

# Guide to Food Law for Artisan/Small Food Producers Starting a New Business



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**Food Safety Authority of Ireland**

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### **Disclaimer**

This document is intended to act as a guide to food legislation. It does not claim to be comprehensive, or to be a legal interpretation, or to constitute legal or other professional advice. Changes to the legislation can be expected in the future which will require the information in this document to be updated.

## Introduction

When starting, or thinking of starting a new food business, there are many things to think about, such as your market, products, premises, recruitment, advertising and promotion. But you will also need to familiarise yourself with the aspects of food law that are relevant to your food business – and this guide will help you.

The main purpose of food law is to ensure a safe food supply and to protect consumers' interests in relation to food. When you start a food business you are regarded as a 'food business operator'. It is your legal responsibility to make sure that your new business complies with food law and produces safe food.

The Food Safety Authority of Ireland (FSAI) is responsible for enforcing food legislation in Ireland, and carries out this enforcement through service contracts with official agencies<sup>1</sup>. Official agencies carry out inspections, take samples and conduct audits of the food businesses they supervise to check that they are complying with the law. They will also take enforcement action if they discover a food business has broken the law. Enforcement officers from the official agencies are also a good source of food safety information.

At the initial stages of starting a food business, it is important that you contact the official agency appropriate to your business. This is so you can register your food business and, if necessary, apply for an approval number<sup>2</sup>.

To operate legally you must:

- Be **registered** or **approved**
- Have a set of controls in place to ensure safe food – formally known as a **food safety management system**
- Have an effective **traceability** system in place, which will allow you to withdraw or recall food from the market if a safety problem is discovered
- Ensure that everyone handling food in your business has received enough food safety **training** to allow them to do their job safely
- **Comply** with the relevant food law

This guide gives you information on how to apply for registration or approval for your new food business. It also gives information on food safety management systems, traceability and training. Finally, this guide gives a summary of the main pieces of food legislation that may apply to your food business.

There are some exemptions in the legislation for food businesses which produce very small quantities of food. So, in the early stages of planning your food business, you should discuss with your enforcement officer how the legislation applies to you.

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If, after reading this document,  
you have any questions email  
[info@fsai.ie](mailto:info@fsai.ie) for advice.

<sup>1</sup> Official agencies include: the Health Service Executive; the Department of Agriculture, Food and the Marine; the Sea-Fisheries Protection Authority; and local authorities. The official agency that supervises your food businesses will depend on the type of activities carried out in your business. For example, most small food businesses producing meat products are supervised by local authorities.

<sup>2</sup> Approval numbers are required for certain food businesses that handle foods of animal origin. This is explained on page 5.



## Terms used in this Document

Below is an explanation of some terms used in this document which you may not be familiar with.

**Competent authority** is an organisation responsible for enforcing and ensuring compliance with food law.

**Food business**, under Regulation (EC) No 178/2002, means “any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food”.

**Food business operator**, under Regulation (EC) No 178/2002, means “the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control”.

**Food safety management system** is the system of controls used by a food business to ensure that the food it produces is safe to eat, when prepared and/or eaten according to its intended use.

**HACCP** stands for Hazard Analysis and Critical Control Point. It is a systematic approach to identifying and controlling hazards (microbiological, chemical or physical) that could pose a danger to the safety of food.

**Hazards** can be microbiological, chemical or physical agents present in a food which could harm consumers of food.

**Official agencies** are agencies which, under contract to the Food Safety Authority of Ireland, enforce food law in Ireland. In the context of this document they include: the Health Service Executive; the Department of Agriculture, Food and the Marine; the Sea-Fisheries Protection Authority; and the local authorities.

**Prerequisites** (prerequisite hygiene requirements) are the basic conditions and activities (such as pest control, waste management, cleaning etc.) that are necessary to maintain a hygienic food production environment.

**Traceability**, under Regulation (EC) No 178/2002, means “the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution”.

## Food Law

A wide range of food is available in Ireland today, and whether that food is produced by a large multi-national company or a small local food producer, it must be safe for consumers to eat.

Food hygiene legislation lays down rules which food business operators must comply with in order to supply safe food. The hygiene rules apply to all food businesses, but the legislation does allow some flexibility based on risk. Other pieces of food legislation deal with issues such as labelling, marketing standards, contaminants, additives and food contact materials (e.g. packaging).

Most of Ireland's food law is derived from EU legislation. Generally EU legislation is transposed into Irish law (Statutory Instruments) in order to authorise organisation(s) to enforce the legislation in Ireland, and also to lay down penalties for infringements of the legislation.

Taking the hygiene of foodstuffs legislation as an example, the EU legislation is Regulation (EC) No 853/2004 on the hygiene of foodstuffs, which is transposed into Irish law as:

- European Communities (Hygiene of Foodstuffs) Regulations, 2006 (S.I. No. 369 of 2006)<sup>3</sup>, and
- European Communities (Food and Feed Hygiene) Regulations, 2009 (S.I. No. 432 of 2009)<sup>4</sup>

### Where do you find the legislation?

It is important that you read the legislation so you can work out how it applies to your food business. There is a comprehensive legislation section on the FSAI's website ([www.fsai.ie](http://www.fsai.ie)) from which both EU and national legislation can be downloaded. Irish legislation can also be purchased from the Stationery Office, Government Publications, Sun Alliance House, Molesworth Street, Dublin 2 (Telephone: 01 6313111; website: [www.irishstatutebook.ie](http://www.irishstatutebook.ie))<sup>5</sup>.

<sup>3</sup> Applies to food businesses supervised by the Health Service Executive.

<sup>4</sup> Applies to food businesses supervised by the Department of Agriculture, Food and the Marine, the Sea-Fisheries Protection Authority or local authorities.

<sup>5</sup> The authoritative legislation version is the printed version. In the case of the European Union, legislation published in paper editions of the Official Journal of the European Union is deemed authentic. For Irish Legislation, the authoritative text is that printed by The Stationery Office, Ireland.

## Registration and Approval

Under food hygiene legislation, food businesses must be registered with an official agency, and in some cases, those handling products of animal origin must be approved.

### Registration

The purpose of registering your food business with an official agency is to let the official agency know that you are operating a food business, where it is located, and what activities you are carrying out.

Under Regulation (EC) No 852/2004, you must let your official agency know about every food business under your control. You must also inform them about any changes to a food business. Changes may include: a change of owner or address, a change in the type of food being handled, or a change in the amount of food being produced.

### Approval

If your food business makes or handles food of animal origin, it must also (with some exceptions) be approved by the official agencies before you place any food products on the market. The types of food business which must be approved are laid down in Annex III of Regulation (EC) No 853/2004.

### Health Marks and Identification Marks

Approved food businesses are issued with a health mark and/or an identification mark. You cannot place on the market, foods of animal origin from approved premises unless they are labelled, as appropriate, with a health mark, in accordance with Regulation (EC) No 854/2004 or, when a health mark is not required, an identification mark in accordance with Regulation (EC) No 853/2004.

In the slaughterhouse, a **health mark** is an oval mark stamped on a carcass or cut of meat to show that the animal has been inspected, before and after slaughter, in line with Regulation (EC) No 854/2004, and that there are no grounds for declaring the meat unfit for human consumption.

The health mark is applied by, or under the responsibility of, the official veterinarian. A health mark contains the approval number of the slaughterhouse and, when applied within the EU, the country's name or abbreviation, e.g. 'IE' for Ireland. A description of how the health mark must be applied and what it must look like is given in Annex I, Chapter III of the Regulation.

### Example of a Health Mark

See Chapter III, Annex 1 of Regulation (EC) No 854/2004

#### Oval Shape

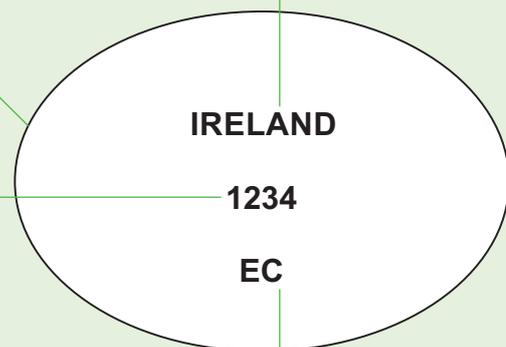
Minimum size 6.5 cm wide by 4.5 cm high. Letters at least 0.8 cm high. Figures at least 1 cm high. (Dimensions may be reduced for marking lamb, kids and piglets)

#### Country

in which establishment is located. For Ireland, must be written as **IRELAND** (in capitals) or **IE**

Slaughterhouse's **approval number**

The mark must include the **abbreviation EC** (or one of the variations listed in Annex 1 Chapter III)



For other food products of animal origin that come under the scope of Regulation (EC) No 853/2004, the food businesses operator must label them with their **identification mark**. The identification mark may be applied to a product of animal origin, only if it has been manufactured in line with the requirements in Regulation 853, in establishments that meet the requirements of Article 4 of that Regulation.

The identification mark must indicate:

- The name of the country in which the establishment is located (e.g. IRELAND, or IE)
- The approval number of the establishment
- The abbreviation 'EC' (or one of the variations listed in Annex II, Section 1 of Regulation (EC) No 853/2004)

When applied in an establishment located within the EU, the mark must be oval in shape. It must be legible and indelible, and the characters easily decipherable. The mark must be clearly displayed for the competent authorities. A full description of what the identification mark must look like and how it should be applied are detailed in Annex II, Section 1 of the Regulation.

## Food Safety Management System

Food hygiene legislation places the responsibility of producing safe food on food business operators. A food safety management system is the system of controls used by a food business to ensure that the food it produces is safe to eat, when prepared and/or eaten according to its intended use. This food safety management system must be based on HACCP principles.

**HACCP** stands for **H**azard **A**nalysis and **C**ritical **C**ontrol **P**oint. It is a tool used by food businesses to identify and control food safety hazards in their operations. Hazards can be microbiological (e.g. *Salmonella*), chemical (e.g. pesticide residues, aflatoxins) or physical (e.g. a piece of plastic) agents present in a food which could cause harm to consumers of that food.

### Basic Hygiene (Prerequisites)

Before implementing HACCP, you should have in place basic good hygiene conditions and practices called **prerequisites**. Prerequisites are designed to control hazards in a general way and include (where appropriate):

- Cleaning and disinfection/sanitation
- Maintenance of equipment and buildings
- Personnel hygiene and training
- Pest control
- Plant and equipment
- Premises and structure
- Services (compressed air, ice, steam, ventilation, water etc.)
- Storage, distribution and transport
- Supplier control
- Waste management
- Zoning (physical separation of activities to prevent potential food contamination)

Once the pre-requisites are in place, HACCP can then be used to identify and control any steps which are essential to ensure that safe food is produced. These steps in your process will therefore require extra attention.

### HACCP steps

HACCP has seven steps which are set out in the Regulation (EC) No 852/2004 on the hygiene of foodstuffs. In simple terms, the seven steps are:

- 1) Identify **hazards** (microbiological, chemical and physical) that may occur in your food business
- 2) Identify **critical control points** – these are the most important points in your process where you can prevent or eliminate a hazard, or reduce it to acceptable levels
- 3) Set **critical limits** at each critical control point – for example, a cooking time/temperature combination that will kill harmful bacteria that may be present in your raw product
- 4) **Monitor** your critical control points to make sure the critical limits you set are being adhered to
- 5) State what **corrective action** you will take if monitoring shows that a critical limit has not been adhered to
- 6) **Verify** (prove) that your HACCP plan is working. This means that you carry out regular checks to make sure that your critical control points are being monitored, and that corrective action is being taken if your critical limits are not adhered to
- 7) **Document** your HACCP plan and keep **records** to show that you have carried out the steps above

### HACCP, the Law and Flexibility

Because all food businesses are different and do not present the same level of risk to food safety, the legislation allows some flexibility in the requirement for HACCP. Article 5 of Regulation (EC) No 852/2004 requires food business operators to put in place, implement and maintain a food safety management system based on HACCP principles. This flexibility means that the principles of HACCP can be applied to all food businesses, even very small ones.

Not all food businesses need a HACCP system which uses all seven steps – some may only need a simplified version. So, depending on the food safety risk your business presents, you can choose one of three methods to implement a food safety management plan based on HACCP principles:

- 1) For low risk businesses, complying with the basic hygiene rules (i.e. prerequisites) in the legislation (Article 4 and Annex II) may be enough to control hazards
- 2) Follow a relevant recognised guide to good practice, e.g. Irish Standard (I.S.) 341:2007 Hygiene in Food Retailing and Wholesaling (see page 16), or
- 3) Develop your own HACCP system

As all food businesses are unique, you must look at all your products and processes so that you can identify and control the particular hazards that may occur in your food business. Whatever method you choose to implement your food safety management system, you must be able to show that your method can control the hazards in your food business. You should discuss this with your enforcement officer.

## Developing your Food Safety Management System

When developing your food safety management system, it is useful to assemble a small team of staff, although in the case of a small business, one person may develop the system. It is important that those involved in developing your food safety management system have a basic understanding of HACCP and have a good knowledge of your business. If it is necessary to seek assistance from a consultant, make sure your staff understand how the new system works and have received enough training to ensure the system is used effectively.

## Safe Catering Pack

Our Safe Catering Pack is a tool designed to help caterers develop a system to manage food safety and comply with the food hygiene regulations. It presents options for businesses to choose how they are going to do this.

The pack costs €70 (incl. €10 postage) and consists of a:

- Workbook and pen (the workbook presents options for businesses to choose how they are going to manage food safety)
- Set of nine record books (e.g. records on temperature monitoring, training, fitness to work and a hygiene inspection checklist)
- DVD which explains how to use the workbook and record books

You can get more information and order the pack on our website at [www.fsai.ie/safecatering](http://www.fsai.ie/safecatering)



The FSAI has produced **HACCP Information Leaflets**, which are available to download or order free of charge from [www.fsai.ie/resources\\_publications](http://www.fsai.ie/resources_publications)

Information on HACCP is also available on the FSAI's website: [www.fsai.ie](http://www.fsai.ie)



The FSAI's **Guidance Note No. 11 - Assessment of HACCP Compliance** gives guidance on HACCP flexibility. This document is available to download or order free of charge from [www.fsai.ie/resources\\_publications](http://www.fsai.ie/resources_publications)



## Training

It is the food business operator's responsibility to ensure that they, or any staff that handle food, have received enough training in food hygiene matters to allow them to do their job safely. For example, the person responsible for setting up the food safety management system in a food business must be adequately trained in HACCP principles.

Chapter XII of Regulation (EC) No 853/2004 states that "Food business operators are to ensure:

- 1) that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;
- 2) that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles; and
- 3) compliance with any requirements of national law concerning training programmes for persons working in certain food sectors."

There are a number of ways that food business operators can meet their legal obligation to train employees including: designing and delivering your own in-house programme; using 'off the shelf' packages for in-house training; recruiting an outside trainer; or using an e-learning programme.



The FSAI has produced leaflets and guides to assist food businesses with food safety training.

These documents are available to download or order free of charge from [www.fsai.ie/resources\\_publications](http://www.fsai.ie/resources_publications)

Information on training is also available from the FSAI's website: [www.fsai.ie](http://www.fsai.ie)



## Traceability and Recall

If a safety problem is discovered, the affected batch of food may need to be withdrawn from trade, or even recalled from consumers. It is essential, therefore, that food businesses have an effective traceability system in place so that they can identify the location of all the items in an affected batch, lot or consignment.

Traceability, under Regulations (EC) No 178/2002 means “the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution”.

**Article 18** of the Regulation requires that food business operators must be able to say who supplied them with ingredients and, in turn, who they supplied their food to. This is called the “one step up and one step down” process. But it doesn’t mean that food businesses have to identify the consumers who bought their food. This traceability information must be made available to the competent authorities on demand.

**Article 19** of the Regulation requires that if you suspect that a food you have produced or distributed may not be safe, then you must inform the competent authorities immediately and withdraw or recall the food as necessary. If affected food has reached the consumer, you must also tell the consumer. To ensure this is done efficiently it is important that you have a recall plan. Although this is not required in law it is highly recommended and will help to minimise the damage to your business should a problem arise.

Traceability is also required for packaging and other materials and articles intended to come into contact with food. Regulation (EC) No 1935/2004 requires that food business operators should at least be able to identify the businesses from which, and to which, materials and articles are supplied.

The FSAI has produced a **Guidance Note on Food Recall and Traceability**.

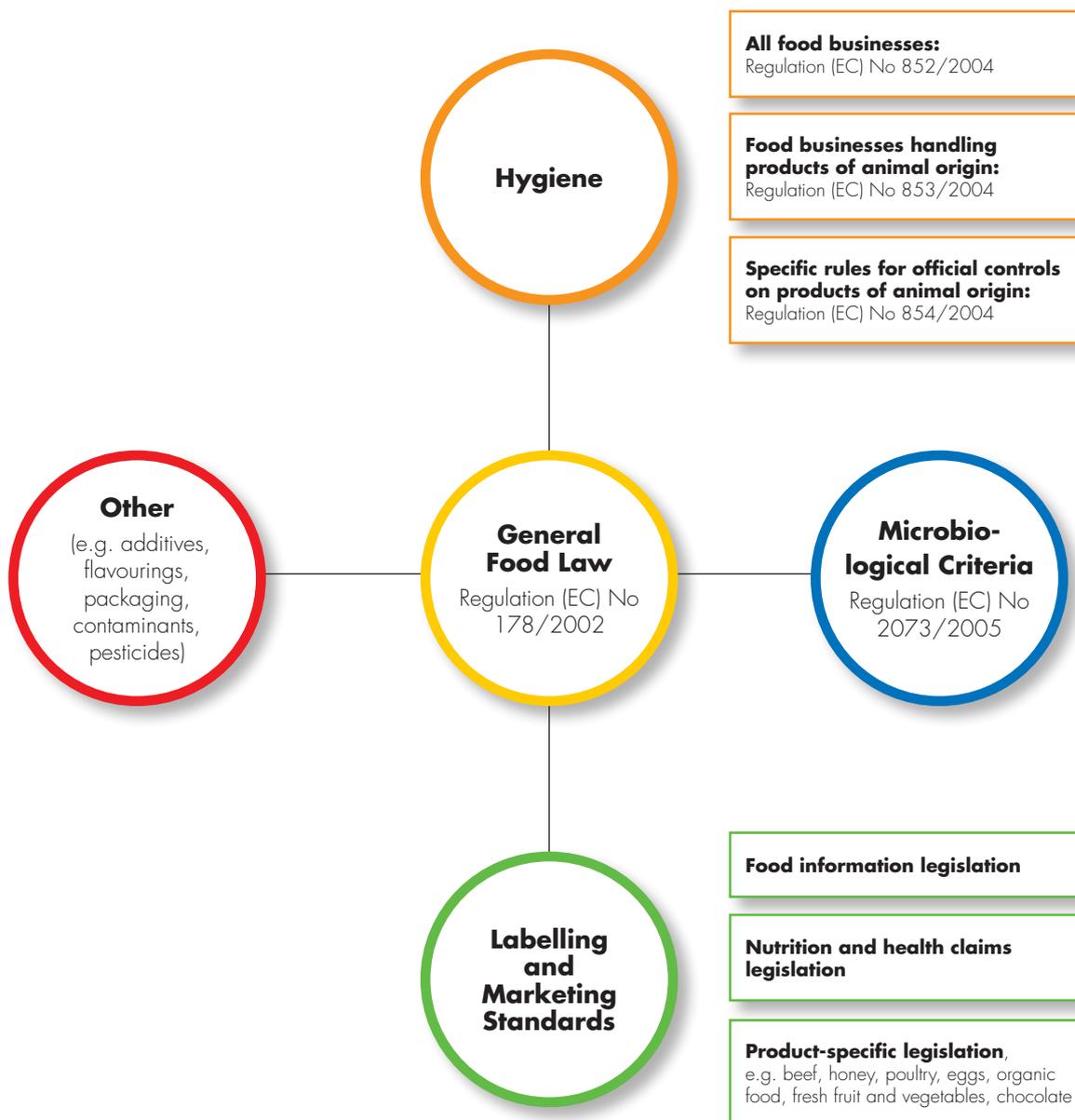
This document is available to download or order free of charge from [www.fsai.ie/resources\\_publications](http://www.fsai.ie/resources_publications)



## Legislation Summary

Summary of the main pieces of food legislation which may apply to your food business

(See pages 12–15 for further details)



## General Food Law

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

This Regulation, known as the General Food Law, sets out a range of general principles and obligations that food business operators must adhere to.

The obligations of food businesses are:

**Safety** (Article 14): Food businesses must ensure that food satisfies the requirements of all applicable food law and unsafe food must not be placed on the market

**Honesty** (Article 16): Food businesses must not advertise, present or label food in a way that misleads consumers

**Responsibility** (Article 17): Food business operators are responsible for the safety of the food that they produce, transport, store or sell

**Traceability** (Article 18): Food business operators must keep records of their suppliers and businesses that they supply to in order to assure traceability and be able to rapidly make this information available

**Withdrawal and Recall** (Article 19): Food businesses must initiate withdrawal and recall of unsafe food and inform consumers of the reasons for the recall. Food businesses must notify the FSAI or official agency of such withdrawals and recalls

**Cooperation** (Article 19): Food business operators must cooperate with the official agencies, the FSAI and other food businesses on actions taken to reduce or remove risks to consumers

This Regulation also establishes the European Food Safety Authority and gives legal effect to the Rapid Alert System for Food and Feed (RASFF).

## Food Hygiene Legislation

**Regulation (EC) No 853/2004** on the hygiene of foodstuffs

This Regulation lays down general rules on hygiene of foodstuffs for food business operators. However, the rules *do not apply* to:

1. Primary production for private domestic use
2. The domestic preparation, handling or storage of food for private domestic consumption
3. 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; or
4. 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

Food business operators must ensure that all stages of production, processing and distribution of food under their control comply with the relevant hygiene requirements laid down in the Regulation. Food business operators must put in place, implement and maintain a food safety management system based on the HACCP principles. Food business operators must also ensure that food handlers have received enough food safety training to allow them to do their job safely.

**Annex 1** covers primary production. Primary products include: products of plant origin (e.g. grains, fruits, vegetables, herbs, mushrooms); products of animal origin (e.g. eggs, raw milk, honey, fishery products, live bivalve molluscs); and products harvested wild, either from plant or animal origin (e.g. mushrooms, berries, snails).

**Annex 2** applies to food businesses other than primary production. It is divided into 12 chapters which cover:

- 1) General requirements for food businesses
- 2) Specific requirements in rooms where foodstuffs are prepared, treated or processed
- 3) Requirements for moveable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles), premises used primarily as a private dwelling-house but where foods are regularly prepared for placing on the market and vending machines
- 4) Transport
- 5) Equipment requirements
- 6) Food waste
- 7) Water supply
- 8) Personal hygiene
- 9) Provisions applicable to foodstuffs
- 10) Provisions applicable to the wrapping and packaging of foodstuffs
- 11) Heat treatment
- 12) Training

The European Commission has issued a guidance document on *Implementation of certain provisions of Regulation (EC) No 852/2004 on the hygiene of foodstuffs*. This guidance document is available at: [www.fsai.ie/uploadedFiles/EU\\_Guidance\\_852.pdf](http://www.fsai.ie/uploadedFiles/EU_Guidance_852.pdf)

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

This Regulation lays down the specific hygiene rules for processed and unprocessed food of animal origin. These rules supplement those laid down in Regulation (EC) No 852/2004. However, these rules *do not apply* to:

- 1) Primary production for private domestic use
- 2) The domestic preparation, handling or storage of food for private domestic consumption
- 3) 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\*
- 4) The direct supply, by the producer, of small quantities<sup>†</sup> of meat from poultry and lagomorphs<sup>6</sup> slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat\*
- 5) Hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer\*

\* National rules are required to be put in place to regulate activities 3, 4 and 5 (above). Please contact the FSAI for advice.

<sup>†</sup> 'Small quantities' is defined in S.I. No. 432/2009 as follows:

- **for poultry**, no more than 1,000 birds per week and no more than 10,000 birds per year
- **for lagomorphs** (e.g. rabbits), no more than 1,000 animals per week and no more than 10,000 animals per year.

**Article 4** describes which premises dealing with foods of animal origin require approval, and which require registration.

**Article 5** explains which food products require health marks and which require identification marks.

**Article 6** covers requirements for products of animal origin imported from outside the EU.

**Annex 2** covers identification marking, HACCP and food chain information.

**Annex 3** is divided up into 15 sections, which cover the specific requirements for the following foods of animal origin:

- 1) Meat of domestic ungulates<sup>7</sup>
- 2) Meat from poultry and lagomorphs
- 3) Meat of farmed game
- 4) Wild game meat
- 5) Minced meat, meat preparations and mechanically separated meat
- 6) Meat products
- 7) Live bivalve molluscs<sup>8</sup>
- 8) Fishery products
- 9) Raw milk, colostrum, dairy products and colostrum-based products
- 10) Eggs and egg products
- 11) Frogs' legs and snails
- 12) Rendered animal fats and greaves
- 13) Treated stomachs, bladders and intestines
- 14) Gelatine
- 15) Collagen

The European Commission had produced a guidance document on the *Implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin*. This document is available at: [http://www.fsai.ie/uploadedFiles/EU\\_Guidance\\_853.pdf](http://www.fsai.ie/uploadedFiles/EU_Guidance_853.pdf)

**Regulation (EC) No 854/2004** laying down specific rules for the organisation of official controls on products of animal origin

This Regulation lays down specific rules for organising official controls on products of animal origin. Official controls are carried out by the official agencies to check that food businesses comply with food legislation and that the food on the market is safe. Official controls involve inspecting premises, auditing food safety management systems and taking samples; also taking enforcement action where non-compliance with food law is identified.

**Annex 1, Chapter 3** explains how a health mark should be applied and what it should look like. A health mark is an oval mark stamped on a carcass or cut of meat to show that the animal has been inspected before and after slaughter in line with Regulation (EC) No 854/2004, and that there are no grounds for declaring the meat unfit for human consumption.

<sup>6</sup> For example, rabbits and hares.

<sup>7</sup> Ungulates are 'hoofed animals', e.g. horses, cows, goats, sheep, pigs.

<sup>8</sup> For example, mussels, scallops, oysters.

## Microbiological Criteria Legislation

### Regulation (EC) No 2073/2005 on microbiological criteria of foodstuffs

Foodstuffs should not contain microorganisms (e.g. *Salmonella*) or their toxins (e.g. staphylococcal enterotoxins) or metabolites (e.g. histamine) in quantities that present an unacceptable risk for human health. Food safety is mainly ensured by a preventative approach, such as implementing good hygienic practice and putting in place procedures based on HACCP principles.

This Regulation sets out microbiological criteria for certain foodstuffs. A microbiological criterion defines the limit above which a food is considered to be contaminated at an unacceptable level with a microorganism, its toxin or metabolite, and is therefore considered unsafe for consumption. Food business operators should test against criteria set down in the Regulation so that they can validate or verify that the food safety systems they have in place are working properly.

The absence of a criterion for a specific pathogen does not imply that the presence of that pathogen in a food is acceptable. Regulation (EC) No 178/2002, which lays down the general principles for all food legislation, requires that food businesses operators do not place unsafe food on the market.

Food business operators should also determine the shelf-life of their product by conducting studies (which may need to be supplemented by microbiological testing) to make sure the criteria are met over the entire shelf-life of their product. In particular, this applies to ready-to-eat foods that are able to support the growth of *Listeria monocytogenes* and that may pose a *L. monocytogenes* risk for public health (Article 3.2).

#### Chapter 1 of Annex 1 sets down food safety criteria.

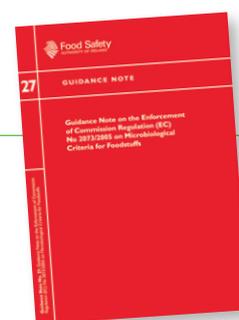
Food safety criteria define the acceptability of a food in terms of its microbiological safety. They are applicable to food placed on the market and throughout the shelf-life of the food.

**Chapter 2 of Annex 1** lays down **process hygiene criteria**. Process hygiene criteria indicate if the production process is operating in a hygienic manner. They apply to foodstuffs at various stages throughout their production.



For more information on shelf-life determination you can have a look at **Guidance Note No. 18 on Validation of Product Shelf-Life (Revision 2)**.

This document is available to download or order a copy free of charge at [www.fsai.ie/resources\\_publications](http://www.fsai.ie/resources_publications)



The FSAI has also produced a guidance note on the microbiological criteria legislation – **Guidance Note No. 27**.

This is available to download or order free of charge from [www.fsai.ie/resources\\_publications](http://www.fsai.ie/resources_publications)

The criteria are set out by food category, microorganism, sampling plan, limits, analytical reference method, stage where the criterion applies, and (for process hygiene criteria) action in the event of unsatisfactory results.

The European Commission has produced a *Guidance Document on Listeria monocytogenes shelf-life studies for ready-to-eat foods under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs*.

This guidance is directed at food business operators who produce ready-to-eat foods and conduct *Listeria monocytogenes* shelf-life studies for them in accordance with Article 3(2) and Annex II of Regulation (EC) No 2073/2005.

The document is available at:  
[http://www.fsai.ie/uploadedFiles/EU\\_Guidance\\_listeria\\_monocytogenes.pdf](http://www.fsai.ie/uploadedFiles/EU_Guidance_listeria_monocytogenes.pdf)

## Provision of Food Information (Labelling)

### Prepacked Foods

**Regulation (EU) No 1169/2011** on the provision of food information to consumers

Food information means information concerning a food and made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools (such as a website or facebook) or verbal communication.

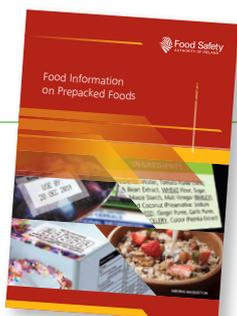
'Labelling' means any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food.

Food information must be clear and accurate and not mislead the consumer. It must be legible and easy to understand. Food products sold in Ireland, including imported foods, must be labelled in English (with optional labelling in Irish in addition).

### Compulsory food information requirements for prepacked foods

The following mandatory information must appear on the packaging of the prepacked foodstuff or on a label attached:

1. The name of the food\*
2. List of ingredients
3. Any ingredient or processing aid listed in Annex II of the Food Information to the Consumer legislation (FIC) or derived from a substance or product listed in Annex II of FIC causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in altered form
4. Quantity of certain ingredients or categories of ingredients
5. Net quantity of the food\*
6. 'Best-before' or 'use-by' date
7. Any special storage conditions and/or conditions of use
8. The name or business name and address of the food business operator



The FSAI has produced a booklet summarising the main food information requirements: **Food Information on Prepacked Foods**.

This document is available to [download or order free of charge at www.fsai.ie/resources\\_publications](http://www.fsai.ie/resources_publications)

9. The country of origin or place of provenance where its absence may mislead the consumer as to the true origin or provenance of the food or where country of origin is specifically required under legislation
10. Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions
11. With respect to beverages containing more than 1.2% by volume of alcohol, the actual alcoholic strength by volume\*
12. A nutrition declaration (from 13th Dec 2016)

\* Must appear in same field of vision<sup>1</sup>

### Non-prepacked Food

Food sold in loose form or packed on the premises at the request of the consumer or packed for direct sale or supply to the final consumer or mass caterer is considered non-prepacked food.

It is now a legal requirement for information on allergens to be declared for this type of food. This affects businesses like restaurants, cafés, delis, hospital canteens, crèches, takeaways and food stalls.

We have produced a booklet: **Allergen Information for Non-prepacked Food** that details the allergens and how the information must be communicated to consumers.

You can download or order it free of charge at [www.fsai.ie/resources\\_publications](http://www.fsai.ie/resources_publications)

### Nutrition and Health Claims made on Foods

If you wish to make a nutrition claim (e.g. low in fat, high in fibre) or health claim about your product you need to comply with the requirements set out in Regulation 1924/2006/EC. We have produced a booklet 'Information on Nutrition and Health Claims' which helps food business operators to understand their legal obligations when making these claims. We also have a link to the Community Register of health claims on our website. The register lists the authorised health claims and conditions for their use. Health claims not on this list are no longer permitted.

## Other Legislation on Labelling and Marketing Standards

For some foods, there are other details which need to be included on the label, in addition to the general labelling requirements. Examples include:

- Beef
- Cocoa and chocolate
- Eggs
- Fishery and aquaculture products

<sup>1</sup> 'Field of vision' means all the surfaces of a package that can be read from a single viewing point

- Foods for particular nutritional uses
- Foods for which the manufacturer makes nutrition or health claims
- Food supplements
- Fresh fruit and vegetables
- Fruit jam, jelly, marmalade and chestnut puree
- Fruit juices
- Honey
- Meat products
- Milk and milk products
- Organic food
- Poultrymeat

This list is not exhaustive. For more details about the labelling requirements that may apply to the food you make or sell, you should consult the relevant legislation available at [www.fsai.ie/legislation](http://www.fsai.ie/legislation).

Detailed information on labelling is also available from various FSAI publications, available at [www.fsai.ie/resources\\_publications](http://www.fsai.ie/resources_publications).

## Other Food Legislation which may Apply to Your Food Business

There are other pieces of food legislation which may apply to your food business. It is advisable to consult the food legislation section of the FSAI's website or your enforcement officer for further information.

### Legislation on Additives

Food additives are substances added intentionally to foodstuffs to perform certain technological functions, for example to colour, sweeten or preserve. The legislation which deals with the use of additives in food is Regulation (EC) No 1333/2008 on food additives.

Only food additives that are authorised at EU level (i.e. have an 'E' number) may be used. Food additives may only be used in limited quantities in certain foodstuffs.

The use of food additives must always be labelled on the packaging by their category (e.g. anti-oxidant, colour) with either their 'E' number or their full name.

### Legislation on Flavourings

Flavourings are substances used to give taste and/or smell to foodstuffs. They are not considered food additives and separate rules have been developed to govern the conditions for their use, provide definitions and set out labelling requirements: see Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods.

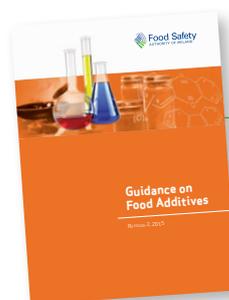
## Materials and Articles Intended to Come into Contact with Foodstuffs

Food businesses operators must ensure that the foods they produce are not at risk of becoming contaminated with chemicals that could migrate from the materials and articles with which the food has been in contact, e.g. food packaging or food contact surfaces. The rules concerning materials and articles intended to come into contact with food are covered in Regulation (EC) No 1935/2004. This Regulation also requires that packaging and other materials and articles intended to come into contact with food can be traced through the food chain.

## Chemical Contaminants

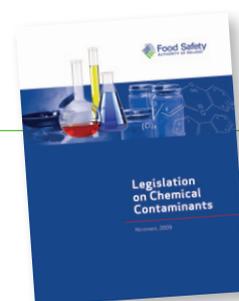
A chemical contaminant is defined as "any substance not intentionally added to food which is present in such food as a result of the production, manufacture, processing, preparation, treatment, packing, packaging, transport, holding and/or storage of such foodstuffs, or as a result of environmental contamination". The presence of such substances in food must be kept to a minimum because of their potential adverse effects on health.

Food business operators have a legal responsibility to supply safe food, and to this end they must ensure that their products comply with the legislative maximum limits for contaminants in food, as laid down in Regulation (EC) No 1881/2006 and other relevant legislation.



The FSAI has produced a report on **Guidance on Food Additives (Revision 2)**.

This document is available to download free of charge at [www.fsai.ie/resources\\_publications](http://www.fsai.ie/resources_publications)



The FSAI has produced a guidance document for **Legislation on Chemical Contaminants** in food.

This document is available on the FSAI's website, [www.fsai.ie](http://www.fsai.ie)

## Voluntary Irish Standards

The hygiene legislation allows voluntary standards to be used as an aid for food businesses to comply with food law. The guides describe in more detail how food business operators can comply with the legal requirements which are written in more general terms in the legislation.

The National Standards Authority of Ireland has published a series of voluntary industry standards that are a guide to good hygiene practice. It is highly recommended that you obtain a copy of the standard or standards relevant to your food business. If you comply with the standard you comply with the food law.

If you are unsure which standards apply to your food business, you can contact your official agency, or the FSAI for advice.

### **I.S. 340:2007 Hygiene in the Catering Sector**

This standard applies to food businesses where food is prepared and served to consumers, for example, restaurants, hotels and catering facilities.

### **I.S. 341: 2007 Hygiene in Food Retailing and Wholesaling**

This standard applies to food businesses that carry out food retail.

### **I.S. 22000:2005 Food Safety Management Systems**

This standard specifies requirements for implementing a food safety management system in all food businesses, regardless of size, across the food chain. This is an international standard that some of your customers may expect you to meet.



The Irish Standards are available to purchase from the National Standards Authority of Ireland, IRI Standard Distributors, 42-44 Northumberland Road, Ballsbridge, Dublin 4.  
Telephone: 01 8576730  
Website: [www.standards.ie](http://www.standards.ie)



## Resources for Further Information

### Artisan Food Producers' Forum

This forum is a platform for discussion between artisan food producers, artisan stakeholders, the FSAI and official agencies. It is chaired by the FSAI and represents the range of artisan food production in Ireland, as well as key representative bodies. The objective of the forum is to facilitate compliance with the food law and the uptake of the highest standards of food safety and hygiene. Further information is available from the FSAI's website.

### Guidance Note No. 16: Food Stalls

This document, produced by the FSAI, is intended to provide guidance for food stall operators, on the standards and arrangements necessary to comply with the hygiene regulations and associated legislation. Although this guidance note is currently being updated, the existing version may be downloaded from the FSAI's website.

### From Concept to Completion – A Roadmap for Food Entrepreneurs

This guidebook was developed by Teagasc to assist food entrepreneurs in bringing an idea to market. Contact: Carol Griffin, Artisan Food Technologist (Meat Sector), Ashtown Food Research Centre, Teagasc, Ashtown, Dublin 15. Tel: 01 8059592 or email: carol.griffin@teagasc.ie

### A Guide to Starting a Small Food Business in Ireland

This guide, intended for those entering the rural micro-food sector, was prepared by Tipperary LEADER Group. Contact: Tipperary LEADER Group, The Bridewell, St. Michael Street, Tipperary Town. Tel: 062 33360/33450 or email: tlg@iol.ie

### Guide to Selling Through Farmers' Markets, Farm Shops and Box Schemes in Ireland

This guide was developed by Bord Bia to assist growers, producers and other entrepreneurs who wish to set up in business through farmers' markets, farm shops and box schemes. The guide is available on Bord Bia's website ([www.bordbia.ie](http://www.bordbia.ie)) or you can email [vantage@bordbia.ie](mailto:vantage@bordbia.ie) for a free copy.

### Village Market Handbook – A simple guide to becoming a market trader

This booklet contains information on insurance requirements, casual trading and licences, food safety, HACCP, business registration, financial considerations, banking and legal advice. It is available at [www.irishvillagemarkets.ie](http://www.irishvillagemarkets.ie) and [www.fsai.ie](http://www.fsai.ie)

### Useful Links

#### Associated Craft Butchers of Ireland

[www.craftbutchers.ie](http://www.craftbutchers.ie)

#### Bord Bia

[www.bordbia.ie](http://www.bordbia.ie)

#### Bord Iascaigh Mhara

[www.bim.ie](http://www.bim.ie)

#### Caís (the Association of Irish Farmhouse Cheese Makers)

[www.irishcheese.ie](http://www.irishcheese.ie)

#### Comhar LEADER na hEireann

[www.irishleadernetwork.org](http://www.irishleadernetwork.org)

#### Dublin Institute of Technology Food Product Development Centre

[www.fpsc.dit.ie](http://www.fpsc.dit.ie)

#### Food Safety Authority of Ireland

[www.fsai.ie](http://www.fsai.ie)

#### IBEC

[www.ibec.ie](http://www.ibec.ie)

#### Irish Commercial Horticultural Association

[www.ifa.ie](http://www.ifa.ie)

#### Irish Farmers Association

[www.ifa.ie](http://www.ifa.ie)

#### Irish Organic Farmers and Growers Association

[www.iofga.org](http://www.iofga.org)

#### Irish Small and Medium Enterprises

[www.isme.ie](http://www.isme.ie)

#### Irish Statute Book

[www.irishstatutebook.ie](http://www.irishstatutebook.ie)

#### Organic Trust Limited

[www.organictrust.ie](http://www.organictrust.ie)

#### National Standards Authority of Ireland

[www.nsai.ie](http://www.nsai.ie)

#### safefood

[www.safefood.eu](http://www.safefood.eu)

#### Teagasc

[www.teagasc.ie](http://www.teagasc.ie)

#### The Food Technology Centre (St. Angela's College)

[www.thefoodcentre.ie](http://www.thefoodcentre.ie)



**Food Safety Authority of Ireland**

The Exchange  
George's Dock, IFSC  
Dublin 1  
D01 P2V6

Advice Line: 0818 33 66 77  
Tel: 01 817 1300  
Email: [info@fsai.ie](mailto:info@fsai.ie)  
Website: [www.fsai.ie](http://www.fsai.ie)

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