



Approved Establishments

Scottish National Protocol

Prepared by

Scottish Food Enforcement Liaison Committee, Approved Establishment Working Group

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Contents

1. BACKGROUND	2
2. INTRODUCTION – THE LEGISLATIVE REQUIREMENTS AND PURPOSE OF APPROVAL .	
3. LEGISLATION	4
4. ESTABLISHMENTS THAT REQUIRE APPROVAL	5
5. EXEMPTIONS TO APPROVAL	12
6. APPLICATION FOR APPROVAL	21
7. DETERMINATION	23
8. DOCUMENTATION	29
9. APPROVAL NUMBERS	31
10. ID MARKING	33
11. SPECIFIC CLASSES/TYPES OF APPROVED ESTABLISHMENTS	35
12. CHANGES TO AN APPROVAL	39
13. ENFORCEMENT	49
14. DEFINITION AND GLOSSARY	54

1. BACKGROUND

1.1. Responsibility for the approval and enforcement in establishments approved under Regulation (EC) 853/2004 in Scotland is specified within the Food Hygiene (Scotland) Regulations 2006 (as amended). In general terms, Food/Local Authorities are responsible for all food establishments except those where an Official Veterinarian is required i.e. slaughterhouses, game handling establishments and cutting plants which fall to Food Standards Scotland (FSS).

1.2. During the formation of FSS, it was proposed that the existing arrangement be reviewed in order that Food Standards Scotland may adopt responsibility for formal approval of all establishments so liable under Regulation (EC) 853/2004.

1.3. The Society of Chief Officers of Environmental Health in Scotland (SoCOEHS) and the SFELC Approved Establishment Working Group proposed that a Joint Approval Process Model be implemented identifying the relationship between and respective roles of FSS and Local Authorities (LA) in the context of the approval process.

1.4. Key to this document is the application of Official Control Verification.

1.5. This national protocol applies to all approved establishments (both LA and FSS approvals) and replaces the two guidance documents 'Guidance for LA Authorised Officers on the approval of establishments' and 'Operational Policy for the Approval of Meat Establishments Undertaken by the Food Standards Agency and Food Standards Scotland'.

2. INTRODUCTION – THE LEGISLATIVE REQUIREMENTS AND PURPOSE OF APPROVAL

2.1. Regulation (EC) 853/2004 requires that food business establishments handling food of animal origin that fall under the categories for which Annex III (see table 1) stipulates requirements must, with some limited exceptions, be approved by the CA (CA). Compliance with the relevant requirements of Regulation (EC) 853/2004 is required in addition to full compliance with Regulation (EC) 852/2004. Registration under Article 6(2) of Regulation (EC) 852/2004 is not required for approved establishments.

2.2. Establishments that require approval must be approved prior to commencing activities or operating in a manner that requires approval. Where an establishment is identified trading without the necessary approval, appropriate action (including where necessary formal enforcement action) should be taken to ensure that activity which requires approval ceases immediately. Consideration should also be given to dealing with food already placed on the market.

3. LEGISLATION

3.1. [Regulation \(EC\) 178/2002](#) – General Food Law Regulation: This regulation provides a framework for food and feed law in the EU and applies to Member States and food and feed business operators. It applies to all stages of production, processing and distribution of food and feed, but does not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption. The principal aim of the regulation is to protect public health and consumers' interests in relation to food.

3.2. [Regulation \(EC\) 852/2004](#) of the European Parliament and of the Council on the hygiene of foodstuffs: This sets out general hygiene rules that apply to all registered and approved food businesses including structural requirements and the implementation of procedures based on hazard analysis and critical control point (HACCP) principles. The regulation sets out objectives for 'good hygiene practices' to protect consumers.

3.3. [Regulation \(EC\) 853/2004](#) of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin: This includes requirements for businesses producing Products of Animal Origin (POAO) that apply in addition to those set out in Regulation (EC) 852/2004, including the requirement for establishments to be approved.

3.4. [Regulation \(EC\) 2073/2005](#) on microbiological criteria for foodstuffs. This provides the microbiological parameters for foods.

3.5 [Regulation \(EU\) 2017/625](#) of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (Official Controls Regulation): As of 14 December 2019, this regulation repealed and replaced Regulation (EC) 882/2004 and Regulation (EC) 854/2004. This regulation includes procedures to be followed concerning the approval of establishments as required under Regulation (EC) 853/2004. It also includes the specific requirement for inspection and auditing activities by the CA to be carried out in relation to establishments that require approval under Regulation (EC) 853/2004.

3.6 [Commission Delegated Regulation \(EU\) 2019/624](#) concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs (LBMs) in accordance with Regulation (EU) 2017/625: This regulation, made under Article 18(7) of Regulation (EU) 2017/625, includes - but not limited to - minimum training requirements for tasks relating to official controls and criteria and conditions to determine, by way of derogation, when: ante-mortem inspection (AMI) in certain slaughterhouses may be performed under the supervision or under the responsibility of an Official Veterinarian (OV); when AMI may be performed outside the slaughterhouse in case of emergency slaughter; when AMI may occur at the holding of provenance and when post-mortem inspection (PMI) and auditing activities may be performed under the responsibility of an OV.

3.7 [Commission Implementing Regulation \(EU\) 2019/627](#) laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625: This regulation, made under Article 18(8) of Regulation (EU) 2017/625, includes specific requirements for the performance and uniform minimum frequency of official controls for POAO; the practical arrangements of AMI and PMI to ensure that sufficient guarantees are met when the controls are performed under the responsibility of the OV; conditions for the classification and monitoring for LBMs and technical requirements of the health mark and practical arrangements for its application.

4. ESTABLISHMENTS THAT REQUIRE APPROVAL

4.1. Establishments that require approval are split between FSS and LAs depending upon whether veterinary supervision is required.

4.2. Abattoirs, Cutting Plants and Game Handling Establishments require veterinary control in accordance with Article 18 of Regulation (EU) 2017/625 and must therefore be approved and subject to enforcement by FSS.

4.3. Any co-located Cold Store, Re-wrapping Establishment, Minced Meat, Meat Preparations, and Mechanically Separated Meat activities are also approved by FSS. When stand-alone, these establishments are approved by the relevant LA.

4.4. Other co-located activities will be considered on a case by case basis. Where possible, the intention of the policy is to avoid dual approving authorities (see 12.6) but discussion will be required between FSS and the relevant LA to agree responsibility for official control arrangements at such establishments.

4.5. Table 1 lists commodities and activities that require approval; the relevant section of Annex III, and the appropriate approval authority.

Table 1. Commodities and activities that require approval.

Product	Relevant Annex of 853/2004	Establishment Type	Operation for which establishment may be approved	CA
Red Meat	Annex III, Section I	Abattoir	Slaughter of Domestic Ungulates	FSS
		Cutting Plant	Red Meat Cutting	FSS
Poultry and Lagomorphs	Annex III, Section II	Abattoir	Slaughter of Poultry and Lagomorphs	FSS
		Cutting Plant	Cutting of Poultry and Lagomorphs	FSS
Farmed Game	Annex III, Section III	Abattoir	Slaughter of Farmed Game	FSS
Wild Game	Annex III, Section IV	Game Handling Establishment	Processing of Wild Game	FSS
Minced meat, meat preparations and mechanically separated meat	Annex III, Section V	Processing Plant	Producing minced meat, meat preparations and mechanically separated meat	LA (FSS if co-located with Slaughter or Cutting)
Meat products	Annex III, Section VI	Processing Plant	Production of meat products	LA (FSS if co-located with Slaughter or Cutting)
Live Bivalve Molluscs	Annex III, Section VII	Dispatch Centre	Reception, conditioning, washing, cleaning, grading, wrapping and packaging of LBMs	LA

		Purification Centre	Purification of LBMs in tanks fed by clean seawater for the time necessary to reduce contamination to make them fit for human consumption	LA
Fishery products	Annex III, Section VIII	Factory vessel	Filleting, slicing, skinning, shelling, shucking, mincing or processing of fishery products on board	LA
		Freezing vessel	Freezing of fishery products after bleeding, heading, gutting, and removal of fins and, where necessary, followed by wrapping or packaging.	LA
		Processing Plant	Processing of fishery products	LA
		Fresh fishery products Plant	Handling of unprocessed fishery products that have not undergone any treatment to ensure preservation other than chilling	LA
		Auction hall	Storing and displaying of fishery products for auction sale	LA
Raw Milk & Dairy Products	Annex III, Section IX	Collection centre	Collection of raw milk where it is cooled and filtered	LA
		Processing Plant	Treating, processing and/or wrapping of dairy products (milk or any milk-based product)	LA
Eggs and Egg Products	Annex III, Section X	Packing Centre	Packing and grading of eggs by quality and weight	LA
		Processing Plant	Processing of egg products	LA
		Liquid egg plant	Handling of unprocessed egg contents after removal of shell	LA

Frogs Legs and Snails	Annex III, Section XI	Processing Plant	Slaughter and Processing	LA
Rendered animal fats and greaves	Annex III, Section XII	Storage	Intermediate storage of rendered animal fats and greaves	LA (FSS if co-located with Slaughter or Cutting)
Treated stomachs, bladders and intestines (Processing Plant)	Annex III, Section XIII	Processing Plant	Processing of treated stomachs, bladders and intestines	LA (FSS if co-located with Slaughter or Cutting)
Gelatine	Annex III, Section XIV	Processing Plant	Processing of gelatine	LA (FSS if co-located with Slaughter or Cutting)
		Collection Centre / Tannery	Authorisation - not approval	LA (FSS if co-located with Slaughter or Cutting)
Collagen	Annex III, Section XV	Processing Plant	Processing of collagen	LA (FSS if co-located with Slaughter or Cutting)
		Collection Centre / Tannery	Authorisation - not approval	LA (FSS if co-located with Slaughter or Cutting)
General POAO	N/A	Cold store	Storage of products of animal origin	LA (FSS if co-located with Slaughter or Cutting)
General POAO	N/A	Wholesale Market	Establishment that includes separate sub-units operating independently as food business, but sharing common facilities	LA
General POAO	N/A	Re-wrapping and re-packaging Establishment	Re-wrapping and re-packaging of products of animal origin	LA (FSS if co-located with Slaughter or Cutting)

General POAO	N/A	Re- packaging Establishment	Re-packaging of products of animal origin	LA (FSS if co-located with Slaughter or Cutting)
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4.6. The approval of establishments relates to the food being processed and supplied from an establishment, not an intermediate step in the process. Therefore establishments involved in cutting meat as part of the process of manufacturing meat preparations, do not require cutting plant approval, but do require meat preparations approval. Likewise, an establishment making mince or meat preparations, as part of the process of manufacturing meat products does not require minced meat and meat preparations approval, but does require meat products approval. The exemption to this, relates to abattoirs. The slaughter process requires approval irrespective of the product supplied from the establishment.

4.7. Collection centers and tanneries may supply raw material for the production of gelatine and collagen intended for human consumption. They are not subject to the requirements of Regulation (EC) 852/2004, nor are they subject to approval under Regulation (EC) 853/2004. They will, however, need to be specifically authorised by the relevant LA or FSS in accordance with Annex III, Section XIV, Chapter 1(5) of Regulation (EC) 853/2004 (gelatine) and Section XV, Chapter 1(5) of Regulation (EC) 853/2004 (collagen).

Maintenance of the Approval Chain

4.8. Although there is no specific requirement for the approval chain to be maintained, this is the general effect of the legislation, this is because establishments require approval in order to supply to other approved establishments. An approved establishment is not considered to be a retailer and therefore the retail to retail exemption is inapplicable.

Determining whether approval is required

4.9. Establishments handling food of animal origin must, with some limited exceptions, be approved by the CA (CA).

4.10. A new approval is required whenever a new or existing food business establishment (intends to) undertake activities that require approval. In this regard, it is vitally important that the definition of an establishment is understood.

4.11. A food business establishment is defined as a unit of a food business. In this regard, it is distinctly different to a premises – which relates to the physical structure. In relation to approval, it should be considered to consist of a combination of the food business operator, the premises and the activity being conducted. Therefore an approved establishment cannot change hands, as the new owner operating at the premises creates a new establishment and the previous establishment ceases to exist.

4.12. FSS should be consulted where there is any doubt about whether a new approval is required.

4.13. There are a number of scenarios that fit the criteria for requiring a new approval including:

- A new food business operator, at new premises.
- A new food business operator taking over a premises previously operated as an approved establishment by a different food business operator.
- An existing food business operator relocating to a new premises.
- An existing food business operator expanding/changing operations so that approval is required.
- An existing food business operator changing the operations covered by their approval, where this is considered to be more than a variation of the existing approval.

4.14. As a general rule, where a change would involve change to the characteristics of the product e.g. water activity, allergens etc. or require a revision to the FSMS due to a change in the risks, CCPs etc. then this would be considered significant enough to justify a new approval rather than a variation.

4.15. Where an FBO intends to process a new category of POAO, e.g. the addition of meat products to a meat preparation establishment, this would require a new approval. In addition, new approval will be required where significant changes within a category are planned, e.g. a fishery products establishment currently producing fishery products that require to be heat treated prior to consumption, that intends to produce RTE fishery products; or a manufacturer of pasteurised dairy products intends to produce unpasteurized cheese. The revised or new process should be subject to conditional approval, whilst the existing processes would remain under the existing full approval (See 8.11). Other changes that do not introduce significant new risks would be considered as a variation, and would not require a new approval.

5. EXEMPTIONS TO APPROVAL

5.1. The exemptions to approval are:

- a) Direct supply of POAO to the final consumer
- b) Direct supply of small quantities of primary products
- c) Direct supply of small quantities of meat from poultry and lagomorphs slaughtered on the farm
- d) Direct supply of small quantities of wild game or wild game meat
- e) Slaughter for private domestic consumption
- f) Composite products
- g) Satellite operations
- h) Supply to farmers markets
- i) Supply of small quantities of POAO from retailers to other retailers
- j) Cold storage of POAO in final retail packaging

5.2. '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 establishment.

Direct supply of POAO to the final consumer (Regulation (EC) 853/2004 Article 1(5))

5.3. Regulation (EC) 853/2004 does not apply to establishments where supply is limited to retail (including catering operations) to the final consumer. The Regulation does, however, apply to retail if food of animal origin is supplied to another food business establishment (wholesale) unless the activities in Article 1(5) (b) (i) or (ii) are undertaken. Although a 'wholesale outlet' may be considered to be 'retail' as defined, approval may nonetheless be required depending on the specific activities undertaken.

Direct Supply of Small Quantities of Primary Products (Regulation (EC) 853/2004 Article 1(3)(c))

5.4. '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'.

5.5. 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.

5.6. The expression 'small quantities' is not defined in Regulations, FSS therefore, suggest the following as maximum amounts (Table 2), which could be considered as small quantities for individual products of animal origin:

Table 2. Maximum amounts considered as small quantities for individual products of animal origin.

Products	Maximum amounts
Milk	Not applicable in Scotland
Eggs	<p>Less than 360 eggs (i.e. less than one full case) per week.</p> <p>Note: <i>This exemption only applies to the producer supplying directly to the final consumer from the farm and farmers markets and door to door.</i></p> <p><i>If the producer sells the eggs, to other food businesses (e.g. local shops, restaurants or bakeries etc.), they must first be graded as Class A; and, therefore, the establishment must also be approved and authorised as a packing centre for activity.</i></p>
Fishery products	Up to 25 tonnes in a calendar year
Live Bivalve Molluscs	<p>Up to 25 tonnes in a calendar year, but subject to maximum limits for individual species as set out below:</p> <ul style="list-style-type: none"> • Cockles - 25 tonnes • Oysters - 5 tonnes • King Scallops - 10 tonnes • Queen Scallops - 10 tonnes • Mussels - 20 tonnes • Other Live Bivalve Molluscs – 10 tonnes • Marine Gastropods – 20 tonnes

5.7. As well as being exempt under Regulation (EC) 853/2004, the direct supply of small quantities of primary products is exempt under Regulation (EC) 852/2004. The only food law that applies to these situations is the obligations under Regulation (EC) 178/2002.

Direct Supply of small Quantities of meat from poultry and lagomorphs slaughtered on the farm

(Article 1(3)(d)(also refer to Schedule 5 of the Food Hygiene Regulations))

5.8. *'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.'*

5.9. 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. Only birds or lagomorphs that have been reared on that site can be included within this exemption. No birds or lagomorphs can be brought to site for slaughter.

5.10. **Small quantities** is not defined in the legislation, but FSS'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.

5.11. 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, however, in the first year, the 10,000 must be applied. 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.

5.12. Although there is no limit to the number of birds or lagomorphs that producers in the second category may slaughter, FSS 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.

5.13. 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.

5.14. Meat produced under this exemption may be supplied:

- Direct to the final consumer; or
- Direct to local retail establishments directly supplying such meat to the final consumer.

5.15. 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.

5.16. 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' except for the two weeks preceding Christmas and Easter and (for geese) Michaelmas (late September).¹

5.17. Establishments benefiting from this exception remain subject to the requirements of Regulation (EC) 852/2004 and the additional requirements contained in Regulation 31 and Schedule 5 to the Food Hygiene (Scotland) Regulations 2006, as amended.

Direct Supply of Small Quantities of wild game or wild game meat (Regulation (EC)853/2004 Article 1(3)(e))

5.18. 'Hunters who supply small quantities² of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.'

Wild Game Carcasses in Fur or Feather;

5.19. There is an exemption from Regulation (EC) No 852/2004 for primary producers (individual hunters and/ or shooting estates) to supply small quantities of primary products (i.e. wild game carcasses in fur/feather) directly to the final consumer or to local retail establishments directly supplying the final consumer. This supply is not subject to the requirements of the EU Food Hygiene Regulations. However, the hunter/shooting estate is responsible for supplying safe food under The Food Safety Act 1990 and Regulation (EC) No 178/2002.

Wild Game Meat;

5.20. There is also an exemption from Regulation (EC) No 853/2004 for hunters and active members of a hunting party supplying small quantities of wild game or wild game meat directly to the final consumer or to local retailers directly supplying the final consumer. The meat must be prepared by an individual who has played an active part in the shoot, such as a beater, so the exemption is available to shooting estates. Operations under this exemption are required to be registered with the LA as a food business under Regulation (EC) No. 852/2004.

5.21. Persons who hunt wild game with a view to placing it on the market for human consumption must have sufficient knowledge of the pathology of wild game, and of the production and handling of wild game and wild game meat after hunting, to undertake an initial examination of wild game on the spot. In addition, large wild game intended for supply to an approved game handling establishment (AGHE) must be accompanied by a declaration stating that no abnormalities were observed either before or after shooting.

For more information: see the separate Wild Game Guide [here](#).

Slaughter that is carried out for private domestic consumption

5.22. Keepers of animals who slaughter livestock on farm for their own personal consumption or that of members of their household living there fall out of the scope of both Regulation (EC) No.

¹Regulation (EC) No 2017/185 extends the transitional measures contained in Regulation (EC) No 1079/2013 until 31 December 2020.

² The definition of 'small quantities' is set out in the [Wild Game Guide](#).

852/2004 and Regulation (EC) No. 853/2004.

Composite Products

5.23. Article 1(2) of Regulation (EC)853/2004: 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.

5.24. Thus a food business operator who:

- Merely **assembles** processed products of animal origin with products of plant origin does **not** require approval as it is a composite product, even if that product is then further processed – e.g. sandwich assembly. Regulation (EC) 852/2004 would be appropriate to that operation or those operations;
- Processing of a POAO **prior** to combining it with food of plant origin would require approval under Regulation (EC) 853/2004 for that processing activity.
- Assembles food of plant origin with **unprocessed** food of animal origin which is further processed together would need approval under Regulation (EC) 853/2004 as it is not considered to be a composite product e.g. manufacture of a steak pie from raw steak.³

5.25. The addition of a product of plant origin to a processed product of animal origin does not automatically mean that the resulting food would be a composite product. For example, cheese to which herbs are added or sausages to which garlic or soya are added would fall within Regulation (EC) 853/2004.

5.26. The EC Guidance document on the implementation of the provision of Regulation (EC) 852/2004 gives an overview of the scope of this Regulation. However the list is not exhaustive and therefore purely indicative.

Satellite Operations

5.27. Where the only supply of relevant POAO is from the establishment to other local retail outlets under the same ownership, operating under a combined Food Safety Management System, it may be appropriate to consider these as satellite operations. These can be regarded as an extension of the producer's establishment. Therefore such supply should be treated as other sales to the final consumer.

5.28. This flexibility is mainly to remove the need for the approval of smaller food businesses where the processing of POAO and the retail element (i.e. the place or point of supply to the consumer) are not at the same 'site' but there is a strong association between sites and a single 'controlling mind' overseeing the activities. The controlling mind will have sole and effective control of the HACCP based procedures from the production site through their own retail outlet/s to the final consumer.

³Where raw egg is used as an ingredient in a composite product e.g. cakes, an assessment should be undertaken to consider the business HACCP, scale of production and availability/feasibility of alternative heat treated liquid/powdered egg, to assess whether approval is proportionate and would provide a greater level of public health protection than that afforded by (EC) 852/2004 alone

5.29. Where supply changes to include other establishments not under the same ownership, these 'satellite operations would need to be considered as supply to other establishments', especially when considering the marginal requirement of the retail to retail exemption.

5.30. The interpretation of local in this context is intended to be more restrictive than applied elsewhere. It is intended to indicate that establishments are sufficiently local to be under the direct supervision of an individual.

Supply to Farmers Markets

5.31. This exemption can be considered to be an extension of the Satellite Operations exemption, but without the local restriction.

5.32. Establishments producing POAO for supply to the final consumer at farmers' markets, or at other markets supplying the final consumer, are not subject to approval under Regulation 853/2004.

5.33. This is subject to the following conditions:

- There is no change of control of the POAO (e.g. FBO A cannot cut meat and supply it to FBO B to sell at the market);
- It does not involve supply to other than the final consumer.

5.34. FBOs 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 originating establishment. Furthermore, such sales should be treated as other sales to the final consumer and are not limited to the 'localised' sale criteria.

Supply of Small Quantities from Retailers to other Retailers (Regulation (EC) 853/2004, Article 1(5)(ii))

5.35. Article 1 (5)(ii) provides for the supply of POAO from a retail establishment to another retail establishment to be exempt from approval where the supply to other retail establishments is **marginal, restricted** and **localised** as defined below. All three criteria must apply in order for an establishment to be exempt.

5.36. In order to be considered a retailer, there must be genuine retail sales to the final consumer from the establishment, including via mail order or internet sales as well as by delivery or collection.

'Marginal':

5.37. Where supply of POAO to other retail establishments is up to a 25% of all the food handled within the establishment. This should be calculated by measuring the amount (either by weight or volume) of relevant 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.) handled at the establishment.

5.38. Where the only relevant POAO handled is meat (fresh or processed, excluding wild game meat) up to 2 tonnes a week. This can be averaged over a 12 month period.

5.39. 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'

5.40. Supply to other retail establishment must be limited sales within the establishment's own LA plus the greater of either: the neighbouring LA or LAs; or 30 miles/50km from the boundary supplying establishment's LA;

5.41. In relation to LAs bordering England, localised should be interpreted as supply to other retail establishment must be limited sales within the establishment's own LA plus the greater of either: the neighbouring LAs or English Counties; or **30 miles/50km from the boundary supplying establishment's LA.**

5.42. 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, or rare product could not find a sufficient and/or specialist market on a local basis as defined above.

'Restricted'

5.43. Recital 13 of Regulation (EC) 853/2004 describes 'restricted' 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.

5.44. Officers should interpret 'restricted' as 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 (EC) 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.

Storage and Transport Undertakings (Regulation (EC) 853/2004 Article 1(5) (b) (i))

5.45. '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;'

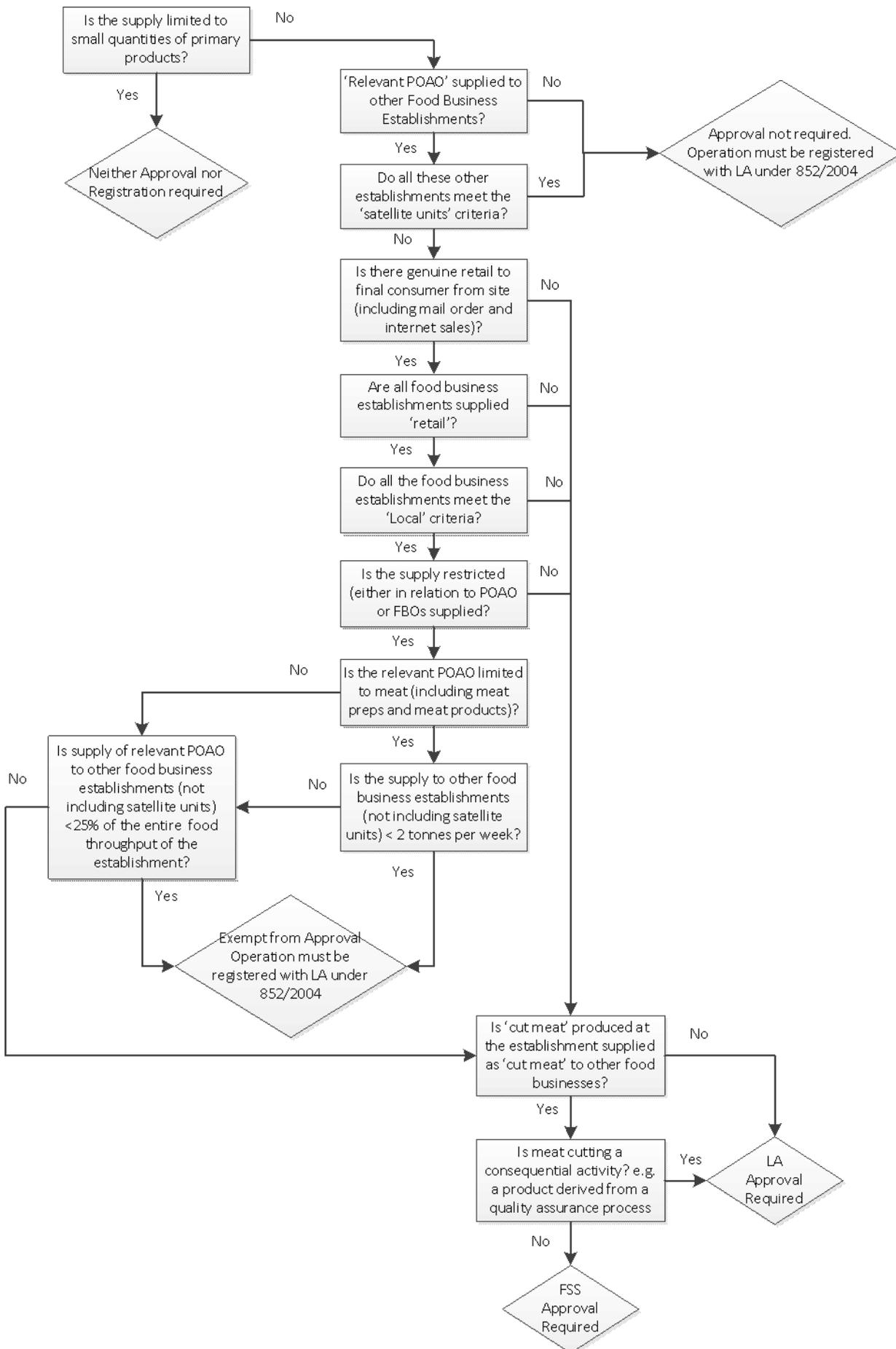
5.46. Therefore establishments where operations are limited to non-temperature controlled storage and transport are exempt from approval. These establishments should be registered and considered in relation to Regulation (EC) 852/2004. Establishments involved in temperature controlled storage may need to be considered for approval as 'Cold Stores'.

[Registered Cold Storage \(See also 12.1\)](#)

5.47. Cold stores engaged in the following activities require registration under Regulation 852/2004:

- Cold stores engaged exclusively in retail operations (i.e. establishments, or as part of establishments, supplying only the final consumer);
- Cold stores engaged in retail operations and also supplying other retail food business establishments (including caterers) on a “marginal, localised and restricted” basis;
- Cold stores that are part of the logistical chain for distributing, to a retailer, finished POAO which is packaged for retail sale to the final consumer and whose activities are physically limited to transport or storage. This does not apply to cold stores that store finished POAO which is packaged for retail sale and sell to other establishments not as part of a logistical distribution chain. Where the activity consists of only storage or transport, approval is not required, but as with all businesses undertaking cold storage activities (whether or not), any specific temperature requirements laid down in Annex III of Regulation 853/2004 are applicable.
- Cold stores that exclusively handle “composite products” as per Article 1(2) of Regulation 853/2004.
- Cold stores undertaking other activities require to be approved.

5.48. Determination if Approval is Required – Decision Tree



6. APPLICATION FOR APPROVAL

6.1. 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) 852/2004 applying to undertake activities that require approval;
- Establishments approved under Regulation (EC) 853/2004 applying to undertake additional activities or significant changes; and
- Change of food business operator.

6.2. In considering applications for approval, Competent Authorities should ensure that they fully consider any exemption that may be afforded to the applicant by Article 1 of Regulation (EC) 853/2004.

6.3. Following an enquiry from a prospective FBO or a relevant establishment comes to the attention of the enforcing authority; the officer should ensure that the FBO is provided with an application form. Templates of Application for [Approval forms](#).

6.4. FSS Approval Establishments Application can be found [here](#) or by contacting us at Approvals@fss.scot.

6.5. Approval cannot be granted unless an application and all relevant supporting documentation has been submitted.

6.6. An FBO can only make an application for approval for an establishment under their control and only for processes and/or activities that they intend to carry out.

6.7. The applicant must provide details of:

- a) The premises for which approval is requested;
- b) The activities for which approval is sought; and
- c) The identity of the FBO including relevant contact details. The legislation allows for natural and legal persons to be FBOs therefore the applicant is required to identify themselves (including the name of officers, address and proof of status) as either a:
 - Sole trader or partnership (natural person/s) who is required to be compliant with food law.
 - Incorporated and registered company (legal person) which is required to be compliant with food law.
 - Other business types such as cooperatives, registered charities and other specialised types of organisation will have to establish the natural or legal person who will have control and responsibility for the operation of the food business.

6.8. Applications for approval of establishments can 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) 853/2004. However, where an establishment is exempt from approval through application of the 'retail to retail' exemption, consideration should be given to providing conditional approval to establishments that require approval in order to tender for contracts or commercial purpose.

Application and Supporting Documentation

6.9. An application for approval requires supporting documentation as well as the application form itself. A CA cannot make a determination to issue an approval or conditional approval until all relevant information has been received.

6.10. In relation to LA approvals, once an application has been received, information regarding the application must be communicated to the FSS Enforcement Delivery Branch enforcement@fss.scot. Information must include the name and contact details of the FBO, the address of the establishment and the nature of the approval sought.

6.11. In relation to FSS approvals, all supporting documentation together with the application form itself, must be submitted to Approvals@fss.scot mailbox.

6.12. Relevant documentation required to support the application includes, but is not limited to:

- A detailed scale plan of the (proposed) establishment showing the location of rooms and other areas to be used for the storage and processing of raw materials, product and waste, and the layout of facilities and equipment;
- A description of the (proposed) food safety management system based on HACCP principles;
- A description of the (proposed) establishment and equipment maintenance arrangements;
- A description of the (proposed) establishment, equipment and transport cleaning and disinfection arrangements;
- A description of the (proposed) waste collection and disposal arrangements;
- A description of the (proposed) water supply;
- A description of the (proposed) water supply quality testing arrangements;
- A description of the (proposed) arrangements for product testing;
- A description of the (proposed) pest control arrangements;
- A description of the (proposed) monitoring arrangements for staff health;
- A description of the (proposed) arrangements for record keeping;
- A description of the (proposed) arrangements for applying the ID mark to product packaging or wrapping (where applicable);
- A description of the traceability arrangements for all ingredients, packaging and final products;
- A description of the products to be produced including, where appropriate, the physiological characteristics of the product.

6.13. Where other documents are requested prior to the application being considered, e.g. specific details of any particular control e.g. in-line pasteurisation, or challenge testing results, these requests should be made at the earliest opportunity.

6.14. The level of detail required will vary on a case by case basis, and officials are required to use their discretion on the documentation required. E.g. in some circumstances, a brief paragraph on the water supply arrangements may be sufficient, in others, a sketch plan of the pipework may be required and in others, formal plans of the water distribution network will be required.

6.15. Assessment of an application can commence prior to all the necessary documentation being submitted at the discretion of the CA. However a determination cannot be made without all supporting documentation having been provided.

7. DETERMINATION

Qualification and competency requirements of Officers

7.1. All officers involved in the assessment of approval applications and the enforcement of food law within approved establishments must be appropriately qualified, experienced and competent. As a minimum, officers need to meet the following requirements:

For all approved establishments;

- Have knowledge and understanding of HACCP equivalent to Advanced HACCP (Level 4) (with particular focus on the manufacturing sector);
- Have suitable knowledge on the specific commodities being handled, the processes involved and the associated risks;
- Have been assessed as being competent by the Lead Food Officer or the FSS Assessment Panel in relation to approved establishments, the commodities being handled, the processes being undertaken and the assessment of food safety management systems.

For LA approved establishments;

- Be an EHO or Food Safety Officer holding the Higher Certificate in Food Premises Inspection (see Code of Practice)
- Meet the requirements of the SFELC Competency Matrix (for LAs)

For FSS approved establishments;

Official Controls

- Official Veterinarian Qualification as per Regulation (EU) 2017/625 and Commission Delegated Regulation (EU) 2019/624
 - o Wild Game designation (where applicable)
 - o RTE designation (where applicable)
- Meat Hygiene Inspector Qualification as per Regulation (EU) 2017/625 and Commission Delegated Regulation 2019/624,
 - o Red meat designation
 - o White meat designation
 - o Wild Game designation (where applicable)
 - o UAI designation (where applicable)
- Membership of the Royal College of Veterinary Surgeons for OV's and Veterinary MHIs
- For non-Veterinary Managers; have knowledge and understanding of HACCP equivalent to Intermediate HACCP (Level 3)

Approvals and audit

- All of the requirements for Official Veterinarians

7.2. Where a LA does not have an officer that meets the above requirements, they must request assistance from the FSS Enforcement Delivery Branch.

Determination of an Approval Application

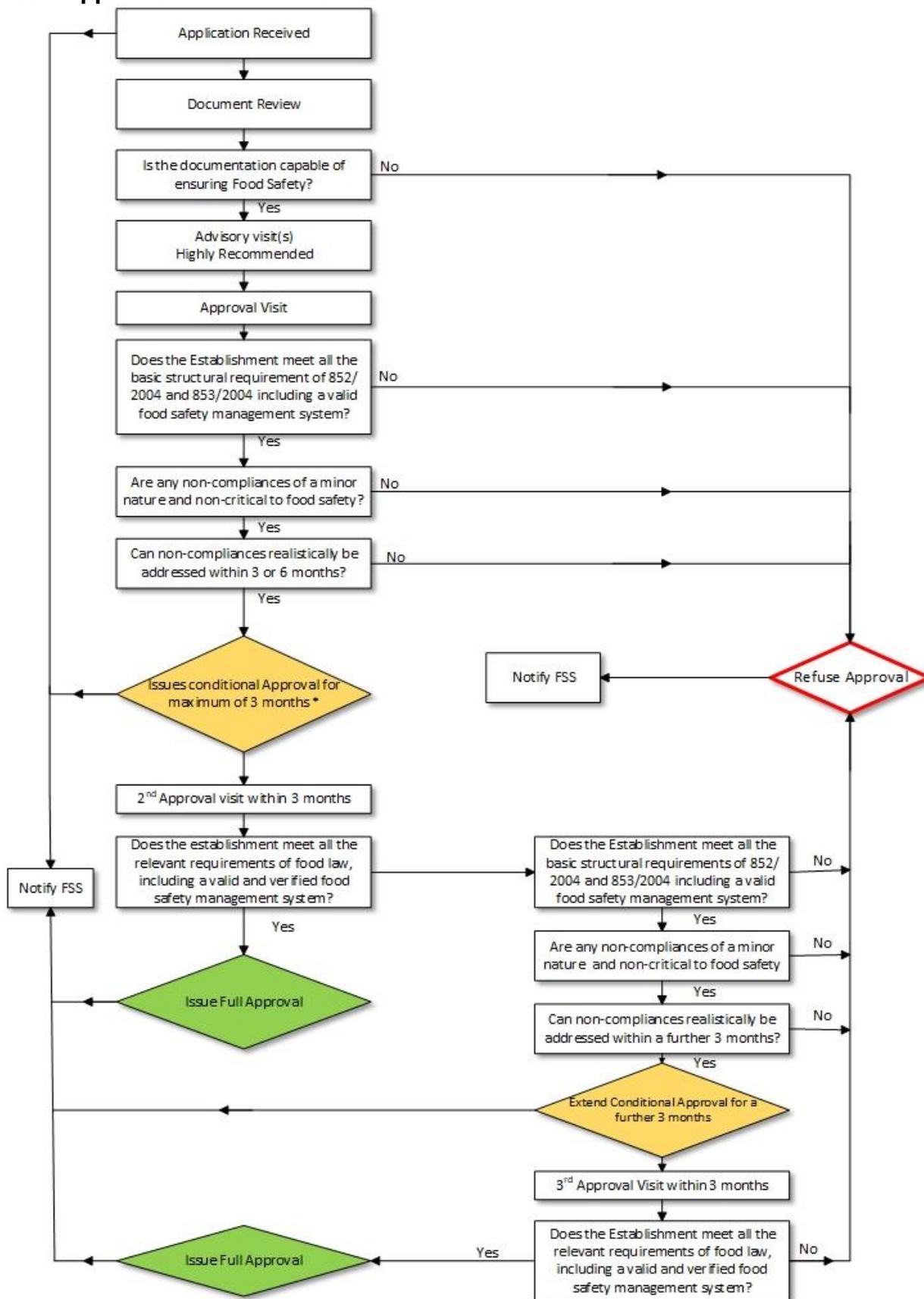
7.3. Officers are required to verify that the food safety management system is capable of ensuring food safety.

7.4. In addition to the HACCP controls, it is necessary to confirm that the CA is satisfied that the establishment is compliant with the relevant specific requirements of Regulation (EC) 852/2004, Regulation (EC) 853/2004, and where applicable Regulation (EC) 2073/2005. These should be considered as pre-requisites to the application of the HACCP. In order for an establishment to be granted full approval, an establishment must be fully compliant with the specific requirements of Regulation (EC) 852/2004, Regulation (EC) 853/2004, and where applicable Regulation (EC) 2073/2005. In order to be granted conditional approval, the establishment must comply with the structural requirements including a valid food safety management system.

7.5. The final decision on the determination of an application for approval must be undertaken by:

- For LA approvals, the Lead Officer for Food or an appropriate individual identified for this function.
- For FSS approvals, an appropriate individual delegated by the Chief Executive of Food Standards Scotland.

7.6. Approvals Process Schematic



4 * In the vast majority of cases, it is not appropriate to issue a full approval at the first approval visit (the exception relates to a specific change of FBO circumstance [see 13.4])

Document Review

7.7. It is vital that a thorough document review is undertaken prior to the approval visit.

Use of Advisory Visits

7.8. Following receipt of an application, the CA should give consideration to undertaking advisory visits 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 as to avoid any potential difficulties when the establishment is formally assessed for approval. The CA needs to make the FBO aware of the differences between advisory and approval visits.

7.9. It is anticipated that in the majority of cases, an advisory visit will be required.

Structural or Maintenance Issues

7.10. The Regulations are clear, that conditional approval cannot be issued unless there is full compliance with structural requirements of Regulation (EC) 852/2004 and Regulation (EC) 853/2004. Officers will require to make a determination as to whether any non-compliance is a structural deficiency (conditional approval not appropriate) or maintenance issue (conditional approval may be appropriate).

Determination of Approval

7.11. Following an approval visit, a determination on the approval **must** be made. This must be:

- To issue a Full Approval;
- To issue a Conditional Approval – an approval for a 3 month period, which can be extended up to a maximum of 6 months;
- To refuse to issue an Approval.

7.12. It is not appropriate to refrain from making a determination following an approval visit.

7.13. Approval, including conditional approval should not be given unless/until all the relevant requirements of the legislation have been met. The decision whether or not to grant conditional approval to an establishment which does not fully comply rests with the CA.

7.14. The officer should use their professional judgement when determining whether it is appropriate to issue a conditional approval to establishments that are not fully compliant. The officer must be satisfied that any non-compliance:

- Is minor and not critical to food safety; and
- Can be addressed within a maximum of 3 or 6 months (i.e. before full approval is issued).

7.15. In considering whether a non-compliance is minor, it is important that it is recognised that the specific structural requirements of Regulation (EC) 852/2004 and Regulation (EC) 853/2004 must be complied with.

7.16. The CA may only grant conditional approval if the establishment meets all the infrastructure and equipment requirements. This includes having a validated food safety management system

based on HACCP principles. If the establishment is not operational, it will not be possible to assess how effectively this works in practice.

Time-scales for Determination of Approval

7.17. A determination of the approval status of an establishment must be made within 20 working days of all necessary relevant information having been supplied by the FBO. At this time, the establishment should be conditionally approved, fully approved or the approval should be refused.

7.18. Once the CA has determined that the FBO has provided all the necessary relevant information, this should be confirmed with the business in writing, so that it is clear when a determination will be made.

7.19. The enforcing authority must ensure that sufficient resources are available to permit a determination within the 20 working days limit.

Approval of Establishments

7.20. Competent authorities shall establish approvals procedures, as set out in Article 148(1) of Regulation (EU) 2017/625. An overview of the approval process is set out in a flow chart at 7.6.

Use of Conditional approval

7.21. In the vast majority of cases, it is not appropriate to issue a full approval at the first approval visit (the exception relates to a specific change of FBO circumstance (see 13.4). This is because approvable activity cannot be undertaken until an approval has been granted, and therefore it is not possible for operational standards to be observed, or for the FBO to demonstrate that the food safety management system is valid and to verify its effectiveness at the time of the first visit.

7.22. A second and possibly third approval visit will be necessary after the conditional approval has been granted to make a determination for a full approval.

7.23. The CA must not permit establishments to undertake approvable activity until an approval has been granted. However, the establishment may be able to operate within the restrictions of the 'retail to retail' exemption until approval is granted.

Concurrent Use of Full and Conditional Approval

7.24. Where an additional activity or significant change requires a new approval to be added to an existing approval, it will normally be appropriate for the new activity to be subject to Conditional Approval. This is because the operation will not have been able to be witnessed by the CA and the HACCP based controls will not have been verified.

7.25. It is not appropriate for the existing operations to revert to Conditional Approval, and therefore it will be necessary for the establishment to be subject to both Conditional and Full Approval. This will require two separate approval documents, one for the full approval and a separate one for the conditional. Both will refer to the same approval number, as it is not appropriate for a single establishment to have two approval numbers.

7.26. Once the CA is satisfied that the conditional approval can progress to full approval, a single approval document should be issued replacing both the existing full and conditional approvals within a single approval.

First approval visit

7.27. If the establishment is compliant with infrastructure and equipment requirements, and if the CA is satisfied that any non-compliance is minor and non-critical to food safety, conditional approval may be granted (see 8.7).

7.28. A validated food safety management system based on HACCP principles must be available. If the establishment is not operational, it will not have been possible for the effectiveness of the food safety management system to have been verified.

7.29. 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.

7.30. 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 officer but it is essential before considering recommendation for approval.

7.31. If not compliant with infrastructure and equipment requirements refuse application.

Second approval visit (within 3 months)

7.32. If fully compliant with operational requirements and compliance with infrastructure and equipment requirements are maintained, grant full approval.

7.33. If not fully compliant, but compliant with infrastructure and equipment requirements, and the CA is satisfied that any non-compliance is minor and non-critical to food safety and that adequate progress has been made, conditional approval may be extended for a further 3 months but cannot exceed a total of 6 months. Otherwise, refuse approval.

Third approval visit [if required] (within 6 months)

7.34. If fully compliant, grant full approval. If not refuse approval.

Seasonal Establishments

7.35. In the case of establishments operating a seasonal pattern, conditional approval may be split into two or more periods as long as the combined period does not exceed 6 months. Wherever possible, the CA will aim to conclude the approval process within one season even if it means that conditional approval will last for less than the allowed three or six months. However, where this is not practicable, conditional approval may be split.

7.36. In these cases, the officer undertaking the assessment must satisfy themselves that:

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

8. DOCUMENTATION

Approval Documentation

8.1. Once a determination to issue an approval or conditional approval has been made, the FBO must be issued with an appropriate approval document.

8.2. Model approval documentation for LAs is contained within the Food Law Practice Guidance (Scotland).

8.3. For LA approvals, once a determination to issue an approval has been made by the CA, information regarding this must be communicated to the FSS Enforcement Delivery Branch enforcement@fss.scot.

8.4. For FSS approvals, once recommendation is made to FSS by the visiting AO, confirmation of approval will be made in writing to the FBO. The establishment will be issued with an Annex A (approval document listing all the activities approved either conditionally or fully). Once a business has been conditionally approved it will get added to the published list of approved establishments by the CA.

Refusal to issue an approval

8.5 Where the CA refuses to issue an approval or conditional approval, a record of the reasons of these decisions must be recorded. 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. Model approval documentation for LAs is contained within the Food Law Practice Guidance (Scotland).

8.6. Once a determination to refuse an approval has been made by the LA, information regarding this must be communicated to the FSS Enforcement Delivery Branch, enforcement@fss.scot.

8.7. 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 (Scotland) Regulations 2009 (as amended). 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.

8.8. 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.

Notifying FSS of issues pertaining to approval

8.9. In addition to notifying the FBO, LA must also notify FSS at Enforcement@fss.scot of any establishment for which they:

- Receive an application for approval;
- grant approval;
- grant conditional approval;
- extend conditional approval;
- refuse approval;
- withdraw approval;
- accept surrender of approval; or
- vary the approval.

8.10. Minimum information provided should include the following:

- approval number;
- name of the establishment;
- town/region;
- category of food establishments;
- associated activities;
- species (where relevant) and;
- remarks;
- date of change.

8.11 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 website](#). Details of the establishments are then updated on the [FSS website](#).

9. APPROVAL NUMBERS

Approval Number

9.1. The CA must give a unique approval number to each food business establishment it approves, or conditionally approves, in accordance with Article 148 of Regulation (EU) 2017/625. For LA approved establishments, the convention is the LA's two-letter code followed by a unique three digit number (E.g. AA123 for an approved business in Aberdeen City Council). For FSS approved establishments, the convention is a unique four digit number (e.g 1234).

9.2. Although, in principle, CA should use this protocol, there are exceptions to this rule. CAs may allow FBOs to retain an approval code that had been allocated by another CA, where an establishment is passed from FSS to the LA or vice versa. This would avoid the need for businesses to change their packaging, labeling etc., thereby avoiding any potential cost implications. However, the Competent Authorities are advised to consider phasing these out over a period of six months, by which time such businesses should have used up all existing stocks of pre-printed labeling materials.

9.3. This would require the approval document to indicate:

- the new approval number for the establishment;
- the old approval number that can continue to be used for a fixed period;
- clarification that only one approval number can be used at a time and, hence, once the new number is used, use of the old number MUST be discontinued.

9.4. 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 premises, that establishment would have to be given a new approval number, unless they apply to the CA to retain the approval number when moving to a new establishment in the same LA area. More details in section 10.5 below. A further exception is under specific unforeseen circumstances such as changes to LA boundaries or force majeure.

Approval number - Change of Ownership

9.5. Where a premises has been re-assessed for approval due to a change of ownership of the premises and approval is granted, generally a new approval number should be given. However, to have regard to issues of risk, cost and proportionality, the approval number may not need to be changed where, other than for the change of FBO, the operations are to remain essentially the same, i.e. the type of food production and the food safety control arrangements will remain essentially the same.

Approval number - Co-located establishments

9.6. For new co-located establishments subject to dual enforcement by FSS and the LA, in order to avoid the allocation of dual approval numbers, FSS should issue the approval relevant to all the operations. 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.

Moving premises within the same CA area – retaining approval numbers

9.7. If an FBO of an approved establishment moves from their existing premises to a new one, the CA may allow the FBO to retain the same approval number which was provided to them for the establishment which they are vacating.

9.8. The FBO must apply for approval at the new establishment. The operation at the new premises will be subject to a new approval including application for approval, a site visit and assessment of compliance with the requirements of the legislation.

9.9. The FBO must have been granted approval prior to operations commencing in the new location. Where this move is within the same Authority boundary, the LA may allow the FBO to retain its existing approval number. For FSS approved establishments, Scotland is considered one area.

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

9.11. In addition to the above, re-allocation of an approval number would only be permissible where the FBO of the business remains the same, and the activities remain substantially the same, when the establishment moves to a new location.

9.12. If an FBO of an approved establishment moves to another CA's area, the approval number cannot be retained.

10. ID MARKING

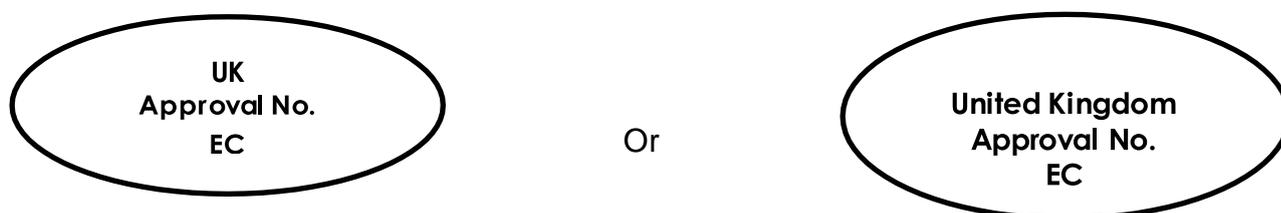
10.1. Article 5 of Regulation (EC) 853/2004 requires that products of animal origin handled in establishments subject to approval are not placed on the market unless they bear an identification mark (ID) or health mark (health marks do not apply to LA-enforced establishments), in accordance with Regulation (EU) 2017/625 and Commission Implementing Regulation (EU) 2019/627. Annex II, Section I B of Regulation (EC) 853/2004 requires that the mark must indicate the approval number of the establishment.

10.2. 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) 853/2004. Competent authorities 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) 853/2004. (see Practice Guidance, Section 5, Chapter 5.1 for example of identification marks)

10.3. 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 Regulation (EC) 1234/2007 on marketing standards for eggs and poultry meat. However an LA approval number should still be allocated and, some FBOs may choose to use that approval number on commercial documentation.

10.4. The requirements for the form of the ID mark are as follows:

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



Requests for flexibility in the use of approval numbers

10.5. There may be occasions where FBOs ask the Competent Authorities to permit products to bear an approval number other than the one relating to the establishment where the product was manufactured or handled.

10.6. It is the position of FSS that the practice of allowing POAO to bear an identification mark 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'.

10.7. The Recitals to Regulation (EC) 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’.

10.8. 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).

10.9. If an FBO approaches a CA for consideration of extreme circumstances, such a decision **can be only** made through the FSS single contact point, enforcement@fss.scot. The CA 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;
- any additional supervision arrangements needed to be made as products produced or handled during the period of alternative arrangements should be for the UK market only.

Published lists of Approved Establishments

10.10. FSS maintain up to date lists of all Scottish approved establishments at. [These lists](#) are updated on a monthly basis.

10.11. The UK (as a Member State) is required to maintain a [central list](#) of all approved establishments within the UK.

10.12. The European Commission maintains a record of all [EC approved establishments](#). A list of all [3rd country approvals](#) is also available.

11. SPECIFIC CLASSES/TYPES OF APPROVED ESTABLISHMENTS

Cold stores (see also 6.12)

11.1. EU guidance advises that cold stores require approval in so far as they are used in relation to activities for which Annex III of Regulation (EC) 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 in Regulation (EC)853/2004. This means that unless they are exempt, stand-alone cold stores used for the storage of POAO must be approved.

11.2. Cold stores which are not engaged in any form of retail activity to the final consumer themselves should not be considered as exempt under a retail exemption as wholesalers. Guidance from the EU Commission states: In the context of food hygiene, retail [as defined in regulation (EC) 178/2002] should generally have a more limited meaning as follows: 'activities involving direct sale or supply of food of animal origin to the final consumer'. The activity of selling POAO to other establishments (approved establishments, retail establishments, catering establishments) means that the FBOs which do this are not limited to storage and transport. Activities limited to storage or transport refer to cold storage by an FBO of their own products.

11.3. POAO should be handled in approved establishments up to the point it reaches a genuine retail establishment with supply to the final consumer, or a point at which an exemption applies (e.g. no specific temperature requirements, composite products see below).

11.4. Unless any of the exemptions from approval are applicable, cold stores engaged in the following activities would need approval under Regulation 853/2004, rather than registration under Regulation 852/2004:

- Cold stores engaged in the storage of raw POAO which has been brought in from other establishments for the supply to a further establishment;
- Cold stores engaged in the storage of processed, or partly processed "intermediate" POAO brought in from other establishments to be supplied to other establishments for use as an ingredient in other products;
- Cold stores which store finished POAO but which sell to retail or to other food businesses but not as part of a logistical distribution chain.

11.5. The Registration of a cold store (Article 6 of Regulation (EC) 852/2004) is required if that cold store is exempt from approval. Stand-alone cold stores supplying the final consumer exclusively (i.e. retail) or supplying the final consumer and, on a 'marginal, localised and restricted' basis, other retail establishments (including caterers) are exempt from approval.

11.6. 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.

11.7. 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

(Regulation (EC) 853/2004, Annex II, Section I, A, 2). Therefore cold stores that only keep product for storage purposes need not apply their ID mark onto the product. The FBO could consider including their ID mark on paperwork associated with POAO that they supply to other establishments to assist traceability and in this case, the ID mark should be in the appropriate format (see 11.3).

11.8. If a cold store intends to undertake re-wrapping (see 12.2), then it must be additionally approved as a re-wrapping centre and apply its own ID mark to any POAO it rewraps and/or repacks. Cold stores that do not have additional approval as a re-wrapping centre must not undertake re-wrapping of damaged products. Under no circumstances can the manufacturer's identification mark be applied. If products are found to be damaged upon delivery or during handling, they should either be returned to the manufacturer or disposed of as food waste as per Chapter VI of Regulation (EC) 852/2004. Where cold stores wish to operate with a view to carrying out additional activities which are subject to approval (for example re-wrapping) or are registered but wish to be able to carry out activities subject to approval part of the time, they should discuss an application for approval with the CA.

11.9. Approved establishments, that are approved for other commodities or processes but which as part of their operations receive and supply other relevant POAO without directly handling it (i.e. cold store operations) must explicitly be approved as a cold store on the approval documentation.

Rewrapping and repackaging establishments

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

11.11. Re-wrapping establishments unwrap POAO that were wrapped in another establishment, and further handle them before rewrapping them. Since rewrapping establishments handle exposed POAO that are covered by Annex III of Regulation (EC) 853/2004, they fall within the scope of Article 4, paragraph 2 of the Regulation. Approval is therefore required.

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

11.13. In order to ensure traceability, an identification mark must be applied before POAO leaves the establishment of production. However, when the product's packaging and/or wrapping is removed or it is further processed in another establishment, a new mark must be applied to the product. In such cases, the new mark must indicate the approval number of the establishment where these consequent operations take place.

11.14. Establishments limited to re-packaging of foods, without re-wrapping activity should have their approval restricted to re-packaging only.

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

Wholesale Markets

11.15. Wholesale markets must be approved in relation to the common parts, and the separate units within the market must be approved separately. For clarity, the wholesale market should be

allocated an approval number and the individual units have the same number combined with a suffix. 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.

11.16. Responsibility for complying with the Hygiene Regulations 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.

11.17. Where the approval of the market is withdrawn, suspended or surrendered, it will be necessary to consider the approval of the individual units that rely on common areas under the market's approval.

Multiple FBOs in one premises

11.18. Where more than one FBO intends to use a single premises 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 must be assessed on a case by case basis. In this case both the FBOs will require separate approvals.

11.19. 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 including traceability. When undertaking the assessment, the CA must satisfy themselves that infrastructure, equipment and the FBO/s 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 documents as a precondition to the approval.

11.20. Where this is achieved, approval or conditional approval will be granted to each FBO individually with each FBO receiving their own approval number.

11.21. In the event that the CA, 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.

11.22. Where different FBOs are approved by the LA and FSS, it will be necessary to ensure cooperation and sharing of relevant information.

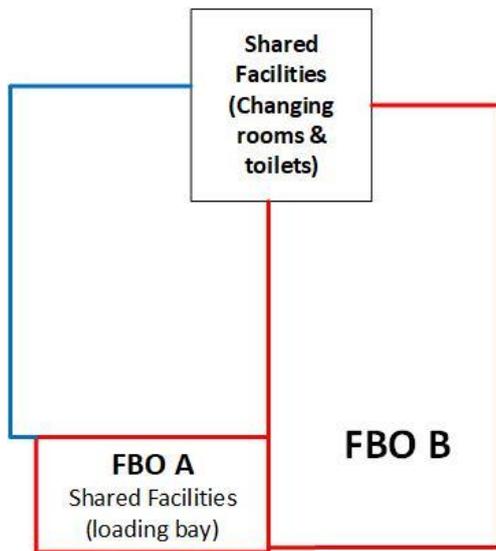
Shared Facilities

11.23. 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 must be treated on a case by case basis but examples would include sharing facilities such as changing rooms, toilets, loading bays and chiller capacity.

11.24. The FBO requiring approval using shared facilities will need to demonstrate how food safety risks are managed. When undertaking the assessment, the CA 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. Where different FBOs are approved by the LA and FSS, it will be necessary to ensure cooperation

and sharing of relevant information.

11.25. An example site plan identifying the shared facilities:



Co-located Approval Activities establishments

11.26. Where an approved meat establishment subject to veterinary control is also handling other POAO, FSS in discussion with the relevant LA will consider approving all operations requiring approval under Regulation (EC) 853/2004 that are co-located.

Co-located 852/2004 Activities within FSS Approved Establishment

11.27. For FSS approved establishments also undertaking operations that fall within Regulation (EC) 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.

11.28. The LA must reach agreement with the FSS Approving Officer as to the split of enforcement responsibilities and refer to this in their approval recommendation for inclusion in the approval document.

11.29. The term 'co-located establishments' should only be applied to establishments that require approval under 853/2004 within a common curtilage, e.g. a slaughterhouse and processing plant. Any business subject only to the requirements of Regulation (EC) 852/2004 fall to the LA e.g. a retail butcher's shop attached to a slaughterhouse and where the establishment is also handling non-POAOs.

12. CHANGES TO AN APPROVAL

General requirements

12.1. FBOs are required to notify the relevant CA of any significant changes in activities in existing establishments under Regulation (EC) 852/2004, Article 6.2. FBOs should be reminded of this during all programmed interventions. The CA should also include this in approval documentation and/or correspondence with FBOs so that the FBOs' obligations are clear.

12.2. Where the FBO notifies the CA of such changes, officers need to consider whether a visit should be made to inspect the alterations and whether an amended HACCP based food safety management system is required. This will depend on the extent of the changes, such as:

- Proposed additional activities and changes to activities;
- Change to approved curtilage/re-structuring;
- Change of ownership;
- Change of name;
- Closure of an approved establishment;
- Surrender of approval.

Additional activities

12.3. If a FBO, of an approved establishment wishes to undertake additional approvable activities, the FBO must apply to the relevant CA for approval before commencing the operation of that additional activity.

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

12.5. Depending upon the circumstances, it may be necessary to issue conditional approval in relation to additional activities. This will be the case where new risks not adequately controlled by the existing food safety management procedures are introduced.

12.6. Where an additional activity requires conditional approval, the conditional approval relates specifically to this activity. The existing full approval continues to apply to the other activities. In effect, the establishment has two concurrent approvals, albeit with one approval number.

12.7. A revised approval document will need to be issued to reflect changes in the approval. Once the additional activity is assessed as being appropriate for full approval, a single revised approval document should be issued for all the relevant activities at the establishment.

12.8. For LA approvals, once a determination has been made to alter an approval in relation to additional activities has been made by the CA, information regarding this must be communicated to the FSS Enforcement Delivery Branch enforcement@fss.scot.

12.9. When considering the approval of an additional activity, the CA should give consideration to wider compliance issues within the establishment and the compliance history of the establishment. This does not preclude additional activities being approved, where non-compliance is minor or is of limited relevance to the additional activity.

12.10. For FSS approved establishment's, if the most recent audit has the outcome 'Improvement Necessary' or 'Urgent Improvement Necessary' FSS will not consider any applications for further

activities or species until such time as the FBO has demonstrated sufficient improvement to exit the Improvement Necessary or Urgent Improvement Necessary status during a subsequent audit.

Change to approved curtilage / restructuring

12.11. A notification to the CA of significant curtilage changes and/or restructuring to the approved establishment will require the FBO to provide revised plans indicating those changes. An 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.

12.12. Once acknowledged by the CA, 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.

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

Change of food business operator

12.13. A food business establishment is defined as a unit of a food business. In this regard, it is distinctly different to a premises – which relates to the physical structure. In relation to approval, it should be considered to consist of a combination of the food business operator, the premises and the activity being conducted. Therefore, an approved establishment cannot change hands, as the new owner operating at the premises creates a new establishment and the previous establishment ceases to exist.

12.14. If a premises used for an approved establishment changes ownership, the new establishment will have to be assessed and granted a new approval before it can operate. Carrying out activities which require approval in an establishment which is not approved is an offence.

12.15. On change of FBO, the premises may continue to operate under the approval for the previous FBO for a short period of time, but not exceeding a maximum of **25 working days** after the change of FBO, until an approval determination is carried out by the CA.

12.16. This provision is on condition that:

- a) The new FBO submits an application for a new approval that is received by the CA within one calendar week of the change of FBO. If no application is received within one week, the CA will formally notify the FBO that the approval is no longer in force and all approvable activity must cease with immediate effect. In relation to FSS approvals, FSS will inform the LA and request appropriate checks to ensure that the premises has stopped carrying out any activity subject to approval; and
- b) In order to safeguard public health, the new FBO must not change the operation at the premises in any significant way until a new approval is given, e.g. the new FBO must not change the nature of products produced / handled, and the HACCP based controls.

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

12.18. The CA may, on request by the FBO, carry out a pre change of FBO advisory visit, (see 8.5). However, any views given at such a visit will in no way provide a guarantee as to the future approval status of the business.

12.19. Article 6(2) of Regulation (EC) 852/2004 requires the FBO to inform the CA when there is a change of FBO. This will be by means of an application form (see 7.5), 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 CA informed about significant changes to those details.

12.20. The key issue in determining whether a change requires a new approval 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.

12.21. Table 3 outlines the different situations where a change in FBO, between different business entities, requires a new approval or where the approval can be retained are detailed below.

Table 3 Situations where a change in FBO, between different business entities, requires a new approval or where the approval can be retained are detailed below.

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

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.

12.22. Once an application is received, the CA 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 (see 10.1).

12.23. Information that requires to be submitted to FSS Enforcement Delivery Branch enforcement@fss.scot includes:

- Details of the previously approved establishment that has expired;
- Details of the application;
- Decision to issue approval or conditional approval; or
- Refusal.

12.24. A copy of the relevant documentation provided to the FBO should be supplied to FSS at enforcement@fss.scot.

12.25. The FBO will not be able to undertake activities that require approval until approval or conditional approval is granted.

12.26. Where the CA becomes aware of a change of FBO that continues placing food on the market without seeking a new approval after the change of operator, the action regarding withdraw/recall of such food should be risk-based and proportionate. Advice should be sought from the FSS Scottish Food Crime and Incidents Unit incidents@fss.scot. However, food not yet placed on the market should be detained until the new FBO has been able to gain approval.

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

- The overall approval for the market (common parts) will be treated in the same way as an individual premises ownership change. Therefore, the change in FBO would necessitate a re-approval and there might be a need for a new approval number to be granted for the wholesale market. The individual units within the market do not need to be individually re-approved, however if the markets approval number is changed, the units can be re-allocated a new corresponding number using the new market approval number (for common areas of the market). The impact on the individual units should be considered before changing their approval numbers.
- In the event that the common parts of a wholesale market are not granted approval, the individually approved units are not able to operate as the approval of the common parts facilities is a prerequisite to their approval. Where the units are able to become self-sufficient in their own right, separate approval as an individual establishment can be sought.
- If an individual unit of a wholesale market changes ownership, this will be treated in the same way as an individual premises ownership change.

Change of trading name

12.28. 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. A copy of the relevant documentation provided to the FBO should be supplied to FSS at enforcement@fss.scot.

12.29. For FSS approved establishments, any change to the trading name must be submitted by email to Approvals@fss.scot or by post to Approvals Team, Pilgrim House, Aberdeen AB11 5RL. This should be made by the owner of the business or at least by one director of the Company.

NB. This is not to be confused with a change of ownership, which would warrant a re-assessment for approval. 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

12.30. Where an establishment has a break in operation or closure, the FBO is obliged to keep the CA informed (Article 6 (2) of Regulation (EC) 852/2004). 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 CA 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 operations the CA 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 [Regulation (EC) 852/2004 Article 6] the CA informed regarding these significant changes to the operational pattern. In these cases the FBO must notify the CA at least two weeks before operations re-commence.

- **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 CA informed about this significant change to the operational pattern and must notify the CA at least two weeks before operations re-commence [Regulation (EC) 852/2004 Article 6]. The CA may consider suspending the approval of the establishment during the closure.

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

12.31. During non-operational periods official controls undertaken by the CA should be partially suspended, with the exception of ad hoc controls.

12.32. Following a period of closure the FBO must not start operations until the CA has been notified and undertaken a pre-opening visit. This visit is to assess that the establishment meets all structural and equipment requirements and other relevant requirements of food law, including the existence of a food safety management system based on HACCP principles.

12.33. The FBOs food safety management system must be available at the visit but as the establishment will not be operational, it will not be possible to assess how effectively this works in practice. The effectiveness of the FBO's food safety management system will therefore be assessed at the first scheduled visit undertaken by the CA.

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

- Where the pre-opening assessment results in the CA being confident that the requirements of food law are met, the FBO will be notified that operations at the establishment can re-commence;
- Where the pre-opening assessment identifies serious deficiencies in meeting the requirements of food law, the FBO may provide the CA with guarantees on how the deficiencies will be resolved on a permanent basis and within a reasonable time;
- 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. (See 14.1)

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

12.36. In the event that the CA is not content for operations to re-commence, the FBO will be notified of the deficiencies and appropriate enforcement action will be taken until the deficiencies are resolved on a permanent basis or a formal review of approval has been undertaken.

12.37. Where the CA becomes aware of an establishment that has re-commenced operations without first notifying them 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 CA's action regarding withdraw/recall of food will be risk-based and proportionate. Advice should be sought from the FSS Scottish Food Crime and Incidents Unit incidents@fss.scot. However, food not yet placed on the market can be detained under Regulation 9 of the Food Hygiene (Scotland) Regulations 2006 until the FBO has been notified that operations

can recommence;

If on further investigation and examination, the CA deems the food has not been produced in accordance with the Hygiene Regulations, they can certify the food as such using Regulation 27 of the Food Hygiene (Scotland) Regulations 2006.

Surrender of approval

12.38. Where the FBO of an establishment under their control, holding an approval granted by the CA, wishes to surrender that approval, the FBO is required to provide formal notice under Article 6(2) of Regulation (EC) 852/2004.

12.39. Once acknowledged by the CA, the approval will cease to exist and the use of the approval number will also come to an end.

12.40. For LA approved establishments, the CA must notify the FSS Enforcement Delivery Branch accordingly (enforcement@fss.scot). Upon notification by the CA of the surrender, the establishment will be removed from the official list of approved establishments maintained by the FSS.

12.41. For FSS approved establishments, the surrender of approval is formally acknowledged. In cases of slaughterhouse approvals, arrangements will be made to secure official health mark stamps accordingly. The establishment will be removed from the official list of approved establishments published by FSS.

12.42. It would be an offence to resume activities subject to Regulation (EC) 852/2004 or Regulation (EC) 853/2004 at the establishment, before the FBO is granted approval or conditional approval or registered as appropriate by the relevant CA.

12.43. Following the surrender, the FBO should be advised that it would be an offence to apply the ID Mark on any food or to resume activities for which approval is required without being reassessed for and granted a new approval.

Establishments no longer engaged in Approvable Activity

12.44. Only establishments engaged in (or with the intent to engage in) the supply of relevant POAO to other food business establishments can be approved. Where the nature of a food business changes so that approval is no longer relevant, the FBO should be requested to surrender the approval (see 13.7). Where the FBO fails to do so, the CA should write to the FBO to inform them that because the nature of the business no longer meets the requirement for approval has ceased to have any validity, has been removed from the official list and that the ID mark can no longer be applied to products.

12.45. Where an approved establishment's operations have been reduced in scope, or due to changes in approvals policy, are within scope of the retail to retail exemptions from approval. The establishment can be considered exempt from approval. In such circumstances the CA will consider on a case by case basis.

12.46. FBOs are required to inform the CA of any changes to operational activity. Where operations on an approved activity become inactive and the FBO wishes to retain approval they will be required to maintain a validated HACCP-based FSMS on the activity at all time during any non-operational period and it will be subject to Ad hoc Official Controls. This would apply for a

period of up to 12 months.

12.47. Exceeding the 12 months period, where operations do not commence and the FBO still wishes to retain the approval for the activity, the FBO will notify the CA to “suspend approval for the activity”. The FBO will also be required to inform the CA of intentions to commence to allow the activity to be re-assessed to confirm suitable controls are in place.

Transfer of official controls from FSS to LA

12.48. Where the FBO holding an approval granted by FSS 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 FSS will notify the relevant LA accordingly. As FSS had already approved the standalone activity, the LA may not have to undertake a separate re-approval.

12.49. LAs may allow FBOs to retain an approval code that had been allocated by FSS, where an establishment is passed from FSS to the LA and vice versa. This would avoid the need for businesses to change their packaging, labelling etc., thereby avoiding any potential cost implications. However, the competent authorities are advised to consider phasing these out over a period of six months, by which time such businesses should have used up all existing stocks of pre-printed labelling materials. This is provided that it is satisfied that the establishment can continue to meet all the requirements of the Regulations, and that the establishment’s food safety management system is adequate to cover the stand alone activity or activities subject to approval.

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

- deciding to limit their activities to meet the exemption criteria and surrendering the approval granted by FSS; or
- losing their right to operate through withdrawal or suspension or refusal of approval but deciding to limit their activities to meet the exemption criteria.

12.51. The establishment will remain subject to the requirements of Regulation (EC) 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 FSS approved establishments.

Transfer of official controls from LA to FSS

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

- A registered FBO operating within the limits of an exemption, who wishes to expand e.g. a retail butcher wishing to supply over 2 tonnes per week to other retail/catering establishments;
- An approved establishment under LA jurisdiction (e.g. meat preparations), who also wishes to cut and sell fresh meat, where this product is not a consequential activity, to other establishments.

12.53. In both scenarios, the LA should contact FSS approvals team to arrange a joint visit. If the FBO is already operating in a way that requires FSS approval, any enforcement action remains

the responsibility of the LA, until approval has been granted. In the second scenario, transfer of responsibility for enforcement of all approved activity co-located with cutting and/or slaughter to FSS will normally be transferred to FSS, but may, with agreement of both parties, be considered on a case-by case basis. All such cases should be referred to FSS for consideration to Approvals@fss.scot

13. ENFORCEMENT

Review with a view to suspension or withdrawal of an approval

13.1. Article 148(5) of Regulation (EU) 2017/625 requires the competent authority (CA) to keep the approval of establishments under review when carrying out official controls. If the CA identifies serious deficiencies or has to stop production at an establishment repeatedly and the feed or food business operator is not able to provide adequate guarantees regarding future production, the CA shall initiate procedures to withdraw the establishment's approval, in accordance with Article 138(2)(j) of Regulation (EU) 2017/625. However, the CA may suspend an establishment's approval if the feed or food business operator can guarantee that it will resolve deficiencies within a reasonable time.

13.2. An interpretation of the term serious deficiency that provides the basis for withdrawal of approval has not been specified in the regulations. For consistency of approach, a working definition has been developed by FSS detailed below:

13.3. General indicator of serious deficiency and/or actual or potential risk to public health;

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

Structure

- Major structural deficiency
- Poor maintenance preventing effective cleaning

Contamination

- Contamination of products
- Failure to control contamination from any source
- Visibly contaminated product without action from FBO
- Inadequate separation between products of different risk categories

Temperature control

- Inadequate temperature control

Pest control

- Serious rodent or insect infestation

Water

- Inadequate supply of potable water

Food safety management system

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

13.4. In the case of a wholesale market, Article 138(2)(j) of Regulation (EU) 2017/625 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.

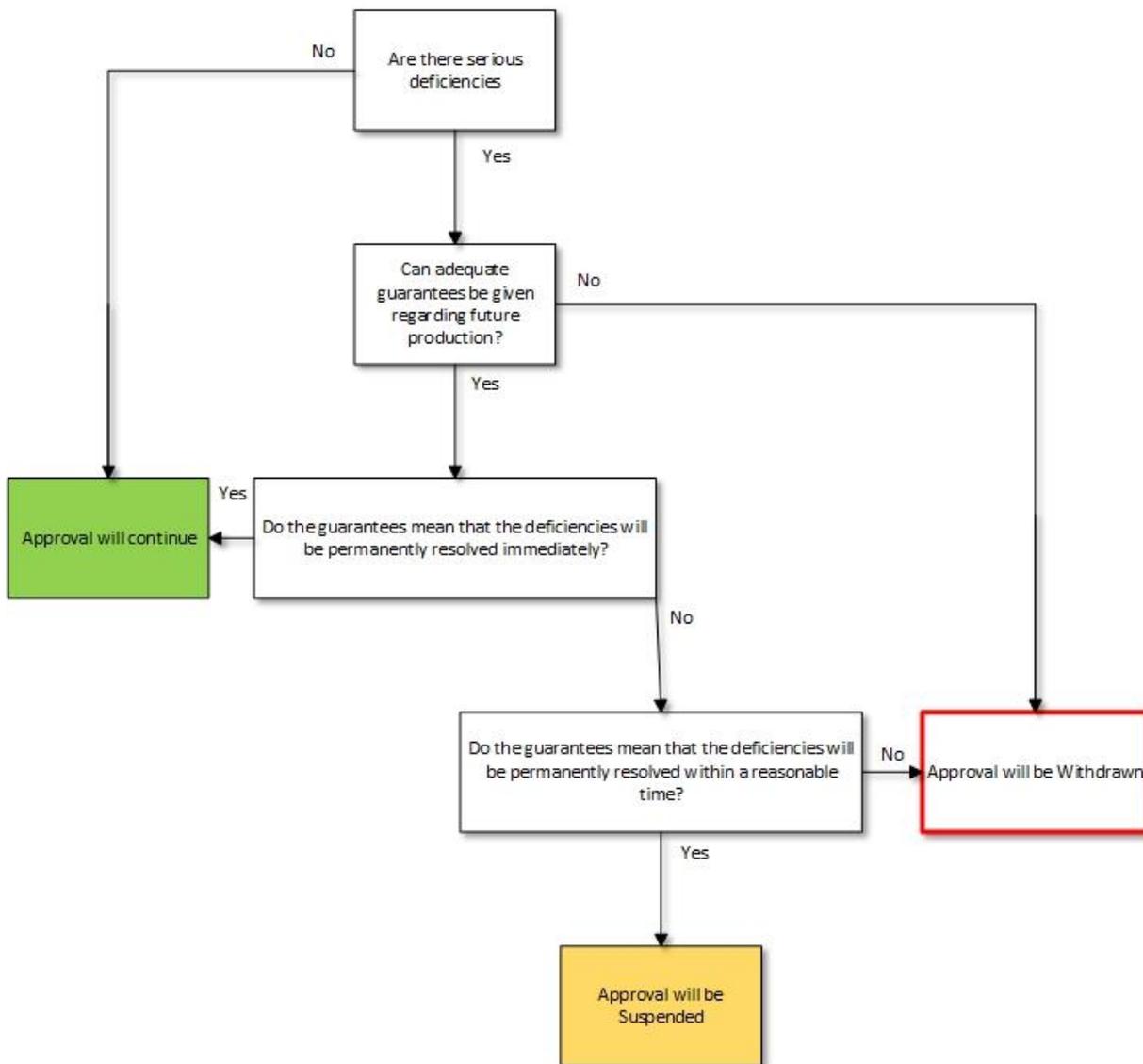
13.5. Review of approval may be triggered as a result of carrying out routine official controls (compliance and enforcement) or as a result of local intelligence for example where the establishment has been non-operational (long-term), major curtilage change/rebuild or acts of God (e.g. flooding) and/or where there is a strong likelihood that serious deficiencies will have developed.

Note: - the CA should monitor establishments which have ceased operating and not informed them of their future plans. If the FBO does not confirm the surrender of their approval in writing **within six months** of the establishment ceasing operations then the CA should write to the FBO to confirm their approval no longer has effect and the establishment will be removed from the published list of approved establishments.

13.6. Where the preliminary evidence suggests that there may be serious deficiencies the officer should:

- Carry out an unannounced inspection of the establishment when production is taking place (this will not be possible where the establishment is not operating due to enforcement action or where the operator has voluntarily ceased to operate); and
- Undertake an assessment of the FBO's history of compliance with regulatory requirements at the approved establishment, the relevant history of enforcement and any reports to the Procurator Fiscal involving the FBO.

13.7. Where the officer undertaking the review decides serious deficiency exists, the following process should be followed.



13.8. The provisional decision to review the approval must be communicated in writing to the FBO. The FBO must provide the CA (within 14 calendar days from the date of letter) with any guarantees that it will resolve the deficiencies within a reasonable time.

13.9. 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 CA 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 CA accepts that the guarantees mean that the serious deficiencies will be permanently resolved within a reasonable time and the situation will be such that, once the serious deficiencies have been resolved, there will be no foreseeable future deficiencies serious enough to warrant stoppages of production, the approval will be suspended.
- Where the FBO does not provide guarantees approval will be withdrawn.

13.10. Suspension of approval will be lifted in writing by the CA, once the serious deficiencies are permanently resolved and the situation is such that there will be no foreseeable cause for future stoppages of production. If this has not been undertaken within a reasonable time the approval will be withdrawn.

13.11. The FBO has the right to appeal to the Sheriff Court against the decision to withdraw or suspend an approval or conditional approval. Rights of appeal are governed by the Official Feed and Food Controls (Scotland) Regulations 2009 (as amended). From the date on which the notice of the decision is served on the relevant person the establishment cannot continue operating whilst the appeal is being determined. Model forms for the suspension and withdrawal of approvals can be found in Food Law Practice Guidance (Scotland).

Transfer of establishment to LA following refusal, suspension, or withdrawal by FSS

13.12. There will be occasions when FSS decides to refuse, suspend or withdraw approval of an establishment under Regulation (EC) 853/2004 or identifies establishments undertaking activities for which approval from FSS is required but, has not been granted. Although FSS is the CA responsible for the approval of certain categories of establishments, where approval is refused, suspended or withdrawn, or activities are carried out without the necessary approval, enforcement responsibility immediately falls to the relevant LA. The Food Law Code of Practice (Scotland) 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.

13.13. In cases concerning refusal, suspension or withdrawal of approval, FSS 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's approval was being considered:

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

13.14. Following the notification of refusal, suspension or withdrawal by FSS, 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 operations to meet the exemption criteria, and operates under Regulation (EC) 852/2004. LAs are requested to arrange a visit to such establishments as soon as possible to confirm that the establishment has indeed stopped carrying out any activity or activities that require approval under Regulation 853/2004, or that their current operation is restricted to only meet the requirement of an exempt activity (by nature or scale). LAs should consider organising a joint visit with FSS staff where appropriate to facilitate an effective transfer. LAs should continue to monitor such establishments to ensure on-going compliance with the exemption criteria.

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

- all products that have been produced without approval on the premises could be certified

using Regulation 27 of the Food Hygiene (Scotland) Regulations 2006 as not being produced, processed or distributed in accordance with the Regulations. Food certified in this way is then treated for the purposes of Section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements and should be dealt with accordingly;

- serve a Remedial Action Notice under Regulation 9 of the Food Hygiene (Scotland) Regulations 2006;
- Consideration should also be given to reporting this as an incident to the FSS Scottish Food Crime and Incidents Unit (incidents@fss.scot), for example where there is a serious hazard or wide distribution of food.

13.16. If the FBO still continues to carry out activities that require approval without approval, after the LA has taken action detailed above, the FBO will be guilty of an offence and could be reported to the Procurator Fiscal. Irrespective of the above enforcement actions, the operator has one month to appeal against FSS's decision to refuse, withdraw or suspend its approval from the date that decision is made.

13.17. If the operator wishes to submit a new application for approval, it should be made clear that until such an approval is granted, the establishment cannot carry out the activity requiring approval above the exemption threshold.

Establishments subject to approval operating without approval

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

N.B. LAs can consider the use of RANs for establishments which are subject to approval, but which are not yet approved. Regulation 9 of the Food Hygiene (Scotland) Regulations 2006 states that RANs can be served in respect of an establishment that Article 4(2) of Regulation (EC) 853/2004 requires to be approved.

14. DEFINITION AND GLOSSARY

Animal by-products	Parts of animal which are not intended for human consumption.
Assurance Schemes	Voluntary systems which verify, through regular independent inspections, that farmers and growers are meeting certain stated standards of production. The scope of assured food schemes covers both primary production and processes covering the rest of the food chain as far as retail sale. Production standards are set by the assurance scheme and vary across different schemes, generally covering foodsafety and traceability, animal welfare and environmental protection. Members of a particular scheme can use the scheme's logo on their produce, and/or use a specific claim, to advertise to consumers that the product has been produced to these standards.
Audit	A systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
Authorised Officer (AO)	In relation to an enforcement authority, any person (whether or not an officer of the Authority) who is authorised by the CA in writing, either generally or specifically, to act in matters arising under the Food Hygiene (Scotland) Regulations 2006.
Cold Store	A wholesale establishment used for the storage under temperature controlled conditions of POAO intended for sale for human consumption.
Collection Centre	An establishment where raw milk is collected and where it may be cooled and filtered; or an establishment where edible co-products are collected and stored prior to being dispatched to a gelatin or collagen production establishment.
CA (CA)	The central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country.
Composite Products	This is the term generally used for food containing both products of plant origin and processed products of animal origin as indicated in Article 1.2 of Regulation (EC) 853/2004.

Desinewed Meat	Also known as mechanically desinewed meat, Baader meat, 3mm meat.
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.
EC	European Commission
Edible Co-products	<p>Parts of animals that are unsuitable for human consumption but which can later be processed for use in human food, e.g. hides and skins processed into gelatine and collagen, sheep intestines processed into sausage casings, and stomach (omental) fat processed into lard.</p> <p>In order to be considered as an edible co-product, the product should not have been at any stage considered or handled as Animal By-product and must have been handled and stored in accordance with the Hygiene Regulations. Edible co-products must be handled in accordance with the food hygiene legislation at all stages of their production. At no point should they come into contact with or be categorised as animal by-product. If this happens they should immediately be removed from the human food chain and down-graded to animal by-product.</p>
Establishment (Also refer to definition of a 'Premises')	<p>Any unit of a food business</p> <p>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).</p>
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 or Foodstuff	Means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.
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)	<p>Means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control’.</p> <p>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).</p> <p>A ‘legal person’ has a legal name and has rights, protections, privileges, responsibilities, and liabilities under law, just as natural persons (humans) do. Legal personality allows one or more natural persons to act as a single entity (a composite person - considered under law separately from its individual members or shareholders) for legal purposes. E.g. A Limited Company is considered a ‘legal person’.</p>
Food law	Means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals.
FSS	Food Standards Scotland
FSMS	Food Safety Management System
Greaves	The protein-containing residue of rendering, after partial separation.
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 Article 18(2)(a), (b) and (c) of Regulation (EU) 2017/625.
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 any aspect of food, in order to verify that such aspect(s) comply with the legal requirements of food law.
LA	Local Authority
Lagomorphs	Rabbits, hares and (edible) rodents.

LBM s	Live bivalve molluscs
Meat	Edible parts of the following animals, including blood: <ul style="list-style-type: none"> • 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 raticities and farmed land mammals
Meat preparations	Fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasoning or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat.
Meat products	Processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat.
Mechanically separated meat (or MSM)	The product obtained by removing meat from flesh-bearing bones after boning or from poultry carcasses, using mechanical means resulting in the loss or modification of the muscle fibre structure.
Minced meat	Boned meat that has been minced into fragments and contains less than 1% salt.
Official controls	Any form of control that the CA 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.
POAO	Product of animal origin means: <ul style="list-style-type: none"> • 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 <i>amongst other things</i> : <ul style="list-style-type: none"> • Products of plant origin: grains, fruits, vegetables, herbs etc. • Products of animal origin: eggs, raw milk, honey, fishery products, LBMs • 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
Retail	'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.
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.
RTE	Ready to eat
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, thawed, frozen etc.
Wholesale market	A food business that includes several separate units which share common installations and sections where foodstuffs are sold to food business operator.
Wrapping	Placing of foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself.