

# Business Start-up Information

**Health risks related to poor hygiene conditions in the production and preparation of foodstuffs are seen by consumers and food experts as an increasingly more significant risk to human health. As a result, simple good food safety and hygiene practices are an essential component of any food business in order to protect the consumers' health.**

Under *Regulation (EC) 178/2002* laying down general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, a **food business** is defined as '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.'

BUSINESS	FUNCTION	EXAMPLE
Primary producers	Produce unprocessed food for human consumption	Fruit & vegetable producers, poultry farmers, cereal producers, vine growers
Manufacturers & packers	Manufacture/ Process/ Package foods	Manufacturing / processing / packaging establishments
Distributors & transporters	Pre-retail distribution activities	Importation, wholesaling, wholesale storage, multi-purpose wholesalers
Retailers	Retail of food (excludes take-away food stalls)	Supermarkets, vending machines, market stalls
Service sector	Catering	Restaurants, canteens, caterers, public houses, hospitals
Manufacturers selling directly to the consumer	Produce food for sale to the final consumer	Butchers, bakers, confectioners, manufacturing/ processing activities on farms for sale to the final consumer.

**TABLE 1:** CLASSIFICATION OF FOOD BUSINESSES

**Note:** *The information contained within this document aims to provide general guidelines for those involved in setting up a food business. It outlines initial steps to be followed along with a brief description of legislation. However, the responsibility lies with the individual business proprietor to determine how the regulations apply in practice to them, as this leaflet is not an interpretation of the law.*

## STEPS TO BE TAKEN

### STEP 1: OBTAIN THE RELEVANT LEGISLATION

New Food Hygiene Legislation came into force on 1 January 2006. Hygiene rules that were previously scattered over 17 Directives have been replaced by 5 new pieces of legislation commonly referred to as the 'Hygiene Package'.

All food business operators must comply with **European Communities (Hygiene of Foodstuffs) Regulations 2006 (S.I. No. 369 of 2006)**

This Regulation transposes **Regulation (EC) No 853/2004** of the European Parliament and of the Council of 29 April 2004 on the Hygiene of Foodstuffs which is part of the new 'Hygiene Package'.

**These Regulations set out the statutory requirements in relation to food hygiene and premises. The main provisions of which include:**

- a) Primary responsibility for food safety rests with the food business operator
- b) It is necessary to ensure food safety throughout the food chain, starting with the primary producer
- c) It is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain
- d) General implementation of procedures based on HACCP (Hazard Analysis and Critical Control Points) principles, together with the application of good hygiene practice,

- should reinforce food business operator's responsibility
- e) Guides to good practice are a valuable instrument to aid FBOs at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles
  - f) It is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment
  - g) It is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in the Community, or are of an equivalent standard
1. The Regulations set out general requirements for all food business operators, as well as more specific requirements, in Annex II. These include, among others, general and specific requirements for layout, construction etc. of food premises, transport, equipment, water supply, food waste and personal hygiene.
  2. All FBOs must register with the Health Service Executive. Compliance with the Regulations will be assessed by the Health Service Executive in the locality. An Environmental Health Officer (EHO), on behalf of the Health Service Executive may inspect food premises at any time, in order to ensure compliance with the Regulations
  3. The onus is on the proprietor to ensure food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.

Further information on the 'Hygiene Package' and a copy of these Regulations is available on our website at:  
[http://www.fsai.ie/legislation/eu\\_hygiene\\_regs/index.asp](http://www.fsai.ie/legislation/eu_hygiene_regs/index.asp)

### **Additional legislation**

- Regulation (EC) No 178/2002 which requires businesses to have a traceability system in place.

- Food Hygiene Regulations 1950 – 1989  
 All FBOs must also comply with these Regulations with the exception of Regulations 26B, 26C, 26D and Part IV which have been revoked by S.I. No. 369 of 2006.

Additional legislation may be required depending on the category of business.

This legislation is published by the Stationery Office, Government Publications, Sun Alliance House, Molesworth Street, Dublin 2.  
 Tel: (01) 6613111. Fax: (01) 6725449

## **STEP 2: REGISTER BUSINESS WITH THE LOCAL OFFICE OF THE HEALTH SERVICE EXECUTIVE**

### **How to register**

A person proposing to operate a food business is legally obliged to apply to the local office of the Health Service Executive (HSE) for registration prior to commencement of trade, and failure to do so is an offence. The HSE will then determine whether or not the food premises complies with the relevant hygiene criteria.

An application form for registration is available from the HSE in the locality.

*Note: Food businesses which do not handle, process or store any food – such as the office of a food broker, an internet sales company or a food importer/exporter - are also required to register with the HSE. The establishment the business is operating from will be the establishment that is required to register.*

### **Inspection of the premises**

The frequency with which a business is inspected following registration, depends upon its risk categorisation.

The inspection will include an assessment of the food safety hazards associated with the business, with particular attention to the critical control points identified by the business and an assessment of whether the correct monitoring and verification controls are in place. However, such scheduled inspections do not include visits following

receipt of a complaint, or those for the purpose of taking samples. In addition, visits are usually unannounced.

Some businesses may fall into more than one risk category. In such cases they are treated on the basis of the highest risk category into which they fall. Furthermore, a food business may be placed in a higher risk category than that listed in table 2, but it may not be placed in a lower category.

RISK CATEGORISATION OF BUSINESS	Reason for category	Examples of businesses
HIGH-RISK	Where the potential exists to put vulnerable groups (infants, elderly, pregnant women & the sick) or large numbers of consumers at risk	<ul style="list-style-type: none"> <li>• Shellfish production;</li> <li>• Manufacturing / processing of baby food, meat &amp; milk products, cook – chill products, salads;</li> <li>• Fish products / cooked meat distribution;</li> <li>• Delicatessen;</li> <li>• Hospital catering;</li> <li>• Butcher (mixed products)</li> </ul>
MEDIUM-RISK	Where high-risk ready-to-eat foods are not prepared, but the scale of business is large	<ul style="list-style-type: none"> <li>• Manufacturing / processing of oils &amp; fats, chocolate products</li> <li>• Frozen food distributor, cold stores, cash &amp; carry</li> <li>• Health food shop, fish monger (raw only)</li> <li>• B&amp;B (≥ 6 people)</li> <li>• Butcher (raw meat only)</li> </ul>
LOW-RISK	Where the potential to cause harm to consumers is low.	<ul style="list-style-type: none"> <li>• Honey production</li> <li>• Manufacturing / processing of cereal products, jam &amp; jelly</li> <li>• Dry goods distribution</li> <li>• Greengrocer</li> <li>• B&amp;B (≤ 6 people)</li> <li>• Bakery</li> </ul>

**TABLE 2: RISK CATEGORISATION FOR BUSINESSES**  
Factors considered in categorising a business include type of food, scale of the operation, nature of the handling or processing, facilities provided, control systems in place etc.

### Penalties for non-registration and non-compliance with these Regulations

Operation of an unregistered food business, along with non-compliance with any other requirements of these Regulations, is an offence. The penalty for such an infringement is a fine not exceeding €5000 or, at the discretion of the Court, imprisonment for a term not exceeding six months or both.

### STEP 3: OBTAIN A COPY OF THE NATIONAL STANDARDS AUTHORITY OF IRELAND (NSAI) GUIDELINES

#### The NSAI

The National Standards Authority of Ireland Act 1996 established the NSAI which acts on behalf of the Minister for Enterprise, Trade and Employment. Its primary role is for the publication of national standards; the provision of a comprehensive product and management system certification service; and the establishment of confidence in trade measurements. The NSAI have published a series of standard catalogues that are a guide to good hygiene practices in the food catering, processing, retailing and wholesaling industries.

#### I.S. 3219:1990 “Code of Practice for Hygiene in the Food and Drink Manufacturing Industry”

This is a code of practice for hygiene in the food and drink manufacturing industry. It is currently being reviewed.

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

Applies to all food businesses where food is prepared and served to consumers, for example, restaurants, hotels, fast food outlets, cafes, catering facilities and licensed premises. Its essential features include:

- The requirements that must be met by caterers to ensure that the storage, preparation, handling and where applicable transportation and distribution of food is carried out in a hygienic way.
- Reference to hygiene policy, food safety, traceability, recall and labelling, maintenance of the cold chain, personnel hygiene, cleaning, pest control, storage,

distribution, zoning, services, premises, equipment, training and records.

**I.S. 342:1997 “Guide to Good Hygiene Practice for the Food Processing Industry in accordance with the Council Directive 93/43/EEC on the Hygiene of Foodstuffs.”**

Applies to all *food processing* companies with the exception of the fish, dairy and meat sectors. Its essential features include:

1. Principles of HACCP, along with recommended procedures in order to implement a HACCP plan in a food business.
2. General hygiene recommendations with reference to the layout and design of a food premises, personal hygiene, transport, equipment, waste, pest control, training and food storage on the premises.

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

Applies to food businesses that operate in the food retail sector and include independent and multiple retailers, service stations and other retailers of food to consumers. It also applies to food businesses whose activities include the wholesale and distribution of food products. Its essential features include guidance to compliance with requirements for:

- food identification, traceability and labelling;
- maintenance of the cold chain;
- food operation requirements.

It also includes guidance on hygiene requirements and the control of food safety hazards, either through the application of the HACCP principles or by adopting a more flexible approach to the application of these principles.

**I.S 344:2002 “Hygiene for Domestic-Scale Production”**

Applies to all caterers producing food, for sale or supply, who are working either in or from their home. By “domestic-scale” is meant the quantity of food that can be produced safely in a domestic kitchen, using domestic-scale equipment and appliances.

Such food producers would include people involved on a domestic scale, in the production of cooked or baked goods,

preserves, salads, sandwiches and packaging of honey.

**I.S. 22000:2005 “Food Safety Management incorporating HACCP”**

Specifies requirements for a food safety management system that combines the following generally recognised key elements to ensure food safety along the food chain up to the point of final consumption:

- Interactive communication
- System management
- Prerequisite programmes
- HACCP principles

However a key aspect of these Standards is that the proprietor’s compliance while advisable, is non-compulsory.

The NSAI guides may be purchased from the National Standards Authority of Ireland, I.L.I. Standard Distributors, 42-44 Northumberland Road, Ballsbridge, Dublin 4. Tel: (01) 8576730 / 8576731. Fax: (01) 8576729

**WEBSITES:**

The following websites may provide additional information for food businesses.

1. **Food Safety Authority of Ireland:** [www.fsai.ie](http://www.fsai.ie)
2. **Enterprise Ireland:** [www.enterprise-ireland.com/english.asp](http://www.enterprise-ireland.com/english.asp)
3. **World Health Organization:** [www.who.it](http://www.who.it)
4. **Eur-Lex:** [www.eur-lex.europa.eu](http://www.eur-lex.europa.eu)
5. **NSAI:** [www.nsai.ie](http://www.nsai.ie)
6. **Dept. of Health and Children:** [www.dohc.ie/welcome.htm](http://www.dohc.ie/welcome.htm)
7. **Regional Health Boards:** [www.hse.ie](http://www.hse.ie)
8. **National Hygiene Partnership:** [www.nhp.ie](http://www.nhp.ie)
9. **Excellence Ireland:** [www.eiqa.com](http://www.eiqa.com)
10. **FAS:** [www.fas.ie](http://www.fas.ie)
11. **National Accreditation Board:** [www.forfas.ie/nab/](http://www.forfas.ie/nab/)
12. **Ashtown Food Research Centre** [www.teagasc.ie/ashtown](http://www.teagasc.ie/ashtown)

