1 Legal requirements for producers selling canned fish into Europe

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1.1 INTRODUCTION

The European Union (EU) represents a single market of nearly 500 million consumers across 27 Member States. Whilst large, it is less than half the size of India and a little more than one third of the size of China. The need to compete effectively with such global economies has been a major factor in the expansion of the EU over the last 50 years, from an initial Economic Community of just six Member States.

The EU remains first and foremost a 'Common Market' and in pursuit of this most of the food laws that apply in the 27 individual Member States have been developed and agreed by the EU.

As with most food law in well-developed market economies, the main functions of the controls are:

- To protect the health of people, animals and plants;
- To ensure that consumers are not misled about the composition and origin of the food that they purchase;
- To support fair competition in order that well run businesses that meet their legal obligations are not put at a competitive disadvantage in comparison with companies that take a less rigorous approach to compliance; and
- To promote free trade so that goods legally manufactured or imported into one Member State can then move freely across the entire EU.

EU food law is part of a wider legislative framework that is designed to secure the free movement of people, services, capital and goods, including food and feed, throughout its Member States. The French term *Acquis Communautaire* is often used to denote the various treaties, regulations and directives passed by the European institutions, as well as judgements reached by the European Court of Justice. The elements that control the production and marketing of food and feed are described in this chapter.

But first it is necessary to understand and distinguish the different types of EU legal instruments.

Much of the earlier body of EU food law was developed in the form of Directives. As the term suggests, they directed Member State governments to give effect to the detailed requirements set out in the Directive, but crucially left Member States with the flexibility to adopt their own national legislation to achieve this. One potential disadvantage of this approach was that Member States might implement the Directive into their national legislation slightly differently, and that any divergences might then impede the free movement of goods, one of the original objectives of developing the legislation.

For this reason, therefore, in recent years most EU food laws have been made in the form of Regulations. These apply fully and equally in all Member States without the need for implementing legislation and thus without the danger of national variations. All that is normally required in national legislation is a simple legal instrument to provide for the execution and enforcement of the EU Regulation and to put in place a system of sanctions in cases of non-compliance.

1.2 IMPORTS INTO THE EU

Against this background, it is clear that the rules that apply to imports from countries outside the EU, often termed 'third countries', are vital to ensure the most complete possible protection of EU consumers and industries.

The controls placed on such imports differ according to the type of food concerned.

Commission Decision 2007/275/EC (European Union, 2007a) draws up a list of animals and animal products, including fish that are subject to controls at border inspection posts.

Commission Decision 2001/881/EC (European Union, 2001b), as amended, lists the designated Border Inspection Posts where official veterinarians undertake veterinary checks on live animals and animal products in conjunction with the competent authorities.

Each year, the infrastructure, equipment and working of each post are inspected by a Commission veterinary expert in cooperation with the competent national authorities.

Border Inspections Post checks are carried out in close cooperation with customs officials; the list of products subject to inspection is defined by reference to the combined nomenclature (CN) established by Council Regulation (EEC) No. 2658/87 (European Union, 1987) on the tariff and statistical nomenclature.

The following products are specifically listed under, amongst others, the following principal headings:

- 16 04 Prepared or preserved fish; caviar and caviar substitutes prepared from fish eggs; and
- 16 05 Crustaceans, molluscs and other aquatic invertebrates, prepared or preserved.

At Border Inspection Posts, the product's identity and documentation are checked and some physical checks are also made, for example, on the product's packaging and labelling: laboratory testing may also be undertaken.

Consignments of food found not to comply with EU legislation are either destroyed or, under certain conditions, re-despatched within 60 days.

Because products of non-animal origin are inherently less hazardous than those of animal origin, the controls on their importation into the EU are less strict.

In broad terms, such products must meet the safety requirements of the EU General Food Law Regulation; they must not be unsound or unwholesome; and they must comply with any other specific legislative controls.

1.3 GENERAL FOOD LAW

Despite the agreement of many product and subject-specific EU food controls, until 2002 there was no EU instrument that laid down broad principles governing food and feed in general and their safety in particular. To fulfil this need, and because a number of different concepts, principles

and procedures had been included in pre-existing national food laws, Council Regulation (EC) No. 178/2002 (European Union, 2002a), laying down the general principles and requirements of food law, was adopted. This instrument also established a body charged with undertaking risk assessment known as the European Food Safety Authority (EFSA).

Under Council Regulation 178/2002, food must not be placed on the market if it is unsafe. Food is deemed to be 'unsafe' if it is considered to be:

- Injurious to health; or
- Unfit for human consumption.

In deciding whether or not food is 'unsafe', it is necessary to take into account:

- The normal conditions of use of the food by the consumer and at each stage of production, processing and distribution; and
- The information provided to the consumer, including information on the label or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

In determining whether a food is 'injurious to health', the Regulation goes on to say that it is necessary to consider:

- Not only the probable immediate and/or short-term and/or long-term effects of that food on the health of the person consuming it, but also on subsequent generations;
- The probable cumulative toxic effects; and
- The particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

Furthermore, food business operators at all stages of production, processing and distribution must ensure that foods satisfy the requirements of food law which are relevant to their activities and must verify that such requirements are met.

Whilst the general food safety requirements would, in almost all respects, have been preceded by earlier national legislation in each EU Member State, the Regulation did introduce more novel requirements for traceability and for the withdrawal and/or recall of unsafe food.

Specifically, the Regulation requires that the traceability of food and any other substance intended to be, or expected to be, incorporated into a food to be established at all stages of production, processing and distribution.

Although at first reading this may appear to be onerous, in fact it is a simple requirement for food business operators to be able to identify any person who has supplied them with a food or any substance intended to be, or expected to be incorporated into a food or feed. Similarly, food business operators must be able to identify businesses (but not, crucially, the ultimate consumer) to which they have supplied their products. In each case, this information must be made available to the competent authorities on demand.

The requirement thus falls far short of requiring full internal traceability, whereby it would be necessary to identify which consignments and deliveries of raw materials and ingredients had been incorporated into what batches of finished food.

The second new responsibility placed on food business operators by Council Regulation 178/2002 was for those who consider or have reason to believe that a food which they have imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements. In

such cases, where the food has left the immediate control of that food business operator, the food business operator must immediately initiate procedures to withdraw the food from the market and inform the competent authorities. Where the product may have reached the consumer, the operator must effectively and accurately inform the consumers of the reason for its withdrawal and, if other measures are not sufficient to protect public health, recall from consumers products already supplied to them.

One such case in 2007 involved the withdrawal of canned fish liver containing very high levels of dioxins and in particular dioxin-like polychlorinated biphenyls (PCBs). Although no maximum level had then been established for these substances in fish liver and processed products thereof, the concerned competent authorities prohibited the marketing of the products because they were deemed to be unsafe.

1.4 PRODUCT-SPECIFIC CONTROLS

In its earliest years, the then European Economic Community comprised a much smaller and arguably more coherent group of six nations. At that time, a key objective of food law was to reach Community-wide agreement on the composition and labelling of a wide range of internationally traded foodstuffs.

As the Community enlarged, however, the food-processing industries and the culinary traditions of the various Member States became ever more varied. As a consequence, it became much harder to reach agreement on compositional and related controls governing the production and marketing of particular types of food.

In the face of such difficulties and in the wake of an important judgement of the European Court of Justice in the Cassis de Dijon (European Court of Justice, 1979) case, a new approach became necessary.

In 1982, therefore, the European Commission (in effect the civil service of the EU) abandoned further plans to harmonise food standards in this way. Instead it suggested that, as a general principle, products legally manufactured and marketed in one Member State should, provided they were properly and informatively labelled, be capable of being traded freely across the EU.

Initially, the new approach was largely forward looking. Although, since then, there have been initiatives designed to modernise and simplify earlier controls, notably as part of the Simplification of the Internal Market (SLIM) (SLIM, 1996) Programme, a number of compositional standards remain in place, including those controlling preserved sardines and sardine-type products and separately canned tuna and bonito.

Both were developed under Regulation (EEC) No. 3796/81 (European Union, 1981) on the common organisation of the market in fishery products, which allows for Community-wide marketing standards for fishery products to be developed, particularly to ensure that products of unsatisfactory quality are marketed as well as to facilitate trade based on fair competition.

Council Regulation (EEC) No. 2136/89 (European Union, 1989c) as amended by Commission Regulation (EC) No. 1181/2003 (European Union, 2003b) defines the standards governing the marketing of preserved sardines and the trade descriptions for preserved sardines and preserved sardine-type products marketed in the EU.

Only products covered by CN codes 1604 13 11, 1604 13 19 and ex 1604 20 50, prepared exclusively from fish of the species *Sardina pilchardus* Walbaum, pre-packaged with any appropriate covering medium in a hermetically sealed container and sterilised may be marketed as preserved sardines.

The Regulations prescribe and define the presentations in which preserved sardines may be marketed ('sardines', 'sardines without bones', 'sardines without skin or bones', 'sardine fillets', 'sardine trunks' or any other form clearly distinct from these), names for certain covering media, quality criteria and labelling requirements.

The 2003 amendment was designed to ensure that the labelling of preserved products marketed and presented in the same way as preserved sardines made a clear distinction between the two, so that consumers would not be misled.

The definition of sardine-type products was those marketed and presented in the same way as preserved sardines and prepared from fish of the following species:

(a) *Sardinops melanosticus*, *S. neopilchardus*, *S. ocellatus*, *S. sagax* and *S. caeryleus*;
(b) *Sardinella aurita*, *S. brasiliensis*, *S. maderensis*, *S. longiceps* and *S. gibbosa*;
(c) *Clupea harengus*;
(d) *Sprattus sprattus*;
(e) *Hyperlophus vittatus*;
(f) *Nematalosa vlaminghi*;
(g) *Etrumeus teres*;
(h) *Ethmidium maculatum*;
(i) *Engraulis anchoita*, *E. mordax* and *E. ringens*; and
(j) *Opisthonema oglinum.*

The name 'sardines' can be used only in the marketing of preserved sardine-type products if it is in combination with one of the above scientific names of the species. Common names not including the word 'sardines' may continue to be used for the marketing of sardine-type products in compliance with the food-labelling directive.

A second such Regulation, Council Regulation (EEC) No. 1536/92 (European Union, 1992), defines the standard governing the marketing of preserved tuna and bonito in the EU.

The trade descriptions tuna and bonito are reserved for products falling within the following CN codes:

- Tuna: CN codes 1604 14 10 and ex 1604 20 70; and
- Bonito: CN codes 1604 14 90, ex 1604 20 50, 1604 19 30, ex 1604 20 70, ex 1604 19 99 and ex 1604 20 90

and prepared exclusively from fish of one of the following genera:

- Tuna
  - Species of the genus *Thunnus*
    (a) Albacore or long-finned tuna (*Thunnus alalunga*)
    (b) Yellowfin tuna (*T.* (*neothunnus*) *albacores*)
    (c) Bluefin tuna (*T. thynnus*)
    (d) Bigeye tuna (*T.* (*parathunnus*) *obesus*)
    (e) Other species of the genus *Thunnus*.
  - Skipjack or stripe-bellied tuna
    (*Euthynnus* (*Katsuwonus*) *pelamis*).

- Bonito
  - Species of the genus *Sarda*
    (a) Atlantic bonito (*Sarda sarda*)
    (b) Pacific bonito (*S. chiliensis*)
    (c) Oriental bonito (*S. orientalis*)
    (d) Other species of the genus *Sarda*.
  - Species of the genus *Euthynnus*, with the exception of the species *E.* (*Katsuwonus*) *pelamis*
    (a) Atlantic little tuna (*E. alleteratus*)
    (b) Eastern little tuna (*E. affinis*)
    (c) Black skipjack (*E. lineatus*)
    (d) Other species of the genus *Euthynnus*.
  - Species of the genus *Auxis*
    (a) Frigate mackerel (*Auxis thazard*)
    (b) *A. rochei*.

The Regulations prescribe the presentation in which tuna and bonito may be marketed and the description of the presentation to accompany 'tuna' or 'bonito' in the name of the food (i.e. solid [declaration optional], chunks, fillets, flakes, grated/shredded tuna and any other form of presentation clearly identified in the product's name).

The conditions for the use of covering media, to be declared as part of the product's name, are laid down. For example, the word 'natural' may be used only for media using the liquid exuding from the fish during cooking as the covering medium, a saline solution or water, possibly with the addition of herbs, spices or flavourings. In addition, the proportion by weight of fish in the container after sterilisation relative to the net weight must be at least 70%.

The word 'natural' may be used only to describe a preserved tuna or bonito product as a whole when the 'natural' criteria for the covering medium are met and the product is presented in 'solid' form, as 'chunks' or as 'fillets'.

Where the covering medium is not described as 'natural', the proportion by weight of fish in the container after sterilisation relative to the net weight must be at least 65%, but only at least 25% in the case of forms of presentation other than as solid, chunks, fillets, flakes or grated/shredded tuna.

1.5 HYGIENE RULES

EC hygiene legislation was consolidated and simplified in 2004 through a series of regulations, the most important of which are:

- Regulation (EC) No. 852/2004 (European Union, 2004a) on the hygiene of foodstuffs;
- Regulation (EC) No. 853/2004 (European Union, 2004b) laying down specific hygiene rules for foods of animal origin;
- Regulation (EC) No. 854/2004 (European Union, 2004c) laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption; and
- Regulation (EC) No. 882/2004 (European Union, 2004d) on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

The overall aim was to create a single, transparent hygiene policy applicable to all food and all food operators, together with effective instruments to manage food safety and potential food crises, throughout the food chain.

The revised rules are based on the following key measures:

- Implementation of a 'farm to table' approach;
- Introduction of a 'hazard analysis and critical control points' (HACCP) system in all food sectors, except the primary sector;
- Registration or approval of certain food establishments; and
- Development of guides to good practice for hygiene and the application of HACCP principles.

Under Regulation (EC) No. 852/2004, food business operators must, as appropriate, adopt the following specific hygiene measures:

- Compliance with microbiological criteria for foodstuffs: since developed as Commission Regulation (EC) No. 2073/2005 (European Union, 2005c);
- Procedures necessary to meet targets set to achieve the objectives of the Regulation;
- Compliance with temperature control requirements;
- Maintenance of the cold chain; and
- Sampling and analysis.

The food business operators must also put in place, implement and maintain a permanent procedure based on HACCP principles. This applies to food business operators carrying out any stage of production, processing and distribution of food after primary production and associated operations.

The Regulation also puts in place requirements for food premises, food preparation rooms, movable and/or temporary premises, transport, equipment, food waste, water supply, personal hygiene, foodstuffs, wrapping and packing of foodstuffs, heat treatment and training.

Specifically, the following applies in relation to heat treatment of food placed on the market in hermetically sealed containers:

- Any heat treatment is to raise every part of the product to a given temperature for a given period of time and to prevent the product from becoming contaminated during the process;
- Food business operators must check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including the use of automatic devices; and
- The process used should conform to an internationally recognised standard (e.g. for pasteurisation, ultra high temperature or sterilisation).

Regulation (EC) No. 853/2004 lays down supplementary specific rules on the hygiene of food of animal origin for food business operators involved in these sectors. It is important to appreciate that these are *additional* to the rules laid down in Regulation (EC) No. 852/2004, not *replacements* for them, and that the Regulation applies to unprocessed and processed products of animal origin.

Products of animal origin mean:

- Food of animal origin, including honey and blood;
- Live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption; and
- Other animals destined to be prepared with a view to being supplied live to the final consumer.

Establishments handling products of animal origin, including those involved in the production of fishery products, can operate only if a competent authority has approved them. The exceptions are establishments carrying out only:

- Primary production;
- Transport operations;
- The storage of products not requiring temperature-controlled conditions; or
- Retail operations other than those to which the Regulation otherwise applies.

EC guidance (European Commission, 2006) includes a non-exhaustive list of 'unprocessed products of animal origin' including fresh fishery products, live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods.

'Fresh' with regard to fishery products means unprocessed fishery products, whether whole or prepared, including products purchased in a vacuum or in a modified atmosphere that have not undergone any treatment to ensure preservation other than chilling.

Similarly, a non-exhaustive list of 'processed products of animal origin' is accompanied by an explanation that these are obtained by submitting raw materials to a process, such as heating, smoking, curing, maturing, drying or marinating, which leads to a substantial alteration of the initial product.

Most importantly, however, the Regulation does not extend to foods containing both products of plant origin and processed products of animal origin, although clearly the products of animal origin used to prepare such foods must be obtained and handled in accordance with Regulation (EC) No. 853/2004.

Food business operators must not use any substance other than potable water or, when Regulation (EC) No. 852/2004 or 853/2004 permits its use, clean water to remove surface contamination from products of animal origin, unless use of that substance has been approved. At present no such substances have been authorised.

Food business operators may place products of animal origin manufactured in the Community on the market only if they have been prepared and handled exclusively in establishments:

(a) That meet the requirements of Regulations (EC) No. 852/2004, and 853/2004, as appropriate, and other relevant requirements of food law; and
(b) That the competent authority has registered or, where required, approved.

1.6 FISHERY PRODUCTS FROM OUTSIDE THE EU

Food business operators importing fishery products from non-EU countries must ensure that:

(a) The exporting country appears on a list, drawn up in accordance with Regulation (EC) No. 854/2004, of third countries, from which imports of that product are permitted;
(b) The establishment from which the product was dispatched, and in which it was obtained or prepared, has been approved;
(c) In the case of live bivalve molluscs, echinoderms, tunicates and marine gastropods, the production area appears on a list drawn up;

(d) The product satisfies the requirements of Regulation (EC) No. 853/2004, including the requirements on identification marking (see below), the requirements of Regulation (EC) No. 852/2004 and any import conditions laid down.

In particular, Regulation (EC) No. 853/2004 contains specific requirements on the structure of vessels, landing sites, processing establishments and operational processes, freezing and storage; and

(e) The requirements of Regulation (EC) No. 854/2004 concerning certificates and documents are met to ensure that they are a credible guarantee of public and animal health.

When required, food business operators must ensure that certificates or other documents accompany consignments of products of animal origin.

The following third countries are approved for the import of fishery products into the EU. In each case, specific factory vessels, fishery vessels and processing plants in which these exports can be handled and prepared are approved as appropriate.

Algeria
Albania
Antigua and Barbuda
Argentina
Armenia
Australia
Bahamas
Bangladesh
Belarus
Belize
Brazil
Canada
Cape Verde
Chile
China
Columbia
Costa Rica
Cote D'Ivoire
Croatia
Cuba
Ecuador
Egypt
El Salvador
Falkland Islands
Faroe Islands
French Polynesia
Gabon
Gambia
Ghana
Greenland
Grenada
Guatemala
Guinea
Guyana
Honduras
Hong Kong
India
Indonesia
Iran (Islamic Republic of)
Jamaica
Japan
Kazakhstan
Kenya
Korea (Republic of)
Madagascar
Malaysia
Maldives
Mauritania
Mauritius
Mayotte
Mexico
Montenegro
Morocco
Mozambique
Namibia
Netherlands Antilles
New Caledonia
New Zealand
Nicaragua
Nigeria
Oman
Pakistan
Panama
Papua New Guinea
Peru
Philippines
Russian Federation
Saudi Arabia
Senegal
Seychelles
Singapore
South Africa
Sri Lanka
St Pierre and Miquelon
Suriname
Taiwan
Tanzania
Thailand
Tunisia
Turkey
Uganda
Ukraine
United Arab Emirates
United States
Uruguay
Venezuela
Vietnam
Yemen
Zimbabwe

1.7 IDENTIFICATION MARKING

Identification marks (and a similar scheme of health marks that apply only to carcases of fresh red meat) are applied to ensure the traceability of products of animal origin throughout the food supply chain.

The identification must:

- Indicate the name of the country in which the establishment is located. This may be written out in full or shown as a two-letter code in accordance with the relevant ISO standard (International Organization for Standardization, 2006);
- Indicate the approval number of the establishment, as allocated by the appropriate Competent Authority; and
- Be legible and indelible and the characters easily decipherable.

1.8 MICROBIOLOGICAL CRITERIA

Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs applies to all food businesses involved in food production, processing and distribution including retail. Two types of microbiological criteria are laid down:

- A food safety criterion defines the acceptability of a product or a batch of foodstuff placed on the market and
- A process hygiene criterion which indicates the acceptable functioning of the production process. This type of criterion is not applicable to products placed on the market. Rather, it sets a level of contamination which, if exceeded, requires corrective actions in order to maintain the hygiene of the processing in compliance with food law.

The food safety criteria set down in the Regulation include two criteria for fishery products set out in Table 1.1.

Results from histamine in fishery products from fish species associated with a high amount of histidine are satisfactory if:

- The mean value observed is less than or equal to m;
- A maximum of c/n values observed are between m and M;
- No values observed exceed the limit of M.

Results are unsatisfactory if the mean value observed exceeds m, or more than c/n values are between m and M, or one or more values observed are greater than M.

No process hygiene criteria are laid down for fishery products, other than for cooked crustaceans and molluscan shellfish, such as oysters, clams and winkles.

Table 1.1 Food safety criteria for fishery products.

Food category	Microorganisms/ their toxins, metabolites	Sampling plan[a]		Limits[b]		Analytical reference method[c]	Stage where the criterion applies
		n	*c*	*m*	*M*		
Fishery products from fish species associated with a high amount of histidine[d] Examples: tuna, mackerel, sardines, mahi	Histamine	9[e]	1	100 mg/kg	200 mg/kg	High performance liquid chromatography (HPLC)	Products placed on the market during their shelf life
Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine Example: anchovies	Histamine	9	2	200 mg/kg	400 mg/kg	HPLC[f]	Products placed on the market during their shelf life

[a] *n*, number of units comprising the sample; *c*, number of sample units giving values more than *m* or between *m* and *M*.
[b] For points 1.1–1.24 $m = M$.
[c] The most recent edition of the standard shall be used.
[d] Particularly fish species of the families: Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae and scomberesosidae.
[e] Single samples may be taken at retail level. In such a case, the presumption laid down in Article 14(6) of Regulation (EC) No. 178/2002, according to which the whole batch should be deemed unsafe, shall not apply.
[f] References: (1) Malle P., Valle M. and Bouquelet S. (1996) Assay of biogenic amines involved in fish decomposition. *Journal of AOAC International*, **79**, 43–49. (2) Duflos G., Dervin C., Malle P. and Bouquelet S. (1999) Relevance of matrix effect in determination of biogenic amines in plaice (*Pleuronectes platessa*) and whiting (*Merlangus merlangus*). *Journal of AOAC International*, **82**, 1097–1101.

1.9 LABELLING

Food labelling in the EU is principally controlled by Council Directive 2000/13/EC (European Union, 2000b) (which consolidated an earlier and much-amended Directive 79/112/EEC) on the labelling, presentation and advertising of foodstuffs.

> It requires that the labelling information with which it is legally required to be labelled in a language that is readily understood by the consumer. (UK case law has determined that in practice this means the English language for products marketed in the UK.)

The 'General Food Labelling Requirement' set out in the Directive applies to almost all food for human consumption including canned fish, other than preserved sardines, tuna and bonito which, as explained earlier, are subject to more specific regulations.

These products are, however, subject to other controls on labelling set out in Directive 2000/13, notably those on claims; nutrition labelling, misleading descriptions; manner of marking or labelling; and intelligibility.

1.9.1 Name of food

If a name for a food is prescribed by EU law, that name must be used for the food.

Although a number of names are prescribed by law for certain fish species within Council Regulation (EC) No. 104/2000 (European Union, 2000a) and Commission Regulation (EC) No. 2065/2001 (European Union, 2001a), these naming rules extend only to the sale of:

- Live fish;
- Fish chilled and frozen fish;
- Fish fillets and other fish meat (whether minced or not);
- Dried, salted or brined fish;
- Smoked fish; and
- Crustaceans (except crustaceans which are both cooked and peeled) and (molluscs) except cooked molluscs.

Thus, canned fish are outside their scope.

Where there is no name prescribed by law, a customary name may be used. A customary name is one that over time has come to be accepted by consumers in the area where the food is sold, without the need for further explanation. An example in the UK might be Cullen Skink, a soup made from smoked haddock.

If there is no name laid down by law and no customary name, or it is not used, a descriptive name must be used. The name of the product must be sufficiently precise to inform the purchaser of the true nature of the food, to enable it to be distinguished from products with which it could be confused and, where necessary, to include a description of its use. For example, 'true nature' means a clear and accurate description of the characteristics of the food but does not require a detailed description including all of the main ingredients. A trademark, brand name or fancy name cannot legally be regarded as the name of the food, however well recognised they may be.

Although a scheme has been established within the EU to protect certain types of food names as Protected Designations of Origin, as Protected Geographical Indications or as Traditional Speciality Guaranteed, at present these extend only to certain types of agricultural products and foodstuffs. So, although it is possible to register names of qualifying fresh fish, molluscs, crustaceans and products thereof, no such facility exists for processed products.

1.9.2 Indication of treatment in the name of the food

Where a purchaser could be misled by the omission of an indication that the food is in a particular physical condition, for example flaked, or has been subjected to a treatment, such as smoking, the legal name of the food must be coupled with such an indication. This could be particularly relevant to fish products incorporating minced fish.

1.9.3 Ingredient listing

Almost all manufactured foods are also required, when pre-packed, to carry a list of ingredients. These are defined as any substance, including any additive and any constituent of a compound ingredient, which is used in the preparation of the food and which is still present in the finished product.

To simplify food labels, certain generic names listed may be used instead of more specific ingredient names, provided that any specified conditions are met.

Amongst the permitted generic names are:

Generic name	Ingredients	Conditions of use of generic name
Fish	Any species of fish	The label of the food must not refer to specific species of fish.
Herb, herbs or mixed herbs	Any herb or parts of a herb or combination of two or more herbs or parts of herbs	The proportion in the food must not exceed 2% by weight of the food.
Oil	Any refined oil other than olive oil	*Oil* must be accompanied by either the description *animal* or *vegetable*, as is appropriate, or an indication of the specific animal origin or the specific vegetable origin of the oil (as is appropriate). In the case of hydrogenated oil, the description *hydrogenated* must also be used.
Spice, spices or mixed spices	Any spice or any combination of two or more spices	The proportion in the food must not exceed 2%.

1.9.4 Allergen labelling requirements

Council Directive 2003/89/EC (European Union, 2003a) sets out requirements for the labelling of allergenic ingredients and ingredients derived from an allergenic ingredient.

The requirement is to list specified allergens and, where pre-packed foods are made using these allergens, or their derivatives, a clear reference to the source allergen must be made in the ingredients list (where appropriate). The list of allergenic ingredients that must be declared in this way includes:

- Crustaceans and products thereof;
- Fish and products thereof; and
- Molluscs and products thereof.

Although the legal requirement is for the word 'fish' to appear, the use of common names such as salmon, tuna and mackerel would normally be taken to indicate the presence of 'fish'. The nature of any more exotic species should, however, be made clear.

A similar approach applies in relation to the presence of crustaceans.

Molluscs include oysters, squid, cockles, mussels, periwinkle and scallops.

All added ingredients and components of added ingredients are covered by the requirements if they are present in the finished product, even in an altered form. This includes carry-over additives, any substances used as processing aids, and solvents and media for additives or flavourings.

There are currently no statutory rules governing labelling for a possible low-level presence of allergens due to cross-contamination of foods. Advisory labelling on possible cross-contamination with allergens would normally be justified on the basis of a risk assessment applied to a responsibly managed operation. Generally, warning labels should only be used where there is a demonstrable and significant risk of allergen cross-contamination and should not be used as a substitute for good manufacturing practice.

1.9.5 Quantitative ingredient declaration

To provide consumers with useful comparative information about potentially competing products prior to their purchase and as an alternative to the development of further compositional standards and reserved descriptions, rules for Quantitative Ingredient Declaration (QUID) have been introduced in the EU.

The quantity of an ingredient or category of an ingredient used in the preparation of food must be indicated when:

- The name of the ingredient appears in the name of the food (mackerel in tomato sauce);
- The name of a category of ingredients appears in the name of the food (fish soup);
- The consumer usually associates an ingredient or category of ingredient with the name of the food (fish in Bouillabaisse); and
- The ingredient or category of ingredients concerned is emphasised on the labelling in words, pictures or graphics.

QUID is not, however, required where a product's net drained weight is indicated along with its net weight as referred to in Directive 2000/13. This requires solid foods presented in a liquid medium to declare their drained net weight in addition to the net weight. 'Liquid medium' means the following, including in mixtures and also where frozen or quick frozen, provided that the liquid is merely an adjunct to the essential elements of the preparation and thus is not a decisive factor for purchase:

- Aqueous solutions of salts, food acids, sugars or other sweetening substances;
- Water;
- Brine; and
- Vinegar.

Guidance for the Verification of Drained Weight, Drained Washed Weight and Deglazed Weight and Extent of Filling of Rigid Food Containers has been published by WELMEC (2006).

The exemption will not apply if, on mixed ingredient products, one or more ingredient was emphasised in some way, because the amount of that ingredient could not be calculated from the given weight indications.

The quantity of an ingredient or category of ingredients is generally expressed as a proportion of the total food at the 'mixing bowl' stage.

QUID declarations on products, the composition of which has been changed by cooking or other treatments involving the loss of moisture, may be based on the amount of the ingoing ingredient expressed as a percentage of the weight of the final product.

Where this calculation leads to declarations exceeding 100%, the declaration should be replaced with statements giving the amount of the ingredient used to make 100 g or mL of the final product, for example, 'Made with *x* grams of fish per 100 g'.

1.9.6 Date marking

Long-life products such as canned or jarred fish and fish products with a shelf life of more than 18 months are required to carry a durability indication in the form of 'best before' followed by the date up to and including which the food can reasonably be expected to retain its specific properties, if properly stored.

Where the food has a shelf life of more than 18 months, the date may be expressed in terms of the year only if the words 'best before' are replaced by the words 'best before end', for example, 'best before end 2010'.

Where a food has a shelf life of less than 18 months, it may be expressed in terms of a month and a year only, for example 'best before end December 2010'.

Such declarations need to be followed by any storage conditions that need to be observed if the unopened food is to retain its specific properties up to the date indicated. In the case of canned food, it would be unlikely that any specific storage conditions would need to be specified.

Such storage conditions relate to the food whilst it remains unopened. In addition to this, however, special storage conditions or conditions of use have to be given if the consumer needs to observe certain practices once the packaging of the food has been opened, for example 'once open, remove from can, keep refrigerated and covered and consume within 3 days'.

It is possible to 'signpost' a date mark, for example, to indicate that the best before date is stamped or printed onto the base or lid of a can. In this case words such as 'for best before see can end' would be appropriate.

1.9.7 Name and address

It is also a requirement to indicate the name or business name and an address or registered office of either or both of:

- A manufacturer or packer; or
- A seller established within the EU.

This requirement enables consumers to contact a person responsible for the foodstuff and the details should therefore be sufficient to allow such contact to be made by post. Whilst customer care telephone numbers and website address can be supplied additionally, they cannot replace the postal address.

1.9.8 Origin marking

Particulars of the place of origin or provenance of a food are required where any indication or pictorial representation might mislead a consumer to a material degree as to the true origin or provenance of a food. Care is therefore required to ensure that the true place of origin is given if a food's name, or its brand or trade name, includes a reference to a place in such a way which, when taken with other written illustrative information given on the label, could imply that the food comes from or has been made in a particular place or area. Where it is not possible to refer to a single country, information that is given should be as specific as possible, for example, by listed alternative supplier countries or groups of countries recognisable to consumers; even phrases like 'origin will vary' may be more helpful than no information at all.

1.9.9 Instructions for use

Instructions for use must be given if it would be difficult to make appropriate use of the food without them. Any instructions provided must be sufficiently detailed to enable appropriate preparation or use to be made of the food.

1.9.10 Location of information

All of the labelling requirements are required to appear on the packaging (or on a label attached to the packaging or on a label that is clearly visible through the packaging).

When the food is sold otherwise than to the ultimate consumer, for example to a caterer, then the details may be contained in the relevant commercial documents, providing it could be guaranteed that these documents can be provided when or before the food is delivered. In such cases, however, the name of the food, the indication of durability and the manufacturer, packer or seller's name and address details must always appear on the outermost packaging in which that food is sold.

1.9.11 Intelligibility

To ensure clarity of labelling information under normal conditions of purchase, all of the labelling information should be easy to understand. This would normally mean that it is provided in the official language(s) of the country(ies) to which the foods are being exported, should also be clearly legible and indelible and marked in a conspicuous place so as to be clearly visible and not hidden, obscured or interrupted by other written or pictorial matter.

1.9.12 Field of vision

Certain information must be provided in the same field of vision at least once on the label, namely:

- The legal name;
- The durability indication (or a signpost to it); and
- The quantity mark.

The same field of vision is understood to mean simultaneously readable under normal conditions of retail sale. It does not necessarily mean on the same face of the pack, but it does mean that the consumer must be able to read the information without having to keep turning the product in order to find it. So, for example, part of the side of a can and its top or bottom might well be in the same field of vision, but opposite sides of a can would not.

1.9.13 Nutrition labelling

Under Council Directive 90/496/EEC (European Union, 1990b) on nutrition labelling for foodstuffs, the provision of nutrition labelling is optional unless a nutrition or health claim is made about a food.

So, for example, whilst the indication of a fish product's content would not constitute a nutrition claim, statements such as 'low saturates' or 'reduced salt' would.

When nutrition information is provided, either the 'Group 1' format or the 'Group 2' format as set out below, must be used. However, where a nutrition claim is made for sugars, saturates, fibre or sodium, the Group 2 format is mandatory.

Group 1	
Energy	kJ and kcal
Protein	g
Carbohydrate	g
Fat	g

Group 2	
Energy	kJ and kcal
Protein	g
Carbohydrate of which:	g
Sugars	g
Fat of which:	g
Saturates	g
Fibre	g
Sodium	g

The following nutrients may be added to a Group 1 or Group 2 declaration on a voluntary basis, but must be declared if a claim about them is made:

Polyols	g
Starch	g
Monounsaturates[a]	g
Polyunsaturates[a]	g
Cholesterol[a]	mg
Vitamins[b]	mg/μg
Minerals[b]	mg/μg

[a]When one of these is declared, saturates must also be declared.
[b]Only listed vitamins and minerals may be declared, and they must be present in significant amounts. As a rule this means that at least 15% of the RDA should be supplied by 100 g/mL of the food or, for packages containing a single portion, by a package of the food. Vitamins and minerals which may be included in a nutrition declaration are listed in Directive 90/496/EEC.

Any nutrient not listed above may be declared only if a claim has been made about it and it is a component of a nutrient as defined.

The energy value to be declared must be calculated using the following conversion factors:

Carbohydrate (except polyols)	17 kJ/g	4 kcal/g
Polyols	10 kJ/g	2.4 kcal/g
Protein	17 kJ/g	4 kcal/g
Fat	37 kJ/g	9 kcal/g
Alcohol (ethanol)	29 kJ/g	7 kcal/g
Organic acids	13 kJ/g	3 kcal/g

The factors given above must be used to calculate the total energy value; they must not be determined by analysis. The energy contribution of nutrients with no listed conversion factors can be ignored, unless the statement of total energy becomes untrue or misleading.

The declared value must be an average based either alone or in combination, on:

- The manufacturer's analysis of the food;
- A calculation from the actual average value of the ingredients used in the preparation of the food; and
- A calculation from generally established and accepted data such as McCance and Widdowson's *The Composition of Foodstuffs* (Food Standards Agency, 2002).

'Average' is defined as the figure which best represents the respective amounts of the nutrients which a given food contains, taking into account seasonal variability, and any other factors which may cause the actual amount to vary.

1.9.14 Claims, descriptions and marketing terms

Whilst falsely describing or providing misleading information about a food would be an offence under the EU General Food Law Regulation 178/2002, certain claims must not be made in the labelling or advertising of food except in accordance with specific conditions which are laid down. The controls are detailed and in some cases complex but, for example, they restrict the vitamins in which respect of which claims may be made to the following, subject to conditions set out in Table 1.2.

Table 1.2 Vitamins for which claims may be made, subject to conditions.

Vitamin A	Niacin
Vitamin D	Vitamin B_6
Vitamin E	Folacin/Folic acid
Vitamin C	Vitamin B_{12}
Thiamin	Biotin
Riboflavin	Pantothenic acid

Claims, which may be made in respect of minerals, are similarly controlled, as shown in Table 1.3.

Table 1.3 Minerals for which claims may be made, subject to conditions.

Calcium	Magnesium
Phosphorus	Zinc
Iron	Iodine

1.9.15 Health and nutrition claims

At the end of 2006, after many years of discussion, a Regulation (EC) No. 1924/2006 (European Union, 2006b) on nutrition and health claims was adopted. It comes into force at various dates extending up to and beyond 2010.

The regulation applies to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer. This would probably include product labels, print and broadcast media, statements made on the internet, posters, explanatory leaflets, in-store promotion and any commercial communication. The Regulation also applies to foods intended for supply to restaurants, hospital, schools, canteens and similar mass caterers. The principal types of claims that are controlled are:

- *Nutrition claims*: Any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to the energy (calorific value) it provides, provides at a reduced or

increased rate or does not provide and/or the nutrients or other substances it contains, contains in reduced or increased proportions or does not contain, for example, 'low salt'.

- *Health claims*: Any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.

  'Low-salt foods can help to maintain a healthy cardiovascular system'.
- *Reduction of disease risk claim*: Any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents, significantly reduces a risk factor in the development of a human disease.

  'Eating low-salt foods can help prevent high blood pressure, an important factor in maintaining a healthy cardiovascular system'.

Nutrition and health claims **must not**:

(a) Be false, ambiguous or misleading;
(b) Give rise to doubt about the safety and/or the nutritional adequacy of other foods;
(c) Encourage or condone excess consumption of a food;
(d) State, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general (derogations may be adopted); and
(e) Refer to changes in bodily functions which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations.

By 19 January 2009, the Commission should have, but had not yet established, specific nutrient profiles, including exemptions, with which food or certain categories of food must comply in order to bear nutrition or health claims. The nutrient profiles will be based on scientific knowledge about diet and nutrition and their relation to health, and take into account:

- The quantities of certain nutrients and other substances contained in the food, such as fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium;
- The role and importance of the food (or category of food) and the contribution to the diet of the population in general, or, as appropriate, of certain risk groups including children; and
- The overall nutritional composition of the food and the presence of nutrients that have been scientifically recognised as having an effect on health.

As a relaxation of these rules, however, nutrition claims referring to the reduction of fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium will be allowed without reference to a profile for the specific nutrient for which the claim is made, provided they comply with the conditions of the Regulation. Furthermore, where a single nutrient exceeds the nutrient profile a nutrient claim may be made provided that a statement about the specific nutrient appears in close proximity to, on the same side and with the same prominence as the claim. This statement must read as follows '*High X content'*, where 'X' is the out-of-profile nutrient.

The use of nutrition and health claims is permitted only if:

- The presence, absence or reduced content in a food or category of food of a nutrient, or other substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence;

- The nutrient or other substance for which the claim is made:
  - Is contained in the final product in a significant quantity (as defined in Community legislation), or where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence; or
  - Is not present or is present in a reduced quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;
- Where applicable, the nutrient or other substance for which the claim is made is in a form that is available to be used by the body;
- The quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates, as defined in Community legislation, or where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence; and
- It complies with the specific conditions laid down.

The use of nutrition and health claims is permitted only if the average consumer can be expected to understand the beneficial effects as expressed in the claim.

Nutrition and health claims must refer to the food ready for consumption in accordance with the manufacturer's instructions.

1.9.16 Specific conditions for nutrition claims

Nutrition claims are permitted only if they are listed in Table 1.4, in accordance with the conditions given.

1.9.17 Food assurance schemes

Assurance schemes are voluntary schemes which verify, through regular independent inspections, that certain stated standards of production are met, which can cover both the catching of fish and its processing.

So, for example, the Marine Stewardship Council (MSC) has set an internationally recognised environmental standard for sustainable fishing based on 3 principles and 31 performance indicators. Only seafood from an MSC certified fishery can carry the blue MSC eco label. The standard is science-based and applies to wild-capture fisheries only – whatever their size, type or location – but does not apply to farmed fish.

The complementary MSC Chain of Custody standard for seafood traceability makes sure that the MSC label is only displayed on seafood from an MSC-certified sustainable fishery.

1.10 LOT MARKING

EC Directive 89/396 (European Union, 1989b) on indications or marks identifying the lot to which a foodstuff belongs requires a lot mark to appear on the packaging or on an attached label. Where

Table 1.4 Permitted nutrition claims.

Nutrition claim (and any claim likely to have the same meaning for the consumer)	Conditions of use
Low energy	Product must not contain more than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/100 mL for liquids. For table-top sweeteners the limit of 4 kcal (17 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose) applies.
Energy-reduced	Energy value is reduced by at least 30%, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.
Energy-free	Product must not contain more than 4 kcal (17 kJ)/100 mL. For table-top sweeteners the limit of 0.4 kcal (1.7 kJ/portion), with equivalent sweetening properties to 6 g of sucrose (approximately 1 teaspoon of sucrose) applies.
Low fat	Product must not contain more than 3 g of fat per 100 g for solids or 1.5 g of fat per 100 mL for liquids (1.8 g of fat per 100 mL for semi-skimmed milk).
Fat-free	Product must not contain more than 0.5 g of fat per 100 g or 100 mL. Claims expressed as 'X% fat-free' are prohibited.
Low-saturated fat	The sum of saturated fatty acids and trans-fatty acids in the product must not exceed 1.5 g per 100 g for solids or 0.75 g per 100 mL for liquids and in either case the sum of saturated fatty acids and trans-fatty acids must not provide more than 10% of energy.
Saturated fat-free	The sum of saturated fat and trans-fatty acids must not exceed 0.1 g of saturated fat per 100 g or 100 mL.
Low sugars	Product must not contain more than 5 g of sugars per 100 g for solids or 2.5 g of sugars per 100 mL for liquids.
Sugars-free	Product must not contain more than 0.5 g of sugars per 100 g or 100 mL.
With no added sugars	Product must not contain any added mono- or disaccharides or any other food used for its sweetening properties. If sugars are naturally present in the food, the statement 'Contains naturally occurring sugars' must appear on the label.
Low sodium/salt	Product must not contain more than 0.12 g of sodium, or the equivalent value for salt, per 100 g or per 100 mL. For waters, other than natural mineral waters, the level must not exceed 2 mg of sodium per 100 mL.
Very low sodium/salt	Product must not contain more than 0.04 g of sodium, or the equivalent value for salt, per 100 g or 100 mL. This claim must not be used for natural mineral waters and other waters.
Sodium-free or salt free	Product must not contain more than 0.005 g of sodium, or the equivalent value for salt, per 100 g.
Source of fibre	Product must contain at least 3 g of fibre per 100 g or at least 1.5 g of fibre per 100 kcal.
High fibre	Product must contain at least 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal.
Source of protein	At least 12% of the energy value of the food must be provided by protein.
High protein	At least 20% of the energy value of the food must be provided by protein.

(*Continued*)

Table 1.4 (*Continued*)

Nutrition claim (and any claim likely to have the same meaning for the consumer)	Conditions of use
Source of vitamin and/or mineral	Product must contain at least a significant amount as defined in the Annex to Directive 90/496/EEC (as a rule this means 15% of the RDA supplied by 100 g or 100 mL or per package if the package contains only a single portion).
High vitamin and/or mineral	Product must contain at least twice the value of 'source of' claim.
Contains (name of nutrient or other substance	No specific conditions laid down. Product must comply with the applicable provisions of the Regulation and in particular the 'general conditions'. For vitamins and minerals the conditions of the claim 'source of' apply.
Increased (name of nutrient)	Product must comply with the conditions for the claim 'source of' and the increase in content is at least 30% compared to a similar product.
Reduced (name of nutrient)	Reduction in content must be at least 30% compared to a similar product, except for micronutrients, where a 10% difference in the reference values in Directive 90/496/EEC are acceptable, and for sodium, or the equivalent in salt, where a 25% difference is acceptable.
Light/lite	Product must comply with the conditions for use of the term 'reduced' and the claim must also be accompanied by an indication of the characteristic(s) which make(s) the food 'light' or 'lite'.
Naturally/natural	Where a food naturally complies with the conditions laid down for use of a nutritional claim, the term 'naturally/natural' may be used as a prefix to the claim.

retail packs are enclosed in a wholesale pack, the lot mark should also appear on the outer container. Like other labelling information, it must be easily visible, clearly legible and indelible.

The lot mark must be preceded by the letter 'L', except where it is clearly distinguishable from other labelling information.

There is, however, an important exemption for foods which bear a date mark which consists, as a minimum, of a day and a month. Products described as best before end month are generally recognised as being able to benefit from this exemption.

1.11 FOOD CONTACT MATERIALS

Regulation (EC) No. 1935/2004 (European Union, 2004e) on materials and articles intended to come into contact with food is generally termed the 'Framework' Directive on food contact materials. The regulation applies to materials and articles which are intended to be brought into contact with food and thus includes cans, glass jars and lids, as well as other equipment with which food may come into contact with during its processing. Although the Regulation provides for specific rules to be developed for particular groups of materials and articles, including glass and metals and alloys, specific measures have so far been agreed only for ceramics, plastics and regenerated cellulose and

the epoxy derivatives 2,2-bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether (BADGE), bis(hydroxyphenyl) methane bis(2,3-epoxypropyl) ethers (BFDGE) and novolac glycidyl ethers (NOGE) (see below).

Under the Framework Directive, the traceability of materials and articles must be established at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility. Fish canners must, therefore, have in place systems and procedures to identify the businesses from which materials and articles have been purchased and, where appropriate, the substances or products they have supplied.

Generally, materials and articles must be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- Endanger human health;
- Bring about an unacceptable change in the composition of the food; or
- Bring about a deterioration in the organoleptic characteristics of the food.

1.11.1 Epoxy derivatives

Regulation (EC) No. 1895/2005 (European Union, 2005b) on the restriction of certain epoxy derivatives in materials and articles intended to come into contact with food applies to materials and articles, including active and intelligent food contact materials which are manufactured with or contain one or more of the following substances: BADGE, BFDGE and NOGE.

Materials and articles covered by the scope of the Regulation are:

- Materials and articles made of any type of plastics;
- Materials and articles covered by surface coatings; and
- Adhesives.

The Regulation does not apply to containers or storage tanks having a capacity greater than 10 000 L or to pipelines belonging to or connected with them, covered by special coatings called ‘heavy duty coatings’.

It is not permitted to manufacture, use for the handling of food in the course of a business, sell for the purpose of the handling of food, or import for the purpose of the handling of food, any material or article in contravention of the provisions in the EC Regulation. In particular, the use and/or presence of BFDGE and NOGE in the manufacturing of materials and articles is prohibited.

Furthermore, materials and articles must not release the following substances into food in a quantity exceeding the following limits.

The sum of BADGE, BADGE·H_2O and BADGE·$2H_2O$ must not exceed 9 mg/kg in food or food simulants or 9 mg/6 dm^2 for containers and similar articles with a capacity of less than 500 mL or more than 10 L, or sheet, film or other materials which cannot be filled or for which it is impracticable to estimate the surface area in contact with food.

The sum of BADGE·HCl, BADGE ·2HCl and BADGE·H_2O·HCl must not exceed 1 mg/kg in food or in food simulants or 1 mg/6 dm^2 for containers and similar articles with a capacity of less

than 500 mL or more than 10 L, or sheet, film or other materials which cannot be filled or for which it is impracticable to estimate the surface area in contact with food.

Migration testing must be carried out in accordance with the rules in EC Directive 82/711/EC (European Union, 1882) and Directive 2002/72/EC (European Union, 2002g) (as amended).

At marketing stages before retail, materials and articles containing BADGE and its derivatives must be accompanied by a written declaration stating that they comply with the legislation. Appropriate documentation must be available to demonstrate such compliance.

Finally, Council Directive 94/62/EC (European Union, 1994c) on packaging and packaging waste specifies that packaging should not be marketed if the combined levels of lead, cadmium, mercury and hexavalent chromium, either in the packaging or in any of its packaging components, exceed 100 ppm.

By way of Commission Decision 2001/171/EC (European Union, 2002d) there is an exemption for recycled glass packaging, which may contain up to 200 ppm.

1.12 ADDITIVES

The principal EC controls on additives are:

- European Parliament and Council Directive 94/36/EC (European Union, 1994a) on colours for use in foodstuffs (European Parliament and Council Directive, 1995);
- European Parliament and Council Directive 95/2/EC (European Union, 2002d) on food additives other than colours and sweeteners; and
- European Parliament and Council Directive 94/35/EC (European Union, 1994b) on sweeteners for use in foodstuffs.

All as amended.

Each Directive was developed under Council Directive 89/107/EEC (European Union, 1989a) concerning food additives authorised for use in foodstuffs intended for human consumption. This is generally referred to as the 'Framework Directive' on food additives. It provides that additives may be used only if they perform a useful purpose, are safe and do not mislead the consumer.

Fish, molluscs and crustaceans, as well as their preparations, but not including prepared meals containing these ingredients, must not contain added colours unless specifically provided for elsewhere in the Regulations, other than by carry over (whereby an additive is present in a compound food only having been carried over from one of its ingredients where the additive is permitted).

Amongst the specific provisions are that E514 (Brown FK) is specifically permitted in kippers at up to 20 mg/kg and E160b (Annatto, Bixin and Norbixin) can be used in smoked fish at up to 10 mg/kg.

Furthermore, fish paste and crustacean paste, pre-cooked or cooked crustaceans, salmon substitutes, surimi, fish roe and smoked fish may contain further permitted colours subject to specific maximum levels that apply to their use singly or in combination.

Preservatives and certain other additives are specifically controlled in relevant products as shown in Table 1.5.

Table 1.5 Permitted 'other additives' specifically controlled in named fishery products.

Number	Food additive	Maximum level of use
E251 E252	Potassium nitrate Sodium nitrate in pickled herring and sprat	500 mg/kg (expressed as sodium nitrite)
E315 E316	Erythorbic acid Sodium erythorbate in preserved and semi-preserved fish products	1500 mg/kg (expressed as erythorbic acid)
E338 E339	Phosphates (individually or in combination) in fish and crustacean pastes	5 g/kg (expressed as P_2O_5)
E340 E341 E343 E450 E451 E452	Canned crustacean products	Up to 1 g/kg
E385	Calcium disodium ethylene diamine tetra-acetate (calcium disodium EDTA) may be added to canned and bottled crustacean, mollusc and fish	At 75 mg/kg

Table 1.6 Permitted sweeteners specifically controlled in named fishery products.

Number	Sweetener	Maximum usable dose
E954	Saccharin and its sodium, potassium and calcium salts	160 mg/kg
E955	Sucralose	120 mg/kg
E962	Salt of aspartame–acesulfame	200 mg/kg
E951	Aspartame	300 mg/kg
E950	Acesulfame K	200 mg/kg

Finally, the following sweeteners are permitted in sweet–sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs, as shown in Table 1.6.

1.13 FLAVOURINGS

Flavourings are not currently controlled by positive lists of the type adopted for most other classes of food additives. However, flavouring substances authorised for use in or on foodstuffs have been listed by the European Commission in a register of about 2700 substances adopted as Commission Decision 1999/217/EC (European Union, 1999).

The registered substances are being evaluated in turn by the European Food Safety Authority (the expert body which advises the European Commission on risk assessment) according to a programme which is still under way.

Meanwhile, Regulation (EC) No. 2065/2003 (European Union, 2003c) of 10 November 2003 on smoke flavourings lays down a Community procedure for the evaluation and authorisation of primary smoke condensates and primary tar fractions for use as such in or on foods or in the production of derived smoke flavourings for use in or on foods.

The Regulation also lays down the Community procedure for the establishment of a list of primary smoke condensates and primary tar fractions authorised to the exclusion of all others in the Community and their conditions of use in or on foodstuffs.

1.14 CONTAMINANTS

Council Regulation (EEC) No. 315/93 (European Union, 1993) which lays down Community procedures for contaminants in food defines contaminant as:

> Any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination.

Extraneous matter, such as insect fragments, and animal hair, is not covered by this definition.

The regulation prohibits food containing a contaminant in an amount which is unacceptable from the public health viewpoint, and in particular at a toxicological level, from being placed on the market. Furthermore, contaminant levels must be kept as low as can reasonably be achieved by following good practices at all stages of production, manufacturing, processing, preparation, treatment, packing, packaging, transport and holding of food.

In any event, the presence in food of any contaminant in sufficiently high level would mean that the food failed to meet the food safety requirements set out in Regulation (EC) No. 178/2002.

Nevertheless, in order further to protect public health, a number of regulations setting maximum levels for specific contaminants have also been established via Commission Regulation (EC) No. 1881/2006 (European Union, 2007b) as follows:

- Nitrites: Commission Regulation (EC) No. 563/2002 (European Union, 2002f);
- Mycotoxins: Commission Regulations (EC) No. 257/2002 (European Union, 2002c) and 472/2002 (European Union, 2002e);
- Dioxins and dioxin-like PCBs: Commission Regulation (EC) No. 1883/2006 (European Union, 2006a); and
- Lead, cadmium, mercury and 3-MCPD: EC Commission Regulation (EC) No. 221/2002 (European Union, 2002b).

Table 1.7 sets out statutory maximum levels relevant to canned fish for each specific contaminant.

1.15 PESTICIDES

Council Directive 91/414/EEC (European Union, 1991) on plant protection products provides for the establishment of a list of plant protection products that in due course will be permitted to the exclusion of all others. In each case, the substances will have been evaluated by the European Food Safety Authority, and found to be safe in use from both a public health and an environmental viewpoint.

Regulation (EC) No. 396/2005 (European Union, 2005a) on maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin put in place a new regulatory regime at EU level from September 2008.

Table 1.7 Maximum levels of contaminants specifically permitted in named fishery products.

Product	Contaminant	Maximum level
Muscle meat of fish (except those listed below)	Lead	0.2 mg/kg (wet weight)
Muscle meat of bonito, common-to-banded sea bream, eel, grey mullet, grunt, horse mackerel or scad, sardine, sardinox, spotted sea bass, tuna, wedge sole	Lead	0.4 mg/kg
Crustaceans excluding brown meat of crab	Lead	0.5 mg/kg
Bivalve molluscs	Lead	1.5 mg/kg
Muscle meat of fish (except those listed below)	Cadmium	0.05 mg/kg
Muscle meat of bonito, common-to-banded sea bream, eel, European anchovy, grey mullet, horse mackerel or scad, louvar or luvar, sardine, sardinox, tuna, wedge sole	Cadmium	0.1 mg/kg
Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans	Cadmium	0.5 mg/kg
Bivalve molluscs	Cadmium	1 mg/kg
Fishery products except those listed below	Mercury	0.5 mg/kg
Anglerfish, Atlantic catfish, bass, blue ling, bonito, eel, emperor or orange ruffey, grenadier, halibut, marlin, pike, plain bonito, Portuguese dogfish, rays, redfish, sail fish, scabbard fish, shark (all species), snake mackerel or butter fish, sturgeon, swordfish, tuna	Cadmium	1.0 mg/kg
Muscle meat of fish and fishery products and products thereof	Dioxin (PCDD + PCDF)	4 pg (WHO-PCDD-F-TEQ-G fresh weight)
Canned food other than beverages and products for infants and young children	Tin (inorganic)	200 mg/kg (wet weight)

Once fully developed, a series of annexes will set out the following:

Annex I Products or groups of products for which no specific MRLs have been established, unless the active substance is listed as exempt at Annex IV. In these cases typically a default MRL of 0.01 mg/kg applies;

Annex II EC definitive MRLs;

Annex III EC temporary MRLs; and

Annex IV Exempt active substances.

Whilst there are no MRLs set for fish and similar products, MRLs for certain other ingredients of prepared fish products would need to comply with the relevant MRLs.

1.16 VETERINARY MEDICINAL PRODUCTS

Council Regulation (EEC) No. 2377/90 (European Union, 1990a) lays down a Community procedure for the establishment of residue limits of veterinary medicinal products in foodstuffs of animal origin.

The Regulations bans the sale for human consumption of any animal product which contains an unauthorised substance or an authorised substance exceeding the relevant MRL.

Residues of many pharmacologically active substances are controlled in fish, normally by specifying, in each case, the pharmacologically active substance, marker residue, animal species, MRLs, target tissues and any other provisions.

1.17 WEIGHTS AND MEASURES

Controls on canned fish products are subject to Council Directive 76/211/EEC (European Union, 1976), sometimes known as the Solids Directive.

This is intended to harmonise quantity control procedures across Member States by allowing packages that meet certain standards to be marked with an 'e' mark and for those packages to be allowed free access for metrological control purposes across all other Member States.

The Directive requires that Member States do not, on metrological or related labelling grounds, refuse access to packages which satisfy their requirements. Member States must also establish systems permitting the e-marking of packages and for enforcement.

Packages have to be made up in such a way that they meet the following requirements:

- The actual contents, i.e. the weight of product which in fact contains, shall not be less, on average, than the nominal quantity, i.e. the quantity of product which the pre-package is deemed to contain;
- The proportion of pre-packages having a negative error (the quantity by which the actual contents of the pre-package are less than the nominal quantity) greater than the tolerable negative error laid down for that size of pack shall be sufficiently small for batches of pre-packages to satisfy the requirements of the reference test specified in the Directive; and
- No pre-package shall have a negative error greater than twice the tolerable negative error laid down.

All pre-packages made up in accordance with this Directive must then be marked indelibly, easily legibly and visibly with:

- 'The nominal quantity (weight or volume)'.
- 'A mark or inscription enabling the competent departments to identify the packer or the person arranging for the packing to be done or the importer established in the Community'.
- 'A small "e", at least 3 mm high, placed in the same field of vision as the indication of the nominal quantity. . .'.

For packages produced in the European Economic Area (EEA), i.e. EU plus Iceland, Norway and Liechtenstein, the packer is responsible for meeting this requirement.

For packages produced outside the EEA, the first importer based in the EEA is responsible for meeting this requirement. Domestic legislation may specify whether the company or individual employee is held responsible.

In the case of imports from non-EEC countries, the importer may, instead of measuring and checking, provide evidence that he is in possession of all the necessary guarantees enabling him to assume responsibility. Some of the acceptable guarantees include:

- Evidence from a competent department in a Member State;
- Evidence from an EEA accepted competent department in the exporting country;
- Records of checks carried out by a competent sub-contractor at the place of first entry into the EEA; and
- To obtain records from the packer and to carry out checks to verify the data contained in them.

1.18 WARNING

This description of EU legislation was current at the time of drafting (November 2008). Legislation is subject to regular development or amendment. Readers are therefore encouraged always to consult the most up-to-date legislation.

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