

## **DRAFT**

# **FSA GUIDANCE ON THE REQUIREMENTS OF FOOD HYGIENE LEGISLATION**

## **1. Introduction**

1.1 From 1 January 2006 food hygiene legislation will be changing. Annex A gives details of the relevant EU regulations and associated national legislation. The national regulations are needed to enforce the requirements of the EU regulations. They also contain some national provisions which the EU regulations require or allow us to make.

1.2 This guidance note explains the legal requirements food businesses have to comply with and should be read together with the EU and national legislation mentioned in Annex A.

1.3 While this guidance is not legally binding, it does nevertheless represent the considered views of the Agency and is issued under its statutory powers for the purpose of providing advice and information to food businesses about the new food hygiene rules. But only the courts can give a definitive view on the law.

1.4 In this guidance, references in the legislation are highlighted like this. Annex B gives details of other sources of advice and information which can help you to comply with the law.

## **2. Background**

2.1 The new legislation is needed to modernise, consolidate and simplify EU food hygiene legislation. It is intended to apply effective and proportionate controls throughout the food chain, from primary production to sale or supply to the final consumer. The legislation is also intended to focus controls on

what is necessary for public health protection. It clarifies that it is the primary responsibility of food business operators to produce food safely.

2.2 The legislation brings together requirements for different types of foods which were previously covered under separate specific pieces of legislation. The new legislation has a number of provisions which apply in common to different foods. The type(s) of food you handle or sell will determine the with which requirements you have to comply.

2.3 In general terms, Regulations 852/2004 and 853/2004 lay down requirements for food business operators to comply with. Regulation 852/2004 applies to all food businesses (including those operating at the level of primary production). Regulation 853/2004 applies, in addition, to food businesses handling products of animal origin. Regulation 854/2004 lays down requirements for official controls on products of animal origin and therefore sets out what those enforcing the provisions have to do.

### **3. Scope**

#### **Do I have to comply with the EU Regulations?**

3.1 The EU Regulations lay down rules for food businesses and food business operators, as defined. If you do not meet the definitions, then the EU Regulations do not apply to you.

- “Food business” means any undertaking, whether for profit or not and whether public or private, carrying out any stage of production, processing and distribution of food.”
- “Food business operator” means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.” (Article 3.2 and 3.3 of Regulation 178/2002).

A further indication of what is intended to be covered is found in **recital 9 of Regulation 852/2004** which says:

- “[the Community rules] should only apply to undertakings, the concept of which implies a certain continuity of activities and a certain degree of organisation.”

3.2 The scope excludes activities such as the occasional preparation of food by individuals or groups for gatherings or for sale at charitable events or where for example hairdressers offer refreshments to their customers. Such activities would still be subject to the general legal requirements relating to placing unsafe food on the market contained in the Food Safety (Northern Ireland) Order 1991.

3.3 Certain other activities are also excluded from the scope of the EU Regulations:

- a) primary production for private domestic use;
- b) the domestic preparation, handling or storage of food for private domestic consumption;
- c) 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; and
- d) collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen. **(Article 1(2) of Regulation 852/2004).**

3.4 In the case of 3.3 c), these activities are subject to the general provisions of the Food Safety (Northern Ireland) Order 1991 which would make it an offence to place unsafe food on the market. In the case of eggs supplied in accordance with c), the Ungraded Eggs (Hygiene) Regulations (Northern Ireland) 1990 will also continue to apply. These Regulations prohibit

the direct sale of cracked ungraded eggs by the producer to the consumer on his own farm, in a local public market or by door to door selling. In the case of 3.3 d) collection centres and tanneries supplying raw materials for gelatine or collagen production do nevertheless have to be approved by the local district council and meet certain requirements to prevent contamination. (Annex III, Section XIV, Chapter I (5) and Section XV, Chapter I (5) of Regulation 853/2004).

3.5 Annex C contains a brief guide to whether the provisions of Regulation 852/2004 apply to you and your business. In working through this, you will need to consider all the activities you undertake. Annex D is a guide to whether the provisions of Regulation 853/2004 also apply. Again, you may need to work through this for all your activities to find out how your total business may be affected. Annex G summarises the provisions of the EU regulations and the national legislation which apply to different types of food business and highlights the most significant changes from existing legal requirements.

3.6 The EU Regulations use certain terms to describe activities subject to their provisions. These terms are not defined in the EU Regulations, but nevertheless have meaning in terms of those Regulations. Therefore, we cannot define them (and so give them a different meaning) in national legislation, nor can we offer an absolute definition of what they mean in guidance. We are, however, able to set out the way in which we consider the terms should be interpreted, in respect of different situations. These interpretations are set out in Annex H.

#### **4. Requirements of Regulation 852/2004**

4.1 Under Regulation 852/2004, primary producers are subject to different requirements than are other types of food business. If you are a farmer, fisherman or a hunter of wild game then you are a 'primary producer'. The requirements covering primary production are described in Annex F. The

provisions which apply to all other food businesses are discussed in more detail below.

## **5. Registration**

5.1 Food business operators must register their establishments (i.e. each separate unit of their food businesses, which includes game larders and collection centres) with the relevant competent authority. (Article 6 (2) of Regulation 852/2004) This does not apply to those establishments for which approval only is required (Article 6 (3) of Regulation 852/2004) (see paragraph 6 on approvals below).

5.2 Food business operators must register their establishments with the relevant competent authority and should do so at least 28 days before food operations commence. When registering, food business operators must provide the relevant competent authority with full details of the activities undertaken. A standard registration form, which should be completed for each establishment and submitted to the relevant competent authority, is attached at Annex I. Once their establishments are registered, food business operators must ensure that any changes to the details previously supplied e.g. a change of food business operator, a change to the food operations etc. are notified to the competent authority (Article 6 (2) of Regulation 852/2004). Such notifications should be made as soon as possible and in any event no later than 28 days after the change has happened.

5.3 Establishments in which a number of different activities are carried out may need to be registered in relation to certain activities and approved in relation to others. An example might be a dairy farm (registration) which also produces dairy products not for sale to the ultimate consumer (approval) and has a farm shop (registration) on the premises. A single registration can be submitted to cover the activities which require an establishment to be registered. Annex E contains a guide which will assist in determining whether registration and/or approval is required.

- If your establishment is already registered and there have been no changes since registration or since the last inspection visit by the competent authority, then you need take no further action to comply with this requirement.
- If you need to notify any changes, you should advise the relevant competent authority.
- If you are setting up a new business, you should complete a registration form (see Annex I) and submit this to the competent authority at least 28 days before food operations commence.

## **6. Approval**

6.1 Food business establishments that handle food of animal origin must, with some exceptions, be approved by the competent authority. Annex E contains a guide to whether an establishment needs approval. If your establishment needs approval, you do not need to register it as well. Approvals will replace current approvals and licences. If your establishment is already approved or licensed, it will need to be re-assessed for approval under the new Regulations. However you will be able to continue your business until such time as the enforcement authority carries out this reassessment. You need take no action until further information is sent to you at a later stage. If you are a new business, you will need to apply to the relevant enforcement authority for approval. Application forms will be available at a later stage.

6.2 If your business is:

- one that has only supplied wild game meat for the domestic market; or
- one that produced minced meat and meat preparations for the domestic market

and has been registered with your local environmental health department, you will now need to be approved.

## **7. Specific hygiene requirements**

7.1 Article 4 (2) of Regulation 852/2004 requires that you comply, as appropriate with the general hygiene requirements laid down in Annex II. For more guidance on what that means for your food business see guidance identified in Annex B. In addition, you may need to comply with the specific requirements of Regulation 853/2004 if you are producing products of animal origin (see Annexes D and G). Finally, there are specific additional provisions contained in the national legislation listed in Annex A which may apply to you. These concern:

- bulk transport in sea-going vessels of liquid oils or fats and the bulk transport by sea of raw sugar (Regulation 29 and Schedule 3),
- temperature control requirements (Regulation 30 and Schedule 4),
- direct supply by the producer of small quantities of meat from poultry and lagomorphs slaughtered on the farm (Regulation 31 and Schedule 5) and
- restrictions on the sale of raw milk intended for direct human consumption (Regulation 32 and Schedule 6).

## **8. Food Safety Management**

8.1 With the exception of activities at the level of primary production, you are required to put in place procedures which manage food safety within your establishment. Article 5 (1) of Regulation 852/2004 requires that the procedure or procedures be based upon the HACCP (Hazard Analysis and Critical Control Point) principles set out in Article 5(2). The wording of the Article gives flexibility in that it requires that the procedures be based on those principles. It does not necessarily constrain you to implement a HACCP system, if this is not appropriate. More guidance on how to comply with this requirement can be found in the information listed in Annex B. Guidance materials for different food industry sectors are under development in the Agency, and such guidance for the catering sector is planned for 2005.

## **9. Guides to good practice**

Articles 7-9 of Regulation 852/2004 provide for the development of national or Community guides to good practice for hygiene and the application of HACCP principles. These Guides are to be developed by individual food sectors or, in the case of Community guides, the European Commission, in consultation with interested parties. Food business operators may use these guides, where developed, as an aid to compliance with their obligations under the food hygiene legislation. Enforcement authorities must take into account the use of such guides in the course of official control activities. Article 10(2)(d) of Regulation 882/2004 on official feed and food controls.

## **10. Enforcement**

[To be completed once comments from the consultation have been considered.]

## **ANNEXES**

- A. The Food Hygiene Regulations and other associated legislation.
- B. Sources of advice and information.
- C. Do the provisions of Regulation 852/2004 apply to me and my business?
- D. Do the provisions of Regulation 853/2004 also apply to me and my business?
- E. Does my establishment need approval?
- F. Provisions applying to primary production
- G. Summary guidance to what provisions apply to food businesses
- H. FSA interpretation of terms used in the EU Regulations
- I. Application form for registration of food establishments

**THE FOOD HYGIENE REGULATIONS AND OTHER ASSOCIATED LEGISLATION**

1. The EU Regulations are:

- Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs;
- Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin; and
- Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption<sup>1</sup>.

They were published in the Official Journal of the European Union of 30 April 2004, L139. Corrected versions were published in the Official Journal Of the European Union of 25 June 2004, L226. Copies are obtainable from [ ]

2. This legislation is applied in the UK by:

- [The Food Hygiene (England) Regulations 2005.....]
- [The Food Hygiene (Scotland) Regulations 2005.....]
- [The Food Hygiene (Wales) Regulations 2005.....]
- [The Food Hygiene Regulations (Northern Ireland) 2005.....]

Copies are obtainable from [ ]. These Regulations also lay down some national provisions for food businesses to comply with.

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<sup>1</sup> This has been amended by Regulation (EC) 882/2004 of the European Parliament and of the Council on official controls to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

3. The EU Regulations listed above use definitions laid down in:

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

This was published in the Official Journal of the European Union of 1 February 2002, L031. Copies are obtainable from [        ].

**SOURCES OF ADVICE AND INFORMATION**

[To be completed when existing material, both on the website and in print, has been reviewed.]

## DO THE PROVISIONS OF REGULATION 852/2004 APPLY TO ME AND MY BUSINESS?

<p>1. Is my business a food business as defined?</p> <p><b>Art 3.2 of 178/2002</b></p>	No⇒	<p>Hygiene legislation does not apply.</p>
<p>Yes ↓</p> <p>2. Is my business an undertaking, the concept of which implies a certain continuity of activities and a certain degree of organisation?</p> <p><b>Recital 9 of 852/2004</b></p>	No⇒	<p>Hygiene legislation does not apply.</p> <p><i>However, if you are making food <b>other than</b> for solely domestic use, you will need to comply with the general provisions of the Food Safety (Northern Ireland) Order 1991.</i></p>
<p>Yes ↓</p> <p>3. Does my business undertake primary production for private domestic use?</p> <p><b>Art 1(2)(a) of 852/2004</b></p>	Yes⇒	<p>Hygiene legislation does not apply.</p>
<p>No ↓</p> <p>4. Does my business undertake the domestic preparation, handling or storage of fresh food for private domestic consumption?</p> <p><b>Art 1(2)(b) of 852/2004</b></p>	Yes⇒	<p>Hygiene legislation does not apply.</p>
<p>No ↓</p>		

5. Is my business a collection centre or tannery which falls within the definition of food business only because it handles raw material for the production of gelatine or collagen?  
**Art 1(2)(d) of 852/2004**

No  
↓

6. Does my business supply small quantities<sup>2</sup> of primary products directly to the final consumer or to local<sup>3</sup> retail establishments directly supplying the final consumer?  
**Art 1(2)(c) of 852/2004**

No  
↓

**852/2004 (at least) applies**  
**National rules also apply. See Annex G. Sections A and B.**

Yes⇒

Hygiene legislation does not apply.  
*However, you are required to be approved by your local food authority and meet certain requirements to prevent contamination. See paragraph 3.4.*

Yes⇒

Rules under national law apply to the act of supply. See paragraph 3.4

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<sup>2</sup> For an interpretation of this term, see Annex H

<sup>3</sup> For an interpretation of this term, see Annex H

## DO THE PROVISIONS OF REGULATION 853/2004 ALSO APPLY TO ME AND MY BUSINESS?

1. Does my business manufacture food containing both products of plant origin and processed products of animal origin?

Art 1(2) of 853/2004

Yes⇒

853/2004 does not apply to the production of that food. 852/2004 and national rules do apply. *However, processed products of animal origin **used to prepare such food** shall be obtained and handled in accordance with the requirements of 853/2004.*

Art 1(2) of 853/2004

No  
↓

2. Does my business produce and directly supply small quantities<sup>4</sup> 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?

Art 1(3)(d) of 853/2004

Yes⇒

853/2004 does not apply. 852/2004 and national rules do apply. See Annex G, Section C2.

No  
↓

3. Does my business undertake the hunting and supply of **small** quantities<sup>5</sup> of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer?

Art 1(3)(e) of 853/2004

Yes⇒

853/2004 does not apply. 852/2004 and national rules do apply. See Annex F Section C.

No  
↓

<sup>4</sup> For an interpretation of this term, see Annex H

<sup>5</sup> For an interpretation of this term, see Annex H

4. Does my business undertake the hunting and supply of quantities of wild game or wild game meat (other than “small quantities” – see the preceding question) directly to the final consumer or to local retail establishments directly supplying the final consumer?

Yes⇒

853/2004 does apply.  
**Annex III, Section IV of 853/2004**

No



5. Is my business a retail business **only** supplying food to the final consumer?  
**Art 1(5)(a) of 853/2004**

Yes⇒

853/2004 does not apply, except for certain conditions relating to live bivalve molluscs and fishery products.  
**Annex III, Section VII (3) and Section VIII (2) of 853/2004**

No



6. Does my business carry out [retail] operations with a view to supplying food of animal origin to another establishment?  
**Art 1(5)(b) of 853/2004**

No⇒

853/2004 does not apply, except for certain conditions relating to live bivalve molluscs and fishery products.  
**Annex III, Section VII (3) and Section VIII (2) of 853/2004**

Yes



7. Do these operations consist only of storage or transport?  
**Art 1(5)(b)(i) of 853/2004**

Yes⇒

The specific temperature requirements (if any) laid down in Annex III of 853/2004 shall apply.

No



8. Is the supply of food of animal origin from your retail establishment to other retail establishments only and is it a “marginal, localised and restricted activity”?<sup>6</sup>

Art 1(5)(b)(ii) of 853/2004

No



**853/2004 applies**

Yes⇒

853/2004 does not apply.

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<sup>6</sup> For an interpretation of these terms, see Annex H

**DOES MY ESTABLISHMENT NEED APPROVAL?**

1. Does my business carry out activities to which only 852/2004 applies?  
 Art 6 (3)(b) of 852/2004

No  
 ↓

2. Does my establishment handle products of animal origin for which requirements are laid down in Annex III of 853/2004?  
 Art 4(2) of 853/2004

Yes  
 ↓

3. Does my establishment only carry out primary production?  
 Art 4(2)(a) of 853/2004

No  
 ↓

4. Does my establishment only carry out transport operations?  
 Art 4(2)(b) of 853/2004

No  
 ↓

Yes⇒

Your establishment only needs to be registered as required by 852/2004.  
 Article 6 (2) of 852/2004

No⇒

Your establishment only needs to be registered as required by 852/2004.

Yes⇒

Your establishment only needs to be registered as required by 852/2004.

Yes⇒

Your establishment only needs to be registered as required by 852/2004.

5. Does my establishment only carry out the storage of products not requiring temperature-controlled storage conditions?  
**Art 4(2)(c) of 853/2004**

No  
↓

6. Does my establishment carry out retail operations only supplying food to the final consumer?  
**Art 4(2)(d) of 853/2004**

No  
↓

7. Does my establishment carry out operations with a view to supplying food of animal origin to another establishment?  
**Art 4(2)(d) and Art 1(5)(b) of 853/2004**

Yes  
↓

8. Do those operations consist only of storage or transport?  
**Art 4(2)(d) and Art 1(5)(b)(I) of 853/2004**

No  
↓

Yes⇒

Your establishment only needs to be registered as required by 852/2004.

Yes⇒

Your establishment only needs to be registered as required by 852/2004.

No⇒

Your establishment only needs to be registered as required by 852/2004.

Yes⇒

Your establishment only needs to be registered as required by 852/2004.

9. Is the supply of food of animal origin from my retail establishment to other retail establishments only and is it a “marginal, localised and restricted activity”?<sup>7</sup>

Art 4(2)(d) and Art 1(5)(b)(ii) of 853/2004

No  
↓

**Your establishment requires approval**

Yes⇒

Your establishment only needs to be registered as required by 852/2004.

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<sup>7</sup> For an interpretation of these terms, see Annex H

**PROVISIONS APPLYING TO PRIMARY PRODUCTION**

1. The legislation lays down general and specific requirements for primary production of food. The relevant definitions are:

- “primary production” means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;” (Article 3(17) of Regulation 178/2002)
- “primary products” means products of primary production including products of the soil, of stock farming, of hunting and fishing;” (Article 2(1)(b) of Regulation 852/2004)

This includes farming (arable crops, livestock production, milk production, fish and shellfish farming), horticulture, hunting, fishing and the production and gathering of live bivalve molluscs and other shellfish. Many of these activities are only subject to the requirements of Regulation 852/2004. In some cases additional requirements are laid down in Regulation 853/2004. The guidance later in this Annex will take you through what provisions apply to different primary production activities.

2. If you are a primary producer undertaking food business activities other than primary production (e.g. if you have a farm shop or if you are manufacturing foods) then you need to comply with the relevant provisions of the legislation which apply to those activities.

3. All food business operators, including primary producers, are required to notify the competent authority of the establishments under its control with a view to those establishments being registered. However, the intention is to

use information from existing Agriculture Department sources, e.g. census information and County/Parish/Holding (CPH) number data, to fulfil this requirement as far as is possible. The precise means of meeting this requirement is still being considered. If there are gaps in current information, it may mean that primary producers should inform the competent authorities of their existence and the nature of the operations.

4. Member States are required to apply and to enforce the legislation, including at the level of primary production. The intention is to develop a light-touch, practical and effective enforcement regime in consultation with Agriculture Departments and industry. There is no intention to introduce a new enforcement body for this purpose, but rather to use bodies already going on farm for other purposes to undertake this role. The detail of exactly what an enforcement regime will look like and who will undertake this role is still to be decided. This and the question of registration of primary production establishments will be consulted on further.

## IS MY BUSINESS PRIMARY PRODUCTION AND IF SO WHAT REQUIREMENTS APPLY TO IT?

### A. AGRICULTURE AND HORTICULTURE

#### 1. PRODUCTION/HARVESTING OF PLANT PRODUCTS

1. Does my business carry out an activity covered by the definition of "primary production" including "associated operations"?

Art 3.17 of 178/2002 and Annex I, Part A, I(1) of 852/2004

Yes



2. Does my business produce or harvest plant products?

No⇒

Go to 4.

Yes



3. Requirements:

You have to:

- a) Co-operate with the competent authorities
- b) Register your establishment
- c) Comply with the relevant hygiene provisions of Annex I, as follows:

Art 6(1) of 852/2004

Art 6(2) of 852/2004

Art 4(1) of 852/2004

Annex I, Part A, II(2),(3), (5) and (6), III(7) and (9) of 852/2004

## 2. FARMING OF LIVESTOCK (MEAT PRODUCTION)

4. Does my business produce animals (other than live bivalve molluscs or fish) for food production?

Yes



5. Does my business produce animals for meat production?

No⇒

Go to 15.

Yes



6. Does my business produce animals defined as “domestic ungulates”?

No⇒

Go to 8.

[Annex I, 1.2 of 853/2004](#)

Yes



7. Requirements:

You have to:

- a) Co-operate with the competent authorities
- b) Register your establishment
- c) Comply with the relevant hygiene provisions of Annex I, as follows:

[Annex I, Part A, II\(2\),\(3\), \(4\) and \(6\), III\(7\) and \(8\) of 852/2004](#)

- d) Comply, as required, with the requirements to supply food chain information
- e) Comply with the relevant hygiene provisions of Annex III, as follows:

[Annex III, Section I, Chapter I and Chapter VI of 853/2004](#)

[Art 6\(1\) of 852/2004](#)

[Art 6\(2\) of 852/2004](#)

[Art 4\(1\) of 852/2004](#)

[Art 3\(1\) and Annex II, Section III of 853/2004](#)

[Art 3\(1\) of 853/2004](#)

8. Does my business produce animals defined as “poultry” or “lagomorphs”?

Annex I, 1.3 and 1.4 of 853/2004

Yes



9. Requirements:

You have to:

- a) Co-operate with the competent authorities
- b) Register your establishment
- c) Comply with the relevant hygiene provisions of Annex I, as follows:

Annex I, Part A, II(2),(3), (4) and (6), III(7) and (8) of 852/2004

- d) Comply, as required, with the requirements to supply food chain information
- e) Comply with the relevant hygiene provisions of Annex III, as follows:

Annex III, Section II, Chapter I and Chapter VI of 853/2004

Art 6(1) of 852/2004  
Art 6(2) of 852/2004  
Art 4(1) of 852/2004

Art 3(1) and Annex II,  
Section III of 853/2004  
Art 3(1) of 853/2004

No⇒

Go to 10.

10. Does my business produce animals defined as “farmed game”?

Annex I, 1.6 of 853/2004

Yes



11. Does my business produce even-toed farmed game mammals (*Cervidae* and *Suidae*)?

No⇒

Go to 13.

Yes



12. Requirements

As for 7 above. In addition the following may apply:

[Annex III, Section III, \(3\) and \(4\) of 853/2004](#)

13. Does my business produce farmed ratites?

Yes



14. Requirements

As for 9 above. In addition the following may apply:

[Annex III, Section III, \(3\) of 853/2004](#)

### 3. FARMING OF LIVESTOCK (DAIRY PRODUCTION)

15. Does my business keep farmed animals to produce milk with a view to placing it on the market as food?

No⇒

Go to 17.

Yes



16. Requirements:

You have to:

- a) Co-operate with the competent authorities
- b) Register your establishment
- c) Comply with the relevant hygiene provisions of Annex I, as follows:

Annex I, Part A, II(2),(3), (4) and (6), III(7) and (8) of 852/2004

- d) Comply with the relevant hygiene provisions of Annex III, as follows:

Annex III, Section IX, Chapter I [and Chapter II, as appropriate] of 853/2004

Art 6(1) of 852/2004

Art 6(2) of 852/2004

Art 4(1) of 852/2004

Art 3(1) of 853/2004

#### 4. FARMING OF LIVESTOCK (EGG PRODUCTION)

17. Does my business keep farmed birds to produce eggs for direct human consumption or for the preparation of egg products for food?

No⇒

Go to 19.

Yes



18. Requirements:

You have to:

- a) Co-operate with the competent authorities
- b) Register your establishment
- c) Comply with the relevant hygiene provisions of Annex I, as follows:

Annex I, Part A, II(2),(3), (4) and (6), III(7) and (8) of 852/2004

- d) Comply with the relevant hygiene provisions of Annex III, as follows:

Annex III, Section X, Chapter I of 853/2004

Art 6(1) of 852/2004

Art 6(2) of 852/2004

Art 4(1) of 852/2004

Art 3(1) of 853/2004

## B. FISHING AND AQUACULTURE

### 1. CULTIVATION AND GATHERING OF LIVE BIVALVE MOLLUSCS

19. Does my business cultivate or gather live bivalve molluscs?

No⇒

Go to 23.

Yes



20. Does my business operate a dispatch centre or a purification centre?

Yes⇒

Go to 22.

[Annex I, 2.7 and 2.8 of 853/2004](#)

No



#### 21. Requirements

Operations that take place before live bivalve molluscs arrive at a dispatch or purification centre (including relaying) are primary production.

[Annex III, Section VII \(4\)\(a\) of 853/2004](#)

You have to:

- a) Co-operate with the competent authorities
- b) Register your establishment
- c) Comply with the relevant hygiene provisions of Annex I as follows:

[Art 6\(1\) of 852/2004](#)  
[Art 6\(2\) of 852/2004](#)  
[Art 4\(1\) of 852/2004](#)

[Annex I, Part A, II\(2\), \(3\), \(4\) and \(6\), III\(7\) and \(8\) of 852/2004](#)

- d) Comply with the relevant hygiene provisions of Annex III as follows:

[Art 3\(1\) of 853/2004](#)

[Annex III, Section VII, Chapter I \(2\)-\(7\), Chapter II, Chapter VIII\(1\) and Chapter IX, as appropriate, of 853/2004](#)

## 22. Requirements

Operations that take place after live bivalve molluscs arrive at a dispatch or purification centre are not primary production

Annex III, Section VII  
(4)(b) of 853/2004

You have to:

- a) Co-operate with the competent authorities
- b) Have your establishment approved
- c) Comply with the relevant hygiene provisions of Annex II of 852/2004
- d) Comply with the relevant provisions of Annex III as follows:  
Annex III, Section VII, Chapter I and Chapters III-IX of 853/2004
- e) (If a dispatch centre) apply an identification mark
- f) Put in place, implement and maintain a permanent procedure or procedures based on HACCP principles

Art 6(1) of 852/2004

Art 4(2) of 853/2004

Art 4(2) of 852/2004

Art 3(1) of 853/2004

Art 5(1)(b), Annex II,  
Section I and Annex  
III, Section VII,  
Chapter I(1) of  
853/2004

Art 5(1) of 852/2004

## 2. FISHING AND FISH FARMING

23. Does your business catch, handle or process “fishery products” as defined?

[Annex I, 3.1 of 853/2004](#)

Yes



24. Does my business undertake any of the following activities in relation to fishery products?

- The farming, fishing and collection of live fishery products with a view to their being placed on the market;
- The following operations, if carried out on board fishing vessels: slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping;
- Also, the transport and storage of fishery products the nature of which has not been substantially altered, within fish farms on land; and,
- The transport of fishery products the nature of which has not been substantially altered, including live fishery products from the place of production to the first establishment of destination.

[Annex III, Section VIII\(4\) of 853/2004](#)

Yes



25. Does my business undertake the operations described in the definitions of “factory vessel” or “freezer vessel” on board such vessels, or do you otherwise process fishery products?

[Annex I, 3.2 and 3.3 of 853/2004](#)

No



No⇒

Go to 25.

Yes⇒

Go to 27.

26. Requirements

Fishing operations and associated activities, other than processing operations are primary production

You have to:

- a) Co-operate with the competent authorities
- b) Register your establishment (this includes a fishing vessel)
- c) Comply with the relevant provisions of Annex I as follows:

Annex I, Part A, II(2),(3),(4) and (6), III(7) and (8) of 852/2004

- d) Comply with the relevant hygiene provisions of Annex III as follows:

Annex III, Section VIII, Chapter I, I A and B, II(1) [DN – any others?] of 853/2004

Annex III, Section VIII  
(3)(a) and (4) of  
853/2004

Art 6(1) of 852/2004  
Art 6(2) of 852/2004

Art 4(1) of 852/2004

Art 3(1) of 853/2004

## 27. Requirements

Processing operations, whether on vessel or on land, including the operation of wholesale and auction markets are not primary production.

You have to:

- a) Co-operate with the competent authorities
- b) Have your establishment (including a vessel) approved
- c) Comply with the relevant hygiene provisions of Annex II of 852/2004
- d) Comply with the relevant provisions of Annex III as follows:  
*Annex III, Section VIII ,as appropriate, of 853/2004 [DN All, or is some not appropriate?]*
- e) Apply an identification mark
- f) Put in place, implement and maintain a permanent procedure or procedures based on HACCP principles

*Annex III, Section VII  
(4)(b) of 853/2004*

*Art 6(1) of 852/2004*

*Art 4(2) of 853/2004*

*Art 4(2) of 852/2004*

*Art 3(1) of 853/2004*

*Art 5(1)(b), Annex II,  
Section I of 853/2004  
Art 5(1) of 852/2004*



## C. HUNTING AND PROCESSING WILD GAME

1. The table below describes what elements of the various regulations apply to the hunting of wild game and its placing on the market. Further explanation is given in the paragraphs that follow.

WHAT APPLIES? →	Regulation 852/2004	Regulation 853/2004	Regulation 854/2004
<b>ACTIVITY</b>			
<b>1. Hunters shooting for own consumption</b>	No Art 1(2)(a)	No Art 1(3)(c)	No
<b>2. Hunters supplying small quantities direct to the final consumer or to local retailers (directly supplying the final consumer):</b>			
<b>a. Wild game (including gralloched deer, gutted small game)</b>	No Art 1(2)(c) National rules apply. See paras 2-5 below	No Art 1(3)(c) National rules apply. See paras 2-5 below	No
<b>b. Wild Game Meat</b>	Yes Requirements A to E below.	No Art 1(3)(e) National rules apply. See paras 2-5 below	No
<b>3. Hunters supplying wild game handling/ processing facilities</b>	Yes Requirements A to E below.	Yes Requirements similar to WGMRs <sup>8</sup> , but Annex III, Section IV adds procedures to be carried out by “trained person”. Training must satisfy CA <sup>9</sup> .	Yes OV <sup>10</sup> to examine declaration delivered with carcass(es) and any other information provided by the hunter. Annex I, Section IV, Chapter 8 A paragraph (2)
<b>4. Premises used for the production of Wild Game Birds</b>	Yes Annex 1 applies. Premises to be registered. Art 6(2)	No	No
<b>5. Game Larders/Collection Centres holding/handling primary products</b>	Yes Annex I applies. Premises to be registered. Art 6(2)	No	No

<sup>8</sup> Wild Game Meat (Hygiene and Inspection) Regulations 1995

<sup>9</sup> Competent Authority

<sup>10</sup> Official Veterinarian

<b>6. Game Larders/Collection Centres</b> holding/handling other than primary products.	Yes Classified as establishments to be registered. (Art 6(2) and Annex II, Ch I & III)	No	No
<b>7. Wild game-handling/processing establishment (any place where game meat is prepared for placing on the UK domestic or export market)</b>	Yes Classified as establishments (Annex II, Ch I & III)	Yes Establishments to be approved. (Article 4(2)) Comply with Annex III, Section IV. Game must be presented to OV.	Yes

2. The definition of primary production means that estates engaged in hunting activities are primary producers. “Primary production” excludes farmed animal production after slaughter, but not animals that are killed by hunters. Primary products exempted from Regulation 852/2004 by Art 1(2)(c) are unskinned/unplucked wild game that have only undergone any necessary gralloching, gutting or cutting in the field as a part of normal hunting practice.

3. Art 1.2(a) exempts from Regulation 852/2004 wild game primary products for private domestic use. Art 1.2(c) provides an exemption covering the direct supply by the producer (who can be the hunter) of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer. “Direct supply” must be understood in the light of recital 10 of Regulation 852/2004 and recital 11 of Regulation 853/2004, where the close relationship between the producer and the consumer is stated as the principle justification for the derogation. National rules are required to cover such activities which meet the objectives of Regulations 852/2004 and 853/2004 as appropriate. However, H1 Annex 1 applies to primary production even where that primary production leads to the supply of primary products exempted under Art 1.2(c).

4. These exemptions are repeated in Art 1(3)(c) of Regulation 853/2004. A further exemption in Art 1(3)(e) relates to hunters supplying small quantities etc. of wild game and wild game meat. Hunters supplying wild game meat exempted under Art 1(3)(e) will have to comply with Regulation 852/2004.

5. In summary, the requirements of the EU regulations will not apply to the supply of wild game primary products that can benefit from the small/final consumer/local exemption and that in those circumstances Regulation 852/2004 only will apply to the supply of wild game meat. Local authorities are responsible for undertaking official controls. In both cases of exemption, provisions under national law will be required that achieve the objectives of the EU regulations. These would be the controls in the Food Safety (Northern Ireland) Order 1991 and the General Food Law Regulation (which applies from 1 January 2005) and controls covering labelling and record keeping in the Game Acts.

6. **Regulation 852/2004 requirements**

- A. Food safety management procedures based on HACCP principles, Art 5 (new).
- B. Registration of every food business establishment, Art 6.
- C. Competent Authority must encourage hunters' organisations to produce good hygiene and HACCP guide, Art 7 (new).
- D. Transport provisions, Annex I, Part A, I, 1.(c) and Annex II Ch IV.
- E. General and specific hygiene provisions, including re:
  - a) storage facilities (e.g. collection centres/game larders holding/handling primary products normally at place of production, but could be elsewhere on an Estate), Annex 1.
  - b) food premises (includes movable or temporary premises or private dwelling houses (Annex II, Chs I & 3) and food preparation rooms (Annex II Ch II). Would apply to any collection centre/game larder holding/handling other than primary products – although this unlikely given the limited purpose of such premises.

**SUMMARY GUIDANCE TO WHAT PROVISIONS APPLY TO FOOD BUSINESSES  
(OTHER THAN PRIMARY PRODUCTION)**

(Annex F provides guidance on what requirements apply to primary production)

In this Annex, references to the national Food Hygiene Regulations are to the specific regulations and the Schedules applying specific requirements to certain food businesses, rather than those parts of those Regulations applying the EU legislation.

**A RESTAURANTS, CATERERS AND SHOPS SELLING FOOD TO THE FINAL CONSUMER (including such operations carried out on board ships and aircraft)**

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Registration
Annex II	General requirements for all food business operators

Regulation 853/2004

In general this regulation does not apply with the exception of the following:

- provisions relating to live bivalve molluscs and fishery products which apply to retail sales - Annex III, Section VII (3) and Section VIII (2)
- requirements for eggs that apply until sale to the consumer, e.g. eggs must be delivered within 21 days of lay – Annex III, Section X (1)-(3).

The Food Hygiene Regulations 2005

Regulation 30 and Schedule 4    Temperature control requirements

These national requirements are in addition to the general temperature control requirement in Annex II, Chapter IX (5)-(7) of Regulation 852/2004. The national requirements do not apply to food business operations on ships or aircraft.

Changed requirements

- Documented food safety management procedures based on HACCP principles (Article 5 of Regulation 852/2004)
- Those responsible for the development and maintenance of food safety management procedures to have received adequate training

**B**     OTHER FOOD BUSINESSES, PROCESSING OR HANDLING FOODS ONLY  
SUBJECT TO REGULATION 852/2004

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Registration
Annex II	General requirements for all food business operators

Regulation 853/2004

This Regulation does not in general apply. However, Article 1(2) has the effect of clarifying that food containing both products of plant origin and processed products of animal origin are subject only to the requirements of Regulation 852/2004. The processed products of animal origin used to prepare such food will need to comply with the requirements of Regulation 853/2004 (see below).

The Food Hygiene Regulations 2005

Regulation 29 and Schedule 3	Bulk transport in sea-going vessels of liquid oils and fats and the bulk transport by sea of raw sugar.
Regulation 30 and Schedule 4	Temperature control requirements

Changed requirements

- Documented food safety management procedures based on HACCP principles (Article 5 of Regulation 852/2004)
- Those responsible for the development and maintenance of food safety management procedures to have received adequate training
- Foods containing both products of plant origin and processed products of animal origin are subject only to Regulation 852/2004 requirements
- The national temperature control rules will extend to foods containing both products of plant origin and processed products of animal origin that are currently subject to product-specific temperature requirements and will fall within 852/2004 from 1 January 2006.

## C FOOD BUSINESSES PROCESSING OR HANDLING FOODS SUBJECT TO REGULATION 853/2004

In this section, the relevant provisions of Regulation 854/2004 are also listed. This Regulation concerns the way in which official controls are to be undertaken. As such, it does not describe the duties of food business operators (which are described in Regulations 852/2004 and 853/2004).

### 1. Meat of domestic ungulates

#### Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

#### Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Article 8	Special guarantees (where applicable)
Annex I	Definitions
Annex II	Section II Objectives of HACCP-based procedures (slaughterhouses only)
Annex II	Section III Food chain information (slaughterhouses only)
Annex III	Section I

#### Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004
Article 5	Fresh meat (including health marking, Article 5(2))
Annex I	Fresh meat

#### Changed requirements

- Requirements apply irrespective of the throughput of a premises
- Provision of food chain information
- Change of terminology: “Licences” will be replaced by “Approvals”

## 2. Meat from poultry and lagomorphs<sup>11</sup>

### Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

### Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Article 8	Special guarantees (where applicable)
Annex I	Definitions
Annex II	Section I Identification marking
Annex II	Section II Objectives of HACCP-based procedures (slaughterhouses only)
Annex II	Section III Food chain information (slaughterhouses only)
Annex III	Section II

### Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004
Article 5	Fresh meat
Annex I	Fresh meat

### Changed requirements

- Requirements in general less prescriptive.
- Removal of 'low throughput' poultry meat plant concept, same requirements will apply to all plants irrespective of throughput.
- Use of company staff to carry out inspection activities, when they meet certain requirements.

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<sup>11</sup> The direct supply by the producer of small quantities of meat from poultry and lagomorphs slaughtered on the farm is subject to the provisions of Regulation 852/2004 listed here and to Regulation 31 and Schedule 5 of the Food Hygiene Regulations 2005 only

- Greater possibility for on farm slaughter.
- Ostriches are now covered under farmed game. The provisions relating to poultry slaughterhouses and cutting plants will normally apply. However, producers will no longer be able to take advantage of any 'under 10,000 exemption' as allowed in existing the Poultry Meat Regulations related to on farm slaughter and processing of ostriches. Certain on farm slaughter activities will be permitted in the circumstances described in the Regulation.
- Change of terminology: “Licences” will be replaced by “Approvals”

### 3. Meat of farmed game

#### Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

#### Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section II Objectives of HACCP-based procedures (slaughterhouses only)
Annex II	Section III Food chain information (slaughterhouses only)
Annex III	Section III

#### Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004
Article 5	Fresh meat (including health marking, Article 5(2))
Annex I	Fresh meat

#### Changed requirements

- In general, as for domestic ungulates
- Ostriches are now covered under farmed game. The provisions relating to poultry slaughterhouses and cutting plants will normally apply. However, producers will no longer be able to take advantage of any 'under 10,000 exemption' as allowed in existing the Poultry Meat Regulations related to on farm slaughter and processing of ostriches. Certain on farm slaughter activities will be permitted in the circumstances described in the Regulation.
- Change of terminology: "Licences" will be replaced by "Approvals"

#### 4. Wild game meat

##### Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

##### Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex III	Section IV

##### Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004
Article 5	Fresh meat (including health marking, Article 5(2))
Annex I	Fresh meat

##### Changed requirements

- Chilling of wild game within a reasonable period after killing. Active chilling not necessary where climatic conditions make this unnecessary
- All wild game handling establishments will be approved and meet common hygiene standards irrespective as to whether meat is supplied for the domestic or international market.
- Introduction of food safety management procedures based on HACCP principles (Article 5 of Regulation 852/2004)
- Those responsible for the development and maintenance of food safety management procedures to have received adequate training
- Requirement for certain hunters to be trained in health and hygiene
- Hunting organisations to develop and implement training arrangements which satisfy the competent authority
- Change of terminology: "Licences" will be replaced by "Approvals"

5. Minced meat, meat preparations and mechanically separated meat (MSM)

Regulation 852/2004

- Article 4(2) Compliance with hygiene requirements  
Article 5 Food Safety management procedures based on HACCP principles  
Article 6 Approval of establishments  
Annex II General requirements for all food business operators

Regulation 853/2004

- Article 3 General obligation  
Article 4 Approval of establishments  
Article 5 Health and identification marking  
Article 8 Special guarantees (where applicable)  
Annex I Definitions  
Annex II Section I Identification marking  
Annex III Section V

Regulation 854/2004

- Article 1 Scope  
Article 3 Approval of establishments  
Article 4 General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

Changed requirements

- Manufacture of mechanically separated meat is brought within the scope of 'meat' legislation.
- All establishments will require approval; there will be no exemption from approval for establishments manufacturing for the national market only.
- Application of an identification mark to all production.
- Requirements, in general, less prescriptive.
- Removal of the 'industrial/non-industrial' production levels; the same requirements will apply to all plants irrespective of their production levels.

## 6. Meat products

### Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

### Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section VI

### Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

### Changed requirements

- Requirements, in general, less prescriptive.
- Removal of the 'industrial/non-industrial' production levels, the same requirements will apply to all plants irrespective of their production levels.

7. Live bivalve molluscs

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section VII

Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004
Article 6	Live bivalve molluscs
Annex II	Live bivalve molluscs

Changed requirements

- [To be added]

8. Fishery products

Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

#### Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section VIII

#### Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004
Article 7	Fishery products
Annex III	Fishery products

#### Changed requirements

- [To be added]

### 9. Raw milk and dairy products

#### Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

#### Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section IX

### Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004
Article 8	Raw milk and dairy products
Annex IV	Raw milk and dairy products

### The Food Hygiene Regulations 2005

Regulation 32 and Schedule 6	Restrictions on the sale of raw milk intended for direct human consumption
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### Changed requirements

- Raw milk from any animal showing individually a positive reaction to test for tuberculosis and brucella must no longer be used for human consumption. The milk from all other animals in the herd may continue to be used as long as it is heat treated.
- Removal of provisions contained in the Milk and Dairies (General) Regulations 1959 relating to heat treatment notices which were issued for herds which lost their disease free status or whose milk contained certain pathogens.
- Removal of the ban on the sale of thermised milk direct to the ultimate consumer.
- Removal of the specific requirements for the heat treatment of cream and ice cream.

## 10. Eggs and egg products

### Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

### Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Article 8	Special guarantees (where applicable)

Annex I	Definitions	
Annex II	Section I	Identification marking
Annex III	Section X	

#### Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

#### Changed requirements

- [To be added]

### 11. Frogs' legs and snails

#### Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

#### Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section XI

#### Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

#### Changed requirements

- [To be added]

## 12. Rendered animal fats and greaves

### Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

### Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section XII

### Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

### Changed requirements

- Requirements, in general, less prescriptive.
- Requirement for approval.
- Application of an identification mark to all production.

## 13. Treated stomachs, bladders and intestines

### Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments

Annex II      General requirements for all food business operators

Regulation 853/2004

Article 3      General obligation  
Article 4      Approval of establishments  
Article 5      Health and identification marking  
Annex I      Definitions  
Annex II      Section I      Identification marking  
Annex III     Section XIII

Regulation 854/2004

Article 1      Scope  
Article 3      Approval of establishments  
Article 4      General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

Changed requirements

- Requirements, in general, less prescriptive.
- Requirement for approval.
- Application of an identification mark to all production.

14.      Gelatine

Regulation 852/2004

Article 4(2)    Compliance with hygiene requirements  
Article 5      Food Safety management procedures based on HACCP principles  
Article 6      Approval of establishments  
Annex II      General requirements for all food business operators

Regulation 853/2004

Article 3      General obligation  
Article 4      Approval of establishments  
Article 5      Health and identification marking  
Annex I      Definitions  
Annex II      Section I      Identification marking  
Annex III     Section XIV

#### Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

#### Changed requirements

- Requirements, in general, less prescriptive.
- Requirement for approval.

### 15. Collagen

#### Regulation 852/2004

Article 4(2)	Compliance with hygiene requirements
Article 5	Food Safety management procedures based on HACCP principles
Article 6	Approval of establishments
Annex II	General requirements for all food business operators

#### Regulation 853/2004

Article 3	General obligation
Article 4	Approval of establishments
Article 5	Health and identification marking
Annex I	Definitions
Annex II	Section I Identification marking
Annex III	Section XV

#### Regulation 854/2004

Article 1	Scope
Article 3	Approval of establishments
Article 4	General principles for official controls in respect of all products of animal origin falling within the scope of Regulation 854/2004

#### Changed requirements

- Requirements, in general, less prescriptive.
- Requirement for approval.

**FSA INTERPRETATION OF TERMS USED IN THE EU REGULATIONS****Direct supply of small quantities of primary products (including wild game) to final consumer or local retail establishment.**

(Article 1(2)(c) of Regulation 852/2004 and Article 1(3)(c) of Regulation 853/2004)

1. A meaningful interpretation of what constitutes a small quantity of various primary products will vary enormously from product to product, e.g. potatoes, strawberries, fish etc. For wild game it is suggested that a small quantity is under 10,000 small wild game and under 300 large wild game per year. The interpretation of “local” would be the same as for “localised”, see paragraph 4 b) below. In the case of raw cows’ milk for drinking, the quantity might be a few pints and not more than a single crate.

**Direct supply to the final consumer, or local retail establishment, of small quantities of poultry and rabbits slaughtered on farm.**

(Article 1(3)(d) of Regulation 853/2004)

2. We clarified during the negotiation of the legislation that the intention would be to continue to apply the approach given effect to in the Poultry Meat, Farmed Game Bird Meat and Rabbit Meat (Hygiene and Inspection) Regulations 1995 (as amended). Thus “small quantities” would be interpreted as **under 10,000 birds or rabbits per year reared and slaughtered on farm, as at present**. In addition we would interpret “small quantities” as including the output of those producers who are both members of an appropriate assurance scheme and who either dry pluck by hand or slaughter for up to 40 days per annum. The current provisions in respect of seasonal markets would also be considered to apply.

**Direct supply to the final consumer, or local retail establishment, of small quantities of wild game meat.**

(Article 1(3)(e) of Regulation 853/2004)

3. The intention would be to subject such supply to the general provisions of Regulation 852/2004 and not to apply any more specific rules. **The quantitative**

**limit applied to such supplies would be under 10,000 small wild game and under 300 large wild game per year.** The interpretation of “local” would be the same as for “localised”, see paragraph 4 b) below.

### **Retail-to-Retail Supplies**

4. In the Regulations the definition of ‘retail’ (written in from General Food Law (Regulation EC No. 178/2002)) includes ‘wholesale’. While the intention of Regulation 853/2004 is to exempt businesses retailing products of animal origin to the final consumer (i.e. the public), it is meant to apply to businesses that supply other businesses (e.g. caterers, pubs, restaurants, other retailers). However, an exception applies when the operations consist only of storage or transport, or when the supply to other establishments is a “marginal, localised and restricted activity” when the more general requirements of 852/2004 would apply.

- “marginal”

‘Marginal’ is described in recital 13 of 853/2004 as only a small part of the establishment’s business. In this context, the supply of food of animal origin to other establishments will be treated as “marginal” for the purposes of Article 1.5(b)(ii) if it is a marginal part of the **food business** of the supplier.

Since Regulation 852/2004 will still apply to establishments exempted from Regulation 853/2004 and it is considered sufficient to control retail activities we consider that “marginal” should be interpreted as liberally as possible. However, we are constrained by its description in the recital as “only a small part of the business”. While the earlier consultation proposed proportions of between 50% and 30% of the business, we have come to the view that 25% of the business is the highest interpretation that can reasonably be placed on the term “marginal”. **It is proposed that marginal is interpreted as being up to a quarter of the business’ turnover in terms of food.**

- “Local” / ”localised”

‘Localised’ is described in recital 13 of 853/2004 as in the immediate vicinity of the supplying establishment. **It is proposed that “local” and “localised” be interpreted as ‘sales within the supplying establishment’s own county *plus* the greater of either the neighbouring county or counties or 30 miles/50**

**kilometres from the boundary of the supplying establishment's county'**. "County" would be interpreted here as meaning or an administrative county in Northern Ireland (e.g. Co. Fermanagh).

- "restricted"
4. 'Restricted' is described in recital 13 of 853/2004 as concerning only certain types of products or establishments which may be exempt under the 'retail' to 'retail' exemption in 853/2004. Having to list establishments and products was seen as bureaucratic and a potential barrier to trade and there are other legal requirements for traceability of food products. **It is proposed that "restricted" be interpreted as specified product categories as referenced in 853/2004 (e.g. dairy products, collagen, minced meat) and establishment types (e.g. a butcher's shop, distribution centre).**

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<sup>12</sup> Except that the Isles of Scilly and the combined counties of Mid Glamorgan, South Glamorgan and West Glamorgan shall be regarded as one county each. For some larger authorities in Scotland a finite limit might be considered more appropriate.