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GUIDANCE NOTE

**Guidance on the approval of
food establishments**

Guidance on the approval of food establishments

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Abbreviations

CCP	critical control point
DAFM	Department of Agriculture, Food and the Marine
EU	European Union
FBO	food business operator
FSAI	Food Safety Authority of Ireland
FSMS	food safety management system
GHP	good hygiene practices
HACCP	Hazard Analysis Critical Control Point
HSE	Health Service Executive
ISO	International Organization for Standardization
LA	local authority
MLR	marginal, localised and restricted
MSM	mechanically separated meat
OCR	Official Controls Regulation (Regulation (EU) 2017/625)
PRP	prerequisite programme
SFPA	Sea-Fisheries Protection Authority

Glossary

Term	Text
audit	<i>A systematic and independent examination to determine whether activities and the related results of such activities comply with planned arrangements and whether these arrangements are applied effectively and are suitable to achieve the objectives (Regulation (EU) 2017/625)</i>
collagen	<i>The protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with</i>

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	<i>the relevant requirements of this Regulation (Regulation (EC) No 853/2004)</i>
colostrum	<i>The fluid secreted by the mammary glands of milk-producing animals up to three to five days post parturition that is rich in antibodies and minerals and precedes the production of raw milk (Regulation (EC) No 853/2004)</i>
colostrum-based products	<i>Processed products resulting from the processing of colostrum or from the further processing of such processed products (Regulation (EC) No 853/2004)</i>
composite product	<i>Food containing both products of plant origin and processed products of animal origin (Regulation (EU) 2022/2292)</i>
competent authority	<i>The central authorities of a Member State responsible for the organisation of official controls and of other official activities, in accordance with this Regulation and the rules referred to in Article 1(2); Any other authority to which that responsibility has been conferred; Where appropriate, the corresponding authorities of a third country (Regulation (EU) 2017/625)</i>
cutting plant	<i>An establishment used for boning and/or cutting up meat (Regulation (EC) No 853/2004)</i>
dispatch centre	<i>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 (Regulation (EC) No 853/2004)</i>
eggs	<i>Eggs in shell – other than broken, incubated or cooked eggs – that are produced by farmed birds and are fit for direct human consumption or for the preparation of egg products (Regulation (EC) No 853/2004)</i>
establishment	<i>Any unit of a food business (Regulation (EC) No 853/2004).</i>
final consumer	<i>The ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity (Regulation (EC) No 178/2002)</i>

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fishery products	<i>All seawater or freshwater animals (except for live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, and all mammals, reptiles and frogs) whether wild or farmed and including all edible forms, parts and products of such animals (Regulation (EC) No 853/2004)</i>
factory vessel	<i>Any vessel on board which fishery products undergo one or more of the following operations followed by wrapping or packaging and, if necessary, chilling or freezing: filleting, slicing, skinning, shelling, shucking, mincing or processing (Regulation (EC) No 853/2004)</i>
freezer vessel	<i>Any vessel on board which freezing of fishery products is carried out, where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins and, where necessary, followed by wrapping or packaging (Regulation (EC) No 853/2004)</i>
fresh fishery products	<i>Unprocessed fishery products, whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, that have not undergone any treatment to ensure preservation other than chilling (Regulation (EC) No 853/2004)</i>
food	<i>Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans (Regulation (EC) No 178/2002)</i>
food business	<i>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 (Regulation (EC) No 178/2002)</i>
food business operator (FBO)	<i>The natural or legal person(s) responsible for ensuring that the requirements of food law are met within the food business under their control (Regulation (EC) No 178/2002)</i>
food hygiene	<i>The measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff, taking into account its intended use (Regulation (EC) No 852/2004)</i>

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food law	<i>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 (Regulation (EC) No 178/2002)</i>
food safety	The steps taken to avoid risks to public health arising from food intended for human consumption
food safety management system (FSMS)	Prerequisite programmes, supplemented with control measures at CCP (<i>critical control point</i>), as appropriate, that when taken as a whole, ensure that food is safe and suitable for its intended use. The FSMS is also the combination of control measures and assurance activities. The latter aims at providing evidence that control measures are working properly such as validation and verification, documentation and record keeping (Commission Notice 2022/C 355/01).
fresh meat	<i>Meat that has not undergone any preserving process other than chilling, freezing or quick-freezing, including meat that is vacuum-wrapped or wrapped in a controlled atmosphere (Regulation (EC) No 853/2004)</i>
game-handling establishment	<i>Any establishment in which game and game meat obtained after hunting are prepared for placing on the market (Regulation (EC) No 853/2004)</i>
gelatine	<i>Natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals (Regulation (EC) No 853/2004)</i>
greaves	<i>Protein-containing residue of rendering, after partial separation of fat and water (Regulation (EC) No 853/2004)</i>
health mark	<i>A mark applied after the official controls referred to in points (a) and (c) of Article 18(2) have been performed and which attests that the meat is fit for human consumption (Regulation (EU) 2017/625)</i>

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liquid egg	<i>Unprocessed egg contents after removal of the shell</i> (Regulation (EC) No 853/2004)
marginal, localised and restricted (MLR)	National legislation defines MLR for Ireland. Article 1(5)(b)(ii) of Regulation (EC) No 853/2004 states that the Regulation does not apply to the supply of food of animal origin from a retail establishment to other retail establishments where this activity, in accordance with national law, is an MLR activity.
meat	<i>Edible parts of the animals referred to in points 1.2 to 1.8 (domestic ungulates/poultry/lagomorphs/game), including blood</i> (Regulation (EC) No 853/2004)
meat preparation	<i>Fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings 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</i> (Regulation (EC) No 853/2004). Specific requirements for producing meat preparations are laid down in Annex III, Section V to Regulation (EC) No 853/2004.
meat product	<i>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</i> (Regulation (EC) No 853/2004). Specific requirements for producing meat products are laid down in Annex III, Section VI to Regulation (EC) No 853/2004.
mechanically separated meat (MSM)	<i>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</i> (Regulation (EC) No 853/2004)
mechanically separated fishery product	<i>Any product obtained by removing flesh from fishery products using mechanical means resulting in the loss or</i>

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	<i>modification of the flesh structure (Regulation (EC) No 853/2004)</i>
minced meat	<i>Boned meat that has been minced into fragments and contains less than 1% salt (Regulation (EC) No 853/2004).</i> Specific requirements for producing minced meat are laid down in Annex III, Section V to Regulation (EC) No 853/2004.
official control	<i>Activities performed by the competent authorities, or by the delegated bodies or the natural persons to which certain official control tasks have been delegated in accordance with this Regulation, in order to verify:</i> <i>(a) compliance by the operators with this Regulation and with the rules referred to in Article 1(2); and</i> <i>(b) that animals or goods meet the requirements laid down in the rules referred to in Article 1(2), including for the issuance of an official certificate or official attestation (Regulation (EU) 2017/625)</i>
official veterinarian	<i>A veterinarian appointed by a competent authority, either as staff or otherwise, and appropriately qualified to perform official controls and other official activities in accordance with this Regulation and the relevant rules referred to in Article 1(2) (Regulation (EU) 2017/625)</i>
packaging	<i>The placing of one or more wrapped foodstuffs in a second container, and the latter container itself (Regulation (EC) No 852/2004)</i>
packing centre	<i>An establishment where eggs are graded by quality and weight (Regulation (EC) No 853/2004)</i>
placing on the market	<i>The holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves (Regulation (EC) No 178/2002)</i>
prerequisite programmes (PRPs)	Preventive practices and conditions including all GHP, as well as other practices and procedures such as training and

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	traceability, that establish the basic environmental and operating conditions that set the foundation for implementation of HACCP-based procedures (Commission Notice 2022/C 355/01)
premises	<i>Includes land (including land under water) with or without buildings, an establishment, a vehicle (including a boat, ship, hovercraft, aircraft or off-shore installation (being an offshore installation within the meaning of the Safety, Health and Welfare (Offshore Installations) Act 1987 (No 18 of 1987))), railway wagon, container or other thing used in connection with, or ancillary to, such a thing (S.I. No. 22/2020)</i>
primary products	<i>Products of primary production including products of the soil, of stock farming, of hunting and fishing (Regulation (EC) No 852/2004)</i>
processed products	<i>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 (Regulation (EC) No 852/2004).</i>
processing	<i>Any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes (Regulation (EC) No 852/2004)</i>
products of animal origin	<i>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 (Regulation (EC) No 853/2004)</i>
purification centre	<i>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 (Regulation (EC) No 853/2004)</i>
retail	<i>Handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes</i>

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	<i>distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets (Regulation (EC) No 178/2002)</i>
slaughterhouse	<i>An establishment used for slaughtering and dressing animals, the meat of which is intended for human consumption (Regulation (EC) No 853/2004)</i>
sprouts	<i>The product obtained from the germination of seeds and their development in water or another medium, harvested before the development of true leaves and which is intended to be eaten whole, including the seed (Regulation (EU) No 208/2013)</i>
traceability	<i>The ability to trace and follow a food, or substance intended to be, or expected to be incorporated into a food, through all stages of production, processing and distribution (Regulation (EC) No 178/2002)</i>
unprocessed product	<i>Foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed (Regulation (EC) No 852/2004)</i>
wholesale market	<i>Food business that includes several separate units which share common installations and sections where foodstuffs are sold to food business operators (Regulation (EC) No 853/2004)</i>
wrapping	<i>The placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself (Regulation (EC) No 852/2004)</i>

Introduction

Certain food business operators (FBOs) are required to obtain approval from the competent authority before they commence operating. They also must demonstrate compliance with the relevant requirements of food law to remain approved. This guidance document addresses procedures for competent authorities to follow when approving food businesses.

Regulation (EC) No 853/2004 requires that food establishments handling food of animal origin, for which Annex III to the Regulation lays down specific requirements, must be approved by the competent authority. There are exemptions to this requirement for primary production, transport operations, retail and the storage of foods of animal origin not requiring temperature-controlled storage. Appendix 1 of this guidance note provides more information on these exemptions.

Regulation (EU) No 210/2013, on the approval of establishments producing sprouts, requires that all establishments producing sprouts are approved by the competent authority.

Regulation (EU) 2017/625 (Official Controls Regulation (OCR)) lays down rules for the performance of official controls and other official activities by competent authorities. Article 148 of the OCR sets out the requirements for competent authorities with regard to approving food business establishments.

European Union (Food and Feed Hygiene) Regulations 2020 (S.I. No. 22/2020) is the Irish national legislation that sets out the requirements for the approval process.

In Ireland, competent authorities operating under service contract to the Food Safety Authority of Ireland (FSAI) approve food establishments handling food of animal origin and establishments producing sprouts. The competent authorities for the approval of food establishments handling food of animal origin are:

- The Department of Agriculture, Food and the Marine (DAFM)
- The Health Service Executive (HSE)
- Local authorities (LAs)
- The Sea-Fisheries Protection Authority (SFPA).

The competent authority for the approval of establishments producing sprouts is:

- The Department of Agriculture, Food and the Marine (DAFM).

1. Purpose

This cross-agency guidance is intended to increase consistency in the way competent authorities approve food businesses by clearly setting out the principles to be followed when approving a food business and keeping the approval under review. Competent authority documented procedures should be based on the principles set out in this cross-agency guidance.

While this guidance note is primarily aimed at competent authorities, it provides useful information that can also benefit FBOs.

2. Scope

This guidance note applies to all food businesses requiring approval under Regulation 5 of the European Union (Food and Feed Hygiene) Regulations 2020 (S.I. No. 22/2020), as amended. This guidance note applies from when the competent authority has determined that the establishment requires approval.

3. Legislation

The legislation listed below relates to the approval of food establishments:

- **Regulation (EC) No 852/2004** of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. Hereinafter referred to as Regulation 852/2004
- **Regulation (EC) No 853/2004** of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin. Hereinafter referred to as Regulation 853/2004
- **Commission Regulation (EU) No 210/2013** of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council. Hereinafter referred to as Regulation 210/2013
- **Regulation (EU) 2017/625** of the European Parliament and of the Council of 15 March 2017 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, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives

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89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation). Hereinafter referred to as OCR

- **Commission Implementing Regulation (EU) 2019/627** of 15 March 2019 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 of the European Parliament and of the Council, and amending Commission Regulation (EC) No 2074/2005 as regards official controls. Hereinafter referred to as Regulation 2019/627
- **S.I. No. 22/2020 - European Union (Food and Feed Hygiene) Regulations 2020.** Hereinafter referred to as S.I. No. 22/2020.

An establishment can only be approved by the competent authority if the FBO has demonstrated that it complies with the relevant requirements of food law. Food law in this case refers to European Union (EU) and national legislation governing food in general and food safety in particular. For more details on food legislation that must be complied with before placing food on the market, go to www.fsai.ie.

Where legislation is listed and mentioned throughout this guidance document, the reference is to the amended legislation at the time of publication (2024). Competent authorities should consult the most recently consolidated version of the legislation, taking account of any amendments made since the consolidated version was published.

4. Types of food establishments subject to approval

Regulation 210/2013, on the approval of establishments producing sprouts, requires that all establishments producing sprouts are approved by the competent authority.

Regulation 853/2004 requires that food establishments handling food of animal origin, for which Annex III to the Regulation lays down specific requirements, must be approved by the competent authority, except for primary production, transport operations, retail and the storage of foods of animal origin not requiring temperature-controlled storage. (see Appendix 1 for a further explanation of these exemptions).

Table 1 contains a non-exhaustive list of the types of establishments that must not operate without approval from the appropriate competent authority.

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Table 1 Types of food establishments that must not operate without approval

Establishment type	Approval provided by:
<i>Sprouts</i>	
Sprout producing establishment (Regulation 210/2013)	DAFM
<i>General activity</i>	
Cold store (independent, stand-alone) other than cold stores that are part of a retail operation (see Section 5 'Approval of cold stores')	DAFM/HSE/LA/SFPA
Rewrapping establishment/repackaging establishment (independent, stand-alone)	DAFM/HSE/LA/SFPA
Wholesale market	DAFM/HSE/LA/SFPA
<i>Retail outside of marginal, localised and restricted (MLR) criteria</i>	
Retail butchers operating outside of MLR criteria	LA
Retail catering establishments operating outside of MLR criteria	LA
<i>Non-retail manufacturer using unprocessed food of animal origin</i>	
Manufacturer using unprocessed food of animal origin (e.g., central production kitchens)	HSE
<i>Meat</i>	
Slaughterhouse	DAFM/LA
Cutting plant	DAFM/LA
Establishment producing minced meat	DAFM/LA
Establishment producing meat preparations	DAFM/LA/HSE
Establishment producing meat products	DAFM/LA/HSE
Establishment producing mechanically separated meat (MSM)	DAFM/LA
<i>Game</i>	
Wild game handling establishments	DAFM/LA
Cutting plant	DAFM/LA
<i>Live bivalve molluscs</i>	
Purification centre	SFPA
Dispatch centre	SFPA
<i>Fishery products</i>	
Factory vessel	SFPA
Freezing vessel	SFPA
Fresh fishery products plant	SFPA
Processing plant	SFPA
Wholesale market	SFPA
Auction hall	SFPA
Establishment producing mechanically separated fishery products	SFPA
<i>Dairy</i>	
Colostrum and colostrum-based products processing plant	DAFM

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Establishment type	Approval provided by:
Establishments processing raw milk into dairy products, using raw milk as an ingredient in other food products, pasteurising milk	DAFM
Establishments manufacturing dairy products by the further processing of a dairy products (e.g. butter)	DAFM
Establishments cutting/packaging/blending/processing dairy products	DAFM
Collection centre	DAFM
Milk purchasers	DAFM
<i>Egg and egg products</i>	
Packing centre	DAFM
Liquid egg plant	DAFM
Processing plant	DAFM
<i>Other</i>	
Frog legs/snail processing plant	DAFM
Rendered animal fats and greaves collection centre	DAFM
Rendered animal fats and greaves processing plant	DAFM
Treated stomach, bladder and intestines processing plant	DAFM
Gelatine processing plant	DAFM
Collagen processing plant	DAFM
Gelatine/collagen – collection centres and tanneries authorised for supply of raw materials for the production of gelatine/collagen for human consumption	DAFM
Highly refined products – processing plants (chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass, amino acids, food flavourings, fat derivatives)	DAFM/HSE/LA/SFPA

5. Approval of cold stores

Cold stores that are used for activities for which Annex III to Regulation 853/2004 lays down requirements must not operate without approval, except for cold stores that are part of a retail operation (e.g. central distribution centres).

Stand-alone cold stores, storing foods of animal origin for further supply to food establishments (e.g. cutting plants, meat processing plants, dairy product plants, fishery product plants) must not operate without approval.

Cold stores that are part of an approved establishment are included in the overall approval of the establishment.

Cold stores may undertake a wide range of activities beyond that of simple storage and distribution. For example, rewrapping (i.e. unwrapping products previously wrapped in another

establishment) in a cold store is a separate activity to cold storage, and the cold store must not carry out this activity without approval for rewrapping.

6. Approval of food establishments

Establishments handling food of animal origin for which Annex III to Regulation 853/2004 provides specific requirements, except those establishments exempt from approval (see Appendix 1), must be approved for the activities that they perform.

Establishments producing sprouts must not operate without approval under Regulation 210/2013.

S.I. No. 22/2020 sets out the requirements for the approval of food businesses in Ireland, including listing the competent authorities to which applications for approval should be made. In addition, it sets out the enforcement options available to competent authorities in the case of non-compliance.

S.I. No. 22/2020 permits a competent authority to grant a food business approval, attach a condition to a food business approval, vary or revoke a condition, suspend or revoke a food business approval or refuse an application for approval. A competent authority may, for good and sufficient reason, make a food business approval valid for a limited period. More information on the requirements around the suspension or revocation of a food business approval can be found in Section 9 of this Guidance Note.

Article 148 of the OCR sets out the official control requirements for competent authorities to follow when approving food business establishments:

- Competent authorities must have procedures in place for FBOs to follow when applying for approval in accordance with Regulation 210/2013 and Regulation 853/2004.
- Upon receipt of an application for approval from an FBO, the competent authority must make an on-site visit.
- The competent authority must approve an establishment for the activities concerned only if the FBO has demonstrated that it complies with the relevant requirements of food law.
- The competent authority may grant conditional approval if it appears that the establishment meets all the infrastructure and equipment requirements:
 - The competent authority grants full approval only where it appears from a new official control of the establishment, carried out within 3 months of granting conditional approval, that the establishment meets the other relevant requirements of food law.

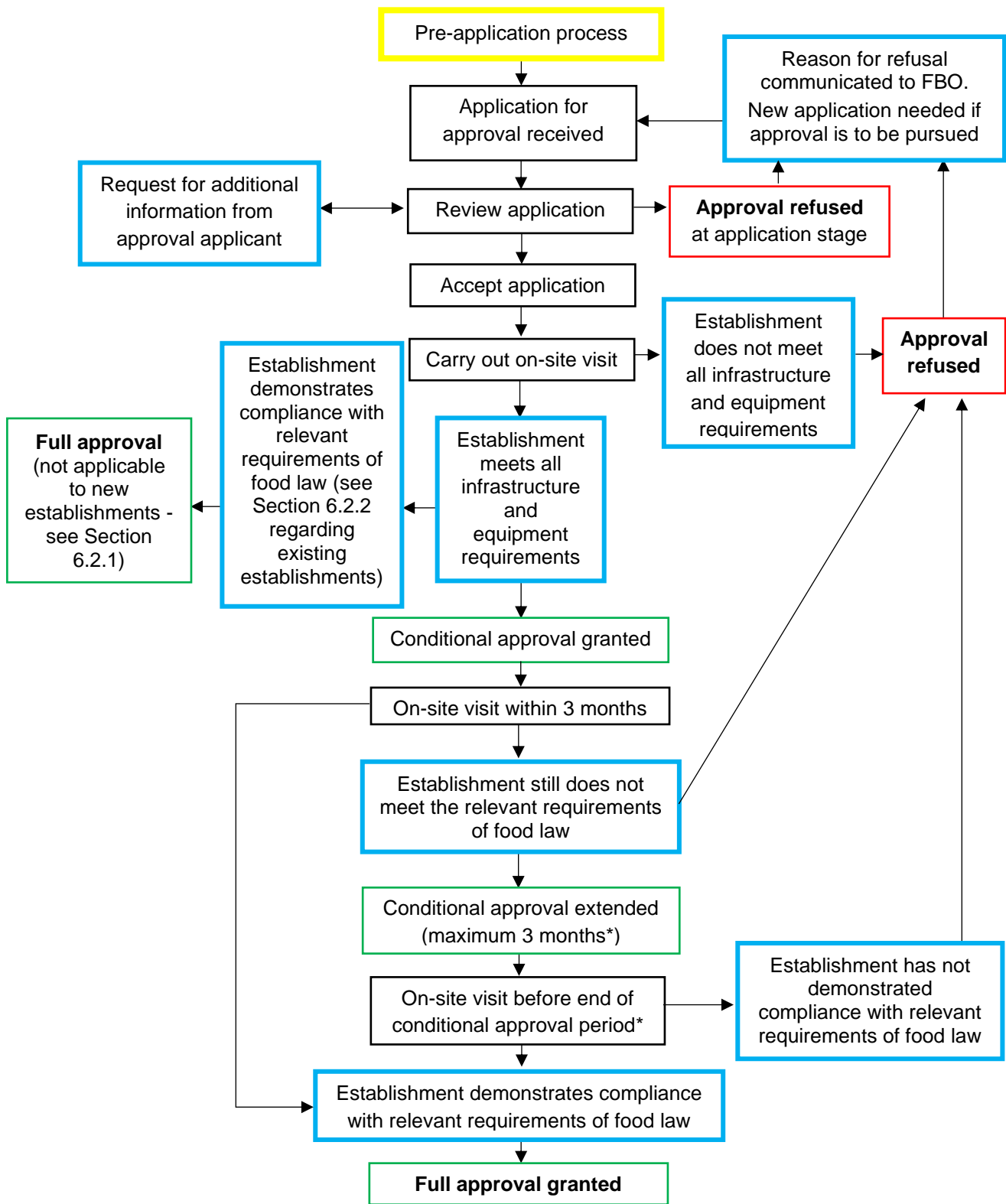
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- If clear progress has been made but the establishment still does not meet all the relevant requirements, the competent authority may prolong the conditional approval. Conditional approval must not exceed a total of 6 months, except for factory and freezer vessels flying the flag of an EU Member State, where conditional approval must not exceed a total of 12 months.
- The competent authority must keep the approval of establishments under review when carrying out official controls.

Article 69 of Regulation 2019/627 sets out requirements for competent authorities when carrying out official controls on factory, freezer or reefer vessels in accordance with Article 148 of the OCR.

Figure 1 sets out the approval process, including decisions required by competent authorities and communication to applicant/FBO.

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*Conditional approval must not exceed a total of 6 months, except for factory and freezer vessels, where conditional approval must not exceed a total of 12 months.

Figure 1 Approval process

6.1. Pre-application process

Food businesses are advised to engage with the competent authority before carrying out any work or purchasing equipment. This will help to ensure that the work carried out will comply with the infrastructural and equipment requirements for an approved premises and avoid expensive remodelling.

Before the applicant submits an application for a food business approval, they should contact the appropriate competent authority (see Table 1) to discuss their plans and outline how they will ensure that Regulation 853/2004 requirements will be met by their proposed food business, including suitability of the establishment for the activities to be carried out. In developing their plans, food businesses may need to obtain their own expert advice. It is the responsibility of food businesses to ensure compliance with legislation at all stages.

Competent authorities may have a pre-approval application process for applicants to complete prior to submitting an application for approval. An example of this is the DAFM [‘Notification of Intent Form’](#) which is part of the DAFM approval process for evaluating proposals to operate meat processing or cold store establishments.

6.2. Application for a food business approval

Applications for approval may relate to a new establishment (applicant) or to an existing establishment (FBO). The applicant/FBO intending to undertake activities that require approval must submit an application to the appropriate competent authority requesting approval for these activities. S.I. No. 22/2020 states that the competent authority shall not consider an application unless the application contains all the material and particulars sought by the competent authority and is accompanied by the fee (if any) in respect to the application for approval.

In the case of an existing establishment, the FBO may already be approved but require approval for additional activities, or it may be registered under Regulation 852/2004 and want to carry out activities requiring approval under Regulation 853/2004.

S.I. No. 22/2020 states that the application for approval must contain any information that the competent authority requires. The information competent authorities require includes:

- Name and legal form of the FBO/person applying for approval. The identity of the person who will hold the approval needs to be clearly established in the application.
- Name and address of the establishment for which the approval application is being made
- Specific activities for which approval is sought

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- Food safety management system including process flow diagrams
- Anticipated future throughput of the establishment.
Throughput/volume is a key parameter that affects the safety of food produced in the establishment. The competent authority must decide whether throughput limits should be attached as a condition to the approval and if so, record these limits on the certificate of approval.
- Site plan/drawing of the establishment indicating location of rooms; storage/processing/waste areas; layout of facilities and equipment, including an outline of the curtilage of the establishment to be approved along with any external areas. Where the competent authority deems it appropriate, for example a small premises, this could be hand drawn to scale.
- Depending on the establishment type and/or the nature and extent of the activities proposed to be undertaken by the FBO, additional information may need to be submitted.

Note: Independent of the approval process, it is the responsibility of the food business operator to ensure compliance with other non-food legislation that needs to be complied with before operating a food business, e.g. planning permission, health and safety requirements, fire regulations, environmental controls etc.

6.2.1. Application for approval of new establishments

New establishments must apply for approval before commencing activities that require approval. Competent authorities should not grant full approval in the first instance for new establishments because the competent authority needs to be able to validate the effectiveness of the food safety management system (FSMS) under operational conditions. It is normally appropriate to grant conditional approval based on satisfactory infrastructure and equipment. This allows the competent authority to verify that the FBO has demonstrated compliance with the relevant requirements of food law before full approval is granted.

6.2.2. Application for approval of existing establishments

Existing approved establishments must not undertake additional activities that require approval without being approved for these activities.

Existing establishments registered under Regulation 852/2004 must apply for approval before commencing activities that require approval under Regulation 853/2004.

Examples include:

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- An establishment registered under Regulation 852/2004 that is going to start carrying out activities that require approval under Regulation 853/2004 or Regulation 210/2013 for the first time
- Change in ownership of an existing approved establishment
- Significant changes in FBO activities, e.g.:
 - Requesting an increase in throughput above the level stated on the approval certificate (where throughput is a condition of the approval)
 - Extending the establishment's curtilage, e.g. extension, additional buildings
 - Significant modification to the internal structure of the establishment or process flows
 - Additional activities (e.g. mincing, production of ready-to-eat products, production of fishery products)
 - Additional species (depending on the activity, e.g. slaughter, cutting).

As existing establishments are already in operation, it may be possible for the FBO applying for a change to the approval to demonstrate compliance with the relevant requirements of food law and for the competent authority to grant full approval without the need for conditional approval following an on-site visit to the establishment (see Section 6.4).

6.3. Assessment of applications for approval

The competent authority should acknowledge receipt of the application for approval. It should make the applicant aware of the procedure involved and how long it should take.

As part of the assessment of the application for approval, the competent authority verifies that:

- It is the appropriate competent authority for the approval application.
- The approval application form has been satisfactorily completed.
- The establishment is not exempt from approval under Regulation 853/2004 (see Appendix 1).

Following the assessment of the application for approval, the competent authority can:

- Seek clarification/request additional information from the applicant on aspects of the application form or supporting documentation. The approval application process is paused until this information is received.
- Accept the approval application as a valid application and contact the applicant to organise and conduct an on-site visit.

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- Refuse the approval application, e.g. where necessary information has not been provided or where the applicant has provided information that is false or misleading in a material respect (see Section 9 for details on the grounds for refusing an application for approval).

6.4. On-site visit

Upon receiving a valid application for approval, the competent authority must conduct an on-site visit to the establishment.

The establishment must meet the relevant infrastructure and equipment requirements before it can be granted conditional approval by the competent authority. The competent authority can only grant full approval where the FBO demonstrates compliance with all relevant requirements of food law i.e. infrastructure and equipment requirements, effective FSMS in place including traceability, labelling, sampling, allergen controls, etc.

Verifying that the establishment meets the infrastructure and equipment requirements requires that:

- Premises structure and layout are suitable for the intended activities.
- Appropriate services are provided, e.g. water, electricity, refrigeration, ventilation, sewage and drainage.
- Equipment layout and process flows are suitable for the intended activities.
- For Regulation 853/2004 approvals, the requirements relevant to infrastructure and equipment in Annex II to Regulation 852/2004 and Annex III to Regulation 853/2004 have been met.
- For Regulation 210/2013 approvals, the requirements relevant to infrastructure and equipment in Annex I to Regulation 852/2004 and the Annex to Regulation 210/2013 have been met.

The on-site approval visits should be organised in advance with the FBO to ensure that the competent authority has access to everything needed to carry out their assessment. In addition, unannounced official controls of the establishment can be carried out by the competent authority at any time during the conditional approval period.

Following the on-site visit, the competent authority may:

- **Grant conditional approval** if the establishment meets the infrastructure and equipment requirements. It may take several on-site visits before the competent authority is in a position to grant conditional approval. Details (e.g. a report) of what the establishment

needs to do in order to be granted conditional approval should be given to the applicant and followed up on at an on-site visit.

- **Grant full approval** if the establishment meets the infrastructure and equipment requirements, and the FBO has demonstrated under operational conditions that their FSMS is effective.

- **Refuse approval.**

Section 9 provides details on the grounds for refusing an application for approval. If the on-site visit identifies serious deficiencies at an establishment and the FBO is not able to provide adequate guarantees regarding future production, then refusal of approval may be appropriate.

Certain provisions for flexibility are provided in Regulation 852/2004 and Regulation 853/2004. Where any flexibility has been authorised by the competent authority, details of the flexibility applied should be assessed as part of the on-site visit and recorded in the official control records for the establishment. The approval of the establishment is based on the application of this flexibility in the establishment and should be included as a condition to the approval on the certificate of approval, as details of the flexibility applied must be clear to the FBO and the competent authority.

The onus is on the FBO to apply to the competent authority for any flexibility they wish to implement with appropriate documented evidence/validation of the proposed method or activity. The competent authority must authorise the flexibility before the FBO can implement it.

6.5. Conditional approval

The competent authority may grant conditional approval if it appears from the on-site visit that the establishment meets all the infrastructure and equipment requirements.

As new establishments are not operational, conditional approval must be granted before full approval so that the establishment can be assessed under operational conditions.

The FSMS will not be implemented for a new establishment. However, the establishment should be assessed for its planned operation (e.g. prerequisite programmes (PRPs)) to inform the decision as to whether granting conditional approval would be appropriate.

S.I. No. 22/2020 permits the competent authority to grant a conditional approval for up to two periods of not more than 3 months each or, in the case of a fishing vessel, for a period of 12 months.

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Establishments that have been granted conditional approval can operate, place product on the market and apply their health or identification mark, or their egg packing centre number. See Section 11 for more information on health and identification marks.

Within 3 months of granting conditional approval, the competent authority must carry out a new official control of the establishment to assess the effectiveness of the FSMS. This new official control should in general be an on-site visit of the establishment.

Following the on-site visit, the competent authority may:

- **Grant full approval** if the establishment meets the relevant requirements of food law
- **Extend conditional approval** where clear progress has been made but the establishment still does not meet all the relevant requirements.

Note: Conditional approval must not exceed a total of 6 months, or, in the case of factory and freezer vessels, 12 months.

At the end of the second conditional approval the establishment must be at a standard for full approval i.e. it must meet the structural, operational and hygiene requirements of an approved establishment. If the establishment is not at the standard for full approval, the competent authority must refuse the application (see Section 9 for the procedure involved when refusing an application for approval).

- **Refuse approval** (see Section 9 for details on grounds for refusing approval).

6.6. Full approval

The competent authority may grant full approval to an establishment only if the FBO has demonstrated that the establishment complies with the relevant requirements of food law. Verifying that the establishment meets these requirements would include an assessment to ensure that it fulfils the structural, hygiene and operational requirements of relevant EU food legislation.

Where an establishment has conditional approval, then full approval can only be granted following a new official control carried out under operational conditions within 3 months of granting conditional approval (see Section 6.5). The competent authority may grant full approval only if it appears from this official control that the establishment meets the other relevant requirements of food law.

For existing establishments, that are food businesses which have been approved or registered, the competent authority may grant full approval without the need for conditional approval, if it is

satisfied that the FBO has demonstrated compliance under operational conditions that their FSMS is effective and in compliance with the relevant requirements of food law.

6.7. Approval of innovation centres/food hubs

A number of different business models exist where multiple FBOs operates separate food businesses out of a single establishment. Examples include innovation centres and food hubs, containing units that avail of the shared facilities provided by the centres/hubs.

The following is relevant to the approval of innovation centres and food hubs:

- Innovation centres and food hubs offering a facility and/or shared services to food businesses are not in themselves food businesses as defined in Regulation (EC) No 178/2002, and therefore do not require registration under Regulation 852/2004 or approval under Regulation 853/2004.
- Food businesses operating out of innovation centres/food hubs must either be registered under Regulation 852/2004 or approved under Regulation 853/2004, according to the activities that are being carried out.
- If more than one FBO operating out of an innovation centre/food hub is undertaking activities that require approval, then separate approval is needed for each FBO. This may mean multiple approval numbers for the same unit. It is important that competent authorities have procedures in place to manage the process of issuing approval numbers, identifying the FBOs using the unit and their listing on approved establishment lists.
- If the activities to be carried out require approval, the competent authority must carry out the procedure outlined in Section 6 for each unit or food business. The identification mark as required by Annex II Section I to Regulation 853/2004 must be applied to product placed on the market from that unit/food business (see Section 11.1 Identification mark).
- The use of shared facilities (e.g. pest control, loading bays, work-in-progress fridges, storage of stock and ingredients) in the innovation centre/food hub should be covered in the service level agreement between the FBO and the innovation centre/food hub in addition to the FBO's FSMS.
- The FBO's site maps should identify the shared facilities. The responsibilities around shared facilities would need to be agreed e.g. cleaning between food businesses using same unit, protection of FBO product from tampering in shared storage, traceability etc. A

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dispute mechanism/measure should be in place to allow for situations where the rules are not followed by any party (i.e. unit provider or FBOs).

- The service level agreement between the innovation centre/food hub and the FBO must be included in the competent authority assessment of the FBO's FSMS.
- Primary responsibility for food safety rests with the FBO, who is responsible for ensuring the requirements of food law are met within the food business under their control. The FBO for the individual food business requiring approval will need to be able to demonstrate how they plan to manage any food safety risks, for example allergen controls.
- Depending on the activities to be carried out in the innovation centre/food hub, there may be different competent authorities involved in the registration or approval of the individual units and food businesses (see Table 1). Good communication is required between the competent authorities which may include joint inspections, where appropriate.
- Where the competent authority needs to take enforcement actions, e.g. for hygiene issues identified when carrying out official controls, this may involve other FBOs using the shared facilities and other competent authorities supervising these FBOs.
- Competent authorities carrying out enforcement action within an innovation centre/food hub should inform other supervising competent authorities within that innovation centre/food hub of this. This allows the other competent authorities to carry out their own risk assessment on whether the issue has any knock-on effect for other FBOs.
- The arrangements regarding the use of the innovation centre/food hub and operating patterns should be attached as a condition to the approval and noted as such on the certificate of approval.
- In some cases, the innovation centre/food hub may be used to develop a new product line for an existing food business - if the activities being carried out in the innovation centre/food hub require approval, then the approval relates to the activities carried out by the FBO in that unit only. The approval number for the unit can only be applied to product produced or rewrapped/repackaged at the unit. The approval number is unique to the approved establishment and therefore separate to any approval number the FBO might have for their other establishments (see Section 7 Issuing an approval number).

6.8. Approval of seasonal establishments

Some establishments have a seasonal pattern and might produce or operate for only a few months of the year. Although production takes place for a limited period each year, the product may be available out of the production season, for example cheese. If the product is available on the market, then the establishment needs to continue to be listed on the approved premises list.

For seasonal establishments seeking approval, conditional approval may span over more than one operating season as long as the total combined period of conditional approval does not exceed six months. Where possible, the competent authority should aim to conclude the approval process within one season. Where conditional approval is split over more than one operating season, the competent authority must be satisfied that this is feasible and any potential risks to public health are managed.

The arrangements regarding the seasonal operation of the establishment, including the time of the year the establishment is in operation, should be attached as a condition to the approval and noted as such on the certificate of approval. Before production recommences the following season, an on-site visit to assess whether the establishment still complies with the relevant requirements of food law should be carried out by the competent authority.

7. Issuing an approval number

When the competent authority has made the decision to grant approval to a food establishment, it assigns a unique approval number. Competent authority approval procedures must include a process for issuing approval numbers for food establishments.

The approval number assigned to an establishment:

- Is a unique reference number that identifies the establishment
- Cannot be used by another FBO or establishment
- Cannot be used for another establishment operated by the same FBO
- In the case of establishments approved under Regulation 853/2004, the approval number must be included in the health or identification mark applied to the product at the approved establishment (see Section 11 Health and identification mark). In the case of eggs, the egg packing centre (EPC) approval number must be indicated on the packaging.

The approval number is issued to a food establishment that has been granted conditional or full approval following a satisfactory on-site visit by the competent authority.

As the approval number is a unique number that identifies the approved establishment, it is recommended that a new approval number is issued in the case of new ownership or new location. A new application for approval is required (see Section 6 for details on the approval procedure).

In some circumstances, establishments previously registered under Regulation 852/2004 need to apply for approval due to changes in their operation or customer base (for example butchers wanting to supply other food businesses outside “marginal, localised and restricted” activity). These are newly approved establishments requiring an application for approval and new approval number.

For existing establishments where there is a change in business trading name with no change to food business ownership – a new application for approval is not required and no change to the existing approval number. The competent authority must issue a new certificate of approval making the change to the business name of the FBO and update the approved premises list accordingly.

The approval number relates to the establishment and the FBO. It cannot be used by the FBO at any other food business operation e.g. satellite plant, innovation centre/food hub. Where approval has been revoked (see Section 9) the operation must cease, and the approval number can no longer be used by the FBO and must also not be reused by the competent authority for another establishment.

The competent authority includes the approval number on the establishment’s certificate of approval (see Section 8) and on the establishments listing on the approved premises list (see Section 12).

8. Certificate of approval

When a competent authority grants a food business approval (full or conditional), it must issue a certificate of approval to the FBO.

S.I. No. 22/2020 Regulation 7(2) sets out what must be contained in the certificate of approval:

- Name of the holder of the food business approval
- Address of the approved establishment
- Nature of the activity to which the food business approval relates
- Conditions to which the food business approval is subject, e.g. restricting the establishment’s throughput in line with its infrastructure capacity to operate under hygienic conditions, or limiting the approved activities to particular days or time, etc.

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- Period of validity (if any) of the food business approval (e.g. seasonal)
- Unique reference number that identifies the food business, i.e. approval number or egg packing centre number
- Name of the competent authority who issued the approval.

Where any flexibility provided for in Regulation 852/2004 and Regulation 853/2004 has been authorised by the competent authority, details of the flexibility applied should be recorded in the certificate of approval as a condition to the approval, because the establishment's approval is based on the application of this flexibility.

Regulation 7(5) of S.I. No. 22/2020 requires the certificate of approval to be displayed prominently at the approved establishment during business hours.

9. Refusing an application for approval, or suspending or revoking an approval

In certain circumstances (see below), a competent authority may decide to refuse an application for approval. The competent authority may also decide to suspend or revoke a food business approval. The circumstances that allow a competent authority to refuse an application for approval, or to suspend or revoke a food business approval, are described in Regulation 6 (3) of S.I. No. 22/2020, namely:

- (a) Establishment or FBO has not complied (or will not comply) with EU legislation or S.I. No. 22/2020.
- (b) Applicant or holder of a food business approval has failed to comply with legislation relating to food, feed, animal or public health, animal welfare or the environment.
- (c) Applicant or holder of a food business approval has failed to comply with a condition of a food business approval.
- (d) Necessary information has not been included in the application, or the application includes information that is false or misleading in a material respect.
- (e) Establishment does not meet the relevant structural, operational and hygiene requirements of relevant EU food legislation.
- (f) Applicant or holder of a food business approval is not a fit and proper person to be approved.
- (g) Holder of a food business approval has ceased to carry out the activity to which approval relates at the establishment to which approval relates

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- (h) The applicant or FBO, having been given 28 days to do so, fails to pay a fee under Regulation 20 of S.I. No. 22/2020.
- (i) It is necessary for the protection of human health, animal health or welfare or the environment, including the prevention, control or eradication of a disease.
- (j) It is necessary in order for an act of the institutions of the EU to have full effect.

Where a competent authority proposes to refuse an application for approval, or to suspend or revoke an approval, it must follow the process laid out in S.I. No. 22/2020 Regulation 6(4) or 6(6) as appropriate.

Under S.I. No. 22/2020, if a competent authority refuses an application or suspends or revokes an approval, it is obliged to notify the applicant or holder of the food business approval of the decision and the reasons for the decision. This is to allow the person to make representations to the competent authority in relation to the decision. Any representations must be made within 14 days of their being notified. The competent authority is obliged to consider any representations made.

Where the competent authority proposes to refuse an application or to suspend or revoke an approval under Regulation 6(3) a–h, the food business can remain in operation during the 14-day period, allowing the FBO to make representations to the competent authority. At the end of this 14-day period, if the competent authority decides to proceed with the suspension or revocation, the establishment must cease operation. In the case of suspension of approval, this would be for the duration of the suspension.

The competent authority can make the decision to immediately suspend or revoke an approval in the following cases:

- (i) It is necessary for the protection of human health, animal health or welfare, or the environment, including the prevention, control or eradication of a disease.
- (j) It is necessary in order for an act of the institutions of the EU to have full effect.

The food business must immediately cease operation, even during the 14-day period during which the FBO can make representations to the competent authority. At the end of the 14-day period the competent authority must confirm, modify or annul the decision.

S.I. No. 22/2020 Regulation 7(3) requires that where a food business approval is suspended or revoked, the holder of the approval certificate must, on request, return the certificate of approval to the competent authority.

If the FBO wants to recommence activities that require approval after approval has been revoked, it must submit a new application for approval to the competent authority (see Figure 1). Where the

competent authority suspends or revokes approval, the establishment is removed from the approved establishments list. In the case of suspension of approval, this would be for the duration of the suspension.

Figure 2 outlines the process when a competent authority refuses an application or suspends or revokes an approval in accordance with Regulation 6(3) a–h and Regulation 6(3)(i) and (j) of S.I. No. 22/2020.

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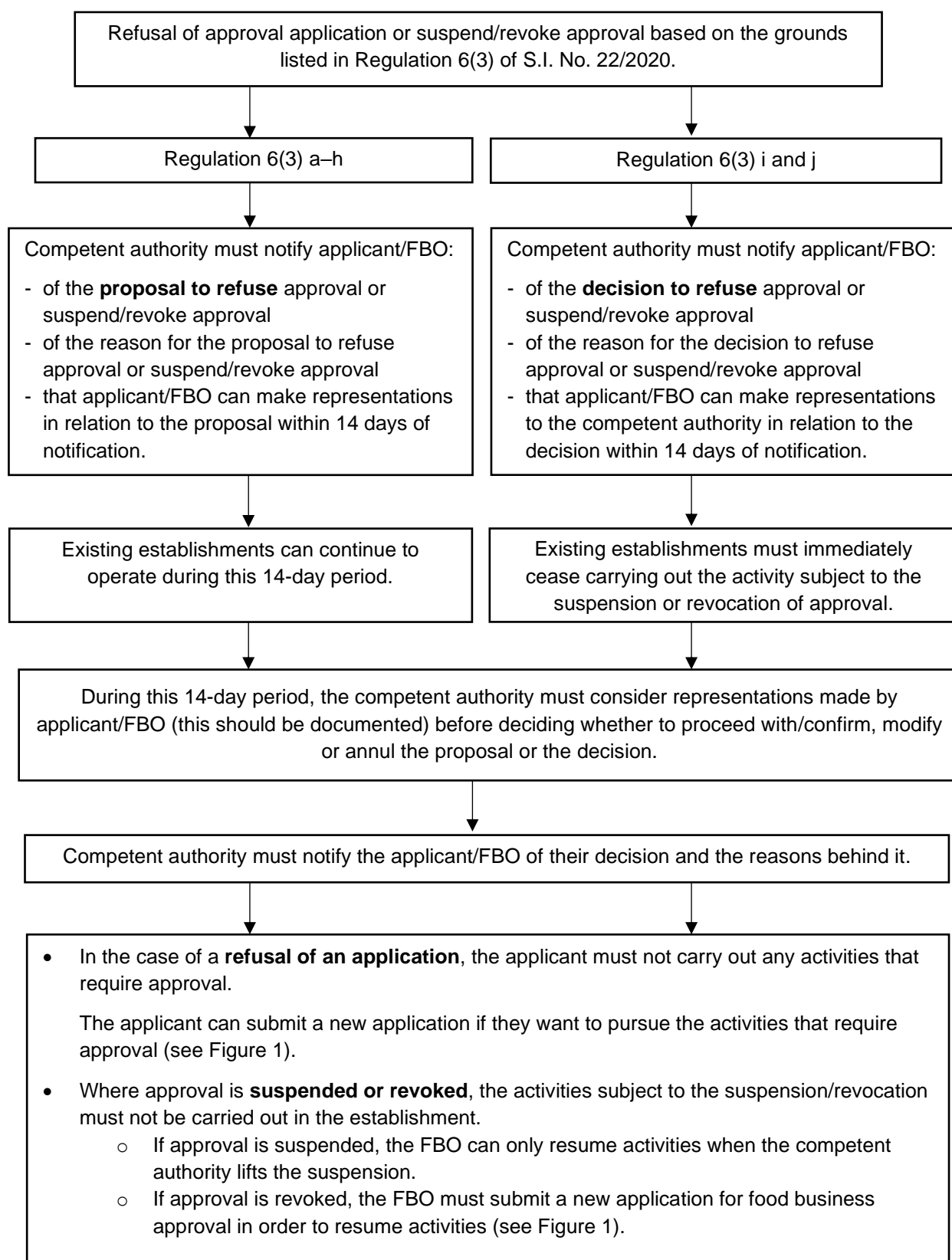


Figure 2 Procedure to refuse an approval application or suspend or revoke approval – Regulation 6 of S.I. No. 22/2020

10. Keeping establishment approval under review

The competent authority must keep the approval of each establishment under review when carrying out official controls. Written records (paper or electronic) must be kept for every official control performed.

The review of approval includes:

- Verification that the establishment continues to meet the structural and equipment requirements
- Verification that the establishment continues to comply with the relevant requirements of food law
- Verification that the activities being carried out are the same as those listed on the approval certificate (see Section 10.1)
- Verification that any conditions to which the approval is subject are still being met (e.g. throughput limits)
- For fishery products, Article 67 of Regulation 2019/627 sets out requirements for official controls on the production and placing on the market of fishery products to verify compliance with the requirements of Annex III, Section VIII to Regulation 853/2004, including whether the conditions for approval are still fulfilled.
- For factory, freezer and reefer vessels, Article 69 of Regulation 2019/627 sets out the requirements for competent authorities when carrying out official controls on these vessels in accordance with Article 148 of the OCR.

10.1. Keeping approved activities under review

Establishments must not undertake activities that require approval without being approved for these activities, FBOs must only be approved for the activities they carry out and for which they meet the relevant legal requirements.

Where approved establishments carry out steps that are implied in the production of the food of animal origin (e.g. salting, cutting, cold storage), separate approval for those steps is not required. Some examples are provided below:

- Establishments that cut raw meat exclusively for the manufacture of meat products, minced meat, meat preparations or MSM are approved for the final food of animal origin manufactured in the establishment, i.e. meat products, minced meat, meat preparations, MSM, and not for cutting as this is an intermediary step in the production process.

However, if the approved establishment supplies cut meat to another establishment, then the establishment would need to be approved for cutting.

- An establishment that produces minced meat (as defined in Regulation 853/2004) as a step in the production of a meat product (e.g. lasagne/cottage pie) or a meat preparation (e.g. burgers/sausages) is approved for meat products or meat preparations and not for minced meat. The mincing is an intermediary step and comes under the meat product or meat preparation approval. However, if the approved establishment supplies the minced meat (as defined in Regulation 853/2004) to another establishment, then the establishment would need to be approved for minced meat.
- Under Regulation 853/2004, the approval for slaughter entails that carcasses of domestic ungulates may be cut into half-carcasses or quarter-carcasses, and half-carcasses into no more than three wholesale cuts in a slaughterhouse. If no further cutting takes place, then this would be covered in approval for slaughter. Further cutting and boning must be carried out in a cutting plant and the slaughterhouse would need to be approved for cutting.
- Fish establishments producing fishery products need to be approved only for the final product, and not for each step in the process. For example, an establishment that salts as a step in the production of smoked fish is approved for smoked fish but not for the salting of fish. The salting is an intermediary step and comes under the fishery product approval. However, if the approved establishment supplies the salted fish to another establishment, then the establishment would need to be approved for salting fish.
- Establishments that store product of animal origin under refrigerated/frozen conditions exclusively as part of the manufacturing process are approved for the final food of animal origin and not for cold storage. For example, the storage of minced meat to make burgers or the chilling of carcasses post-slaughter is an intermediary step of the manufacturing process and comes under that approval. However, if stored product is not manufactured at the establishment, i.e. box-in-box-out, then the establishment needs to be approved for cold storage.

10.2. Review of the certificate of approval

Where changes are made to the establishment's approval (e.g. approval of additional activities or ceasing of an approved activity), the certificate of approval must be updated accordingly. The competent authority must issue an updated certificate of approval to the FBO listing the activities for which the food business approval relates.

Where changes are made to the establishment's approval, the approved establishment list must be updated by the competent authority (see Section 12 for more information on approved establishment lists).

10.3. Review of approval – responding to non-compliances

When carrying out official controls, the competent authority may identify non-compliances (e.g. structural or operational issues, or unapproved activities being carried out).

Article 138 of the OCR lists the actions that competent authorities must take when non-compliance has been identified in a food business.

The competent authority must:

- Take any action necessary to determine the origin and extent of the non-compliance and to establish the FBO's responsibilities
- Take appropriate measures to ensure that the FBO remedies the non-compliance and prevents further such occurrences.

The following actions can be taken where the competent authority has identified non-compliance:

- Allow the establishment to continue operating under its approval, taking appropriate measures to ensure the FBO remedies any non-compliances
- Instruct the FBO to discontinue some or all of the activities being undertaken
- Suspend the approval
- Revoke the approval
- Take any other appropriate action.

The decision taken should be recorded as per the competent authority procedures.

When deciding which measures to take, the competent authorities must take account of the nature of the non-compliance and the FBO's past record regarding compliance.

Where substantial non-compliance is identified, the competent authority may take the measures outlined in OCR Article 138(2)(j), i.e. the suspension or withdrawal of an establishment's approval, using the procedure set out in S.I. No. 22/2020 (see Section 9).

The FSAI's [Food Law Enforcement Policy](#) provides a framework to facilitate the consistent use of enforcement provisions contained in food law.

10.4. Transfer of approved establishments to another competent authority

It may be necessary to transfer an approved establishment from one competent authority to another. Such transfers are guided by the requirements of S.I. No. 22/2020.

Transfer of a food establishment from one competent authority to another should not require the FBO to submit a new approval application, and their approval number should remain unchanged.

Once the transfer is complete, the new supervising competent authority updates their list of approved food establishments using the same approval number as previously issued by the original competent authority. The original competent authority removes the food establishment from their list of approved food establishments.

11. Health and identification mark (Regulation 853/2004)

Article 5 of Regulation 853/2004 requires that food of animal origin handled in an approved establishment is not placed on the market unless it has either:

- A health mark applied in accordance with Regulation 2019/627
- An identification mark applied in accordance with Annex II, Section I to Regulation 853/2004.

11.1. Health mark

A health mark is applied to meat fit for human consumption after ante-mortem and post-mortem inspection. Regulation 2019/627 sets out the technical requirements for the health mark and the practical arrangements for its application. The health mark attests that the meat is fit for human consumption, and its application must be supervised by the official veterinarian.

The requirements for the health mark are as follows:

- It must be an oval mark at least 6.5 cm wide by 4.5 cm high bearing the following information in perfectly legible characters:
 - Name of the country in which the approved establishment is located, which may be written out in full in capital letters or as a two-letter International Organization for Standardization (ISO) code, e.g. "IRELAND", "ÉIRE" or "IE" for Ireland

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- Approval number of the slaughterhouse
- The abbreviation of “European Union” (“EU”) in one of the official EU languages as follows: EC, EU, EL, UE, EE, AE, ES, EÚ. In Ireland, the relevant abbreviation is EU or AE.

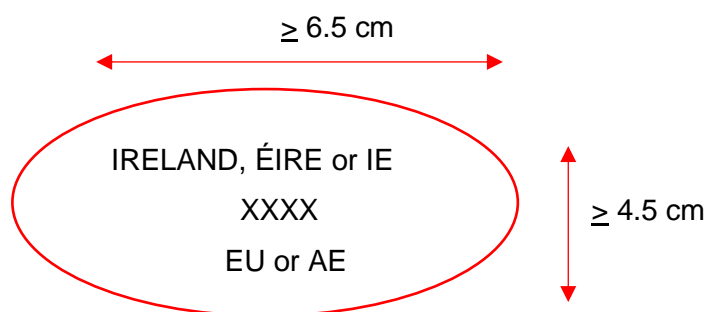


Figure 3 Health mark

Note: Health marks for newly approved establishments should be in the format above as this reflects the amendment to Regulation 2019/627 that changed the abbreviation of “European Union” in the English and Irish language as set out in Figure 3.

For existing approved establishments, health marks can continue to include the abbreviations of “European Community” until 31 December 2028, and meat with health marks applied before that date can remain on the market.

The health mark is applied to the external surface of the carcass by stamping in ink or hot branding, in such a manner that, if carcasses are cut in the slaughterhouse or in a game handling establishment into half- or quarter-carcasses, or if half-carcasses are cut into three pieces, each piece bears a health mark.

FBOs must not remove a health mark applied in accordance with Regulation 2019/627 from meat unless they cut or process it, or work upon it in another manner.

11.2. Identification mark

FBOs can only apply an identification mark to a food of animal origin if the food has been manufactured in an approved establishment, in accordance with Regulation 853/2004.

Regulation 853/2004 Annex II, Section I, sets out the technical requirements for the identification mark.

The identification mark:

- Must be legible and indelible, and the characters easily decipherable. It must be clearly displayed for the competent authorities.
- Must be oval and contain the following:
 - Name of the country in which the approved establishment is located, which may be written out in full or shown as a two-letter ISO code, e.g. “Ireland”, “Éire” or “IE” for Ireland
 - Approval number of the establishment. If an establishment manufactures both food to which Regulation 853/2004 applies and food to which it does not, the FBO may apply the same identification mark to both types of food.
 - The abbreviation of “European Union (EU) in one of the official EU languages as follows: EC, EU, EL, UE, EE, AE, ES, EÚ. In Ireland, the relevant abbreviation is EU or AE.

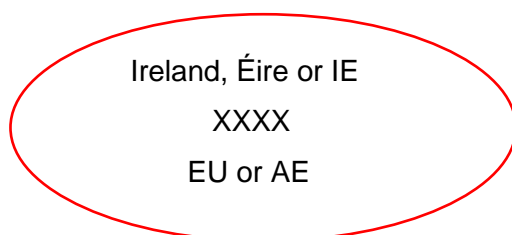


Figure 4 Identification mark

Note: Identification marks for newly approved establishments should be in the format above as this reflects the amendment made to Regulation 853/2004 that changed the abbreviation of “European Union” in the English and Irish language as set out in Figure 4.

For existing approved establishments, identification marks on foods of animal origin can continue to include the abbreviations of “European Community” until 31 December 2028, and food with identification marks applied before that date can remain on the market.

The application of the identification mark is the responsibility of the FBO and must be applied before the product leaves the establishment of production. 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.

The method of marking is set out in Annex II C to Regulation 853/2004:

- The mark may, depending on the presentation of different foods of animal origin, be applied directly to the product, the wrapping or the packaging, or be printed on a label affixed to the product, the wrapping or the packaging. The mark may also be an irremovable tag made of a resistant material.
- In the case of packaging containing cut meat or offal, the mark must be applied to a label fixed to the packaging, or printed on the packaging, in such a way that it is destroyed when the packaging is opened. This is not necessary if the process of opening destroys the packaging. When wrapping provides the same protection as packaging, the label may be affixed to the wrapping.
- For foods of animal origin that are placed in transport containers/large packages and are intended for further handling, processing, wrapping or packaging in another establishment, the mark may be applied to the external surface of the container/packaging, e.g. food of animal origin transported from an approved hospital satellite kitchen to hospital buildings and other facilities.
- In the case of liquid, granulate and powdered foods of animal origin carried in bulk, as well as fishery products carried in bulk, an identification mark is not necessary if accompanying documentation contains the information specified in points 6, 7 and 8 of Annex II B to Regulation 853/2004 (i.e. an oval identification mark containing “Ireland”, “Éire” or “IE”, the approval number and “EU” or “AE”).
- When foods of animal origin are placed in a package that will be directly supplied to the final consumer, it is sufficient to apply the mark to the exterior of that package only.
- When the mark is applied directly to foods of animal origin, the colours used must be

Only an approved egg packing centre (EPC) can pack eggs. Packed eggs are marked with the approved EPC code.

12. Approved food establishment lists

The competent authority must keep the list of approved food establishments up to date.

The FSAI maintains and publishes the list of approved food establishments in Ireland, based on information supplied by the competent authorities.

Approved food establishment lists are available on the [European Commission website](#).

Appendix 1: Food establishments exempt from approval under Regulation 853/2004

Type of food establishment	Approval under Regulation 853/2004 is exempt as follows:
Primary production	Article 4(2)(a) of Regulation 853/2004 lists primary production as a type of establishment, handling foods of animal origin, that is exempt from approval.
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	<p>S.I. No. 22/2020 gives exemptions from approval for direct supply by the producer of primary products for the following:</p> <ul style="list-style-type: none"> • The direct supply of a primary product of fishing or aquaculture, not exceeding 30 kilogrammes per week, to the final consumer or to a local retail establishment supplying directly to the final consumer (with respect to live bivalve molluscs, this exemption applies only to live bivalve molluscs harvested from Class A areas (classified by the SFPA in accordance with Article 53 of Regulation 2019/627), where the area has not been closed due to excessive levels of toxin (in accordance with Article 62 of Regulation 2019/627)) • The direct supply of eggs from a flock of hens (<i>gallus gallus domesticus</i>) or quail not exceeding 50 birds, or a flock of ducks or geese not exceeding 20 birds, to the final consumer or to retail establishments* supplying directly to the final consumer, located no more than 100 kilometres from the production site • The direct supply of raw milk, not exceeding 30 litres per week, to the final consumer or to retail establishments supplying directly to the final consumer, located no more than 20 kilometres from the holding • Hunting, where the primary producer is engaged solely in the supply of wild game that he or she has hunted, if: <ul style="list-style-type: none"> ○ No more than 1 large wild game or no more than 3 small wild game are supplied in a week, with a maximum of 3 large wild game or 30 small wild game supplied in a year, and ○ The wild game is supplied only to final consumers or to retail establishments that supply the final consumer, located no more than 100 kilometres from where the wild game was hunted. <p>*Regarding the supply of hen eggs in Ireland, hen eggs supplied to shops and catering must go via an approved egg packing centre (EPC).</p>
Direct supply, by the producer, of small quantities of meat from poultry and lagomorphs	S.I. No. 22/2020 gives exemptions from approval for direct supply by the producer of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer

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<p>slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer</p>	<p>or to retail establishments supplying the meat directly to the final consumer, located no more than 100 kilometres from the holding if:</p> <ul style="list-style-type: none"> • No more than 1,000 birds are slaughtered in a week, with a maximum of 10,000 birds slaughtered in a calendar year, or • No more than 1,000 animals are slaughtered in a week, with a maximum of 10,000 animals slaughtered in a calendar year.
<p>Hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer</p>	<p>S.I. No. 22/2020 gives exemptions from approval for hunters who supply small quantities of wild game or wild game meat directly to the final consumer, or to retail establishments that supply the final consumer, located no more than 100 kilometres from where the wild game was hunted, if:</p> <ul style="list-style-type: none"> • The meat of no more than one large wild game or no more than three small wild game is supplied in a week, and • The meat of no more than 3 large wild game or 30 small wild game is supplied in a year.
<p>Food containing both products of plant origin and processed products of animal origin, e.g. salami and cheese pizza, Caesar salad with chicken and parmesan, egg and bacon wrap</p>	<p>Unless expressly indicated to the contrary, Regulation 853/2004 does not apply to food containing both products of plant origin and processed products of animal origin.</p> <p>However, processed foods of animal origin (e.g. meat, dairy, fish) used to prepare such food must be sourced from an approved food establishment.</p>
<p>Retail</p>	<p>Regulation 853/2004 does not apply to retail.</p> <p>Where retail includes supply of food of animal origin to another establishment, Regulation 853/2004 applies. These establishments must not operate without approval unless the supply of food of animal origin is to another retail establishment only, and in accordance with national law an “marginal, localised and restricted” (MLR) activity.</p> <p>The criteria for MLR in Ireland are set out in S.I. No. 340/2010 and S.I. No. 168/2012 as follows:</p> <ul style="list-style-type: none"> • S.I. No. 340/2010 – Retail butcher shops. Applies to FBOs supplying other retail establishments with food of animal origin from a retail butcher shop, or a butcher shop unit within a retail establishment. • S.I. No. 168/2012 – Retail caterers. Applies to FBOs supplying other retail establishments with food of animal origin from a retail catering establishment.
<p>Cold stores storing foods of animal origin, which are part of a retail operation</p>	<p>Regulation 853/2004 does not apply to cold stores that are part of a retail operation (unless approval is required for the retail activity). This includes stand-alone central distribution centres.</p>

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<p>Storage of foods of animal origin not requiring temperature-controlled storage conditions</p>	<p>Article 4(2)(c) of Regulation 853/2004 lists the storage of products not requiring temperature-controlled storage conditions as a type of establishment, handling foods of animal origin, that is exempt from approval.</p> <p>Examples include the storage of tinned or dried foods of animal origin, e.g. tinned tuna.</p>
<p>Transport operations for foods of animal origin</p>	<p>Article 4(2)(b) of Regulation 853/2004 lists transport operations as a type of establishment, handling foods of animal origin (for which Annex III lays down requirements), that is exempt from approval.</p> <p>Therefore, transport vehicles and transport hubs do not need approval under Regulation 853/2004 once they are only involved in transport operations, i.e. no cold storage or alterations to the labelling or traceability of the product take place.</p>
<p>Foods of animal origin for which Annex III to Regulation 853/2004 do not provide specific requirements</p>	<p>For certain foods of animal origin (e.g. honey, insects, reptile meat, aquatic mammals), Regulation 853/2004 does not lay down specific requirements in Annex III. Establishments handling these foods of animal origin do not need to be approved, nor do they need to apply an identification mark to the food.</p> <p>These foods of animal origin must be handled in accordance with the relevant requirements laid down in Regulation 852/2004, and with the general rules for foods of animal origin laid down in Regulation 853/2004.</p>

Note: Food businesses that do not require approval must be registered with the appropriate competent authority under Article 6 of Regulation 852/2004.



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