

FSA GUIDANCE ON THE REQUIREMENTS OF FOOD HYGIENE

LEGISLATION

CONTENTS

Section		Pages
1	Introduction	2
2	Background	3
3	Scope	3-5
4	Requirements of Regulation 852/2004 – Primary Producers	5
5	Registration	5-6
6	Approval	6-7
7	Specific hygiene requirements	7
8	Food Safety Management	7
9	Guides to good practice	8
10	Enforcement	8-9
Annexes		
A	The Food Hygiene Regulations and other associated legislation	10-12
B	Sources of advice and information	13-23
C	Do the provisions of Regulation 852/2004 apply?	24-25
D	Do the provisions of Regulation 853/2004 also apply?	26-28
E	Does an establishment need approval?	29-31
F	Provisions applying to primary production	33-47
G	Summary guidance to what provisions apply to food businesses	48-64
H	FSA interpretation of terms used in the EU Regulations	65-68
I	Implementing and transitional measures	69-71
J	Application form for registration of food establishments	72

FSA GUIDANCE ON THE REQUIREMENTS OF FOOD HYGIENE LEGISLATION

1. Introduction

1.1 From 1 January 2006 food hygiene legislation has changed. 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. In addition, the European Commission has produced guidance material on various aspects of the legislation. Details are in Annex B.

1.3 While this guidance is not legally binding, it does nevertheless represent the considered views of the Agency and is issued 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. Please bear in mind that all the web links included in this document, both those to the FSA's web site and to exterior web sites, are subject to change.

1.5 If you have any comments on this guidance or any questions in relation to it, please feel free to contact:

In England:
David Gray, 0207 276 8940,
david.gray@foodstandards.gsi.gov.uk

In Scotland:
Jennifer Howie, 01224 285142,
jennifer.howie@foodstandards.gsi.gov.uk

In Wales:
Owen Davies, 029 2067 8915,
Owen.davies@foodstandards.gsi.gov.uk

In Northern Ireland:
Louise Connolly, 028 9041 7741,
louise.connolly@foodstandards.gsi.gov.uk

2. Background

2.1 The new legislation is intended to:

- modernise, consolidate and simplify EU food hygiene legislation;
- apply effective and proportionate controls throughout the food chain, from primary production to sale or supply to the final consumer;
- focus controls on what is necessary for public health protection; and
- clarify that it is the primary responsibility of food business operators to produce food safely.

2.2 The new legislation has a number of provisions which apply in common to different foods. The type(s) of food which businesses handle or sell will determine with which requirements they have to comply.

2.3 In general terms, Regulations 852/2004 and 853/2004 lay down requirements for food business operators. Regulation 852/2004 applies to all food businesses (including those operating at the level of primary production). Regulation 853/2004 applies, in addition, to certain food businesses handling products of animal origin (See Annex D). 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.

2.4 A number of more detailed implementing and transitional measures have been adopted at the European level. Where these apply to areas covered in this guidance, this is highlighted and details are given in Annex I.

3. Scope

3.1 Who has to comply with the EU Regulations?

Food businesses and food business operators, as defined. If an individual or business does not meet the definitions, then the EU Regulations do not apply.

- | |
|---|
| <ul style="list-style-type: none">• “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). |
|---|

Further clarification 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 What is excluded from the scope?

- Activities such as the occasional preparation of food by individuals or groups for gatherings or for sale at charitable events.

Such activities would still be subject to the general legal requirements relating to placing unsafe food on the market contained in Article 14 of Regulation (EC) 178/2002 as implemented by the General Food Regulations 2004.

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 requirements relating to placing unsafe food on the market contained in Article 14 of Regulation (EC) 178/2002 as implemented by the General Food Regulations 2004. In the case of eggs supplied in accordance with c), the Ungraded Eggs (Hygiene) Regulations 1990¹ 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 authorised by the local food authority 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. Annex D is a guide to whether the provisions of Regulation 853/2004 also apply. Businesses may need to work through both these Annexes for all their activities to find out how their entire business may be

¹ In Scotland, these Regulations were revoked by the Food Hygiene (Scotland) Regulations (2005)

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 that are not defined in the EU Regulations, but nevertheless have a meaning in terms of those Regulations. Therefore, we cannot define them (and so, potentially, 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 different situations. These interpretations are set out in Annex H.

4. Requirements of Regulation 852/2004 – Primary Producers

4.1 Under Regulation 852/2004, primary producers are subject to different requirements than are other types of food business. A farmer, fisherman or a hunter of wild game is undertaking 'primary production' (for the full definition see Annex F). 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). Section 10 explains who this is. 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). If an establishment is already registered under previous legislation and there have been no changes since registration or since the last inspection visit by the competent authority, then no further action is needed to comply with this requirement.

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. A standard registration form, which should be completed for each establishment and submitted to the relevant competent authority, is attached at Annex J. When registering, food business operators must provide the relevant competent authority with full details of the activities undertaken. 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. Where approval for an activity is required, that activity does not need to be registered too. An example might be a dairy farm (registration) which also produces dairy products not for sale exclusively to the final consumer (approval) and has a farm shop (registration) on the premises. A single application 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.

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 an establishment needs approval, it does not need to be registered as well. Approvals will replace current approvals and (in the meat sector) both approvals and meat plant licences granted prior to 1 January 2006. Therefore if your establishment is already approved or has a meat plant licence, it will need to be re-assessed for approval under the new Regulations. However you are entitled to continue your business until such time as the competent authority carries out this reassessment. If you are setting up a new business, you need to apply to the relevant competent authority for approval before you can trade. Details on who to contact are in Annex B.

6.2 If a business is:

- one that has only supplied wild game meat for the domestic market; or
- one that cuts meat for supply to other establishments, including caterers, in excess of the “marginal” and “localised” thresholds (see Annex H for further details); or
- one that produced minced meat and meat preparations for the domestic market; or
- a cold store not previously licensed
- an establishment that grades, or packs, eggs

and has been registered with the food authority, it now needs to be approved, by the FSA in the first two cases and by the food authority in the third, fourth and fifth, unless co-located with a slaughterhouse, cutting plant or game handling establishment, in which case it will also be approved by the FSA. The process of approving (by the FSA in the first two cases) all premises falling within these categories is expected to take between 12 to 18 months to complete, although egg packing establishments have until the end of 2009 to become approved. Egg packing establishments are subject to the general requirements of Annex II of Regulation 852/2004.

6.3 If a business manufactures foods containing both products of plant origin and processed products of animal origin, that manufacture is not subject to the requirements of Regulation 853/2004 (Article 1(2) of Regulation 853/2004 Please note that definitions of ‘processing’ and ‘processed products’ can be found, respectively, in Article 2(1)(m) and (o) of Regulation 852/2004.). Those premises do not need to be approved, nor do they need to put an

identification mark on those foods. However, the processed products of animal origin used to prepare such food have to comply with specific requirements and to have been processed in an approved establishment.

6.4 Transition measures apply. Please refer to Annex I.

7. Specific hygiene requirements

7.1 Article 4 (2) of Regulation 852/2004 requires that food business operators comply, as appropriate with the general hygiene requirements laid down in Annex II of that Regulation. For more guidance on what that means for your food business see guidance identified in Annex B. In addition, you will need to comply with the relevant 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 Food Hygiene Regulations 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), (NI: Regulation 26 and Schedule 3)
- temperature control requirements (Regulation 30 and Schedule 4), (NI: Regulation 27 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) (NI: Regulation 28 and Schedule 5) and
- restrictions on the sale of raw milk intended for direct human consumption (Regulation 32 and Schedule 6)(NI: Regulation 29 and Schedule 6).

7.2 In addition, there are requirements in relation to microbiological criteria. These are set out in Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs. These replaced the previous requirements in sector specific hygiene Directives. Details of where guidance to Regulation (EC) 2073/2005 can be obtained are found in Annex B.

8. Food Safety Management

8.1 With the exception of activities at the level of primary production, food business operators are required to put in place procedures which manage food safety within their 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 food business operators 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.

9. Guides to good practice

Articles 7-9 of Regulation 852/2004 provide for the development of guides to good practice for hygiene and the application of HACCP principles. Food business operators may use these guides as a voluntary aid to compliance with their obligations under the food hygiene legislation. Further information on good practice guides can be found on the FSA website at www.food.gov.uk/foodindustry/hygiene/goodpractice.

10. Enforcement

10.1 Regulation 5 of the national legislation listed in Annex A confers responsibility for enforcing the legislation on food authorities and on the Food Standards Agency. Responsibility for enforcement in different types of premises is set out below.

10.2 Primary producers subject only to Regulation 852/2004

As indicated in Annex F, responsibility for enforcing the legislation at the level of primary production is still under discussion.

10.3 Other food businesses subject only to Regulation 852/2004

Food authorities will be responsible for enforcement.

10.4 Food businesses to which Regulation 853/2004 applies – Meat establishments

In Great Britain

The Food Standards Agency's Meat Hygiene Service (MHS) is responsible for enforcement in

- approved or conditionally approved slaughterhouses, cutting plants and game handling establishments, and
- pending their eventual approval, slaughterhouses, cutting plants and game handling establishments that were operating under cover of a license under the Meat Hygiene Regulations at the end of 2005.

The MHS is also responsible for enforcement in

- meat products, minced meat, meat preparations, mechanically separated meat plants, cold stores (i.e. wrapping) or edible co-products establishments (i.e. treated stomachs, bladders and intestines, rendered animal fats and greaves, gelatine and collagen) co-located with an approved slaughterhouse, cutting plant or game handling establishment.

Food authorities will be responsible for enforcement in

- approved stand alone cold stores, re-wrapping establishments and establishments that produce meat products, minced meat, meat preparations, mechanically separated meat, edible co-products and in establishments exempted from approval under Regulation 853/2004.

Where establishments transfer from food authority to MHS control, this will take place once approval is given. However, enforcement in cold stores operating under cover of a license under the Meat Hygiene Regulations at the end of 2005 transferred to food authorities on 1 January 2006.

In Northern Ireland

DARD Veterinary Service Veterinary Public Health Unit (VPHU) carry out the enforcement role in approved slaughterhouses, cutting plants and game handling establishments on behalf of FSA Northern Ireland.

Enforcement in minced meat, meat preparations, mechanically separated meat premises and cold stores co-located with an approved slaughterhouse, cutting plant or game handling establishment is also carried out by VPHU.

Food authorities (District Councils) are responsible for enforcement in:

- Approved stand alone cold stores, minced meat, meat preparations and mechanically separated meat premises;
- Approved meat products and edible co-products premises (stand alone and co-located);
- Establishments exempted from approval under Regulation 853/2004.

10.5 Other food businesses to which Regulation 853/2004 applies

Food authorities are responsible for enforcement.

In the case of dairy production holdings, the enforcement responsibility in the case of England and Wales remains with the Dairy Hygiene Inspectorate of Defra.. In Scotland, Food Authorities are responsible for dairy production holdings. In Northern Ireland, enforcement responsibility will be carried out by DARD Quality Assurance Branch.

In the case of egg production, egg production units are considered as primary production, but as soon as the egg leaves the production unit and is subject to some other activity such as grading and packing, that activity is not considered to be primary production. Primary production of eggs is subject to Regulation 852/2004 and the position on enforcement is as set out in paragraph 10.2 above. In England, Wales and Scotland, enforcement in respect of egg packing is carried out by the food authority and egg packing centres need to be and approved by food authorities. In Northern Ireland, enforcement responsibilities for egg production holdings and for egg packing centres are carried out by DARD Quality Assurance Branch.

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 consumption².

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.

2. In addition, a number of more detailed measures, including implementing and transitional measures have been published. These are:

² 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.

- Commission Regulation (EC) No. 1688/2005 implementing Regulation (EC) No. 853/2004 of the European Parliament and of the Council as regards special guarantees concerning salmonella for consignments to Finland and Sweden of certain meat and eggs;
- Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs;
- Commission Regulation (EC) No. 2074/2005 laying down implementing measures for certain products under Regulation (EC) No. 853/2004, for the organisation of official controls under Regulations (EC) Nos. 854/2004 and 882/2004, derogating from Regulation (EC) No. 852/2004 and amending Regulations (EC) Nos. 853/2004 and 854/2004;
- Commission Regulation (EC) No. 2075/2005 laying down specific rules on official controls for *Trichinella* in meat; and
- Commission Regulation (EC) No. 2076/2005 laying down transitional arrangements for the implementation of Regulations (EC) No. 853/2004, (EC) Nos. 854/2004 and 882/2004 of the European Parliament and of the Council and amending Regulations (EC) Nos. 853/2004 and 854/2004.

Regulation 1688/2005 was published in the Official Journal of the European Union (OJ) of 15 October 2005, L271. Regulations 2073/2005, 2074/2005, 2075/2005 and 2076/2005 were published in the OJ of 22 December 2005, L 338.

Copies of the Regulations in pdf format can be accessed from the Food Standards Agency's website at:

www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/

Copies of the Official Journal can be accessed from the European Union's website at:

www.europa.eu.int/eur-lex/lex/JOIndex.do?ihmlang=en

Please note that the Food Standards Agency is not responsible for the content of exterior web sites.

3. This legislation is applied in the UK by:

- The Food Hygiene (England) Regulations 2006 (SI 2006/14)
- The Food Hygiene (Scotland) Regulations 2006 (SSI 2006/3)
- The Food Hygiene (Wales) Regulations 2006 (SI 2006/31 (W.5))
- The Food Hygiene Regulations (Northern Ireland) 2006 (SR 2006/3)

Copies are obtainable from the Office of Public Sector Information (OPSI). You can access these from the OPSI website at:

www.opsi.gov.uk

4. 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 the European Union website by following the link above.

SOURCES OF ADVICE AND INFORMATION

This Annex contains a range of other sources of information and guidance aimed at industry, enforcement practitioners and voluntary organisations. The Annex has been organised as set out below.

1. Background information
2. FSA Guidance documents for food industry sectors
3. Food Safety Management / HACCP packs for caterers
4. Other sources of information for small businesses from Government
5. European Commission guidance on Regulations 852/2004, 853/2004, on HACCP and on Imports
6. The statutory Food Law Code of Practice and accompanying Practice Guidance as well as other sources of guidance for environmental health practitioners and enforcement practitioners in port health authorities
7. Guidance for enforcement officers in the Meat Hygiene Service
8. Details of enforcement practitioners in other bodies
9. Government sources of information for farmers, growers and other producers
10. Industry Organisations and Associations
11. Guides to good hygiene for businesses and for the domestic sector
12. Other general sources of information

1. Background information

Background to the new legislation and copies of the EU texts can be found on the FSA web site at:

www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/

Information for businesses and enforcement practitioners in the form of a Q&A on the new food hygiene legislation can be accessed from:

www.food.gov.uk/foodindustry/hygiene/

An electronic version of the EU Official Journal (where the adopted EU Regulations are published) can be found on the European Union's web site at:

www.europa.eu.int/eur-lex/lex/JOIndex.do?ihmlang=en

2. FSA Guidance documents for food industry sectors

The FSA has produced both this generic guide and shorter sector-specific summary guides on the new legislation. Other FSA guidance available covers food hygiene and other regulations for the meat industry, the Microbiological

Criteria Regulation and imports of food of non-animal origin. Links to electronic copies of these guidance documents can be found on the FSA's web site at:

<http://www.food.gov.uk/foodindustry/guidancenotes/foodguid/fhlguidance/>

The guidance documents can be accessed directly:

Meat:

www.food.gov.uk/foodindustry/meat/

Includes draft guidance, HACCP diary, wild game and edible co-products.

On the Microbiological Criteria Regulation:

<http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/microbiolreg>

Import of feed and food of non-animal origin

From 1 January 2006, the legislation concerning the above changed. EC Regulation 882/2004, *the Official Feed and Food Controls Regulation* applied and was given effect in England by the Official Feed and Food Controls (England) Regulations 2006 (SI 2006/15) and equivalent legislation in Scotland, Wales and Northern Ireland. This guidance note, using a Q&A format, helps to explain the legal requirements for businesses as set out in part 3 of these Regulations in England:

<http://www.food.gov.uk/multimedia/pdfs/offcindustryguidancenote.pdf>

3. Food Safety Management / HACCP packs for caterers

The new legislation requires all food businesses to operate a food safety management system based on the HACCP principles. In order to help caterers comply, the FSA has developed guidance packs.

These are 'Safer food better business' in England, 'Safe catering – your guide to HACCP' in Northern Ireland and 'Cooksafe' in Scotland.

Please note that catering businesses do not have to choose the pack developed by the FSA authority in their own country; they may choose any model they wish.

England – ‘Safer food, better business’

Safer food, better business has been developed by the FSA in partnership with small catering businesses and more than 50 local authorities.

If you would like a ‘Safer food, better business’ pack then please contact the Environmental Health Department at your local authority or contact FSA Publications on:0845 606 0667 or email foodstandards@ecgroup.uk.com.

You can also view the pack at:

www.food.gov.uk/foodindustry/hygiene/sfbb/

A pack is also being developed for retailers.

Scotland – ‘Cooksafe’

FSA Scotland has drawn on expertise from the food industry including small businesses, local authorities and the Scottish Food Advisory Committee to develop a HACCP-based system called ‘CookSafe’. Businesses that would like a copy should contact their local authority or this can be downloaded from the FSA web site at:

www.food.gov.uk/foodindustry/hygiene/cooksafe/

Wales

Several local authorities have previously developed guidance packs on HACCP for caterers and FSA Wales has encouraged the sharing of these packs throughout Welsh local authorities. Businesses should contact their local authority Environmental Health Department for more information.

Northern Ireland – ‘Safe Catering – your guide to HACCP’

In Northern Ireland, The Agency working with local authorities and caterers has produced guidance for the catering sector called ‘Safe Catering – your guide to HACCP’. This guidance, which has been developed and refined over a number of years, is promoted by all local authorities in NI and is widely accepted by the catering sector. Further revision of the guidance is planned for the near future. To receive a pack, please contact FSA Northern Ireland on 028 9041 7700.

4. Other sources of information for small businesses from Government

The Small Business Service

www.sbs.gov.uk

tel: 020 7215 5000 (DTI enquiry line)

Practical advice for business can be found at:

www.businesslink.gov.uk

5. European Commission guidance on Regulations 852/2004, 853/2004, on HACCP and on Imports

The European Commission has issued the following guidance documents.

HACCP guidance – this document is mainly directed at food businesses and enforcement practitioners with the aim of giving guidance on the implementation of procedures based on the HACCP principles and on flexibility with regard to the implementation of such procedures, especially in small businesses. It can be downloaded from the EU web site at:

http://europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf

Guidance to Regulation 852/2004 and Regulation 853/2004 – these two documents are mainly directed at food businesses and enforcement practitioners with the aim of giving guidance on the implementation of the new food hygiene requirements and on related subjects. They can be downloaded respectively from the EU web site at:

http://europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance_doc_852-2004_en.pdf

and from:

http://europa.eu.int/comm/food/food/biosafety/hygienelegislation/guidance_doc_853-2004_en.pdf

Guidance on Imports - this document is mainly directed at competent authorities and food businesses in the Member States and in third countries with the aim of giving guidance on certain key questions with regard to the implementation of the new food hygiene import requirements and on related subjects. It can be downloaded from the EU web site at:

www.europa.eu.int/comm/food/international/trade/interpretation_imports.pdf

6. The statutory Food Law Code of Practice and accompanying Practice Guidance as well as other sources of guidance for environmental health practitioners and enforcement practitioners in port health authorities

England & Wales

The statutory Food Law Code of Practice and accompanying Practice Guidance have been amended in the light of the new legislation.

The statutory Food Law Code of Practice and accompanying Practice Guidance for England and for Wales can be found respectively on the FSA's web site at:

www.food.gov.uk/enforcement/foodlaw/copenland

and

www.food.gov.uk/multimedia/pdfs/codeofpracticedraftwales.pdf

The Code of Practice for Wales is currently (early April 2006) being translated and will be submitted late April to Welsh Assembly Government.

These were publicised in a letter to enforcers issued via the Enforcement Portal which can be found at:

www.food.gov.uk/multimedia/pdfs/enf_e_05_045.pdf.

Hard copies of the above documents can be obtained from the FSA on 020 7276 8455 or 020 7276 8454, or from FSA Wales on 029 2067 8902.

You may also wish to contact environmental / port health representative bodies:

Local Authorities Coordinators of Regulatory Services

www.lacors.gov.uk

tel: 020 7840 7200

Chartered Institute of Environmental Health

www.cieh.org

tel: 020 7928 6006

email: info@cieh.org

Chartered Institute for Environmental Health Cymru-Wales

www.cieh-cymruwales.org

tel: 01766 810081

email: ciehcymruwales@cieh.net

Association of Port Health Authorities

www.apha.org.uk

tel: 08707 444505

email: APHA@cieh.org.uk

The FSA web site contains a wide range of information for enforcement practitioners. Links to this information can be found in the Enforcement Portal:

www.food.gov.uk/enforcement/

Scotland

The *draft* Code of Practice and Practice Guidance for Scotland can be found on the FSA'S web site at:

www.food.gov.uk/foodindustry/Consultations/consultscot/copscot2005

Hard copies of the above documents can be obtained from Food Standards Agency Scotland on 01224 285118

You may also wish to contact environmental health representative bodies:

Royal Environmental Health Institute of Scotland

www.rehis.org/

tel: 0131 225 6999

email: rehis@rehis.org.uk

Northern Ireland

The *draft* Code of Practice and Practice Guidance for Northern Ireland can be found on the FSA'S web site at:

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

7. Guidance for enforcement officers in the Meat Hygiene Service and DARD Veterinary Service

England, Scotland & Wales

Guidance is available in the enforcement Manual of Official Control. This can be found at:

www.food.gov.uk/enforcement/meathyg/mhservice/

Northern Ireland

The equivalent of the Manual of Official Controls for DARD Veterinary Service is due to be completed shortly and will be placed on the DARD web site

8. Details of enforcement practitioners in other bodies

Eggs

Egg Marketing Inspectorate

Information is available on the EMI web site at:

www.defra.gov.uk/foodrin/poultry/emi.htm

Information on the Scottish Executive Environment and Rural Affairs Department's Egg and Poultry Unit can be found at:

www.scotland.gov.uk/Topics/Agriculture/Agricultural-Policy/LivestockAndLivestockProd/EggsAndPoultry/Enforcement

Dairy

Dairy Hygiene Inspectorate

www.defra.gov.uk/rds/dhi.htm

Tel: 01823 285540 email: dhi.taunton@defra.gsi.gov.uk

In Scotland, the equivalent work is undertaken by local authorities.

9. Government sources of information for farmers, growers and other producers

England

For more general information regarding the food hygiene regulations as they apply to producers and growers, please see the question and answer page on the FSA web site at:

<http://www.food.gov.uk/foodindustry/hygiene/haccpprimary/>

You can also contact the FSA on 020 7276 8972.

For more information regarding the feed hygiene regulations contact the FSA on 020 7276 8469. Alternatively, for either regulations ring the Defra helpline on 08459 33 55 77.

A leaflet providing general information for farmers and growers on the new food hygiene legislation and on the feed hygiene legislation can be found at:

www.food.gov.uk/multimedia/pdfs/farmgrowhyg.pdf

EC Feed Hygiene Regulation

Guidance is available for feed businesses that make, use or market animal feeds, which sets out the approval and registration requirements from 1 January 2006. This includes most livestock farms (including fish farms) and arable farms that grow, use or sell crops for feed are also within the scope of the provisions of the new EC Feed Hygiene Regulation (183/2005). A Code

on feeding food producing animals is set out in Annex III of Regulation 183/2005.

Scotland

For more information in Scotland please contact FSAS on 01224 285142 (food queries) or 01224 285138 (feed queries).

A range of other information for farmers and growers in Scotland is available on the FSA Scotland web site at:

www.food.gov.uk/news/newsarchive/2005/nov/scothygleaf

Wales

For more information in Wales, please contact FSAW on 029 20678915 (food queries) or 029 2067 8908 (feed queries).

For links to other topics of interest for farmers and growers UK wide, please see the FSA web site at:

<http://www.food.gov.uk/foodindustry/farmingfood/>

10. Industry Organisations and Associations

We have included a list of industry organisations that may be able to provide help and information for businesses on the new legislation as it applies to the food industry sector that they represent. These cover a range of sectors, but we should stress that the list is by no means exhaustive.

British Association of Shooting and Conservation

www.basc.org.uk

British Egg Industry Service

www.britegg.co.uk

tel: 020 7808 9790

British Hospitality Association

www.bha-online.org.uk

tel: 0845 880 7744

email: info@bha.org.uk

British Institute of Innkeeping

www.bii.org

tel: 01276 684449

email: reception@bii.org

British Meat Processors Association
www.bmpa.uk.com
tel: 020 7329 0776
info@bmpa.uk.com

British Poultry Council
www.poultry.uk.com
email: white@poultry.uk.com
tel: 020 7202 4760

British Retail Consortium
www.brc.org.uk
tel: 020 7854 8900

British Sandwich Association
www.sandwich.org.uk
email: admin@sandwich.org.uk

Campden and Chorleywood Food Research Association
www.campden.co.uk
tel: 01386 842000

Chilled Food Association
www.chilledfood.org
email: cfa@chilledfood.org

Farmers Union of Wales
www.fuw.org.uk/

Food and Drink Federation
www.fdf.org.uk
tel: 0207 836 2460

Food and Drink Federation (Scotland)
www.sfdf.org.uk
tel: 0131 229 9415

Freight Transport Association
www.fta.co.uk
tel: 08717 112222

Hospital Caterers Association
www.hospitalcaterers.org
email: alison.mccree@cddah.nhs.uk

Hotel & Catering International Management Association
www.hcima.org.uk
tel: 0208 6614900
email: commdept@hcima.co.uk

Hybu Cig Cymru - Meat Promotion Wales
www.hybucigcymru.org

Leatherhead Food International
www.lfra.co.uk
tel: 01372 376761
email: help@leatherheadfood.com

Meat and Livestock Commission
www.mlc.org.uk
tel: 01908 677577

National Association of Catering Butchers
www.nacb.co.uk
Tel: 020 7248 1896
email: info@nacb.co.uk

National Farmers Union
www.nfu.org.uk/

National Farmers Union of Scotland
www.nfus.org.uk/

National Farmers Union (Cymru)
www.nfu-cymru.org.uk/

National Pig Association
www.npa-uk.net
tel: 020 7331 7650

Nationwide Caterers Association
www.ncass.org.uk
tel: 0871 5041780
email: info@ncass.org.uk

People1st, the Sector Skills Council
tel: 0870 0602550
www.people1st.co.uk

Royal Association of British Dairy Farmers
www.rabdf.co.uk
Tel: 0845 458 2711
email: office@rabdf.co.uk

Scottish Association of Meat Wholesalers
www.scottish-meat-wholesalers.org.uk/

Sea Fish Industry Authority
www.seafish.org
01482 327837

11. Guides to good hygiene practice and other information supporting good food hygiene both for businesses and for the domestic sector

The FSA produces a number of booklets providing practical information on good food hygiene covering a range of different circumstances, including business and domestic catering. A list of those currently available is provided and these will be updated, as necessary, to take into account changes in the legislation

- *Food Hygiene – a guide for businesses*
- *Starting up: Your first steps to running a catering business (currently out of print, but available late March 2006)*
- *Food Law Inspections and Your Business*
- *Eggs – what caterers need to know*

Booklets will be produced in 2006 covering the following areas

- General food hygiene information for consumers
- Home caterers and charities

Advice for caterers and consumers is provided on the Agency's web sites,

www.food.gov.uk

and

www.eatwell.gov.uk

If you wish to order any of the publications, please contact FSA Publications:

tel: 0845 606 0667

minicom: 0845 606 0678

fax: 020 8867 3225

email: foodstandards@ecgroup.uk.com

12. Other general sources of information

To locate your nearest Environmental Health Department please go to:

www.food.gov.uk/enforcement/yourarea/

Copies of the national legislation can be obtained from the Office of Public Sector information. You can access these from the web site at:

www.opsi.gov.uk

The National Farmers' Union (NFU) have produced a food law guide. This can be accessed from the NFU web site **by NFU members only** at:

www.nfuonline.com/stellentdev/groups/members@published/documents/ianda/findyourwayaroundeu_ia4383330c.doc

The Chilled Food Association (for CFA contact details see Annex B, part 10 above) has produced guidance, in conjunction with the Food Standards Agency, to the Microbiological Criteria Regulation. This can be found on the CFA web site at: www.chilledfood.org/content/guidance.asp

DO THE PROVISIONS OF REGULATION 852/2004 APPLY?

<p>1. Is the business a food business as defined?</p> <p>Art 3.2 of 178/2002</p>	No⇒	Hygiene legislation does not apply.
<p>Yes ↓</p> <p>2. Is the business an undertaking, the concept of which implies a certain continuity of activities and a certain degree of organisation?</p> <p>Recital 9 of 852/2004</p>	No⇒	<p>Hygiene legislation does not apply.</p> <p><i>However, if you are making food other than for solely domestic use, you will need to comply with the general provisions of the Food Safety Act 1990 (as amended).</i></p>
<p>Yes ↓</p> <p>3. Does the business undertake primary production for private domestic use?</p> <p>Art 1(2)(a) of 852/2004</p>	Yes⇒	Hygiene legislation does not apply.
<p>No ↓</p> <p>4. Does the business undertake the domestic preparation, handling or storage of fresh food for private domestic consumption?</p> <p>Art 1(2)(b) of 852/2004</p>	Yes⇒	Hygiene legislation does not apply.
<p>No ↓</p>		

5. Is the 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 the business supply small quantities³ of primary products directly to the final consumer or to local⁴ 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 authorised by your local food authority and meet certain requirements to prevent contamination. See paragraph 3.4.

Yes⇒

Hygiene legislation does not apply, but rules under national law apply to the act of supply. See paragraph 3.4

³ For an interpretation of this term, see Annex H

⁴ For an interpretation of this term, see Annex H

DO THE PROVISIONS OF REGULATION 853/2004 ALSO APPLY?

1. Does the 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 from an approved establishment and handled in accordance with the requirements of 853/2004.*

Art 1(2) of 853/2004

No



2. Does the business produce and directly supply small quantities⁵ of meat from poultry and lagomorphs⁶ slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer?

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. Transitional Measures apply. 2076/2005, Article 3.

No



3. Does the business undertake the hunting and supply of **small** quantities⁷ 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. *This is also the case if the business, in addition to those activities described in box 3, also undertakes the preparation by the hunter of small quantities of wild game meat for supply to the final consumer / local retail establishments.*

No



⁵ For an interpretation of this term, see Annex H

⁶ Rabbits or hares

⁷ For an interpretation of this term, see Annex H

4. Does the 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 the 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 the business carry out 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. Meat cold stores also need to be approved.

No



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

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

No



853/2004 applies

Yes⇒

853/2004 does not apply.

⁸ For an interpretation of these terms, see Annex H

DOES AN ESTABLISHMENT NEED APPROVAL?

1. Does the business carry out activities to which only 852/2004 applies?

Art 6 (3)(b) of 852/2004

No



2. Does the 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 the establishment only carry out primary production?

Art 4(2)(a) of 853/2004

No



4. Does the establishment only carry out transport operations?

Art 4(2)(b) of 853/2004

No



Yes⇒

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

Article 6 (2) of 852/2004

No⇒

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

Yes⇒

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

Yes⇒

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

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

No
↓

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

No
↓

7. Does the 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⇒

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

Yes⇒

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

No⇒

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

Yes⇒

The establishment only needs to be registered as required by 852/2004, except for meat cold stores, which are required to be approved.

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

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

No



The establishment requires approval

Yes⇒

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

⁹ 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, egg 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 risk-based practical and effective enforcement regime in consultation with stakeholders. There is no intention to create 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.

WHAT IS CONSIDERED AS PRIMARY PRODUCTION AND WHAT REQUIREMENTS APPLY? (NOT HUNTING OR PROCESSING OF WILD GAME – GO TO PART C)

A. AGRICULTURE AND HORTICULTURE

1. PRODUCTION/HARVESTING OF PLANT PRODUCTS

1. Does the 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 the 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 the establishment
c) Comply with the relevant hygiene provisions of Annex I, as follows:
Annex I, Part A, II(2),(3), (5) and (6), III(7) and (9) of 852/2004

Art 6(1) of 852/2004

Art 6(2) of 852/2004

Art 4(1) of 852/2004

2. FARMING OF LIVESTOCK (MEAT PRODUCTION)

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

Yes



5. Does the business produce animals for meat production?

No⇒

Go to 15.

Yes



6. Does the 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 the 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 II¹⁰,
Section III of 853/2004

Art 3(1) of 853/2004

¹⁰ Food chain information requirements are being phased in by species as provided for in Article 8 of Regulation 2076/2005, with poultry required from 1.1.2006, pigs from 1.1.2008, horses and veal calves by 1.1.2009 and the rest by 1.1.2010.

8. Does the business produce animals defined as “poultry” or “lagomorphs”?
Annex I, 1.3 and 1.4 of 853/2004

No⇒

Go to 10.

Yes



9. Requirements:
You have to:
a) Co-operate with the competent authorities
b) Register the 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**

10. Does the business produce animals defined as “farmed game”?
Annex I, 1.6 of 853/2004

Yes



11. Does the business produce even-toed farmed game mammals (*Cervidae*,¹¹ *Suidae*¹² and *Bison*)?

No⇒

Go to 13.

¹¹ Deer.

¹² Pigs, boar.

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 the 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 the 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 the 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 the 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 the 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 the business cultivate or gather live bivalve molluscs?

No⇒

Go to 23.

Yes
↓

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

Annex I, 2.7 and 2.8 of 853/2004

Yes⇒

Got to 22.

No
↓

21. Requirements

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

You have to:

a) Co-operate with the competent authorities
b) Register the 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 VII, Chapter I (2)-(7), Chapter II, Chapter VIII(1) and Chapter IX, as appropriate, of 853/2004

Annex III, Section VII (4)(a) 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

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 the 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 the business catch, handle or process “fishery products” as defined?

Annex I, 3.1 of 853/2004

Yes



24. Does the 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 the 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 the 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) 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 the 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](#)
- 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

Separate guidance has been produced to cover these activities. Please see Annex B for further details.

**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 2006

Regulation 30 (Regulation 27 for NI) 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 2006

- Regulation 29 and Schedule 3
(NI: Regulation 26 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
(NI: Regulation 27 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 came 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

(See also Annex I on implementing and transitional measures)

Changed requirements

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

2. Meat from poultry and lagomorphs¹³

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

(See also Annex I on implementing and transitional measures)

¹³ 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 2006 only

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.
- Training required for company staff carrying out inspection activities.
- 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 the 'under 10,000 exemption' 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" 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

(See also Annex I on implementing and transitional measures)

Changed requirements

- In general, as for domestic ungulates
- 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
- 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 the 'under 10,000 exemption' related to on farm slaughter and processing of ostriches. Certain on farm slaughter activities are permitted in the circumstances described in the Regulation.
- Change of terminology: "Licences" replaced by "Approvals"
- "Licensed Farm Game Handling Facilities" replaced by "Approved Farm Slaughter Facilities"
- "Farmed Game Processing Facilities" licensed under the Meat Hygiene Regulations need to be approved as slaughterhouses with the condition that they are used only for the dressing of carcasses.

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

(See also Annex I on implementing and transitional measures)

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 need approval and must 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
 - Introducing hunter training arrangements which satisfy the competent authority
 - Change of terminology: “Licences” 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

(See also Annex I on implementing and transitional measures)

Changed requirements

- Manufacture of mechanically separated meat is brought within the scope of 'meat' legislation.
- All establishments require approval; there is 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 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

(See also Annex I on implementing and transitional measures)

Changed requirements

- Requirements, in general, less prescriptive.
- Removal of the 'industrial/non-industrial' production levels, the same requirements apply to all plants irrespective of their production levels.
- The assembly of food containing both products of plant origin with processed products of animal origin and either placed on the market as such or further processed together are subject only to Regulation 852/2004 requirements.

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

(See also Annex I on implementing and transitional measures)

Changed requirements

- Purification establishments are newly required to operate procedures based on the HACCP principles.
- Competent Authorities no longer classify Class B shellfish harvesting waters on the basis that 90% of samples fall within the standard. Classification are based on 100% of sample results.

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

(See also Annex I on implementing and transitional measures)

Changed requirements

- Food containing both products of plant origin and processed products of animal origin are subject only to Regulation 852/2004 requirements.
- Withdrawal of 10% definition of fishery product in UK Regulations.
- Wholesale markets/Auctions can have sub-approval unit numbers for individual businesses.

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

(See also Annex I on implementing and transitional measures)

The Food Hygiene Regulations 2006

Regulation 32 and Schedule 6 (NI: Regulation 29 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.
- Food containing both products of plant origin and processed products of animal origin are subject only to Regulation 852/2004 requirements. However, there are some products which are dairy products (i.e. wholly milk-based) which contain some small amounts of plant material. Examples are given in the Commission's guidance document to Regulation 853/2004 (e.g. cheese containing herbs and yoghurt containing fruit.) Establishments making these

products would require approval as cheese and yoghurt are products of animal origin (dairy products).

- In Scotland, the ban on raw milk and raw cream sales intended for direct human consumption has been extended to include raw milk and cream from all milk producing animals.
- In Wales, the labelling requirement for raw milk sales intended for human consumption has been amended. In respect of Wales only, Regulation 31 of the Food Labelling Regulations 1996 now reads: "This milk/cream has not been heat treated and may therefore contain organisms harmful to health. The Food Standards Agency strongly advises that it should not be consumed by children, pregnant women, older people or those who are unwell or have chronic illness". This requirement applies to raw milk from cows, ewes, goats and buffaloes.

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

(See also Annex I on implementing and transitional measures)

Changed requirements (Eggs)

- Hygiene requirements for shell eggs brought under food hygiene regulations rather than egg marketing regulations.
- For egg packing stations, 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.

Changed requirements (Egg Products)

- Requirements, in general, less prescriptive.
- 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.
- New definition of “egg products” – now means processed egg or egg contents.
- “Liquid egg” defined separately and now means unprocessed egg content.
- Food containing both products of plant origin and processed products of animal origin are subject only to Regulation 852/2004 requirements.

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

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

(See also Annex I on implementing and transitional measures)

Changed requirements

- Requirements, in general, less prescriptive.
- Requirement for approval.
- In Scotland, removal of specific temperature control requirements.

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. The following interpretations are offered for certain types of primary product.
 - For wild game a small quantity is currently set at under 10,000 small wild game and under 300 large wild game per year. The interpretation of “local” is the same as for “localised”, see paragraph 4 below.
 - In Scotland, the ban on raw milk and raw cream sales intended for direct human consumption has been extended to include milk or cream from all milk producing animals.
 - In relation to small quantities of primary fishery products and live bivalve molluscs (LBMs) it is suggested that it will be appropriate to maintain the approach of the outgoing legislation. This would mean that ‘small quantities’ would be interpreted as up to 25 tonnes of fish and/or LBMs together in any calendar year.
 - Where the total amount involved comprises more than one species, it is suggested that the maximum amount of individual LBM species within the overall total should be no more than:

Species	Maximum amount (tonnes per annum)
Cockles	25
Oysters	5
King Scallops	5
Queen Scallops	10
Mussels	20
Other LBMs	10
Marine Gastropods	20

- It is **important** to note that any LBMs marketed under this small quantities exemption may only come from Class A designated shellfish harvesting areas. This is because the Regulations allow only LBMs from Class A waters to be placed **directly** on the market.
- The industry remain responsible for ensuring that any fishery products or LBMs directly marketed under these arrangements are fit for human consumption, notably that they meet the end product standards set out in the Regulations.

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 is 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” is interpreted as **under 10,000 birds or rabbits per year reared and slaughtered on farm**. In addition we 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 provisions in respect of seasonal markets (which do not apply in Scotland) are also 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 is 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” is the same as for “localised”, see paragraph 4 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 outlet’. 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 (except for meat storage which the European Commission expects to be carried out in approved establishments), or transport, or when the supply to other establishments is a “marginal, localised and restricted activity” when the more general requirements of 852/2004 apply.

- “marginal”

‘Marginal’ is described in recital 13 of 853/2004 as only a small part of the establishment’s business. In addition, the European Commission guidance (see Annex B) provides that “marginal” may also be interpreted as a small amount of food of animal origin in absolute terms.

In turn, we are interpreting:

(i) “a small part of the establishment’s business” as meaning **“up to a quarter of the business in terms of food”** ; and

(ii) “a small amount of food of animal origin” as meaning, in relation to meat (fresh or processed, excluding wild game and wild game meat) **up to two tonnes per week**, subject to the establishment having a genuine retail element to its operation supplying the final consumer with part of its production of meat.

If either applies, except in relation to wild game and wild game meat, when only (i) applies, the establishment is exempt from the requirements of Regulation 853/2004.

- “Local” / ”localised”

‘Localised’ is described in recital 13 of 853/2004 as in the immediate vicinity of the supplying establishment. **It has been decided 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” is interpreted here as meaning metropolitan or non-metropolitan counties in England and Wales as defined in the Local Government Act 1972 and London Government Act 1963¹⁴ (e.g. Greater London, North Yorkshire, Leicestershire, Powys), a local authority in Scotland, or an administrative county in Northern Ireland (e.g. Co. Fermanagh). This makes allowance for the imbalance between closely spaced urban authorities and widely spaced remote populations, as well as those on the boundaries or bordered by the sea.

- “restricted”

‘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. In the meat sector, in relation to wild game and wild game meat, supply is subject to the game having been examined by a trained person, and for large game, being accompanied by a declaration stating that no abnormalities were observed either before or after shooting. In relation to other meat, restrictions relate to the amounts of meat supplied and/or the requirement for a genuine retail element to the operation (see interpretation of “marginal” above).

¹⁴ 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.

IMPLEMENTING AND TRANSITIONAL MEASURES

1. Commission Regulation (EC) No. 1688/2005 implementing Regulation (EC) No. 853/2004 of the European Parliament and of the Council as regards special guarantees concerning salmonella for consignments to Finland and Sweden of certain meat and eggs]

This Regulation specifies additional requirements that food businesses have to comply with in order to send consignments of certain meat and eggs to Finland and Sweden.

2. Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs

This Regulation establishes the microbiological criteria that food businesses have to comply with as provided by **Article 4(3) and 4(4) of Regulation 852/2004**. Separate guidance has been produced (please see Annex B for details).

3. Commission Regulation (EC) No. 2074/2005 laying down implementing measures for certain products under Regulation (EC) No. 853/2004, for the organisation of official controls under Regulations (EC) Nos. 854/2004 and 882/2004, derogating from Regulation (EC) No. 852/2004 and amending Regulations (EC) Nos. 853/2004 and 854/2004

This Regulation establishes a number of more detailed provisions which have to be complied with and also amends Regulations 853/2004 and 854/2004. The provisions which might apply to food business operators are described below.

- **Article 1 and Annex I** specify more detailed requirements for food chain information;
- **Article 2 and Annex II** lay down detailed rules relating to visual inspections to detect parasites in fishery products;
- **Article 3 and Annex III** lay down recognised testing methods for detecting marine biotoxins; and
- **Article 4 and Annex IV** lay down the calcium content of mechanically separated meat.

The amendments have the effect of:

- allowing the production of unskinned cattle, goat and sheep's' feet (**Annex VII (2)(a)**);

- prohibiting the placing on the market as fresh meat of poultry meat treated specifically to promote water retention. Poultry meat treated in this way becomes a preparation and can be placed on the market as such. The preparations can also be used to produce processed products (**Annex VII(2)(b)**);
- laying down additional requirements to apply when certain fishery products are placed on the market (**Annex VII(2)(c)**);
- harmonising the approach to the authorisation of teat dips or sprays and establishing more detailed requirements for heat treatments applied to dairy products (**Annex VII(2)(d)**);
- clarifying certain provision relating to egg products and liquid egg (**Annex VII(2)(e)**); and
- maintaining a requirement to label gelatine intended for human consumption (**Annex VII(2)(f)**).

4. Commission Regulation (EC) No. 2075/2005 laying down specific rules on official controls for *Trichinella* in meat

This mainly concerns the duties of the competent authority. Further guidance is available in the Manual of Official Control which can be found at:

www.food.gov.uk/enforcement/meathyg/mhservice/

5. Commission Regulation (EC) No. 2076/2005 laying down transitional arrangements for the implementation of Regulations (EC) No. 853/2004, (EC) Nos. 854/2004 and 882/2004 of the European Parliament and of the Council and amending Regulations (EC) Nos. 853/2004 and 854/2004

This Regulation establishes a transition period (for the most part until 31 December 2009, except where otherwise stated) where the arrangements set out in the Regulation for food businesses producing products of animal origin can apply. The Regulation has the effect of:

- allowing food of animal origin produced before 1 January 2006 and health marked in accordance with the requirements at the time of manufacture to be placed on the market after 1 January 2006 (**Article 2**);
- providing that the direct supply of small quantities of meat from poultry or lagomorphs slaughtered on farm to the final consumer or to local retail establishments supplying such meat to the final consumer shall be subject to national legislation (i.e. not limiting this to direct supply as fresh meat) (**Article 3**);

- allowing establishments that were not previously subject to approval to trade intra-Community to continue putting products on the national market with a national mark, until they have been approved to use the new identification mark by the competent authority (Article 4);
- allowing food businesses to use up stocks of pre-printed wrapping, packaging and labelling purchased before 1 January 2006, until 31 December 2007 (Article 5);
- allowing the continued use of current marking equipment until its replacement or the end of the transition period (Article 6);
- providing for the phased introduction of the requirements for food chain information, other than for the poultry sector where the arrangements apply immediately (Article 8);
- allowing the certificate concerning ante mortem inspection for certain farmed game to be signed by the veterinary service (Article 9);
- maintaining (until they are replaced by other requirements) the composition criteria and labelling requirements for minced meat established by Directive 94/65/EC (Article 10);
- clarifying the requirements for the use of clean water in relation to fishery products (Article 11);
- limiting the requirement to verify compliance with a limit criterion for raw cows' milk immediately before processing (Article 12); and
- allowing the use of cracked eggs to make liquid egg, as well as egg products (Article 13).

ANNEX J: Application Form for the Registration of a Food Business Establishment

APPLICATION FOR THE REGISTRATION OF A FOOD BUSINESS ESTABLISHMENT

(Regulation (EC) No. 852/2004 on the Hygiene of Foodstuffs, Article 6(2))

This form should be completed by food business operators in respect of new food business establishments and submitted to the relevant food authority 28 days before commencing food operations. On the basis of the activities carried out, certain food business establishments are required to be approved rather than registered. If you are unsure whether any aspect of your food operations would require your establishment to be approved, please contact [the Food Authority] for guidance.

1. **Address of establishment** _____
(or address at which moveable establishment is kept)

Post code _____

2. **Name of food business** _____ Telephone no. _____
(trading name)

3. **Full Name of food business operator** _____

4. **Address of food business operator** _____

Post code _____

Telephone no. _____ E-mail _____

5. **Type of food business** (Please tick ALL the boxes that apply):

- | | | | |
|-------------------------------|--------------------------|---|--------------------------|
| Farm Shop | <input type="checkbox"/> | Staff restaurant/canteen/kitchen | <input type="checkbox"/> |
| Food manufacturing/processing | <input type="checkbox"/> | Catering | <input type="checkbox"/> |
| Packer | <input type="checkbox"/> | Hospital/residential home/school | <input type="checkbox"/> |
| Importer | <input type="checkbox"/> | Hotel/pub/guest house | <input type="checkbox"/> |
| Wholesale/cash and carry | <input type="checkbox"/> | Private house used for a food business | <input type="checkbox"/> |
| Distribution/warehousing | <input type="checkbox"/> | Moveable establishment e.g. ice cream van | <input type="checkbox"/> |
| Retailer | <input type="checkbox"/> | Market stall | <input type="checkbox"/> |
| Restaurant/café/snack bar | <input type="checkbox"/> | Food Broker | <input type="checkbox"/> |
| Market | <input type="checkbox"/> | Takeaway | <input type="checkbox"/> |
| Seasonal Slaughterer | <input type="checkbox"/> | Other (please give details): | <input type="checkbox"/> |

6. **Type of business:**

- | | |
|-----------------------------|--------------------------|
| Sole Trader | <input type="checkbox"/> |
| Partnership | <input type="checkbox"/> |
| Limited Company | <input type="checkbox"/> |
| Other (please give details) | <input type="checkbox"/> |

(If Limited Company, please complete 7. below)

7. **Limited company name** _____ **Company no.** _____

Registered Office address _____

Post code _____

8. **Number of vehicles or stalls kept at, or used from, the food business establishment and used for the purposes of preparing, selling or transporting food:**

5 or less 6-10 11-50 51 plus

9. **Water supplied to the food business establishment:** Public (mains) supply Private supply

10. **Full name of manager (if different from operator)** _____

11. **If this is a new business** _____
Date you intend to open

12. **If this is a seasonal business** _____
Period during which you intend to be open each year

13. **Number of people engaged in food business** 0-10 11-50 51 plus (Please tick one box)
Count part-time worker(s) (25 hrs per week or less) as one-half

Signature of food business operator _____

Date _____

Name _____
(BLOCK CAPITALS)

AFTER THIS FORM HAS BEEN SUBMITTED, FOOD BUSINESS OPERATORS MUST NOTIFY ANY CHANGES TO THE ACTIVITIES STATED ABOVE TO [THE FOOD AUTHORITY] AND SHOULD DO SO WITHIN 28 DAYS OF THE CHANGE(S) HAPPENING.