and packaging of LBMs</td>
</tr>
<tr>
<td>Live bivalve molluscs (LBM) (approved in accordance with Annex III, Section VII)</td>
<td>Purification centre</td>
<td>Purification of LBMs in tanks fed by clean seawater for the time necessary to reduce contamination to make them fit for human consumption</td>
</tr>
<tr>
<td>Fishery products (approved in accordance with Annex III, Section VIII)</td>
<td>Factory vessel</td>
<td>Filleting, slicing, skinning, shucking, mincing or processing of fishery products on board</td>
</tr>
<tr>
<td></td>
<td>Freezing vessel</td>
<td>Freezing of fishery products after bleeding, heading, gutting, and removal of fins and, where necessary, followed by wrapping or packaging.</td>
</tr>
<tr>
<td></td>
<td>Processing plant</td>
<td>Processing of fishery products</td>
</tr>
<tr>
<td></td>
<td>Fresh fishery products plant</td>
<td>Handling of unprocessed fishery products that have not undergone any treatment to ensure preservation other than chilling</td>
</tr>
<tr>
<td></td>
<td>Auction hall</td>
<td>Storing and displaying of fishery products for auction sale</td>
</tr>
<tr>
<td>Wholesale market</td>
<td>Establishment that includes separate sub-units operating independently as food business, but sharing common facilities</td>
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</tbody>
</table>

¹⁰ DARD (on behalf of the Agency in NI) authorise collection centres for raw material for the production of gelatine and collagen intended for human consumption in NI.

9 DARD (on behalf of the Agency in NI) authorise collection centres for raw material for the production of gelatine and collagen intended for human consumption in NI.
<table>
<thead>
<tr>
<th>(1)Product</th>
<th>(2)Establishment</th>
<th>(3)Operation for which establishment may be approved</th>
</tr>
</thead>
</table>
| **Raw milk and dairy products**<sup>11</sup>  
(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 | Packing and grading of eggs by quality and weight<sup>12</sup> |
| | Processing plant<sup>13</sup> | 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 food business, but sharing common facilities |
| **POAO** | Re-wrapping establishment (<i>see table footnote</i>) | Re-wrapping of products of animal origin |
| **FOOTNOTE:** Approved by the Agency if situated on the same site as a slaughterhouse, cutting plant or game handling establishment, otherwise approved by LAs |

**COLLECTION CENTRES AND TANNERIES SUPPLYING RAW MATERIAL FOR THE PRODUCTION OF GELATINE AND COLLAGEN INTENDED FOR HUMAN CONSUMPTION**

6. 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 Agency 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).

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<sup>11</sup> In NI, DCs approve standalone dairy processing plants. DARD QAB (on behalf of the Agency in NI) approves liquid milk processing establishments and integrated liquid milk/dairy product establishments.


<sup>13</sup> DARD (on behalf of the Agency in NI) approves egg packing centres.
What are the Exemptions from Approval?

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

(i) **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, sales to local retail shops directly supplying the final consumer and sales to local restaurants.

- 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 Agency, therefore, suggest the following as maximum amounts, which could be considered as small quantity for individual products of animal origin:

<table>
<thead>
<tr>
<th>Products</th>
<th>Maximum amounts</th>
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<tbody>
<tr>
<td>Milk</td>
<td>Up to 24 pints of raw drinking milk(^ {14}) per day (approximately 14 litres)</td>
</tr>
<tr>
<td>Eggs</td>
<td>Less than 360 eggs (i.e. less than one full case) per week.</td>
</tr>
<tr>
<td></td>
<td><strong>Note:</strong> 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, example, to local shops, restaurants or bakeries, they must first be graded as Class A; and, therefore, the premises must also be approved and authorised as a packing centre for that activity(^ {15}).</td>
</tr>
<tr>
<td>Fishery products</td>
<td>Up to 25 tonnes in a calendar year</td>
</tr>
<tr>
<td>Live Bivalve Molluscs</td>
<td>Up to 25 tonnes in a calendar year, but subject to maximum limits for individual species as set out below: -Cockles-25 tonnes</td>
</tr>
</tbody>
</table>

\(^ {14}\) Not applicable in Scotland

\(^ {15}\) 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
**Article 1(3)(d)** (also refer to Schedule 5 of the Food Hygiene Regulations) exempts:

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

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, as long as only small quantities of meat are supplied.

“Small quantities” is not defined in the legislation, but the Agency’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 Agency 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 5, A.5.4.5.1 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).

**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 carcases 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](http://www.food.gov.uk/foodindustry/guidancenotes/meatregsguid/wildgameguidance)

8. “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 31/ Schedule 5 to the Food Hygiene (England) Regulations 2006, as amended; and parallel regulations in Scotland, Wales and Northern Ireland.

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

9. 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.

**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.”

10. ‘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.
11. Although a ‘wholesale outlet’ may be considered to be ‘retail’ as defined, 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.

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.”

12. Marginal, localised and restricted are interpreted as follows:

- **“marginal”:**
  - Where POAO 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

If either applies, the establishment will be exempt from approval under regulation 853/2004.

**Note:**

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

2 tonnes could be averaged over any 12 month period.

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

- **“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 boundary supplying establishment’s county;

However, in exceptional circumstances, the interpretation of “localised” may be extended to the whole of the UK, in cases where the geographical distribution of certain farmed or game animals would otherwise significantly restrict the national supply (e.g. rare breeds meat, grouse), or where a traditional, rare 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 i.e. 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

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.

SUPPLY OF FOOD OF ANIMAL ORIGIN BY THE PRODUCER TO THE FINAL CONSUMER AT FARMERS’ MARKETS

13. Establishments producing POAO for supply to the final consumer at farmers’ markets, or at other markets supplying the final consumer, is 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 would render the establishment subject to approval if supply was above the marginal, local and restricted limits.

14. 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.

SATELLITE OPERATIONS [NOTE FOR OFFICERS: POLICY CURRENTLY BEING CONSIDERED]

(III) “COMPOSITE PRODUCTS”

15. 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”
16. 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 for that processing as it 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**.

17. 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, cheese to which herbs are added or sausages to which garlic or soya are added would fall within Regulation (EC) No. 853/2004.

18. 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.¹⁶

**COLD STORES [NOTE FOR OFFICERS: DETAILED GUIDANCE TO FOLLOW]**

19. 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 slaughterhouses, cutting plants or game handling establishments.

20. EC 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 cold 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. This means that unless they are exempt, stand alone cold stores used for the storage of POAO **must be approved**.

21. 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 other establishments (including caterers) on a “marginal, localised and restricted” basis are exempt from approval.

22. 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.

23. 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.

24. 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. 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.

Re-wrapping Establishments

25. 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.

26. 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.

Retailers’ Distribution Centres

27. Retailers’ distribution centres are not subject to the temperature control requirements for products of animal origin in Regulation (EC) No. 853/2004. In this context retailers’ distribution centres are physical structures and associated delivery vehicles owned and run by retailers that are not necessarily physically connected to a retail shop (where the final consumer buys food) or even in the local area (the term local having a particular meaning in the context of the scope of the Regulation). They supply and deliver a wide range of foods and other goods, including foods of animal origin, to retail shops that are owned and run as part of the same business. No handling or cutting etc of open foods of animal origin takes place in retailers’ distribution centres and they do not supply any third party with foods of animal origin. This is based on the interpretation that they fall within the definition of retail (in Regulation (EC) No 178/2002)\(^{17}\).

28. 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 Hygiene Regulations 2006.

Slaughter for Private Domestic Consumption

29. Slaughter that is carried out for private domestic consumption, and where the meat is not placed on the market (including where it is free of charge) falls out of the scope of both Regulation (EC) No. 852/2004 and Regulation (EC) No. 853/2004. Further information can be found on the Agency’s website at: http://www.food.gov.uk/foodindustry/guidancenotes/meatregsguid/livestockguidance/

\(^{17}\) 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
Responsibilities of Food Business Operators

30. 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.\(^\text{18}\)

31. 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 Hygiene Regulations 2006.

32. 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

33. 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 Annex 11 of the Food Law Practice Guidance. Although the content of this document should be regarded as the minimum required, LAs may adapt them as necessary to meet local requirements. All applications for approval should be dealt with promptly.

34. 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. Under no circumstances should approval be granted to an establishment which is not subject to approval under Regulation (EC) No. 853/2004.

35. 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.

36. 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

\(^\text{18}\) [Links to relevant government websites for enforcement and guidance in England, Scotland, Wales and Northern Ireland]
37. 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.

38. 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.

39. 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.

40. 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 Agency, i.e. “co-located” establishments;
- Change of food business operator – see paragraphs 102-107.

ADVISORY VISITS

41. 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 maintenance; and food safety management, so

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19 In NI, dual enforcement establishments are referred to as “integrated establishments”
as to avoid any potential difficulties when the establishment is formally assessed for approval.

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

**APPROVAL REQUIREMENTS**

43. 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 1.2 (Qualifications and Experience) of the COP for information on the qualification level to carry out approvals.

44. 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:

<table>
<thead>
<tr>
<th>INFRASTRUCTURE AND EQUIPMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>i. Structure of premises/equipment/layout;</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OTHER RELEVANT REQUIREMENT OF FOOD LAW</th>
</tr>
</thead>
<tbody>
<tr>
<td>ii. Prerequisites-applicable to all food establishments, e.g.</td>
</tr>
<tr>
<td>- FBO’s procedures for maintaining environmental hygiene including the management and disposal of waste animal by-products;</td>
</tr>
<tr>
<td>- Traceability including Food Chain Information;</td>
</tr>
<tr>
<td>- Training and supervision</td>
</tr>
</tbody>
</table>

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**

45. Approvals procedures are set out in Article 31.2 of the Official Controls Regulation (EC) No. 882/2004. An overview of the approval process is set out in a flow chart at Annex 1. LAs should note that 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.

46. LAs must not permit establishments to operate (in a manner that requires approval) until conditional approval has been granted.

47. 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. Approval, including “conditional approval” should not be given unless/until all the relevant requirements of the legislation
have been met. 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.

48. 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.

49. Once an approval visit has been made, there can only be three outcomes as set out below:

| 1st visit | If compliant with infrastructure and equipment requirements, grant **conditional approval**. At this stage the establishment may not have a fully developed 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.
| | While compliance with all the requirements of food law cannot be demonstrated before operations start, the officer doing the approval visit should be able to gain some confidence on the prospective FBO’s ability to comply if conditional approval was recommended. An exploration 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 visit should permit this. Ultimately this is a professional judgement on the part of the approval officer but it is essential before considering recommendation for approval. |
| | If not compliant with infrastructure and equipment requirements refuse application. |

| 2nd visit within 3 months | If compliant with operational requirements and compliance with infrastructure and equipment requirements are maintained, grant **full approval**. |
| | If not: |
| | ● refuse application; or |
| | ● **extend conditional approval** for a further 3 months, if adequate progress has been made and the infrastructure and equipment requirements are continuing to being complied with. |
| | **Note:** conditional approval |
REFUSAL TO ISSUE APPROVAL

50. An approval can be refused at any time in the approval assessment process as detailed below:

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

- Full approval subsequent to conditional approval can be **refused**:
  
  a. if, within the three months’ conditional approval, insufficient progress has been made to meet the requirements in full and, in the judgement of the 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 will cease to have effect
  
  b. if, at the end of the six months period there is insufficient compliance with structural, equipment or operational requirements and other relevant requirements of food law, including the implementation of an effective food safety management system based on HACCP principles.

51. 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.

52. Where an AO considers it possible that an establishment’s approval or conditional approval may have to be refused, he/she should keep a record of the reasons of these decisions on the establishment’s record file.

53. The FBO must be given notice of the decision, the reason why the decision was made and a list of deficiencies that were noted at the time of the visit including the requirements of the legislation in relation to hygiene, structure, HACCP or other elements relevant to the type of approval being sought and show how the FBO has failed to satisfy those requirements.

54. 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 appeal is being determined.

**APPROVAL NUMBER/IDENTIFICATION MARK (ID)**

55. 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), in accordance with Regulation (EC) No. 854/2004.

56. 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:

<table>
<thead>
<tr>
<th>Identification Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td>The mark must be legible and indelible, and the characters easily decipherable. <strong>It must be clearly displayed for the competent authorities.</strong></td>
</tr>
<tr>
<td>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).</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>When applied in an establishment located within the community, the mark must be oval in shape and include one of the permitted two letter abbreviations. In the UK this is EC.</td>
</tr>
</tbody>
</table>

57. 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 another LA or the Agency. 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 two to three years, by which time such businesses should have used up all existing stocks of pre-printed labelling materials.

58. The approval code should be incorporated into an identification mark which approved establishments are required to apply to their relevant products, as appropriate. The requirements for the form of the identification mark are set out in Annex II, Section I B of Regulation (EC) No. 853/2004. 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)

59. 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. 1234/2007[^20] on marketing standards for eggs and poultry meat. However an LA or Agency in NI approval number should still be allocated and, some FBOs may chose to use that approval number on commercial documentation.

60. 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 102-107.

61. In order to avoid the allocation of dual approval numbers to the co-located establishment by Agency and LA, the Agency 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.

62. Where an establishment is approved by the LA and the FBO is subsequently granted an approval by the Agency, due to the establishment becoming co-located, the Agency 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.

63. 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. If the FBO then intends to move to a new establishment, that establishment would have to be given a new approval number.

HANDLING BUSINESS REQUEST FOR FLEXIBILITY IN THE USE OF APPROVAL NUMBERS

64. 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.

65. The Agency’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”.

66. 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”.

67. 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).

68. If a FBO approaches a LA for consideration of extreme circumstances, such a decision can be only made through the Agency’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);
• 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.

**USE OF MULTIPLE ID MARKS** [NOTE FOR OFFICERS: POLICY CURRENTLY BEING CONSIDERED]

**NOTIFYING THE FSA OF APPROVALS**

69. In addition to notifying the FBO, LAs must also notify the Agency\(^21\) of any establishment to which they grant approval or conditional approval. Details required are as follows:
- the approval number;
- name of establishment;
- town/region;
- category of food establishments;
- associated activities;
- species; and
- remarks

70. These are based on the specification set out by the EC Commission on the layout of the list of approved food establishment. Further information on the technical specification can be found on the EC Commission’s website at: [http://ec.europa.eu/food/food/biosafety/establishments.techspecs_en.pdf](http://ec.europa.eu/food/food/biosafety/establishments.techspecs_en.pdf). Details of the establishments are then updated on the Agency’s website which can be found at: [http://www.food.gov.uk/enforcement/sectorrules/approvedestabsuk/](http://www.food.gov.uk/enforcement/sectorrules/approvedestabsuk/)

**Types of Approvals**

**WHOLESALE MARKETS**

71. 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.

72. Responsibility for complying with the Hygiene Regulations\(^22\) rests with the landlord 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.

\(^{21}\) For England it should be send to [enforcement@foodstandards.gsi.gov.uk](mailto:enforcement@foodstandards.gsi.gov.uk); and for the rest of the UK notifications must be sent to the relevant contacts detailed at Annex 2.

\(^{22}\) The Food Hygiene Regulations 2006, 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.)
73. 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. 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**

74. 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.

75. 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.

76. 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 55-63.

77. 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**

78. 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.

79. 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.

80. An example site plan identifying the shared facilities:
81. 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.

82. 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 suspend the approval. Also refer to Review of Establishment with the view to Suspension or Withdrawal of an Approval section, paragraphs 128-137. Where the FBO is able to become self sufficient in their own right, separate approval as an individual establishment can be sought.

83. 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 Agency or relevant LA/DC is responsible for official controls. In the event enforcement action is required this will be undertaken by the relevant authority.

Division of Enforcement Responsibilities

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

IN GB

85. 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 Agency.

86. The Agency 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.

87. Where an approved meat establishment subject to veterinary control, in GB, is also handling other POAO the Agency, in liaison with the relevant LA, will consider approving all operations requiring approval under Regulation (EC) No 853/2004 that are co-located. This is with the exception of operations that fall within Regulation (EC) No 852/2004 only, such as
butcher’s shops and where the establishment is also handling non-POAOs. The parts of the establishment where these operations are carried out will be under the control of the LA.

88. Wherever possible dual responsibility for official controls should be avoided but the parts of the establishment where activities covered by Regulation (EC) No 852/2004 only are carried out will be under the control of the LA. The LA must reach agreement with the Agency’s Veterinary Manager as to the split of enforcement responsibilities and refer to this in their approval recommendation for inclusion in the approval document.

89. 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 852/4004 fall to the LA e.g. a retail butcher’s shop attached to a slaughterhouse (refer to Exemption from Approval section, paragraph 12) and where the establishment is also handling non-POAOs.

IN NORTHERN IRELAND

90. DCs are responsible for the approval of, and enforcement of standalone approved establishments where control does not fall to an official veterinarian or DARD Quality Assurance Branch (QAB) authorised officer. These establishments will be producing and/or handling any, or any combination, of the following: Minced Meat, Meat Preparations, Mechanically Separated Meat, Meat Products, Live Bivalve Molluscs, Fishery Products, Dairy Products, Egg Products, Frogs Legs and Snails, Edible Co-products (including Rendered Animal Fats and Greaves, Treated Stomachs, Bladders, and Intestines, Gelatine and Collagen), and will include certain cold stores and certain wholesale markets.

91. In approved establishments, where control falls to an official veterinarian, or DARD QAB authorised officer, which also produce meat products edible co-products, dairy products or egg products referred to as integrated establishments, District Councils are responsible for enforcement in relation to those parts of the establishment in which the meat products edible co-products, dairy products or egg products are produced. In these establishments District Councils are also responsible for recommending approval in respect of meat Product edible co-product, dairy product or egg product activities, to the Agency or DARD (QAB).

92. The Agency in NI is responsible for the approval of 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, cold stores integrated with these establishments and such establishments in which any combination of Minced Meat, Meat Preparations and Mechanically Separated Meat, are also produced.

93. DARD (VPHU) will on behalf of the Food Standards Agency 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.

94. Responsibility rests with the Agency, through DARD (QAB), for approval of, and enforcement at liquid milk processing establishments and egg packing establishments in Northern Ireland.

Changes to Approvals
GENERAL REQUIREMENTS

95. 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

96. 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
- Change to approved curtilage/re-structuring
- Change of ownership
- Change of name
- Closure of an approved establishment
- Surrender of approval

Additional Activities

97. 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.

98. The establishment’s ability to undertake additional activities should be assessed following the same procedures as a new establishment.

99. Professional judgement should be used, in the case of approving additional activities, to grant full approval in the first instance. This is only 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.

Change to Approved Curtilage / Restructuring

100. Upon 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.

101. 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

102. The approval of an “establishment” applies to both the premises and the business operating at the premises. An approved establishment cannot change ownership. If a
premises used as an approved establishment changes ownership, the new establishment will have to be assessed and granted a new approval before it can operate.

103. 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.

104. Annex 3 provides clarification of what the Agency 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.

105. 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.

106. Where the LA becomes aware of a change of FBO that continues placing food on the market without seeking a fresh 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.

107. In the case of wholesale markets the following principles may apply:

- The market overall approval (common parts) will be treated in the same way as an individual premises ownership change but the individual units within the market do not need to be individually re-approved and can transfer over under the new market (common parts) approval.
- In the event that the common parts of a wholesale market are not granted approval, the individually approved units are not able to operate as the approval of the common parts facilities is a 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 name

108. 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
109. 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 Approved Establishment

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

111. Where an establishment has a break in operation or closure the FBO is obliged to keep the Agency 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 Agency informed about any significant changes to those details including any establishment moving to or from a seasonal pattern. When an FBO intends to re-commence operation the Agency needs to be notified at least two weeks before operations are intended to re-commence.

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

23 Seasonal Establishments
- it is practical to split the approval across one or more seasons and any potential risk to public health is managed;
- measures will be taken by the FBO within the expected conditional approval period to remedy any operational or food safety management system deficiencies on a permanent basis; and
- full approval is achievable within three years.
112. During non-operational periods official controls undertaken by the Agency will be partially suspended, with the exception of ad hoc controls as stated in Recital 13 of Regulation EC No 882/2004, until operations re-commence.

113. 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.”

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

115. Following a period of closures the FBO must **not** start operations until the Agency 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.

116. 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 audit visit undertaken by the Agency.

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

- Where the pre-opening assessment results in the Agency 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 Agency with guarantees on how the deficiencies will be resolved on a permanent basis and within a reasonable 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.

24 “Reasonable” would be relative to the nature and magnitude of the deficiencies present
118. 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.

119. Following the pre-opening assessment visit and when the Agency is content that the establishment meets all of the relevant requirements of food law, the FBO will be notified that operations can re-commence.

120. In the event that the Agency 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.

121. Where the Agency becomes aware of an establishment that has re-commenced operations without first notifying the Agency 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 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 Agency’s action regarding withdraw/recall of food will be risk-based and proportionate. However, food not yet placed on the market will be detained until the FBO has been notified that operation can re-commence.

**Surrender of Approval**

122. 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.

123. 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 Agency accordingly. Upon notification by the LA of the surrender, the establishment will be removed from the official list of approved establishments maintained by the Agency.

124. 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

125. Following the surrender, the FBO should be advised that it would be an offence to apply the ID Mark on any food.

**Transfer of Official Controls to LA**

126. As detailed in Categories of Food Establishment section, paragraph 5 the Agency 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.

127. Where the FBO holding an approval granted by the Agency 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 Agency will notify the relevant LA accordingly. As the
Agency had already approved the standalone activity, the LA may not have to undertake a separate re-approval. This is provided that it is satisfied that the establishment can continue to meet all the requirements of the Regulations, and that the establishment’s food safety management system is adequate to cover the stand alone activity.

In the case of FBOs:
- deciding to limit their activities to meet the exemption criteria and surrendering the approval granted by the Agency; 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.

**Formal Enforcement**

**Withdrawal and Suspension of Approval**

**REVIEW WITH A VIEW TO SUSPENSION OR WITHDRAWAL OF AN APPROVAL**

128. 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.”

129. 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 Agency and are detailed below:

<table>
<thead>
<tr>
<th>General indicator of serious deficiency</th>
<th>Likely Issues (this is not an exhaustive listing and some or all elements may be present and to a varying degree)</th>
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<tbody>
<tr>
<td>Actual or potential risk to public health</td>
<td>Structure</td>
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<td>• major structural deficiency</td>
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<td>• poor maintenance preventing effective cleaning</td>
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<td>Contamination</td>
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<td>• contamination of products</td>
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<td>• Failure to control contamination from any source</td>
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<td></td>
<td>• Visibly contaminated product without action from FBO</td>
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<tr>
<td></td>
<td>• Inadequate separation between products of different risk categories</td>
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<td>Temperature control</td>
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<td>• Inadequate temperature control</td>
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<td>Pest control</td>
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<td></td>
<td>• Serious rodent infestation</td>
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<td>Water</td>
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<tr>
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<td>• Inadequate supply of potable water</td>
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</table>
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

130. 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.

131. 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.

132. Where the preliminary evidence suggests that there may be serious deficiency 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 FBOs history of compliance with regulatory requirements at the approved establishment, the relevant history of enforcement and any prosecutions involving the FBO.

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

134. The 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 reasonable time (the Agency recommends ‘a reasonable time’ as being within 14 calendar days from the date of issue of the letter to the FBO).

135. 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 stoppages of production the approval will be suspended. Where this is not the case approval will be withdrawn.
- Where the FBO does not provide guarantees approval will be withdrawn.

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25 “Reasonable” would be relative to the nature and magnitude of the deficiencies present
136. 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 future stoppages of production. If this has not been undertaken within a reasonable time the approval will be withdrawn.

137. 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 subject to 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.

TRANSFER OF ESTABLISHMENT TO LOCAL AUTHORITY FOLLOWING REFUSAL, SUSPENSION, OR WITHDRAWAL BY THE AGENCY

138. There will be occasions when the Agency decides to refuse, suspend or withdraw approval of an establishment under Regulation (EC) 853/2004. Although, the Agency is the competent authority responsible for the approval of certain categories of establishments, where approval is refused, suspended or withdrawn, enforcement responsibility immediately falls to the relevant LA.

139. The Food Law Code of Practice gives the LA enforcement responsibility in establishments engaged in activities that require approval, but that are not approved. Therefore the offence of carrying out an activity that requires approval without first obtaining approval is enforced by the LA.

140. In such cases the Agency will forward a copy of the refusal, suspension or withdrawal letter to the 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 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

141. Following the notification of refusal, suspension or withdrawal by the Agency, 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 operate 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 subject to the requirements of Regulation 853/2004, or that their current operations is restricted to only meet the requirement of an exempt premises.

142. If, at the visit to check that the FBO has stopped handling of product that has been produced without approval, and there is evidence that business has not stopped operating 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 seized using Regulation 27 of The Food Hygiene (England) Regulations 2006 (and parallel legislation in Scotland, Wales and Northern Ireland) to certify them as not being produced, processed or distributed in accordance with the Regulations and then seized using Section 9 of the Food Safety Act 1990/ Article 8 of the Food Safety (Northern Ireland ) Order and removed from the premises;
serve a Remedial Action Notice under Regulation 9 of The Food Hygiene (England) Regulations 2006 (parallel legislation in Scotland, Wales and Northern Ireland) forcing the FBO to stop handling POAO for wholesale beyond the exemption threshold at the premises.

143. If the FBO still continues to wholesale, in a manner that requires approval, after the LA has taken action detailed above, the FBO will be guilty of an offence and could be brought before the relevant Court. Irrespective of the above enforcement actions, the operator has one month to appeal against the Agency's decision to refuse, withdraw or suspend its approval.

144. If the operator wishes to submit a fresh application for approval, it should be made clear that until such an approval is granted, the establishment legally cannot carry out any approvable activity above the exemption threshold.
Enquiry from FBO

Application submitted

Advisory call/visit (if required)

Approval Visit
  Does establishment meet all the infrastructure and equipment requirements?

Consider whether conditional approval is appropriate

- YES: Grant conditional approval. Notify FBO and Agency.
- NO, but clear progress has been made: Extend conditional approval (Conditional approval shall not exceed a total of 6 months)

Secondary inspection (within 3 months of granting conditional approval)
  Does the establishment now meet all the relevant requirements of food law?

- YES: Grant full approval. Notify applicant and Agency
- NO: Notify FBO of refusal to grant approval (the Agency must be notified of the refusal)

Secondary inspection (within 6 months of initial grant of conditional approval)
  Does the establishment now meet all the relevant requirements of food law?

- YES: Grant full approval. Notify applicant and Agency
- NO: Notify FBO of refusal to grant approval (the Agency must be notified of the refusal)
### ANNEX 2

**CONTACT DETAILS FOR INFORMATION ON APPROVED ESTABLISHMENT ACROSS THE UK:**

<table>
<thead>
<tr>
<th>Country</th>
<th>Contact(s)</th>
<th>Tel/Email</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>England</strong></td>
<td>Rachel Patrick</td>
<td>020 7276 8455 <a href="mailto:rachel.patrick@foodstandards.gsi.gov.uk">rachel.patrick@foodstandards.gsi.gov.uk</a></td>
<td>Floor 1B, Aviation House, 125 Kingsway, London, WC2B 6NH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Location map: <a href="http://www.food.gov.uk/multimedia/bigimages/aviation.jpg">http://www.food.gov.uk/multimedia/bigimages/aviation.jpg</a></td>
</tr>
<tr>
<td><strong>Scotland</strong></td>
<td>Andrew Morrison</td>
<td>01224 285196 <a href="mailto:andrew.morrison@foodstandards.gsi.gov.uk">andrew.morrison@foodstandards.gsi.gov.uk</a></td>
<td>St Magnus House, Guild Street, Aberdeen, AB11 6NJ</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Location map: <a href="http://www.food.gov.uk/multimedia/fsascotmap.jpg">http://www.food.gov.uk/multimedia/fsascotmap.jpg</a></td>
</tr>
<tr>
<td><strong>Wales</strong></td>
<td>Rob Wilkins Delyth Murray-Lines</td>
<td>02920678957 <a href="mailto:rob.wilkins@foodstandards.gsi.gov.uk">rob.wilkins@foodstandards.gsi.gov.uk</a> 02920678927 <a href="mailto:Delyth.murray-lines@foodstandards.gsi.gov.uk">Delyth.murray-lines@foodstandards.gsi.gov.uk</a></td>
<td>Food Standards Agency Wales 11th Floor, Southgate House, Wood Street, Cardiff CF10 1EW</td>
</tr>
<tr>
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<td></td>
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</tr>
<tr>
<td><strong>Northern Ireland</strong></td>
<td>Louise Connolly</td>
<td>02890417718 <a href="mailto:louise.connolly@foodstandards.gsi.gov.uk">louise.connolly@foodstandards.gsi.gov.uk</a></td>
<td>10A-10C Clarendon Road, Belfast, BT1 3GB</td>
</tr>
<tr>
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<tr>
<td></td>
<td>Joy Cresswell</td>
<td>02890417700 <a href="mailto:joy.cresswell@foodstandards.gsi.gov.uk">joy.cresswell@foodstandards.gsi.gov.uk</a></td>
<td></td>
</tr>
</tbody>
</table>
## Change of FBO Scenarios

<table>
<thead>
<tr>
<th>Existing Ownership (as per approval documentation)</th>
<th>Change of Ownership (in each case assuming no other changes to the business)</th>
<th>Approval status</th>
<th>Comments</th>
<th>Re-approval required</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Sole trader, Partnership or incorporated company <em>(e.g. Ltd, PLC, etc)</em></td>
<td>Different sole trader, partnership or incorporated company takes over ownership</td>
<td>Expires</td>
<td>Discontinuation of operator/s</td>
<td>Yes</td>
</tr>
<tr>
<td>2 Sole trader or Partnership</td>
<td>Company incorporated <em>(and registered)</em>, Sole trader or partner/s becomes Director/s</td>
<td>Expires</td>
<td>Creation of a Company so the company is responsible not the individual/s</td>
<td>Yes</td>
</tr>
<tr>
<td>3 Sole trader</td>
<td>Creation of a partnership where the sole trader is one of the partners</td>
<td>Retained</td>
<td>Continuation of operator</td>
<td>No</td>
</tr>
<tr>
<td>4 Partnership</td>
<td>Dissolved and one of the partners takes over sole ownership and becomes a sole trader</td>
<td>Retained</td>
<td>Continuation of operator</td>
<td>No</td>
</tr>
<tr>
<td>5 Partnership</td>
<td>New partner joins or a partner leaves <em>(also refer to dissolved partnership)</em> as long as there is a continuation of at least one partner</td>
<td>Retained</td>
<td>Continuation of operator/s</td>
<td>No</td>
</tr>
<tr>
<td>6 Incorporated company</td>
<td>Company goes into administration and is being run as a going concern by the administrators.</td>
<td>Retained</td>
<td>Continuation of operator/s</td>
<td>No</td>
</tr>
<tr>
<td>7 Incorporated company in administration</td>
<td>Company taken over from administrators by a different sole trader, partnership or incorporated company</td>
<td>Expires</td>
<td>Discontinuation of operator/s</td>
<td>Yes</td>
</tr>
<tr>
<td>8 Sole trader, Partnership or Incorporated company</td>
<td>Bankruptcy, insolvency or in liquidation <em>(wound up / dissolved)</em></td>
<td>Expires</td>
<td>Discontinuation of operator/s, approval expires</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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

- **Are there serious deficiencies?**
  - **NO** → Approval will continue
  - **YES** → Can adequate guarantees be given regarding future production?
    - **NO** → Approval will be withdrawn
    - **YES** → Do the guarantees mean that deficiencies will be permanently resolved immediately?
      - **NO** → Approval will continue
      - **YES** → Do the guarantees mean that deficiencies will be permanently resolved within a reasonable time?
        - **YES** → Approval will be suspended
        - **NO** → Approval will be withdrawn

*Note*: suspension can only be invoked where the FBO can satisfy the LA that acceptable corrective action will be taken. The Agency’s opinion is that a very high standard of proof is needed, including evidence that the remedial work can be adequately financed.
Annex 5

Exemption Criteria Flowchart: All POAO (Except Meat (See Annex 6))

Are you supplying POAO to other food businesses? → NO → Only 852/2004 applies (exempt from approval)

YES →

Are you supplying POAO only to retailers and direct to the public?* → NO

YES →

Is the supply of POAO marginal, localised and restricted? → NO

YES →

Are you only storing and transporting POAO, i.e. not re-wrapping or handling open POAO in any way

YES → Only 852/2004 applies (exempt from approval)

NO →

852/2004 and only the temperature requirements of 853/2004 (approval not required)

852/2004 and 853/2004 apply in full (approval required)

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

Is cut and/or processed fresh meat (red & poultry) supplied to other wholesalers/retailers?* & ** (see footnote)

NO
(retail sale)

YES

Does all POAO account for up to 25% or less of ALL FOOD sold by business

NO
>25%

YES

Is the quantity of wholesaled fresh meat (red or poultry) cut and/or further processed into mince and/or meat preps and/or meat products at the establishment 2 tonnes or less per week? (excluding game and game meat)

NO

YES

Does the business have a genuine retail element? *** (see footnote)

NO

Approval required

YES

Exempt

NO

YES

Is all supply within the establishment’s county, plus the greater of, either the neighbouring county or counties or 30 miles/50kms from the boundary of the establishments’ county
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)