

A COMPENDIUM

of Food Law in Ireland

2003



PUBLISHED BY:

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ISBN 1-904465-04-8

This document is intended as a guide to all interested in the area of food law in Ireland and should be read in conjunction with the appropriate legislation. It does not purport to be definitive or an interpretation of the law and in areas of doubt it is advisable to consult a solicitor.

April 2003

FOREWORD

The Food Safety Authority of Ireland Mission Statement:

“To protect consumers’ health by ensuring that food consumed, distributed, marketed or produced in the state meets the highest standards of food safety and hygiene.”

Food law in Ireland dates back to the early 1800’s and has been continually augmented and amended over the years. Today, most if not all of our national food legislation derives from Ireland’s membership of the European Union. The negotiation of these laws and the responsibility to give legal effect to the decisions, directives and regulations agreed in Brussels rests with several Government Departments. Ireland’s food code is considerable in volume and ever evolving. Despite the apparent complexity, when considered in terms of the entire food chain, there is a good degree of logic to the scope and intent of the legislation. From primary production through to the service sector, our food laws tackle every aspect of food production and manufacture. Detailed rules now address many issues such as application of pesticides, hygiene at slaughter, production and processing, control and use of food additives and flavourings, limits on contaminant levels, veterinary drug residues, marine biotoxins, food labelling, compositional standards, dietary supplements and the approval of genetically modified foods.

The diverse range of food laws and State agencies with responsibility for their enforcement was one of the reasons why the Government in 1998 established the Food Safety Authority of Ireland (FSAI). The FSAI is now the single, regulatory authority with responsibility for the enforcement of food safety legislation in Ireland. This work is mainly carried out for the FSAI under contract by staff in the local authorities, health boards, Department of Agriculture and Food, Department of Communications, Marine and Natural Resources and the Office of the Director of Consumer Affairs. It is worth noting that food legislation places obligations not just on food business operators, but also on the enforcement authorities who must carry out official controls and to take action where non compliance is detected and more specifically when consumers are put at risk.

A key focus in enforcing food legislation is to impart a greater understanding to all food businesses of their primary and legal responsibility for producing safe food. Knowledge of the law is essential not just for those who enforce it, but more importantly for those to whom it applies. The FSAI has the legal right to collect all food legislation and to publish it. In recognition of that right, this compendium was prepared. Its main purpose is to act as a reference and guide to the various acts, regulations and orders made at national level as well those directives and regulations made at EU level. This compendium is intended to act as a general guide. For more definitive information the relevant Act or Statutory Instrument should be consulted.

This is the second edition of this compendium, the first having been published in 1998. It brings together all food legislation made in the period to the end of December 2002. Given that food legislation continues to be adapted and amended, it is the Authority’s intention to publish this compendium on its website (www.fsai.ie) where it will be updated quarterly. An updated hardcopy version will be made available annually.

Ensuring that the food produced and marketed in Ireland meets highest standards attainable is the principal role of FSAI. In pursuit of this objective achieving compliance with food law is an important step in the process, but by no means the only one. Food law after all has more than one purpose, as it is designed not only to protect human health but to protect consumer interests, to inform consumers and to facilitate fair trade. Legislation is not always the ideal solution to food safety problems. Technology, new hazards and risks generally emerge and legislation follows in their wake.

If Ireland is truly to become “Ireland the Food Island”, then our food industry has not simply to be mindful of its legal requirements, but must embrace a culture of commitment to food safety, making protection of consumer health and interests a primary goal.

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Irish Legislative Process (Acts)

The Oireachtas (Parliament), which consists of a President and two Houses of the Oireachtas (Dail Eireann and Seanad Eireann), creates new legislation in Ireland. Legislation is found in enacted laws which are called statutes.

Proposed new legislation is known as a Bill, which becomes an Act and is declared law when it is agreed by both houses of the Oireachtas and signed by the President.

First Stage: Permission is sought either by a Minister or Minister of State in either House (Dail Eireann and Seanad Eireann) to introduce the Bill. If granted, the Bill is printed and circulated to members. An Order is made by the Dail for its second reading.

Second Stage: Is a debate where the general principles of the Bill are considered. This may result in amendments or improvements. When these are agreed an Order is made for the Bill to be considered in committee (third) stage.

Third (Committee) Stage: The Bill is considered in great detail. Depending on the technical nature of this Bill this could be either in:

- Committee of the whole House or
- Select Committee or
- Special Committee.

Fourth (Report) Stage: consists of a review of changes made at Third Stage. Consideration is limited to amendments tabled which arise from proceedings at Third Stage.

Fifth (Final) Stage: The Bill is finally considered before it is passed. A Bill amended by the Seanad is sent back to the Dail for its agreement. Finally when the Bill is passed by both Houses, it goes to the President for her/his signature and is declared law.

Enactment: A Bill becomes law on the day it is signed by the President and, unless the contrary intention appears, comes into operation on that day. A Bill may, for example, contain provision for its commencement (in whole or in part) by way of Ministerial order.

Statutory Instruments

Acts often give powers to Ministers of Governments to make secondary laws known as Statutory Instruments. Statutory Instruments (S.I.) can be written in the form of Regulations or Orders and detail specific rules and give enforcement powers to a particular authority e.g. the Health Act, 1947 Part V gives power to the Minister for Health and Children to make Regulations on Food and Drink. Subsequently, the Food Hygiene Regulations, 1950 (S.I. No. 205 of 1950) were introduced to protect the health of consumers consuming food and drink.

European Union (EU)

In general, EU law is composed of three different – but interdependent – types of legislation:

Primary Legislation

Primary legislation, includes, in particular, the Treaties and other agreements having similar status, which is agreed by direct negotiation between the governments of Member States. These agreements are laid down in the form of Treaties which are then subject to ratification by the national parliaments. The same procedure applies for amendments to the Treaties.

The original Treaty of Rome has been amended a number of times, namely through:

- the Single European Act
- the Treaty on European Union – ‘Maastricht Treaty’
- the Treaty of Amsterdam and,
- the Treaty of Nice

Secondary Legislation

Laws approved by the institutions of the EU through the procedures defined within the Treaties are known as secondary legislation. Community law may take the following forms:

EU Regulations are directly applicable and binding in all EU Member States without the need for any national implementing legislation. While regulations have the force of law, Member States are required to introduce measures for their enforcement, such as penalties for infringement and to clearly identify which national agency will be responsible for enforcement.

EU Directives are binding on all Member States as to the objectives to be achieved within a certain time limit and Member States must adapt measures to meet the stated objectives. National authorities have the choice of form and means to be used. Directives have no legal force in Member States until they are transposed into national laws.

EU Decisions are binding in their entirety (not just its objectives) on those to whom the Decisions are addressed such as a Member State, a Third Country, an organisation or an individual.

EU Recommendations and Opinions are not binding but express the Councils or Commissions view on policy to the Member States or to the individuals to which they are addressed. Whilst Recommendations and Opinions are not legally binding they have political and moral significance and can be preliminary requirements to subsequent mandatory rules.

Case Law

Food laws can also come into force as a result of European Union Case Law. Case-law includes judgments of the European Court of Justice and of the European Court of First Instance, for example, in response to referrals from the Commission, national courts of the Member States or individuals.

These types of legislation comprise the *acquis communautaire*.

European Union Legislative Process

The Treaty on the European Union (Maastricht 1992) established three pillars:

- European Community (EC) Pillar covering mostly traditional economic policy areas
- The Second Pillar which deals with Common Foreign and Security Policy
- The Third Pillar dealing with Co-operation in the fields of justice and home affairs.

The EC pillar is the more supranational pillar and most legislative decisions take place in this pillar.

The three institutions i.e. the Commission, Council and Parliament take decisions in the legislative field. The main differences in the decision making process are related to whether the Council decides by qualified majority or unanimity and the degree to which the European Parliament is involved in the process.

The Commission is the initiator of proposals for new legislation; however it has limited legislative power.

The legislative power in the Community will be exercised either by the Council or jointly by Parliament and the Council, who can only act on a proposal from the Commission. In exceptional cases however, the initiative is shared with Member States (Article 67 EC) or with the European Central Bank (Article 111 EC) or the Council can act on its own initiative.

The legal basis of the proposal (i.e. the Treaty article cited as the grounds for making the proposal) also determines which institutions have to be consulted and according to which procedure.

Legislative Procedures

The various procedures which govern the decision-making in the legislative procedure:

- assent
- co-operation procedure
- consultation
- co-decision

Assent

The assent procedure was introduced by the **Single European Act (1986)**. It means that the Council has to obtain the European Parliament's assent before certain very important decisions are taken. Parliament can accept or reject a proposal but cannot amend it.

Cooperation Procedure

The cooperation procedure was introduced by the **Single European Act (1986)** and is generally only used in the EMU.

Consultation

Under this procedure the Council must consult the European Parliament and take its views into account. However, it is not bound by Parliament's position but only by the obligation to consult it. Once it has received this opinion, the Commission can amend its proposal accordingly. The proposal is then examined by the Council, which can adopt it as it is or amend it first. However, if the Council decides to reject the Commission proposal, this must be a unanimous decision. The procedure applies in particular to the common agricultural policy.

The Co-Decision Procedure

The co-decision procedure (Article 251 of the EC Treaty, formerly Article 189b) was introduced by the Treaty of Maastricht. It gives Parliament the power to adopt instruments jointly with the Council. In practice, it has strengthened Parliament's legislative powers in the following fields: the free movement of workers, right of establishment, services, the internal market, education

(incentive measures), health (incentive measures), consumer policy, trans-European networks (guidelines), environment (general action programme), culture (incentive measures) and research (framework programme).

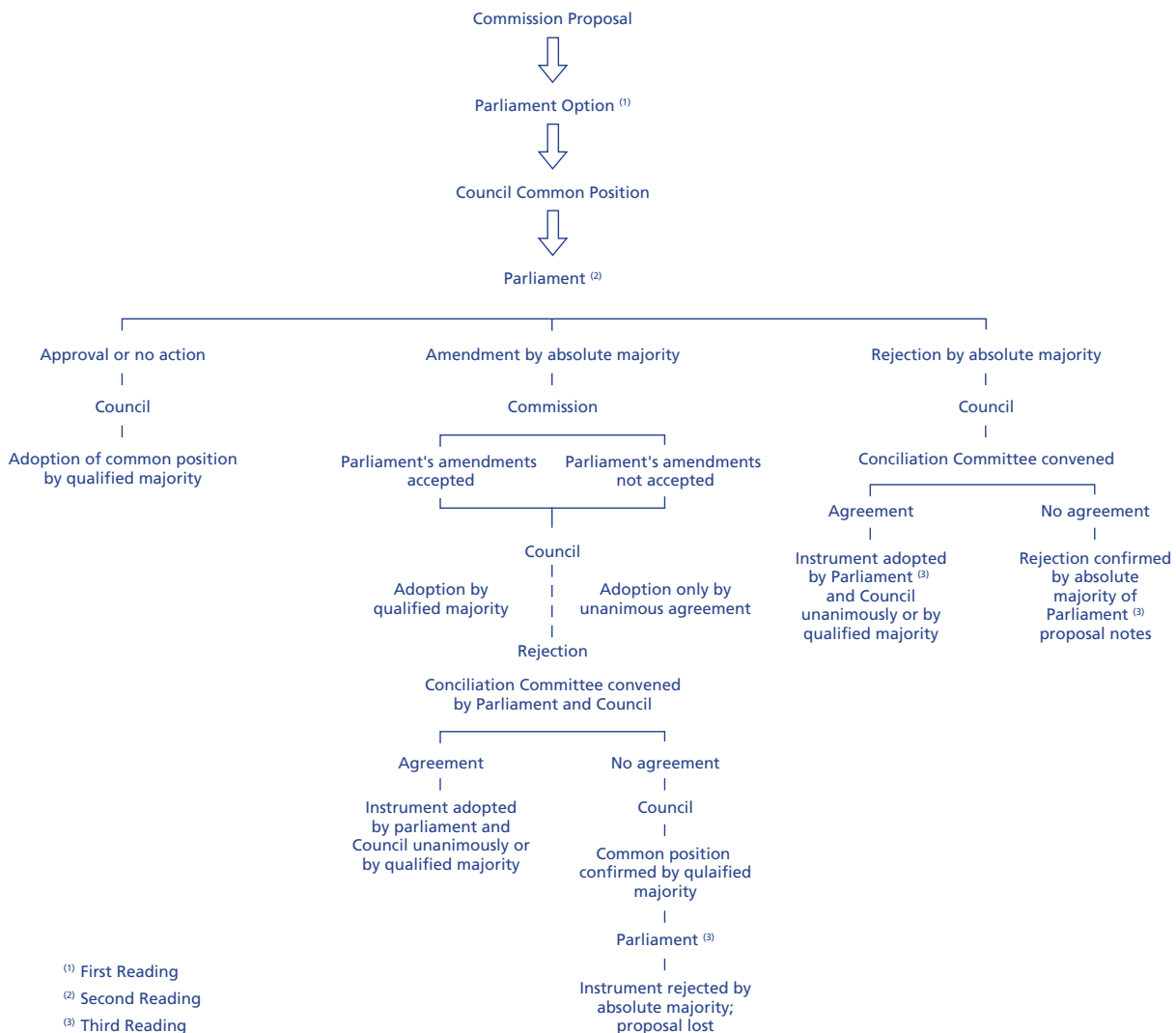
The Treaty of Amsterdam has simplified the co-decision procedure, making it quicker, more effective and more transparent. It has been extended to new areas such as social exclusion, public health and the fight against fraud affecting the European Community's financial interests

A brief outline of the procedure is as follows (See also figure 1):

- The Commission formulates a proposal that is sent to the Parliament and the Council for consultation.
- The Parliament formulates its opinion which it sends to the Council.
- The Council deliberates on the Commission proposal and the Parliaments opinion and adopts a draft Common Position.
- The Common Position is then sent back to the Parliament for its second reading. The Parliament then has three months to either:

- approve (or refrain from reacting to) the Council's Common Position, in which case it will be adopted and become law
- amend the Common Position in which case a Conciliation Committee is set up. This committee consists of equal representatives of the Council and the Parliament who negotiate the amendments which are subsequently adopted or rejected or
- reject the Common Position outright in which case the Council can convene the Conciliation Committee and commence negotiations as (b) above.

- If the Conciliation Committee reaches an agreement and approves the Common Position it becomes law.
- If the Conciliation Committee fails to reach a compromise on a Common Position, the Council may within 6 weeks confirm its own decision by a qualified majority with or without the opinion of the Parliament. The Common Position is then sent back to Parliament for its third reading. If the Common Position is rejected by Parliament at this stage by a qualified majority the proposal is lost and does not become law.



FOOD GENERAL

• EU LEGISLATION

A major part of the reform of food legislation promised in the European Commission's White Paper on Food Safety has now been delivered in the form of the Regulation 178/2002. This legislation will become a standard reference and will be the basis of many future pieces of EU food law. Apart from establishing the European Food Safety Authority (EFSA), the regulation also gives legal effect to the new Rapid Alert System for Food and Feed (RASFF). The system deals with the obligatory notification of any direct or indirect risk to human health, animal health or the environment within a network consisting of national competent authorities, the EFSA and the European Commission. The Regulation also provides special powers to the European Commission for taking emergency measures. Such measures can be taken where it is evident that feed or food originating in the EU, or imported from a third country, is likely to constitute a serious risk to human health, animal health or the environment, and that such a risk cannot be contained satisfactorily by means of measures taken by the Member States.

Equally importantly the Regulation sets down the general principles of food law including the use of the precautionary principle and traceability.

- **Regulation (EC) No 178/2002** (OJ L31, p1, 1/02/2002) **of the European Parliament and of the Council of 28 January 2002** laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

• NATIONAL LEGISLATION

Sale of Food & Drugs Acts 1875-1936 comprising:

- **Sale of Food & Drugs Act, 1875**
- **Sale of Food & Drugs (Amendment) Act, 1879** (62 & 63 Vict. c.51)
- **Sale of Food & Drugs (Amendment) Act, 1899** (7 Edw. 7. c.21)
- **Margarine Act, 1887**
- **Butter and Margarine Act, 1907**
- **Sale of Food & Drugs (Milk) Act, 1935 (No. 3 of 1935)**
- **Sale of Food & Drugs (Milk) Act, 1936 (No. 44 of 1936)**
- **Sale of Food & Drugs (Milk) Act, 1935** (Section 2, Appointed Day) Order, 1936 (S.I. No. 78 of 1936)
- **Sale of Food & Drugs (Milk Sampling) Regulations, 1936** (S.I. No. 312 of 1936)
- **Sale of Food & Drugs (Milk Sampling) (Amendment) Regulations, 1941** (S.I. No. 246 of 1941)

These Acts protect the consumer against adulteration and fraud. The principal sections of the 1875 Act make it an offence to mix, colour, stain or powder any article of food with any ingredient or material so as to render the article injurious to health, with intent to sell the article in that state, or to sell to the prejudice of the purchaser any article of food which is not of the nature, substance and quality of the article demanded. It also makes it an offence to sell to the prejudice of the purchaser any article of food which is not of the nature, substance and quality of the article demanded by said purchaser.

In addition to the broad offences mentioned, the Acts also lay down minimum compositional criteria for milk and certain associated products, for example, cream and butter.

The most frequent reference to this Act is to Section 6 which makes it an offence to sell adulterated food.

While the sale of Food and Drugs Acts are still technically in force today, many of the provisions have been overtaken by more specific legislation. For instance, the Acts laid down qualified standards for certain spirit drinks. These standards have however, been overtaken by absolute standards set by EU Directive and transposed into national legislation by the Minister for Agriculture and Food by Regulations dealing with the description of spirit drinks.

Similarly these Acts set compositional standards for butter, margarine and milk. They also laid down some labelling requirements. As in the case of spirit drinks, these standards too have been overtaken by EU legislation, although in some cases the earlier legislation has not been formally repealed.

Health Acts

- Health Act, 1947 (No. 28 of 1947)
- Health Act, 1953 (No. 26 of 1953)
- Health Act, 1970 (No. 1 of 1970)
- European Communities (Health Act, 1947, Amendment of Sections 54 and 61) Regulations, 1991 (S.I. No. 333 of 1991)

The Health Acts contain enabling powers for the making of Regulations to prevent danger to the public health arising from the manufacture, distribution, importation or sale of food and for the making of compositional standards for foods which are of special importance to the public health. The Acts also give powers of entry to enforcement officers and prescribe the penalties for breaches of the Act or Regulations made thereunder.

OFFICIAL CONTROL OF FOODSTUFFS

• EU LEGISLATION

- **Council Directive 89/397/EEC** (OJ L186, p23, 30/06/1989) **of 14 June 1989** on the official control of foodstuffs
- **Council Directive 93/99/EEC** (OJ L290, p14, 24/11/1993) **of 29 October 1993** on the subject of additional measures concerning the official control of foodstuffs

• NATIONAL LEGISLATION

- **European Communities (Official Control of Foodstuffs) Regulations, 1988 (S.I. No. 85 of 1998)**
- **European Communities (Official Control of Foodstuffs) (Approved Laboratories) Order, 1998 (S.I. No. 95 of 1998)**
- **European Communities (Official Control of Foodstuffs) (Approved Examiners) Order, 1998 (S.I. No. 465 of 1998)**
- **European Communities (Official Control of Foodstuffs) (Amendment) Regulations, 1999 (S.I. No. 210 of 1999)**

These Regulations give full effect to Council Directive 89/397/EEC on the official control of foodstuffs and Council Directive 93/99/EEC on the subject of additional measures concerning the official control of foodstuffs (including the accreditation of laboratories).

The 'official control of foodstuffs' means an inspection by authorised officers of the compliance of foodstuffs, food additives, vitamins, mineral salts, trace elements and other additives intended to be sold as such and materials and articles intended to come into contact with foods. The main controls are inspection, sampling and analysis, inspection of staff hygiene, examination of written and documentary material and examination of verification systems conducted by the food business. Items which are subject to inspections include the site, premises, offices, raw materials, semi-finished products and materials coming into contact with foodstuffs.

Detailed provisions are given for inspection programmes, sampling procedures, official laboratories, powers of authorised officers, issuing of Closure Orders and other possible action where there is non-compliance. It is an offence to offer for sale any foodstuff which is diseased, contaminated or otherwise unfit. Closure Orders are issued where a food business presents a grave and immediate danger to public health.

There is an approved list of laboratories in Ireland for analysis of food samples taken for the purposes of the official control of foodstuffs. It includes among others the Public Analysts Laboratories, Microbiological Laboratories

and the Radiological Institute of Ireland. These laboratories must comply with the general criteria laid down in European Standard EN 45001 and Organisation for Economic and Co-operation and Development (OECD) principles as appropriate. Specified classes of persons are qualified to analyse the samples.

Since 1992, a series of Community-wide food inspection programmes have been conducted to gather information and experience upon which to base future control activities. Each year different aspects of food safety/control are examined. In 2001, the programme focussed on the monitoring of compliance with the QUID aspect of labelling and the bacteriological quality of smoked fish products. Analysis was carried out by the approved official laboratories.

In 2002 the programme included an examination of compliance with the Community rules on labelling of certain foodstuffs that may contain ingredients produced from genetically modified organisms; assessing the bacteriological safety of pre-cut fresh fruit and vegetables and sprouted seeds, and assessing the bacteriological safety of fruit and vegetable juices.

FOOD HYGIENE

• EU LEGISLATION

Council Directive 93/43/EEC (OJ L175, p1, 19/07/1993) of 14 June 1993 on the hygiene of foodstuffs

Derogations granted:

- **Commission Directive 96/3/EC Euratom, ECSC** (OJ L21, p42, 27/01/1996) of 26 January 1996 granting a derogation from certain provisions of Council Directive 93/43/EEC on the hygiene of foodstuffs as regards the transport of bulk liquid oils and fats by sea.
- **Commission Directive 98/28/EC** (OJ L140, p10, 12/5/1998) of 29 April 1998 granting a derogation from certain provisions of Directive 93/43/EEC on the hygiene of foodstuffs as regards the transport by sea of bulk raw sugar.

Future Developments

At present, the European Commission is involved in a major review of the hygiene directives. The Directives (17 in total) have been gradually developed since 1964 in response to the needs of the internal market, taking into account however, a high level of protection for the consumer. The multiplicity of these Directives, the intermingling of different disciplines, (hygiene, animal health, official controls) and the existence of different hygiene regimes for products of animal origin and other food have led to a complex situation, which it is hoped can be improved by recasting the legal requirements and separating aspects of food hygiene from animal health and official control issues.

It is proposed to replace the existing 17 hygiene directives with five new pieces of legislation namely

- Regulation on Food Hygiene
- Regulation on Specific Hygiene rules for food of animal origin
- Regulation on Official Controls on foods of animal origin
- Regulation on Animal Health
- Directive to Repeal existing rules

REGULATION 1 (Proposal for a Regulation of the European Parliament and of the Council on the hygiene of Foodstuffs) sets out the rules applicable to all food – from the farm to the point of sale to the consumer. The Regulation places primary responsibility for the safety of food on food producers.

REGULATION 2 provides for the specific hygiene rules for food of animal origin in addition to the general rules in Regulation 1. This is because animal produce has additional, inherent risks, than other food. All meat, molluscs, fish, eggs, milk, frogs' legs/snails are covered.

REGULATION 3 lays down detailed rules for official controls on products of animal origin.

REGULATION 4 on animal health requirements, again results from the recasting exercise and are not directly related to hygiene. However, the benefit now is that the animal health rules are in one instrument instead of being scattered over seven different texts. The basic principle involved is preventing the spread of animal diseases resulting from placing animal produce on the market.

• NATIONAL LEGISLATION

Numerous Statutory Instruments, (S.I.s) have been made by the Minister for Health and Children using the power granted in the Health Acts. The most notable, apart from those concerning food additives are the Food Hygiene Regulations.

- **Food Hygiene Regulations, 1950 (S.I. No. 205 of 1950)**
- **Food Hygiene Regulations, 1950 (Commencement of Part IV) Order, 1951 (S.I. No. 270 of 1951)**
- **Food Hygiene (Amendment) Regulations, 1952 (S.I. No. 289 of 1952)**
- **Food Hygiene (Amendment) Regulations, 1961 (S.I. No. 24 of 1961)**
- **Food Hygiene (Amendment) Regulations, 1971 (S.I. No. 322 of 1971)**
- **Food Hygiene Regulations Order, 1986 (S.I. No. 21 of 1986)**
- **Food Hygiene (Amendment) Regulations, 1989 (S.I. No. 62 of 1989)**
- **European Communities (Hygiene of Foodstuffs) Regulations, 2000 (S.I. No. 165 of 2000).**

The Food Hygiene Regulations set out statutory requirements in relation to food hygiene and food premises. They apply essentially to those sectors of the food industry to which no vertical, (product specific) or sector specific rules apply.

The Regulations prohibit the sale for human consumption of food which is diseased, contaminated or otherwise unfit for human consumption and require that adequate precautions shall be taken to prevent the contamination of food intended for sale for human consumption at all stages of its importation, manufacture and distribution, including the maintenance of hygienic conditions in food premises and observance of certain hygienic precautions by food handlers. The Regulations provide for the seizure of unfit food and for its destruction.

The Regulations also provide for the registration by health boards of certain categories of food businesses, such as manufacturers, wholesalers, hotels, restaurants and butchers. Application for Registration is required one month in advance of the commencement of business. Registration is granted where a premises is deemed to be in compliance with the provisions of the Regulations. Provisional registration may be granted. There is an appeals mechanism against a decision by a health board to refuse to grant registration or against any conditions given in a provisional registration.

The **European Communities (Hygiene of Foodstuffs) Regulations, 2000 (S.I. No.165 of 2000)** give effect to Council Directive 93/43/EEC on the hygiene of foodstuffs. They cover all stages after primary production and set down the obligations on proprietors of food businesses, including the requirement that such business is operated in a hygienic way. The rules of hygiene cover requirements for the premises, food preparation rooms, foodstuffs, transportation, equipment, food waste, water supply, personal hygiene and training. Proprietors are also obliged to identify steps in the activities of the business which are critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented and reviewed on the basis of the principles used to develop a HACCP system.

The Regulations make provision for the Food Safety Authority of Ireland (FSAI) to approve guides to good hygiene practice, which may be used voluntarily by food businesses. They also cover appropriate remedial action where there is failure to comply with the Regulations.

The Regulations also give effect to **Commission Directive 96/3/EC** and **98/28/EC** which grant derogations from certain conditions of **Commission Directive 93/43/EEC** on the hygiene of foodstuffs as regards the transport of bulk liquid oils and fats by sea and on the hygiene of foodstuffs as regards the transport by sea of bulk raw sugar.

Enforcement

The **Food Safety Authority of Ireland Act, 1998** contains enforcement provisions which are in addition to the powers to prosecute and other provisions in other specific pieces of food legislation. The provisions in the **Food Safety Authority of Ireland Act, 1998** are designed to provide an improved means of reacting to and dealing with situations posing a risk to public health. Enforcement is carried out by authorised officers appointed by the FSAI or its official agents under Section 49 of the Act.

The powers granted to these officers are detailed in Sections 50 and 51 of the Act.

The provisions in the **Food Safety Authority of Ireland Act, 1998** are as follows:

IMPROVEMENT ORDER – It is issued by the District Court if an Improvement Notice is not complied with.

An Improvement Notice is issued where in the opinion of the authorised officer:

- a) any activity involving the handling, preparation etc. of food, or
- b) the condition of a premises (or part thereof) where this activity takes place is such that if it persists, it will or is likely to pose a risk to public health.

CLOSURE ORDER – It is issued if in the opinion of an authorised officer, there is or there is likely to be a grave and immediate danger to public health at/or in the food premises. Closures Orders can refer to the immediate closure of all or part of the food premises, or all or some of its activities. The Orders may be lifted when the premises has improved to the satisfaction of an authorised officer.

PROHIBITION ORDER – It is issued if the activities (handling, processing, disposal, manufacturing, storage, distribution or selling food) involve or are likely to involve a serious risk to public health from a particular product, class, batch or item of food. The effect is to prohibit the sale of the product, either temporarily or permanently.

Note: Orders may pertain to all or part of a food premises, the cessation of all or some of the activities thereat, or the withdrawal/detainment/destruction of described foodstuffs.

LABELLING, PRESENTATION AND ADVERTISING OF FOODSTUFFS

General Labelling Provisions for Foodstuffs

• EU LEGISLATION

Council Directive 2000/13/EC (OJ L109, p29, 06/05/2000) of 20 March on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

Amended by:

- **Commission Directive 2001/101/EC** (OJ L310, p19, 28/11/2001) of 26 November 2001

Commission Directive 2002/86/EC of 6 November 2002 (OJ L 305, p.19, 07/11/2002) amending **Directive 2001/101/EC** as regards the date from which trade in products not in conformity with **Directive 2000/13/EC** of the European Parliament and of the Council is prohibited

• NATIONAL LEGISLATION

- **European Communities (Labelling, Presentation and Advertising of Food stuffs) Regulations, 2002** (S.I. No. 483 of 2002)

Claims on food

A claim on the label of a foodstuff could be described as a declaration regarding the properties of a foodstuff over and beyond those which are compulsory. All claims must be substantiated and the onus is on the manufacturer to demonstrate that the claim is true. Manufacturers must be able to provide documentation and evidence in support of the health claim which outweighs any opposing evidence or opinion.

Under the Labelling Regulations the fundamental rules regarding claims are that claims must not be false or misleading to the consumer and medicinal claims that a food has the property of treating, preventing or curing human disease are prohibited.

Nutrition labelling for foodstuffs

• EU LEGISLATION

Council Directive 90/496/EEC (OJ L276, p40, 06/10/1990) of 24 September 1990 on nutrition labelling for foodstuffs

• NATIONAL LEGISLATION

Health (Nutrition Labelling for Foodstuffs) Regulations, 1993 (S.I. No. 388 of 1993)

A nutritional claim is one that states, suggests or implies that a foodstuff has particular nutritional properties due to the energy and/or the nutrient content. Examples of nutritional claims include the declaration 'low fat', high fibre' or 'contains less than 100 calories' on the label.

The provisions of the **Health (Nutrition Labelling for Foodstuffs) Regulations, 1993** apply where a nutritional claim is made. The only nutritional claims that can be made on the label of a food are those relating to:

- the energy value
- the nutrients: protein, carbohydrate, fat, fibre, sodium and substances that belong to or which are components of these nutrients and
- the vitamins and minerals listed in significant amounts.

Where nutrition labelling is provided, it must conform to the standards set down. In general terms, the labelling will be specific to the claim and may indicate the energy value and the amounts of protein, carbohydrate, fat, sugars, saturates fibre and sodium, as appropriate. The units for expressing these components are prescribed. The Regulations apply to food supplied to the final consumer, restaurants, hospitals, canteens and other similar mass caterers. The sale of food which does not comply with the Regulations is prohibited and the powers of the authorised officers are specified.

Fortified foods

Fortified foods are foods to which nutrients have been added, such as breakfast cereals or fruit juices enriched with vitamins and minerals. Foods were originally fortified with extra vitamins and minerals as a public health measure rather than for any other reason. In Ireland most foods can be fortified (exceptions include butter). There

are no specific rules governing the fortification of food and there is no limit to the level of fortification that can be used except that it must be safe to eat.

If fortified foods make a claim on the label, the General Labelling Rules will apply such that the consumer must not be misled to a material degree and all claims being made must be substantiated by the manufacturer. In addition, the Nutrition Labelling Regulations will apply where the label makes a nutrition claim such as 'fortified with Vitamin A'.

Fortified foods

A draft proposal for an EU Directive on the addition of nutrients to foods is being discussed. It applies to the voluntary addition of nutrients to foods, (vitamins and minerals only) and it specifies the purposes of fortification. A positive list of vitamins and minerals is proposed and a positive list of chemical substances to be used as appropriate sources.

Food supplements

• EU LEGISLATION

Directive 2002/46/EC (OJ L183, p51, 12/07/2002) of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

Due to the increasing number of products marketed in the Community as foods containing concentrated sources of nutrients, intended to supplement the uptake of nutrients from a normal diet there is a need for EU rules to govern these products. The objective of the directive is two-fold. First, to set out a general framework and safety rules for food supplements. As a first step detailed rules on vitamins and minerals are laid down. They require that maximum limits for vitamins and minerals intake will be set based on scientific risk assessment and data on vitamin and minerals intake from other foods, while also taking due account of what is considered an adequate vitamin and mineral intake for an average person.

The second objective is to give the consumer detailed information on the label to ensure consumers can make an informed choice. Labels on, for example, bottles of vitamin pills will have to include clear instructions for daily dosage, a warning about possible health risk in case of excess use, and a statement that the pills should not be used as a substitute for a varied diet. Claims that the product can prevent, treat or cure illness are prohibited.

The Directive concerns food supplements marketed in pre-packaged form as foodstuffs. The general provisions of the Directive are the following.

A 'food supplement' is:

'... foodstuffs that are concentrated sources of nutrients or other substances with a nutritional or physiological function, alone or in combination marketed in dose form, whose purpose is to supplement the intake of those nutrients in the normal diet.'

Only the specified vitamins and minerals, vitamin formulations and the permitted mineral substances may be used in the manufacture of food supplements. Purity criteria for these substances will be specified.

Maximum amounts of vitamins and minerals present in food supplements will be set based on scientific risk assessment and minimum limits will also be specified to ensure that significant amounts will be present in the supplement.

In addition to the general labelling provisions of 2000/13/EC, specific labelling provisions apply to food supplements, including the requirement to use the word 'supplement' on the label.

Where a food supplement is marketed or imported for the first time in a country, there are provisions for the manufacturer or the importer to notify the competent authority and an approval procedure is specified.

Medicinal claims

Medicinal claims for foods are prohibited under National and European Labelling Rules. A medicinal claim is a health claim, which states or implies that a product has the property of treating, preventing or curing human disease. In order to be permitted to make a medicinal claim, a product must be classed as a medicine in accordance with the definition in the **European Council Directive 65/65/EEC** on medicinal products (see below). Whether or not a product is considered as a medicinal product depends on the presentation of the product and the purpose for which it is administered. All medicines must then be licensed with the Irish Medicines Board (IMB) under the **Medicinal Products (Licensing and Sale) Regulations, 1998 (S.I. No. 142 of 1998)** and other relevant European Communities Directives otherwise it cannot be used or sold.

The **Medicinal Products Regulations, 1998** require that a medicinal product shall not be marketed without a Product Authorisation. This ensures that a product complies with required standards of quality, safety and efficacy. However, it is the responsibility of those marketing medicinal products to comply with the relevant legislation and to ensure that such products are marketed accordingly.

The manufacture, importation, distribution and supply of medicinal products for human use in Ireland is regulated by the IMB according to the provisions of the **Irish Medicines Board Act 1995**. IMB has produced *A Guide to the Definition of a Medicinal Product (Edition 1 May 1999)* which describes the IMB's policy in the categorisation of medicinal products for human use.

Sometimes it can be difficult to determine whether a product should be classified as a food or medicine. All products are different and must be judged on an individual basis in accordance with the definition of a medicine depending on its presentation and the purpose for which it is administered. The IMB should be contacted in this respect.

Other labelling provisions for specific foodstuffs

There are numerous European Union laws that relate to food labelling. Specific Commodity legislation contains mandatory labelling provisions for specific products. Please refer to the section on Food Products.

Alcoholic beverages

Commission Directive 87/250/EEC (OJ L113, p57, 30/04/87) of **15 April 1987** on the indication of alcoholic strength by volume in the labelling of alcoholic beverages for sale to the ultimate consumer

This Directive makes it obligatory to indicate the alcoholic strength by volume in the labelling of certain alcoholic beverages intended for the ultimate consumer. It also gives the tolerances allowed in respect of the indications of the alcoholic strength by volume.

• NATIONAL LEGISLATION

- **European Communities (Labelling, Presentation and Advertising of Food stuffs) Regulations, 2002** (S.I. No. 483 of 2002)

These regulations implement the provisions of the **Directives 2000/13/EC, 87/250/EEC, 94/54/EC** as amended by **Council Directive 96/21/EC**, and **Commission Directive 1999/10/EC**. They revoke and replace the **European Communities (Labelling, Presentation and Advertising of Foodstuffs) Regulations, 2000** (S.I. No. 92 of 2000). The labelling **Directive 2000/13/EC** consolidates and repeals the previous **Directive 79/112/EEC** and its amendments.

The current legislation applies to the general labelling of pre-packaged foodstuffs for sale to the consumer and the catering industry within the European Union. Foods for export to a country outside of the EU are exempted. A general requirement is that the labelling, presentation and advertising of foodstuffs must be clear, unambiguous and must not mislead the consumer to a material degree. It must not attribute to a foodstuff, properties for the prevention, treatment or cure of a human illness.

'Labelling' shall mean any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such foodstuffs. The information provided on the label must be easy to understand, be clearly legible, it must also be indelible, easy to see and not obscured in any way. Food products, including food imports sold in Ireland must be labelled in English (with optional labelling in Irish).

The essential information that must appear on the packaging of pre-packaged foodstuffs or on the attached label is as follows:

- the name under which the product is sold
- the list of ingredients
- the quantity of certain ingredients
- the net quantity
- the date of minimum durability
- any special storage instructions or conditions of use
- the name or business name and address of the manufacturer or packager or of a seller within the European Union
- place of origin of the foodstuff if its absence might mislead the consumer to a material degree
- instructions for use where necessary
- beverages with more than 1.2% alcohol by volume must declare their actual alcoholic strength.

Quantitative Ingredient Declaration (QUID)

In certain circumstances it is necessary to state on the label the quantity, in percentage terms, of an ingredient or category of ingredients used in the manufacture or preparation of a foodstuff. The percentage quantity should be in or next to the name of the food or be in the list of ingredients.

The QUID requirement applies to all foods, including beverages, with more than one ingredient unless specially exempt. QUID will also apply to products currently exempt from ingredients listing. For these products, the ingredient quantity will have to be indicated in or immediately next to the name under which the product is sold unless a list of ingredients is voluntarily indicated on the label.

The European Commission has produced a document with the aim of providing informal advice on the implementation of QUID entitled 'General guidelines for implementing Quantitative Ingredient Declaration (QUID)'. It is advisable to consult this document in conjunction with **Directive 2000/13/EC** on labelling for a more detailed explanation of the QUID rules.

Lot Identification

• EU LEGISLATION

Council Directive 89/396/EEC (OJ L186, p21, 30/06/89) of **14 June 1989** on indication or marks identifying the lot to which a foodstuff belongs

Amended by:

- **Council Directive 91/238/EEC**
(OJ L107, p50, 27/04/91) of **22 April 1991**
- **Council Directive 92/11/EEC**
(OJ L65, p32, 11/03/93) of **3 March 1992**

• NATIONAL LEGISLATION

- **European Communities (Identification of Foodstuff Lot) Regulations, 1992 (S.I. No.110 of 1992)**

The Regulations give effect to **Council Directive 89/396/EEC** as amended on indications or marks identifying the lot to which a foodstuff belongs. They require producers, manufacturers, packagers or the first seller in the European Community to provide a reference to the manufacturing lot or batch to which the foodstuff belongs, on the packaging, container or label of most foodstuffs marketed. The requirements in respect of any glass bottle intended for re-use and which is indelibly marked and which therefore bears no label, ring or collar came into force on 1st January 1997.

The purpose of this legislation is to facilitate the withdrawal of foodstuffs, for example in the event of a health scare or product recall.

Packaging of Products

• EU LEGISLATION

Pre-packaged liquids

Council Directive 75/106/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to the making-up by volume of certain pre-packaged liquids.

Amended by:

- **Commission Directive 78/891/EEC**
(OJ L311, p21, 4/11/78) of **28 September 1978**
- **Council Directive 79/1005/EEC**
(OJ L308, p25, 4/11/78) of **23 November 1979**
- **Council Directive 85/10/EEC**
(OJ L004, p20, 5/1/85) of **18 December 1984**
- **Council Directive 88/316/EEC**
(OJ L143, p26, 10/6/88) of **7 June 1988**
- **Council Directive 89/676/EEC**
(OJ L398, p18, 30/12/89) of **21 December 1989**

Other packaged products

Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products.

Amended by:

- **Commission Directive 78/891/EEC of 28 September 1978**

• NATIONAL LEGISLATION

- **Merchandise Marks Act, 1970 (No. 10 of 1970)**
- **Merchandise Marks (Prepackaged Goods) (Marking and Quantities) Order, 1973 (S.I. No. 28 of 1973)**

Amended by:

- **Merchandise Marks (Prepackaged Goods) (Marking and Quantities) (Amendment) Order, 1973 (S.I. No. 267 of 1973), cover a wide range of goods**
- **Merchandise Marks (Prepackaged Goods) (Marking and Quantities) (Amendment) Order, 1979 (S.I. No. 222 of 1979) sugar and coffee**
- **Merchandise Marks (Prepackaged Goods) (Marking and Quantities) (Amendment) Order, 1981 (S.I. No. 394 of 1981) edible vegetable oils and milk**

- **Merchandise Marks (Prepackaged Goods) (Marking and Quantities) (Amendment) Order, 1983 (S.I. No. 367 of 1983)** – Prepacked beer made from malt including all porter, lager and stout
- **Merchandise Marks (Prepackaged Goods) (Marking and Quantities) (Amendment) Order, 1986 (S.I. No. 100 of 1986)** – Prepacked frozen vegetables
- **Merchandise Marks (Prepackaged Goods) (Marking and Quantities) (Amendment) Order, 1985 (S.I. No. 295 of 1985)** – relating to prepacked liquids, insofar as wine is concerned
- **Merchandise Marks (Prepackaged Goods) (Marking and Quantities) (Amendment) Order, 1989 (S.I. No. 284 of 1989)** – relating to prepackaged liquids, insofar as sparkling wines and spirits are concerned
- **Merchandise Marks (Prepackaged Goods) (Marking and Quantities) (Amendment) Order, 1990 (S.I. No. 266 of 1990)** – prepackaged liquids insofar as wine and spirits which are intended either for the provisioning of aeroplanes, ships, trains or for sale in duty-free shops
- **Packaged Goods (Quantity Control) Act, 1980 (No. 11 of 1980)**
- **Packaged Goods (Quantity Control) Regulations, 1981 (S.I. No. 39 of 1981)**
- **Packaged Goods (Quantity Control) Act, 1980 (Commencement) Order (S.I. No. 41 of 1981)**
- **Metrology Act, 1996 (No. 27 of 1996)**

Specific requirements for the size of prepackaged goods and the notices/labels to be attached are set out in the Merchandise Marks legislation. A wide range of foods are covered including sugar, coffee, edible vegetable oils, milk, frozen vegetables and wines and spirits. The foods governed by this legislation are set out in the Principal Act (**No. 10 of 1970**) and shall not be packed in a container, imported or sold by retail unless it complies with the provisions of this Order which apply mainly to permitted size of packets and marking on the container of that quantity. The legislation includes the requirement that certain products must be labelled with an indication of their net content in units of weight, volume and length. Provision is also made for the size of packaging for pre-packed wines, sparkling wines, and pre-packed spirits.

The Packaged Goods Regulations as amended by the **Metrology Act, 1996** make provision for implementing the system of quantity control (commonly known as the “average system”), applicable to packaged goods on which the quantity of the contents is declared by weight or volume. The type of packages which fall within the scope of the system is clearly described. Certain types of packages are excluded unless they are marked with the “e-mark”. The Regulations provide for the type of markings and inscriptions to be provided on packages, the

units of weight and volume to be used and the circumstances in which the “e-mark” can be used. The equipment to be used by the packer is prescribed as are the checks to be carried out and records to be kept by him. The Inspector’s “reference test” is prescribed by regulation. For the purposes of this test, a proportion of the packages in each batch are permitted to contain slightly less than the nominal quantity declared (provided, of course, that the average is correct). The amount of deficiency permitted (known as the “tolerable negative error”) varies according to the weight or volume of the package and is also prescribed.

Labelling of packaging gases

Commission Directive 94/54/EC (OJ L300, p14, 23/11/94) of **18 November 1994** concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in **Council Directive 79/112/EEC**

Amended by:

Council Directive 96/21/EC (OJ L88, p5, 5/04/96) of **29 March 1996**

Commission Directive 94/54/EEC regarding the compulsory indication on the label of certain particulars, requires that food products packaged in a modified atmosphere to prolong shelf life must declare ‘packaged in a protective atmosphere’ on the label.

Packaging gases that are used in the packaging of a foodstuff must be indicated on the label as ‘packaged in a protective atmosphere’ so consumers understand that the shelf-life of the product has been extended.

‘Vacuum packing’ and ‘modified atmosphere packing’ (MAP) are examples of packaging processes that are used as food preservation methods generally for chilled products.

FOODS FOR PARTICULAR NUTRITIONAL USES

The General provisions which apply to foods for particular nutritional uses are set out in the framework **Council Directive 89/398/EEC** which is transposed by the **European Communities (Foodstuffs for Particular Nutritional Uses) Regulations, 2002, (S.I. No. 379 of 2002)**. This S.I. revoked the **Health (Foods for Particular Nutritional Uses) Regulations, 1991 (S.I. No. 331 of 1991)**.

Foodstuffs for particular nutritional uses are defined as:

“foodstuffs which, owing to their special composition or manufacturing process are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability”.

Furthermore, a particular nutritional use must fulfil the particular nutritional requirements of persons whose digestive processes or metabolism are disturbed, or persons who are in a special physiological condition and will benefit from controlled consumption of certain substances, or infants or young children in good health.

The framework Directive specifies that specific provisions applicable to certain groups of foods for particular nutritional uses shall be laid down in specific Directives. These categories are as follows:

- infant formulae and follow-on formulae
- dietary foods for special medical purposes
- foods intended for use in energy restricted diets for weight reduction
- food intended to meet the expenditure of intense muscular effort, especially for sportspeople
- foods for persons suffering from carbohydrate-metabolism disorders, (diabetes).

The specific Directives introduced to date are outlined below.

A specific Directive on foods intended to meet the expenditure of intense muscular effort, especially for sportspeople is proposed (Commission proposal stage). A specific Directive on foods for persons suffering from carbohydrate-metabolism disorders (diabetes) is currently being considered.

General provisions

• EU LEGISLATION

- **Council Directive 89/398/EEC** (OJ L186, 30/06/1989, p27) **of 3 May 1989** on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, as amended by:
- **Directive 96/84/EC** (OJ L48, 19/02/1997, p.20) **of 19 December 1996**
- **Directive 1999/41/EC** (OJ L172, 08/07/1999, p.38) **of 7 June 1999**
- **Commission Directive 2001/15/EC** (OJ L 52, 22/02/2001, p19) **of 15 February 2001** on substances that may be added for specific nutritional purposes in foods for particular nutritional uses

• NATIONAL LEGISLATION

- **European Communities (Foodstuffs for Particular Nutritional Uses) Regulations, 2002 (S.I. No.379 of 2002)**

The Regulations define foodstuffs intended for particular nutritional uses, the composition of which must be such that they are appropriate for the particular nutritional use intended. Conditions for the use of the terms ‘dietetic’ and ‘dietary’ are set out, together with appropriate labelling, presentation and advertising for foodstuffs for a particular nutritional foodstuff. The general labelling requirements of **Directive 2000/13/EC** also apply to these foodstuffs.

Where foodstuffs are newly introduced on the market, the manufacturer or importer must notify the Food Safety Authority of Ireland (FSAI) within seven days of the product being placed on the market. They must provide a copy of the proposed labelling, an indication as to whether the product is on sale in any other Member State and any other information, if requested, to show compliance with the Regulations. Where appropriate, the FSAI can prevent trade in products that do not meet the requirements for foodstuffs intended for particular nutritional uses.

The powers and duties of authorised officers and the penalties for offences are described in the Regulations. The importation, manufacture, preparation, distribution for sale of food contrary to the Regulations is prohibited. Where a sample of food has been certified not to comply with the Regulations, an authorised officer may seize, remove and detain such food as food being unfit for human consumption and in certain circumstances, destroy it.

The **Directive 2000/15/EC** came into effect on 31 March 2002 and applies to all foods for particular nutritional uses. It identifies the substances that can be used and shall result in the manufacture of safe products that fulfil the particular nutritional requirements of the person for whom they are intended. The substances belong to the following groups vitamins, minerals, amino acids, carnitine, taurine, nucleotides, choline and inositol. These chemical substances have been selected on the basis of their safety, their availability for use by humans and their organoleptic and technological properties. The purity criteria generally applied for the manufacture of foods apply to them.

Infant formulae and follow-on formulae

• EU LEGISLATION

- **Commission Directive 91/321/EEC** (OJ L175, 04/07/1991, p35) of **14 May 1991** on infant formulae and follow-on formulae

Amended by:

- **Commission Directive 96/4/EC, Euratom** (OJ L49, 28/02/1996, p12) of **16 February 1996**
- **Commission Directive 1999/50/EC** (OJ L139, 02/06/1999, p29) of **25 May 1999**
- **Council Directive 92/52/EEC** (OJ L179, 01/07/1992, p129) of **18 June 1992** on infant formulas and follow-on formula intended for export to third countries

• NATIONAL LEGISLATION

- **European Communities (Infant Formulae and Follow-on Formulae) Regulations, 1998** (S.I. No. 243 of 1998)
- **European Communities (Infant Formulae and Follow-on Formulae) (Amendment) Regulations, 2000** (S.I. No. 446 of 2000)

These Regulations give effect to **Commission Directive 91/321/EEC**, **Council Directive 92/52/EEC** and **Council Directive 96/4/EEC** on compositional, labelling and marketing requirements for infant formulae and follow-on formulae intended for infants (meaning children under the age of 12 months) in good health. The amendment Regulations transpose **Council Directive 99/50/EC** establishing maximum levels of pesticide residues in these products.

Infant formulae and follow-on formula are defined. Only formulae which comply with the Regulations may be marketed. The protein sources for the manufacture of formulae are prescribed and the use of food ingredients is

subject to prohibitions and limitations. Compositional criteria are set down and the Minister for Health and Children may make Orders to set maximum levels of any substance and microbiological criteria for formulae as appropriate. Detailed labelling requirements for infant formulae and follow-on formulae are prescribed. Restrictions on advertising and provision of information on infant and young child feeding intended to reach pregnant women and mothers of infants and young children are laid down.

Where a sample of food has been certified not to comply with the Regulations, an authorised officer may seize, remove and detain such food as food being unfit for human consumption and in certain circumstances, destroy it.

Donations of equipment or low priced sales to institutions or organisations must be carried out in accordance with guidelines approved by the FSAI. Formulae for export must also comply with the provisions of these Regulations. Specific EU Directives apply to the supply of formulae to certain countries, for example, Romania.

Processed cereal based foods

• EU LEGISLATION

- **Commission Directive 96/5/EC, Euratom** (OJ L49, 28/02/1996, p17) of **16 February 1996** on processed cereal-based foods and baby foods for infants and young children

Amended by:

- **Commission Directive 98/36/EC** (OJ L167, 12/06/1998, p23) of **2 June 1998**
- **Commission Directive 1999/39/EC** (OJ L124, 18/05/1999, p8) of **6 May 1999**

• NATIONAL LEGISLATION

- **European Communities (Processed Cereal-based foods and baby foods for Infants and Young Children) Regulations, 2000** (S.I. No.142 of 2000)

These Regulations transpose **Commission Directive 96/5/EC** as amended. They relate to processed cereal-based foods for particular nutritional use for infants and young children in good health and are intended for use by infants when they are being weaned and as a supplement to the diet of young children. Cereal-based foods and baby foods must meet certain requirements regarding composition and labelling. They must not contain a pesticide residue at a level exceeding 0.01mg/kg. The duties and powers of authorised officers to ensure compliance with the Regulations are outlined.

Dietary foods for special medical uses

• EU LEGISLATION

- **Commission Directive 1999/21/EC** (OJ L91, 7/04/1999, p29) of 25 March 1999 on dietary foods for special medical purposes.

• NATIONAL LEGISLATION

- **European Communities (Dietary Foods for Special Medical Purposes) Regulations, 2001** (S.I. No. 64 of 2001)

These Regulations give effect to **Council Directive 89/398/EEC** and **99/21/EC**. They lay down compositional and labelling requirements and general provisions on dietary foods for special medical purposes. A definition for 'dietary foods for special medical purposes' is given. Control of new foodstuffs within this food category being introduced onto the market are outlined. Rules concerning vitamin and mineral content and additional labelling requirements are provided.

Energy restricted diets

• EU LEGISLATION

- **Commission Directive 96/8/EC** (OJ L55, 6/03/1996, p22) of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction.

• NATIONAL LEGISLATION

- **European Communities (Foods intended for use in energy-restricted diets for weight reduction) Regulations, 1998** (S.I. No. 242 of 1998)

These regulations give effect to **Commission Directive 96/8/EC** on foods intended for use in energy-restricted diets for weight reduction. These Regulations lay down compositional, labelling, advertising and presentation requirements for foods for particular nutritional uses intended for use in energy restricted diets for weight reduction.

There are two categories of such products:

- products presented as a replacement for the whole of the daily diet
- products presented as a replacement for one or more meals of the daily diet.

FOOD STANDARDS

• NATIONAL LEGISLATION

- **Food Standards Act, 1974 (No.11 of 1974).**

This is an enabling Act which allows several Ministers to make regulations governing food standards for foods.

The provisions of the **Food Standard Act, 1974** have not been invoked by the Minister of Health. Food Standards Regulations have been made by the Minister for Agriculture and Food as follows:

- **Food Standards (Honey) (European Communities) Regulations 1976 (S.I. No. 155 of 1976)**
- **Food Standards (Fruit Juices and Fruit Nectars) (European Communities) Regulations 1978 (S.I. No. 173 of 1978 and amendments)**
- **Food Standards (Cocoa and Chocolate Products) (European Communities) Regulations 1975 (S.I. No. 180 of 1975)**

Refer to Section on "Food Products" for further information (Page 18).

FOOD PRODUCTS

Caseins and Caseinates

• EU LEGISLATION

Council Directive 83/417/EEC (OJ L237, p25, 26/8/1983) of **25 July 1983** on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption

Implementing measures:

Commission Directive 85/503/EEC (OJ L308, p12, 20/11/1985) of **25 October 1985** on methods of analysis for edible caseins and caseinates

Commission Directive 86/424/EEC (OJ L243, p29, 28/8/1986) of **15 July 1986** laying down methods of sampling for chemical analysis of edible caseins and caseinates

• NATIONAL LEGISLATION

- **European Communities (Caseins and Caseinates) Regulations, 1985 (S.I. No. 248 of 1985)**
- **European Communities (Caseins and Caseinates) (Methods of Sampling and Analysis) Regulations, 1987 (S.I. No. 123 of 1987)**

The purpose of **S.I. No. 248 of 1985** to give effect to **Council Directive 83/417/EEC** relating to:

- a) the composition and manufacturing characteristics of caseins and caseinates intended for human consumption within the community either as such or incorporated in another foodstuff
- b) the labelling and marking of edible caseins, caseinates and mixtures thereof in moving in trade within the Community.

The words 'edible acid casein', 'edible rennet casein' and 'edible caseinates' are reserved descriptions. It is unlawful to use them for any product unless it complies with the prescribed heat-treatment process and technological adjuvants and bacterial cultures.

The purpose of **S.I. No.123 of 1987** is to give effect to **Commission Directives 85/503/EEC** and **86/424/EEC** on the approximation of laws of the Member States relating to the methods of sampling for the chemical analysis of edible caseins and caseinates. These Directives lay down Community methods of analysis and establish sampling procedures which must be followed when testing edible caseins and caseinates, as provided for by **Directive 83/417/EEC**

Cocoa and Chocolate

• EU LEGISLATION

Council Directive 73/241/EEC (OJ L228, p23, 16/8/1973) of **24 July 1973** on the approximation of the laws of the Member States relating to cocoa and chocolate products intended for human consumption

Amended by:

- **Council Directive 74/411/EEC** (OJ L221, p17, 12/8/1975) of **1 August 1974**
- **Council Directive 74/644/EEC** (OJ L349, p63, 28/12/1974) of **19 December 1974**
- **Council Directive 75/155/EEC** (OJ L64 p21, 11/3/1975) of **4 March 1975**
- **Council Directive 76/628/EEC** (OJ L223, p1, 16/8/1976) of **20 July 1976**
- **Council Directive 78/842/EEC** (OJ L291, p15, 17/10/1978) of **10 October 1978**
- **Council Directive 80/608/EEC** (OJ L170, p33, 3/7/1980) of **30 June 1980**
- **Council Directive 85/7/EEC** (OJ L2, p22, 3/1/1985) of **19 December 1984**
- **Council Directive 89/344/EEC** (OJ L142, p19, 25/5/1989) of **3 May 1989**

Repealed from the 3rd August 2003 by:

European Parliament and Council Directive 2000/36/EC (OJ L197, p19, 3/08/2000) of **23 June 2000** relating to cocoa and chocolate products intended for human consumption.

• NATIONAL LEGISLATION

- **Food Standards (Cocoa and Chocolate Products) (European Communities) Regulations 1975 (S.I. No.180 of 1975)**

The Regulations give effect to the **Council Directives 73/241/EEC** as amended, which prescribed standards for the composition and labelling of cocoa and chocolate. From 3 August 2003, **Council Directive 73/241/EEC** will be repealed by **Council Directive 2000/36/EC**. The new Directive was introduced to simplify Community provisions on the composition, manufacture and labelling of cocoa and chocolate products and to guarantee their free movement within the Community.

The Directive lays down rules for the composition and labelling of cocoa and chocolate products and defines different categories of chocolate products including chocolate, milk chocolate, family milk chocolate, white chocolate, filled chocolate etc. Cocoa and chocolate products may not be marketed in the Community unless they conform to the definitions and rules laid down in the Directive.

A significant change is the authorised use in the production of chocolate of six tropical vegetable fats to a maximum 5% of the chocolate component in the finished product. Chocolate products containing vegetable fats other than cocoa butter must be labelled appropriately, including the statement 'contains vegetable fats in addition to cocoa butter'.

In due course, new national Regulations will be introduced to transpose **Directive 2000/36/EC** relating to chocolate and chocolate products.

Labelling requirements

Specific Labelling requirements are laid down in **Directive 2000/36/EC**. These include requirements regarding the sales name, chocolate product containing vegetable fat other than cocoa butter, chocolate products with a filling etc.

Coffee and Chicory

• EU LEGISLATION

Council Directive 99/4/EC (OJ L66, p26, 13/03/1999) of **22 February 1999** relating to coffee extracts and chicory extracts

• NATIONAL LEGISLATION

- **European Communities (Marketing of Coffee Extracts and Chicory Extracts) Regulations, 2000 (S.I. No.281 of 2000)**

These Regulations give legal effect to **Directive 1999/4/EC** which prescribes, and harmonises within the European Union, standards for the composition and labelling of coffee extracts and chicory extracts. Only products produced in compliance with the Regulations can be placed on the market. Product descriptions, definitions and characteristics for 'coffee extract', 'soluble coffee extract', 'soluble coffee' and 'instant coffee' are set down. The powers of authorised officers are outlined in the national Regulations.

The methods of analysis for checks on the authenticity of coffee extracts have been developed by the ISO and therefore, previously specified Community methods of analysis for coffee extracts and chicory extracts have been repealed.

Figs, Hazelnuts, Pistachios, Peanuts and Star Anise

In recent times the European Commission has increasingly published Decisions to give effect to remedial or protective measures in response to food alerts. The Department of Health and Children has subsequently given legal effect to these decisions by means of a statutory instrument. These decisions are short term and reviewed after a number of months. Recent decisions include those relating to the control on imports of figs and peanuts due to the presence of the contaminant aflatoxins. The decision usually places import restrictions on certain foods unless accompanied by appropriate certificates of testing for the presence of contaminants.

• EU LEGISLATION

Commission Decision 2002/80/EC (OJ L34, p26, 05/02/2002) of **4 February 2002** imposing special conditions on the import of figs, hazelnuts and pistachios and certain products derived thereof originating in or consigned from Turkey

Amended by:

- **Commission Decision 2002/679/EC** (OJ L229, p37, 27/08/2002) of **22 August 2002**
- **Commission Decision 2002/233/EC** (OJ L78, p14, 21/3/2002) of **20 March 2002**

Commission Decision 2002/79/EC (OJ L34, p21, 5/2/2002) of **4 February 2002** imposing special conditions on the import of peanuts and certain products derived from peanuts originating in or consigned from China

Amended by:

- **Commission Decision 2002/678/EC** (OJ L229, p33, 27/08/2002) of **22 August 2002**
- **Commission Decision 2002/233/EC** (OJ L78, p14, 21/3/2002) of **20 March 2002**

Commission Decision 2002/75/EC (OJ L33, p31, 2/2/2002) of **1 February 2002** laying down special conditions on the import from third countries of star anise

• NATIONAL LEGISLATION

- **European Communities (Imposing special conditions on the import of figs, hazelnuts and pistachios and certain products derived thereof originating in or consigned from Turkey) Regulations, 2002 (S.I. No. 79 of 2002)**
- **European Communities (Import from third countries of star anise) Regulations, 2002 (S.I. No. 80 of 2002)**
- **European Communities (Import of peanuts and certain products derived from peanuts originating**

in or consigned from China) Regulations, 2002 (S.I. No. 81 of 2002).

- European Communities (Imposing special conditions on the imports of figs, hazelnuts and pistachios and certain products derived thereof originating in or consigned from turkey)(amendment) Regulations, 2002 (S.I. No.127 of 2002)
- European Communities (Imports of peanuts and certain products derived form peanuts originating in or consigned from China) (Amendment) Regulations, 2002 (S.I. No.135 of 2002)

Foodstuffs Containing Quinine and/or Caffeine

Commission Directive 2002/67/EC (OJ L191, p20, 19/07/2002) of 18 July 2002 on the labelling of foodstuffs containing quinine, and of foodstuffs containing caffeine

The purpose of this Directive is to make it necessary to provide labelling which gives the consumer clear information on the presence or otherwise of quinine or caffeine in a foodstuff and, in the case of caffeine, to provide a warning message and an indication of the amount of caffeine, where this is in excess of a specific level, in beverages which do not naturally contain caffeine. The Member States shall prohibit trade in products which do not comply with this Directive as of 1 July 2004. However, products which do not comply with this Directive and which were labelled before 1 July 2004 shall be authorised while stocks last.

Member States are obliged to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than 30 June 2003

Fruit Juices and Certain Similar Products

• EU LEGISLATION

Council Directive 93/77/EEC (OJ L244, p23, 30/09/1993) of 21 September 1993 relating to fruit juices and certain similar products

Implemented by:

Commission Directive 93/45/EC (OJ L159, p133, 01/07/1993) of 17 June 1993 concerning the manufacture of nectars without the addition of sugars or honey

Commission Regulation 93/558/EC (OJ L58, p50, 11/03/1993) of 10 March 1993 on the refractometry method of measuring dry soluble residue in products processed from fruit and vegetables.

Repealed from the 12th July 2003 by:

Council Directive 2001/112/EC (OJ L10, p58, 12/01/02) of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption

• NATIONAL LEGISLATION

- **Food Standards (Fruit Juices and Fruit Nectars) (European Communities) Regulations 1978** (S.I. No. 173 of 1978)
- **Food Standards (Fruit Juices and Fruit Nectars) (European Communities) (Amendment) Regulations, 1984** (S.I. No. 266 of 1984)
- **Food Standards (Fruit Juices and Fruit Nectars) (European Communities) (Amendment) Regulations, 1992** (S.I. No. 27 of 1992)
- **Food Standards (Fruit Juices and Fruit Nectars) (European Communities) (Amendment) Regulations, 1994** (S.I. No. 203 of 1994)

The purpose of these Regulations is to give effect to the EU Directives on fruit juice. The main Directive is **93/77/EEC** which lays down requirements with regard to the composition and labelling of fruit juice and fruit nectars. The sale of products which do not comply with the Directive is prohibited. The Directive defines:

- fruit
- fruit puree, concentrated fruit puree
- sugars
- fruit juice, concentrated fruit juice
- fruit nectar and dried fruit juice

Substances and manufacturing processes permitted in the production of fruit juices are specified. Certain fruits, individually or mixed together, are authorised in the manufacture of nectars without the addition of sugars or honey where their naturally high sugar content so warrants. The refractometry method for determining the sugar content in products processed from fruit and vegetables is outlined in **Regulation 93/558/EC**.

The new **Directive 2001/112/EC** will repeal the existing **Directive 93/77/EC** with effect from 12 July 2003. This new directive defines:

- fruit juice
- fruit juice from concentrate
- concentrated fruit juice
- dehydrated/powdered fruit juice
- fruit nectar

It also provides definitions of the following raw materials:

- a) fruit
- b) fruit purée
- c) concentrated fruit purée
- d) sugars
- e) honey:
- f) pulp or cells

Member States are obliged to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive no later than the 12th July 2003.

Gelatine

• EU LEGISLATION

Commission Decision 1999/724/EC (OJ L290, p32, 12/11/1999) of 28 October 1999 amending Annex II to **Council Directive 92/118/EEC** laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to **Directive 89/662/EEC** and, as regards pathogens, to **Directive 90/425/EEC**

• NATIONAL LEGISLATION

- **European Communities (Gelatine) Regulations, 2002 (S.I. No. 44 of 2002)**

These Regulations implement **Commission Decision 1999/724/EC** and set out rules for production, sale and import of gelatine intended for human consumption. Establishments for the production of gelatine may be registered by the Minister for Agriculture and Food if they meet the requirements of the regulations. Gelatine for human consumption may only be produced in a premises authorised by the Minister. The source material for gelatine is prescribed. Gelatine for human consumption must be labelled in accordance with the regulations. Collection centres and tanneries intending to supply raw material for the production of gelatine must meet certain requirements and be authorised and registered by the Minister for Agriculture and Food.

Honey

* EU LEGISLATION

Council Directive 74/409/EEC (OJ L221, p10, 12/08/74) of 22 July 1974 on the harmonisation of the laws of the Member States relating to honey

Repealed from the 1st August 2003 by:

- **Council Directive 2001/110/EC** (OJ L010, p47, 12/01/02) of 20 December 2001 relating to honey

• NATIONAL LEGISLATION

Food Standards (Honey) (European Communities) Regulations 1976 (S.I. No. 155 of 1976)

These Regulations give effect to the EU Directive which prescribes standards for the composition and labelling of honey. The package or container must contain the term 'honey' or in certain instances a more specific description, for example, 'comb honey', 'chunk honey' etc., and must also show the net weight of the contents and the name and address of the producer, packer or seller established within the Community. Compositional criteria are laid down in respect of sugar, moisture, sucrose solids, minerals and acids. Also included are minimum levels of diastase activity and a maximum level of hydroxymethylfurfural content determined after processing and blending.

Honey which does not meet the compositional requirements of the Directive but which is still suitable for human consumption may be sold as 'baker's honey' or 'industrial honey'. Maximum moisture contents of 23% are permitted for heather and clover honey, 21% for other honey and 25% for baker's honey.

Net weights must be expressed in grams or kilograms. Trade in products which do not conform is prohibited. Authorised officers are granted power of entry and sampling.

Directive 2001/110/EC has been adopted and will repeal the existing **Directive 74/409/EC** with effect from 1 August 2003. New national regulations to give effect to this new directive will be required by that date. The new directive contains specific requirements on the labelling of honey

Fruit Jam, Jelly, Marmalade and Chestnut Puree

• EU LEGISLATION

Council Directive 79/693/EEC (OJ L239, p24, 03/08/79) of 24 July 1979 on the approximation of the laws of the Member States relating to fruit jams, jellies and marmalades and 'sweetened chestnut puree'

Amended by:

- **Council Directive 80/1276/EEC** (OJ L375, p77, 31/12/1980) of 22 December 1980
- **Council Directive 88/593/EEC** (OJ L318, p44, 25/11/88) of 18 November 1988

Repealed from the 12th July 2003 by:

Council Directive 2001/113/EC (OJ L010, p67, 12/01/02) of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut puree intended for human consumption

• NATIONAL LEGISLATION

- **European Communities (Fruit Jams, Jellies and Marmalades and Chestnut Puree Regulations, 1982 (S.I. No. 250 of 1982))**
- **European Communities (Fruit Jams, Jellies and Marmalades and Chestnut Puree (Amendment) Regulations, 1991 (S.I. No. 319 of 1991))**

The purpose of these Regulations is to give effect to the EU Directives which prescribe standards for the composition and labelling of fruit jams, jellies, marmalades and chestnut puree products. Trade in such products which do not comply with the Directive is prohibited. Substances which may be added to the products and their conditions for use are specified this governs aromatics, additives and maximum levels for sulphur dioxide.

The Directives define:

- extra jam
- jam
- extra jelly
- jelly
- marmalade
- chestnut puree.

Definitions are also given for the following raw materials which may be used in the manufacture of these products:

- fruit
- fruit pulp
- fruit puree

- fruit juice
- aqueous extracts of fruit
- citrus peel
- sugars.

For the purposes of this Directive, tomatoes, the edible parts of rhubarb stalks, carrots and sweet potatoes are considered as fruit.

A new **Directive 2001/113/EC** has been adopted and it will repeal the existing **Directive 79/693/EC** with effect from 12 July 2003. New national regulations to give effect to this new directive will be required by that date.

Olive Oil

• EU LEGISLATION

Council Regulation (EEC) 136/66 (OJ L172, p3025, 30/05/66) of 22 September 1966 on the establishment of a common organisation of the market in oils and fats

Implementing measures:

Commission Regulation (EEC) 2568/91 (OJ L248, p1, 5/09/91) of 11 July 1991 on the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis

Amended by:

- **Commission Regulation (EC) No 656/95** (OJ L069, p001, 29/03/1995) of 28 March 1995 amending **Regulation (EEC) No 2568/91** on the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis and **Council Regulation (EEC) No 2658/87** on the tariff and statistical nomenclature and on the Common Customs Tariff
- **Commission Regulation No 796/2002 of 6 May 2002** (OJ L128, p8, 15/05/2002) amending **Regulation (EEC) No 2568/91** on the characteristics of olive oil and olive-pomace oil and on the relevant methods of analysis and the additional notes in the Annex to **Council Regulation (EEC) No 2658/87** on the tariff and statistical nomenclature and on the Common Customs Tariff

Commission Regulation (EC) 528/99 (OJ L62, p8, 11/03/99) of 10 March 1999 laying down measures to improve the quality of olive oil production

Amended by:

- **Commission Regulation (EC) No 593/2001** (OJ L088, p006, 28/03/2001) of 27 March 2001
- **Commission Regulation (EC) No 1019/2002** (OJ L155, p0027, 14/06/2002) of 13 June 2002

Amended by:

- **Commission Regulation (EC) No 1964/2002** (OJ L300 p003, 05/11/2002) of **November 2002**

- NATIONAL LEGISLATION

No national legislation at present.

The basic **Regulation 136/66/EEC** is mainly a market support Regulation. It includes an Annex setting out the classifications for nine different types of olive oil and olive-pomace oil. Only oil in these categories and named accordingly can be marketed. This Regulation has been amended many times and is now being reviewed which should/will result in changes to the classifications of olive oils in the next 2-3 years.

Commission Regulation 2568/91/EEC further defines these nine categories and distinguishes them from each other and from other oils/fats. Other EU rules exist covering the appropriate methods of analysis, measures to improve the quality of olive oil production and controls for the designation of extra virgin and virgin olive oil and associated labelling and packaging requirements.

Spirit Drinks

- EU LEGISLATION

Council Regulation (EEC) 1576/89 (OJ L160, p1, 12/06/89) of **29 May 1989** laying down general rules on the definition, description and presentation of spirit drinks

Amended by:

- **Council Regulation (EEC) 3280/92** (OJ L327, p3, 3/11/92) of **9 November 1992**
- **Regulation (EC) 3378/94** (OJ L366, p1, 31/12/94) of **22 December 1994**

Commission Regulation (EEC) 1014/90 (OJ L105, p9, 25/04/90) of **24 April 1990** laying down detailed implementing rules on the definition, description and presentation of spirit drinks

Amended by:

- **Commission Regulation (EEC) 1180/91** (OJ L115, p5, 8/05/91) of **6 May 1991**
- **Commission Regulation (EEC) 1781/91** (OJ L160, p5, 25/06/91) of **19 June 1991**
- **Commission Regulation (EEC) 3458/92** (OJ L350, p59, 1/12/92) of **30 November 1992**
- **Commission Regulation (EC) 2675/94** (OJ L285, p5, 4/11/94) of **3 November 1994**

- **Commission Regulation (EC) 1712** (OJ L164, p4, 14/07/95) of **13 July 1995**
- **Commission Regulation (EC) 2626/95** (OJ L269, p5, 11/11/95) of **10 November 1995**
- **Commission Regulation (EC) 2523/97** (OJ L346, p46, 17/12/97) of **16 December 1997**
- **Commission Regulation (EC) 2140/98** (OJ L270, p9, 7/10/98) of **6 October 1998**

Commission Regulation (EEC) No 2009/92 (OJ L203, p10, 21/07/1992) of **20 July 1992** determining Community analysis methods for ethyl alcohol of agricultural origin used in the preparation of spirit drinks, aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails

Commission Regulation (EC) 1267/94 (OJ L138, p7, 2/06/94) of **1 June 1994** applying the agreements between the European Union and third countries on the mutual recognition of certain spirit drinks

Amended by:

- **Commission Regulation (EC) 1434/97** (OJ L196, p56, 24/07/97) of **23 July 1997**

Commission Regulation (EC) No 2870/2000 (OJ L333, p20, 29/12/2000) of **19 December 2000** laying down Community reference methods for the analysis of spirits drinks

- NATIONAL LEGISLATION

- **Irish Whiskey Act, 1980 (No. 33 of 1980)**
- **European Communities (Definition, Description and Presentation of Spirit Drinks) Regulations, 1995 (S.I. No. 300 of 1995)**
- **European Communities (Definition, Description and Presentation of Spirit Drinks) (Amendment) Regulations, 1996 (S.I. No. 60 of 1996)**
- **European Communities (Definition, Description and Presentation of Spirit Drinks) (Amendment) Regulations, 1998 (S.I. No. 7 of 1998)**

These Regulations give effect to the EU Regulations governing the definition, description and presentation of spirit drinks. The principal of the national Regulations is to provide penalties for breach of certain provisions of the EU Regulations which relate to the compositional standards for spirit drinks and for their description. Power of entry is granted to authorised officers.

Volume strength are as follows:

Whiskey	40.0%
Rum	37.5%
Gin	37.5%
Brandy	36.0%

These are absolute standards.

The amending Regulations provide for the protection of the terms used to describe certain spirit drinks produced in the United States of America and the United Mexican States.

The Regulation (EEC) 1576/89 takes precedence over the qualified standards laid down previously by Section 6 the **Sale of Foods and Drugs (Amendment) Act, 1879** and the **Intoxicating Liquor Act, 1960**.

The **Irish Whiskey Act, 1980** defines the production and labelling requirements of Irish whiskey and blended Irish whiskey.

Spreadable Fats

• EU LEGISLATION

Council Regulation (EC) 2991/94 (OJ L316, p2, 09/12/94) of **5 December 1994** laying down standards for spreadable fats

The Regulation deals with the definition of a wide range of spreadable fats, from dairy fats, (butter) to the more diverse mixtures of dairy and vegetable fats. Compositional requirements are specified for each category.

Implementing measures:

Commission Regulation (EC) 577/97 (OJ L087, p3, 2/04/97) of **1 April 1997** laying down rules for the application of **Council Regulation 2991/94** laying down standards for spreadable fats and of **Council Regulation 1898/87** on the protection of designations used in the marketing of milk and milk products

Amended by:

- **Commission Regulation (EC) 1278/97** (OJ L175, p6, 3/07/97) of **2 July 1997**
- **Commission Regulation (EC) 97/2181** (OJ L299, p1, 4/11/97) of **3 November 1997**
- **Commission Regulation (EC) 623/98** (OJ L85, p3, 20/03/98) of **19 March 1998**
- **Commission Regulation (EC) 1298/98** (OJ L180, p5, 24/06/98) of **23 June 1998**
- **Commission Regulation (EC) 2521/98** (OJ L315, p12, 25/11/98) of **24 November 1998**
- **Commission Regulation (EC) 568/99** (OJ L070, p11, 17/03/99) of **16 March 1999**

• NATIONAL LEGISLATION

There is no specific national legislation at present.

Compulsory labelling requirements

Only milk fats, fats and fats composed of plant and/or animal products adhering to the prescribed compositional requirements are covered by this Regulation. It sets out specific information which must be declared in the labelling and presentation of products.

Sugar

• EU LEGISLATION

Regulation 1265/69/EEC (OJ L163, p1, 1/07/1969) of **1 July 1969** establishing methods for determining the quality of sugar bought in by intervention agencies

Corrected by:

- **Commission Regulation (EC) No 187/1999** (OJ L021, p009 28/01/1999) of **27 January 1999** correcting the Spanish, Greek, English and Portuguese language versions of **Regulation (EEC) No 1265/69** establishing methods for determining the quality of sugar bought in by intervention agencies

Council Directive 73/437/EEC (OJ L356, p71, 27/12/73) of **11 December 1973** on the approximation of the laws of the Member States concerning certain sugars intended for human consumption

Repealed by:

- **Council Directive 2001/111/EC** (OJ L010, p53, 12/01/02) of **20 December 2001** relating to certain sugars for human consumption

First Commission Directive 79/796/EEC (OJ L239, p24, 24/12/79) of **26 July 1979** laying down Community methods of analysis for testing certain sugars intended for human consumption

Commission Directive 98/28/EC (OJ L140, p10, 12/05/98) of **29 April 1998** granting derogation from certain provisions of **Directive 93/43/EEC** on the hygiene of foodstuffs as regards the transport by sea of bulk raw sugar

Regulation 2730/75/EEC (OJ L281, p20, 1/11/75) of **29 October 1975** on glucose and lactose

• NATIONAL LEGISLATION

- **Food Standards (Certain Sugars) (European Communities) Regulations, 1975** (S.I. No.118 of 1975)
- **Food Standards (Certain Sugars) (European Communities) Regulations, 1981** (S.I. No. 412 of 1981)

The purpose of these Regulations is to give effect to **Directives 73/437/EEC** and **79/796/EEC**. The Directives define several kinds of sugar and lay down rules for their labelling and packing.

The following sugars are defined:

- a) semi-white sugar
- b) sugar or white sugar
- c) extra white sugar
- d) sugar solution
- e) invert sugar solution
- f) invert sugar syrup
- g) glucose syrup
- h) dried glucose syrup
- i) dextrose monohydrate
- j) dextrose anhydrous.

A limit of 15mg/kg is prescribed for the residual sulphur dioxide content of these products, excluding glucose syrup and dried glucose syrup, for which a limit of 20mg/kg is set. Higher limits are permitted where these products are used in the manufacture of other foodstuffs and where such limits can be justified by technological requirements. Methods of analysis for testing certain sugars intended for human consumption are also set down.

A recasting of **Council Directive 73/457/EEC** was discussed at EU level, to bring the laws of the Member States concerning sugars into line with general Community legislation on foodstuffs. This has now taken the form of **Directive 2001/111/EC** which repeals **Directive 73/437/EEC** with effect from 12 July 2003. The new directive includes a definition of fructose.

Wines (aromatised)

• EU LEGISLATION

Council Regulation (EEC) 1601/91 (OJ L149, p1, 14/06/91) of **10 June 1991** laying down general rules on the definition, description and presentation of aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails

Amended by:

- **Council Regulation (EC) 3279/92**
(OJ L327, p1, 13/11/92) of **9 November 1992**
- **Commission Regulation (EC) 122/94**
(OJ L21, p7, 26/01/94) of **25 January 1994**
- **Council Regulation (EEC) 3378/94**
(OJ L366, p1, 31/12/91) of **22 December 1994**

- **Council Regulation (EC) 2061/96**
(OJ L277, p1, 30/10/96) of **8 October 1996**

Commission Regulation (EEC) 2009/92 (OJ L203, p10, 21/07/92) of **20 July 1992** laying down the analytical methods for ethylic alcohol from agricultural origin used for the production of spirit drinks, aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails

Commission Decision 2002/624/EC (OJ L200, p34, 30/07/2002) of **24 July 2002** authorising Italy to allow the export of an aromatised wine-based drink not complying with **Council Regulation (EEC) No 1601/91** laying down general rules on the definition, description and presentation of aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails

• NATIONAL LEGISLATION

- **European Communities (Definition, Description and Presentation of Aromatized Wines, Aromatized Wine-based drinks and Aromatized Wine-product Cocktails) Regulations, 1998 (S.I. No. 254 of 1998)**

The EU legislation is similar in nature to that for spirit drinks, in that it deals the compositional standards and the protection of designation. The principal effects of the Regulations are to confer powers of entry on authorised officers and provide for penalties for breaches of the EU legislation on aromatised wines. They transpose the EU legislation relating to aromatised wines.

FOOD ADDITIVES

The Community legislation on food additives is governed by the **Framework Directive 89/107/EEC** and is based on the principle that only authorised additives may be used in the manufacture or preparation of foodstuffs.

An additive is defined in the Framework Directive as:

‘any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment,

packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods’.

Prior to their authorisation, food additives are evaluated for their safety by the Scientific Committee on Food. In effect, a ‘positive list’ of approved additives has been developed. Additives are categorised as follows:

• CATEGORIES OF FOOD ADDITIVES

Acid	Emulsifying salt	Modified starch
Acidity regulator*	Enzyme**	Preservative
Anti-caking agent	Firming agent	Propellant gas and Packaging gas
Anti-foaming agent	Flavour enhancer	Raising agent
Anti-oxidant	Flour treatment agent	Sequestrant***
Bulking agent	Gelling agent	Stabiliser****
Colour	Glazing agent*****	Sweetener
Emulsifier	Humectant	Thickener

* *These can act as two-way acidity regulators*

** *Only those used as additives*

*** *Inclusion of these terms in this list is without prejudice to any future decision or mention thereof in the labelling of foodstuffs intended for the final consumer*

**** *This category also comprises foam stabilisers*

***** *These substances include lubricants*

Note: Carriers and foaming agents were not included in this original list of categories. However, they were added in Directive 95/2/EC on food additives other than colours and sweeteners.

Source: Council Directive 89/107/EEC

Food additives may only be authorised if:

- there is a technological need for their use,
- they do not mislead the consumer,
- they present no hazard to the health of the consumer.

Specific conditions for the use of the food additive may include the foodstuff to which it can be added, the conditions under which it may be added and the maximum permitted levels of use. Most food additives may only be used in limited quantities in certain foodstuffs. For certain food additives, no maximum levels

are specified. However, they must be used in accordance with good manufacturing practice, at a dose level no higher than is necessary to achieve the intended purpose and its use should not mislead the consumer. This is commonly referred to as the ‘quantum satis’ principle.

In addition to the general criteria for food additives, the framework Directive recommends that the detailed provisions on categories of food additives be included in separate Directives. Three technical Directives have addressed the use of sweeteners (**94/35/EC**), colours (**94/36/EC**) and all other additives (**95/2/EC**) (the so called

'miscellaneous additives'), outlining the foods in which they can be used and the maximum levels of use.

Strict purity criteria for these main groups of food additives have also been introduced. The criteria lists chemical specifications, which ensure that additives are safe and do not contain harmful substances that can be carried in to foodstuffs. Only food additives which comply with the relevant purity criteria can be used in the preparation of a foodstuff. Appropriate methods of analysis have been agreed to verify that the criteria of purity are met by certain additives (colouring matters, preservatives and antioxidants).

In general, the presence of a food additive in a food product must be indicated on the label, by stating the category, (anti-oxidant, preservative, colour etc.) and either its name or E number. However, certain exceptions apply such as carry-over additives. The EU system has additives numbered in the range from E100 up to E1520. The provisions for labelling the presence of an additive are contained in **Directive 2000/13/EC** (general labelling), **Regulation 50/2000/EC** (genetically modified) and **Directive 89/107/EEC** (framework on food additives). Additional labelling requirements exist for sweeteners and are set out in **Directive 94/36/EC**. Food additives sold direct to food producers and consumers must adhere to the specific labelling provisions set out in the framework **Directive 89/107/EEC**.

More detailed information is given below on general criteria, colours and sweeteners, miscellaneous additives and purity criteria.

General Legislation

• EU LEGISLATION

First Commission Directive 81/712/EEC (OJ L257, p1, 10/09/1981) of **28 July 1981** laying down Community methods of analysis for verifying that certain additives used in foodstuffs satisfy criteria of purity.

Council Directive 89/107/EEC (OJ L40, p27, 11/2/1989) of **21 December 1988** on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption

Amended by:

- **European Parliament and Council Directive 94/34/EC** (OJ L237, p1 10/09/1994) of **30 June 1994**

Decision 292/97/EC of the European Parliament and of the Council (OJ L48, p13, 19/02/1997) of **19 December 1996** on the maintenance of national laws prohibiting the use of certain additives in the production of certain specific foodstuffs

Council Directive 67/427/EEC (OJ L148, p1, 11/07/1967) of 27 June 1967 on the use of certain preservatives for the surface treatment of citrus fruit and on the control measures to be used for the qualitative and quantitative analysis of preservatives in and on citrus fruit

A draft proposal to amend **Council Directive, 89/107/EEC** is under discussion.

• NATIONAL LEGISLATION

- **European Communities (Food Additives) (Purity Criteria Verification) Regulations, 1983** (S.I. No. 60 of 1983)
- **European Communities (Additives, Colours and Sweeteners in Foodstuffs) Regulations, 2000** (S.I. No. 437 of 2000)

Colours and sweeteners

• EU LEGISLATION

- **European Parliament and Council Directive 94/36/EC** (OJ L237, p13, 10/09/1994) of 30 June 1994 on colours for use in foodstuffs
- **European Parliament and Council Directive 94/35/EC** (OJ L237, p3, 10/09/1994) of 30 June 1994 on sweeteners for use in foodstuffs

Amended by:

- **Directive 96/83/EC** (OJ L48, p16, 19/02/1997) of 19 December 1996

Commission Recommendation 78/358/EEC (OJ L103, p32, 15/04/1978) of 29 March 1978 to the Member States on the use of saccharin as a food ingredient and for sale as such in tablet form to the final consumer

Purity criteria

Commission Directive 95/45/EC (OJ L226, p1, 22/09/1995) of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs

Amended by:

- **Commission Directive 1999/75/EC** (OJ L 206, p19, 05/08/1999) of 22 July 1999
- **Commission Directive 2001/50/EC** (OJ L190, p14, 12/07/2001) of 3 July 2001
- **Commission Directive 95/31/EC** (OJ L178, p1, 28/7/1995) of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs

Amended by:

- **Commission Directive 98/66/EC** (OJ L257, p35, 19/09/1998) of 4 September 1998
- **Commission Directive 2000/51/EC** (OJ L198, p41, 04/08/2000) of 26 July 2000
- **Commission Directive 2001/52/EC** (OJ L190, p18, 12/07/2001) of 3 July 2001

• NATIONAL LEGISLATION

- **European Communities (Additives, Colours and Sweeteners in Foodstuffs) Regulations, 2000** (S.I. No. 437 of 2000)
- **European Communities (Additives, Colours, and Sweeteners in Foodstuffs) (Amendment) Regulations, 2001** (S.I. No. 342 of 2001)
- **European Communities (Additives, Colours, and Sweeteners in Foodstuffs) (Amendment) Regulations, 2002** (S.I. No. 344 of 2002)
- **European Communities (Additives, Colours, and Sweeteners in Foodstuffs) (Amendment no. 3) Regulations, 2002** (S.I. No. 380 of 2002)

These Regulations implement the Directives on colours and sweeteners 94/35/EEC and 94/36/EEC and the relevant Directives on purity criteria. 'Sweeteners' and 'Colours' are defined, a list of permitted sweeteners and colours to be added to foodstuffs is given along with their conditions of use.

Permitted substances may be used as colours in foodstuffs and may only be used in certain foodstuffs under specified conditions. Some foods cannot contain added colours. Colouring matters must be used according to good manufacturing practice and at a level not higher than necessary to achieve the intended purpose. Specific colours only can be used for the purpose of health marking of meat products and the stamping of eggshells. The type of colours permitted for sale direct to the consumer is controlled.

The Regulations control the sale of sweeteners direct to the public (table-top sweeteners) and specify additional labelling requirements for these products. Maximum usable doses are given for ready-to-eat foodstuffs and in general sweeteners may not be used in foods for infants or young children. Sweeteners shall be used in accordance with good manufacturing practices, at a dose level not higher than is necessary to achieve the intended purpose and should not mislead the consumer. Definitions are given for the terms 'with no added sugar' and 'energy-reduced'. In addition, foodstuffs containing sweeteners must be labelled 'with sweeteners' the specific provisions are provided in **Directives 94/54/EC** and **96/21/EC** (refer to the section on labelling for further information).

The manufacturer of a product containing sweeteners and colours shall comply with the purity criteria established for these additives. The sale of colours or sweeteners and food containing sweeteners and colours which do not comply with the Regulations is prohibited. An authorised officer may seize, remove and detain such food as food being unfit for human consumption and in certain circumstances, destroy it. The Regulations set out rules for the appointment of authorised officers, their powers and duties of inspection of premises and records, sampling and analysis procedures.

Additives other than colours and sweeteners

• EU LEGISLATION

European Parliament and Council Directive No 95/2/EC (OJ L61, p1, 18/03/1995) of **20 February 1995** on food additives other than colours and sweeteners

Amended by:

- **Directive 96/85/EC of the European Parliament and of the Council** (OJ L86, p4, 28/03/1997) of **19 December 1996**
- **Directive 98/72/EC of the European Parliament and of the Council** (OJ L295, p18, 4/11/1998) of **15 October 1998**
- **Directive 2001/5/EC of the European Parliament and of the Council** (OJ L55, p59, 24/02/2001) of **12 February 2001**

Purity criteria

Commission Directive 96/77/EC (OJ L339, p1, 30/12/1996) of **2 December 1996** laying down specific purity criteria on food additives other than colours and sweeteners

Amended by:

- **Commission Directive 98/86/EC** (OJ L334, p1, 9/12/1998) of **11 November 1998**
- **Commission Directive 2000/63/EC** (OJ L277, p1, 30/10/2000) of **5 October 2000**
- **Commission Directive 2001/30/EC** (OJ L146, p1, 31/05/2001) of **2 May 2001**
- **Commission Directive 2002/82/EC** (OJ L292, p1, 28/10/2002) of **15 October 2002**

• NATIONAL LEGISLATION

- **European Communities (Food Additives other than Colours and Sweeteners) Regulations, 2002** (S.I. No. 613 of 2002)
- **European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) Regulations, 1998** (S.I. No. 541 of 1998)

- **European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations, 2000** (S.I. No. 438 of 2000)
- **European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations, 2001** (S.I. No. 343 of 2001)
- **European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) (Amendment) Regulations, 2002** (S.I. No. 260 of 2002)

The Regulations, **S.I. No. 613 of 2002** (which revoke the earlier legislation, **S.I. No. 288 of 1999**) implement **Directive 95/2/EC** as amended on food additives other than colours and sweeteners, for use in foodstuffs, which is commonly known as the 'miscellaneous additives Directive'.

The Regulations set out the detailed provisions which apply to the use in food of the categories of food additive specified in Article 1(3) of the Directive. These categories include, among others, preservatives, antioxidants, emulsifiers, anti-caking agents and flavour enhancers. They set out the foodstuffs in which these additives may be used and their conditions of use.

All categories of food additives other than colours and sweeteners for use in foodstuffs must comply with the purity criteria set out in **Directive 96/77/EC**, which is transposed by **S.I. No. 541 of 1998**, as amended. The amendment Regulations on purity criteria transpose EU Directives establishing new purity criteria for some categories of additives listed in **Directive 95/2/EC**.

Labelling of food additives, colours and sweeteners

The **European Communities (Additives, Colours and Sweeteners in Foodstuffs) Regulations, 2000** (S.I. No. 437 of 2000) outlines the labelling requirements for food additives for sale to the ultimate consumer and food additives not intended for sale to the ultimate consumer.

Food additives for sale to the ultimate consumer may be marketed only if their packaging or containers bear the following information, which must be conspicuous, clearly legible and indelible:

- The name under which the product is sold and its EC number
- The name and EC number of each food additive, whether sold singly or mixed together, in descending order of weight and the name and EC number of any substances or additives incorporated into the additives in descending order of weight,

- One of the following statements: 'for use in food' or 'restricted use in food' or a more specific reference to its intended food use,
- Special conditions of storage and use where necessary,
- Directions for use where necessary,
- A lot or batch number,
- The name or business name and address of the manufacturer or packager, or of a seller established within the Community,
- The net quantity,
- The date of minimum durability and
- Any other requirement provided in the **Framework Directive 89/107/EC**.

Food additives not intended for sale to the ultimate consumer may be marketed only if their packaging or containers bear the following information, which must be conspicuous, clearly legible and indelible:

- The name and EC number of each food additive, whether sold singly or mixed together, in descending order of weight* and the name and EC number of any substances or additives incorporated into the additives in descending order of weight,
- One of the following statements: 'for use in food' or 'restricted use in food' or a more specific reference to its intended food use,
- Special conditions of storage and use where necessary,
- Directions for use where necessary,*
- A lot or batch number,*
- The name or business name and address of the manufacturer or packager, or of a seller established within the Community,*
- An indication of the percentage of any component which is subject to a quantitative limitation in a food,*
- The net quantity and
- Any other provided in the Framework Directive 89/107/EC.

* *These indications need only appear on the commercial documents accompanying the consignment provided "intended for the manufacture of foodstuffs and not for retail sale" appears as a conspicuous part of the packaging or container of the product in question.*

Additional Labelling requirements for sweeteners:

The **European Communities (Additives, Colours and Sweeteners in Foodstuffs) Regulations, 2000 (S.I. No. 437 of 2000)** outlines the labelling requirements for sweeteners. These rules on the use of sweeteners in foodstuffs defines the terms 'with no added sugar' and 'energy-reduced'. For example, 'no added sugar' is defined as 'without any added mono- or disaccharides or any other foodstuff used for its sweetening properties'.

Directive 96/21/EC provides additional labelling provisions concerning the details that must appear on the label of a food containing a sweetener.

- Foodstuffs containing a sweetener or sweeteners (as authorised by **Directive 94/35/EC**) must be labelled "with sweeteners(s)" near the name of the food.
- Foodstuffs containing both an added sugar or sugars and a sweetener or sweeteners (as authorised by **Directive 94/35/EC**) must be labelled "with sugar(s) and sweeteners(s)" near the name of the food.
- Foodstuffs containing aspartame must be labelled "contains a source of phenylalanine" and
- Foodstuffs containing more than 10% added polyols must be labelled "excessive consumption may produce laxative effects."

FLAVOURINGS

Flavourings are substances used to give taste and/or smell to food. They are not food additives and at a Community level separate rules have been developed to govern the conditions for their use, provide definitions and labelling requirements.

A 'flavouring' includes 'flavouring substances, flavouring preparations, process flavourings, smoke flavourings or mixtures thereof'. All are defined in the **Framework Directive on flavourings 88/388/EC**. **Commission Decision 1999/217/EC** adopted an EU Register of flavouring substances used in or on foodstuffs.

The general Framework Directive requires that flavourings used in the manufacture or preparation of foodstuffs comply with the conditions of the Directive and restrictions on dangerous or undesirable constituents or substances. They should not present any risk to the health of the consumer and should not mislead the consumer. There is provision for developing specific purity criteria. However, to date they have not been developed.

In a foodstuff, flavourings shall be designated on the ingredient list either by the word 'flavouring' or by a more specific name or description of the flavouring. Additional labelling should indicate where the flavouring has been genetically modified. In addition to the Framework Directive on flavourings, more detailed provisions are contained in **Commission Directive 2000/13/EC** (general labelling Directive) and **Regulation 50/2000** (genetically modified flavourings).

Where flavourings are sold direct to the consumer and to a manufacturer for use as a food ingredient, specific labelling requirements are set out in the Framework Directive. They must be appropriately packaged and labelled and this may include the name and address of the manufacturer, the intended use, any special storage conditions, minimum durability, substances contained in the flavouring and other specified details.

Draft proposals being discussed at EU level include:

- draft proposal for a new EU Council and European Parliament Regulation on flavourings and food ingredients with flavouring properties for use in and on foods, replacing **Directive 88/388/EEC** is under discussion.
- draft Regulation on smoke flavourings.

• EU LEGISLATION

Council Directive 88/388/EEC (OJ L184, p61, 15/7/1988) of **22 June 1988** on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production

Completed by:

Commission Directive 91/71/EEC (OJ L42, p25, 15/2/1991) of **16 January 1991** completing **Council Directive 88/388/EEC** on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production

Council Decision 88/389/EEC (OJ L184, p67, 15/07/1988) of **22 June 1988** on the establishment, by the Commission of an inventory of the source materials and substances used in the preparation of flavourings

Regulation (EC) No 2232/96 (OJ L299, p1, 23/11/1996) of **28 October 1996** laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs

• EU LEGISLATION

Commission Communication (OJ C131, p3, 29/04/1998) on the ways in which the Commission is to protect the intellectual property in connection with the development and manufacture of flavouring substances covered by **Regulation (EC) No 2232/96** of the European Parliament and of the Council.

Commission Recommendation 98/282/EC (OJ L127, p32, 29/04/1998) of **21 April 1998** on the ways in which the Member States and the signatory States to the Agreement on the European Economic Area should protect intellectual property in connection with the development and manufacture of flavouring substances referred to in **Regulation (EC) No 2232/96** of the European Parliament and of the Council

Commission Decision 1999/217/EC (OJ L84, p1, 27/03/1999) of **23 February 1999** adopting a register of flavouring substances used in or on foodstuffs drawn up in application of **Regulation (EC) No 2232/96** of the European Parliament and of the Council of **28 October 1996**

Amended by:

- **Commission Decision 2000/489/EC** (OJ L197, p53, 03/08/2000) of **18 July 2000**
- **Commission Regulation (EC) No 1565/2000** (OJ L180, p8, 19/07/2000) of **18 July 2000**
- **Commission Decision 2002/113/EC** (OJ L49, p1, 20/02/2002) of **23 January 2002**
- **Commission Regulation No 622/2002** (OJ L10, p18, 18/04/2002) of **11 April 2002** establishing deadlines for the submission of information for the evaluation of chemically defined flavouring substances used in or on foodstuffs

- NATIONAL LEGISLATION

- **European Communities (Flavourings for use in Foodstuffs for Human Consumption) Regulations, 1992 (S.I. No. 22 of 1992)**

These Regulations transpose **Council Directive 88/388/EEC** as amended. They prohibit the importation, marketing or use of flavourings which do not comply with the Regulations. Definitions are given for different types of flavourings, such as natural, natural-identical or artificial flavouring substances, flavouring preparations of plant or animal origin and process flavourings which evolve flavour after heating and smoke flavourings. General rules for their use and labelling requirements are also given.

Flavourings must not contain any element or substance in a toxicologically dangerous quantity. Maximum levels for heavy metal content and other undesirable substances are set. The use of the word 'natural' or any word having substantially the same meaning is restricted. Where a sample of food has been certified not to comply with the Regulations, an authorised officer may seize, remove and detain such food as food being unfit for human consumption and in certain circumstances, destroy it.

With respect to flavouring substances, a major initiative is underway to develop a list of flavouring substances approved for the use in foodstuffs. **Council Regulation 2232/96/EC**, sets out the basic rules for the use of these substances in or on foodstuffs in the EU. Under this Regulation, the Member States have informed the Commission which flavouring substances are currently authorised for use in foodstuffs at a national level. This resulted in a register of about 2,800 substances which will form the basis for a five-year evaluation programme of these flavouring substances.

This evaluation is being undertaken by bodies such as Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Scientific Committee for Foodstuffs (SCF). Certain flavouring substances have received priority in the evaluation programme due to concern about their use. Upon completion of the evaluation programme, a Community-wide positive list of flavouring substances for use in foodstuffs shall be established. It is envisaged that this task will be completed in 2005.

CONTAMINATION OF FOODSTUFFS

• NATIONAL LEGISLATION

Council Regulation (Euratom) 3954/87 (OJ L371, p11, 30/12/1987) of **22 December 1987** laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency

Corrected by:

- Corrigendum (OJ L018, p74, 22/01/1988) to **Council Regulation (Euratom) No 3954/87 of 22 December 1987**
- Corrigendum (OJ L281, p55, 14/10/1988) to **Council Regulation (Euratom) No 3954/87 of 22 December 1987**

Amended by:

- **Council Regulation (Euratom) 2218/89** (OJ L211, p1, 22/07/1989) of **18 July 1989**

Implementing Measures:

Commission Regulation (Euratom) 944/89 (OJ L101, p17, 13/04/1989) of **12 April 1989** laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological activity

Council Directive (Euratom) 618/89 (OJ L357, p31, 07/12/89) of **27 November 1989** on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency

Commission Regulation (EEC) 2219/89 (OJ L211, p4, 22/07/89) of **18 July 1989** on the special conditions for exporting foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological activity

Council Regulation (EEC) 737/90 (OJ L82, p1, 29/03/90) of **22 March 1990** on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station

Amended by:

- **Council Regulation (EC) 2000/616** (OJ L75, p1, 24/03/2000) of **20 March 2000**

Exclusions:

Commission Regulation 2000/1609/EC (OJ L185, p27, 25/07/2000) establishing a list of products excluded from the application of **Council Regulation 737/90/EEC** on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl power station

Implementing measures:

Commission Regulation (EC) 1661/99 (OJ L197, p17, 29/07/1999) of **27 July 1999** laying down detailed rules for the application of **Council Regulation 737/90/EEC** on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power-station

Amended by:

- **Commission Regulation (EC) No 1621/2001** (OJ L215, p18, 09/08/2001) of **8 August 2001**
- **Commission Regulation (EC) No 1608/2002** (OJ L243, p7, 11/09/2002) of **10 September 2002**

Council Decision (Euratom) 600/87 (OJ L371, p76, 30/12/87) of **14 December 1987** on Community arrangements for early exchange of information in the event of a radiological emergency

Commission Regulation (Euratom) 770/90 (OJ L83, p78, 30/03/90) of **29 March 1990** laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency

• NATIONAL LEGISLATION

- **Radiological Protection Act, 1991 (No. 9 of 1991)**
- **Radiological Protection Amendment Act, 2002 (No. 3 of 2002)**

Under the **Radiological Protection Act**, the Radiological Protection Institute of Ireland (RPII) was established. Their functions include the responsibility to monitor activity or ionising radiation levels in any thing in the State and in any waters, including international waters surrounding the State. In particular, and without prejudice to the generality of the foregoing, they will monitor any activity or ionising radiation levels in individuals, animals, fauna, poultry, eggs, crops, fish, seaweed, or any food, soil, minerals (including rocks of all descriptions), air, or water.

The Act gives power to the Minister for Public Enterprise, following consultation with other Ministers, to prescribe by regulation levels of radioactivity in water and any food. The Act further provides that, where Regulations have been made either under the Act or by the European Council or Commission, any food which contains radioactivity in excess of that prescribed, shall be deemed to be unfit in accordance with the Health Act, 1947.

The Act also allows for various Ministers to control or restrict harvesting, movement, sales of foods, the slaughter of animals, the use of feedingstuffs or the destruction of food and animals in the event of radiological emergency.

To date, all of the controls in Ireland are directed by European legislation. Maximum levels of radioactivity in foods have been set, controls are in place for imported and exported foods, and the procedures to be followed in the event of a radiological emergency are all governed by EU legislation.

Current Controls:

In the event of a future nuclear accident, the Commission is empowered by Council to make a Regulation to give effect to maximum permitted levels of radioactivity for foodstuffs and feedingstuffs, which may be placed on the market. Levels for baby foods, dairy produce, other foodstuffs except minor foodstuffs, liquid foodstuffs and feedingstuffs are set out in **Regulation 3954/87**. Minor foodstuffs are covered by **Regulation 944/89**. The levels for feedingstuffs are set out in **Regulation 770/90**. These levels are also applied to the export of foodstuffs and feedingstuffs.

In the case of imports to the Community, agricultural products imported from third countries following the accident at Chernobyl nuclear power station must comply with the maximum permitted levels of radioactivity expressed in Bq/kg (becquerels per kilogram). The general limit is 600 Bq/kg for foodstuffs with lower limits set for certain food products, in the case of milk and foodstuffs intended for the special feeding of infants the maximum permitted level is only 370 Bq/kg. These levels are set out in **Regulation 737/90/EEC** and by common consent are also observed by Member States.

If, in the event of a radiological emergency, one Member State takes measures to protect the general public they must notify the Commission of the action taken. The information must include the nature and time of the event, its exact location and the nature of the facility or activity involved, the cause, the foreseeable development and the protective measures taken or planned. Other Member States that may be affected are required to advise the Commission of the levels of radioactivity measured by their monitoring facilities in foodstuffs, feedingstuffs, drinking water and the environment.

The European Commission proposes to introduce new legislation to replace **Council Regulation 737/90/EEC**. This regulation lays down maximum permitted levels (MPLs) of radiocaesium contamination, of Chernobyl origin, in agricultural products originating from countries outside the Community that may be imported into the Community. The new legislation proposed would set MPLs on all food products offered for sale in the Community, wherever they are produced.

Food Contaminants

The general Community procedures for contaminants in food are set down in **Council Regulation 315/93/EEC**.

A '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 or holding of such food or as a result of environmental contamination'.

Any food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular, at a toxicologically significant level shall not be placed on the market. Furthermore, contaminant levels shall be kept as low as can be reasonably achieved by following good practices.

To protect public health, **Regulation 315/93/EEC** provides that maximum levels be set for certain contaminants as part of a non-exhaustive Community list. Until recently, maximum limits were only set for nitrates and aflatoxins and some heavy metals. The main piece of legislation was **Regulation 194/97/EEC**. Due to the number of amendments to **Regulation 194/97/EEC** and in the interest of clarity, it was deemed necessary to recast the Regulation. This occurred in 2001 and the result has been the introduction of **Regulation 466/2001/EC** which sets limits for nitrates, aflatoxins, the heavy metals, (lead, cadmium, mercury) and 3-MCPD.

The Regulation also makes reference to the sampling and analysis methods to be used for their detection. The methods of sampling and analysis for the levels of lead, cadmium, mercury and 3-MCPD in certain foodstuffs are described in **Directive 2001/22**. **Directive 98/53/EC** sets out the methods of sampling and analysis for aflatoxins and nitrates.

It should be noted that there are discussions at EU level to revise some of the levels set for contaminants in **Regulation 466/2001/EC** and new levels may be introduced in due course. The contaminants under discussion are lead, cadmium and mercury in fish species and bivalve molluscs and 3-MCPD.

For the sake of clarity, the main contaminants are addressed separately below, with the relevant legislation indicated, however, since the core legislation i.e. **466/2001/EC** addresses many different contaminants, amendments to the **Regulation 466/2001/EC** may relate to individual contaminants.

General provisions

• EU LEGISLATION

Council Regulation (EEC) No 315/93 (OJ L37, p1 13/02/1993) of 8 February 1993 laying down Community procedures for contaminants in food.

Commission Regulation (EC) No 466/2001 (OJ L77, p1, 16/03/2001) of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs

Amended by:

- **Council Regulation (EC) No 2375/2001** (OJ L321, p1, 06/12/2001) of 29 November 2001
- **Commission Regulation (EC) No 221/2002** (OJ L37, p4, 07/02/2002) of 6 February 2002
- **Commission Regulation (EC) No 257/2002** (OJ L41, p12, 13/02/2002) of 12 February 2002
- **Commission Regulation (EC) No 472/2002** (OJ L75, p18, 16/03/2002) of 12 March 2002
- **Commission Regulation (EC) No 563/2002** (OJ L86, p5, 03/04/2002) of 2 April 2002

• NATIONAL LEGISLATION

European Communities (Certain Contaminants in Foodstuffs) Regulations, 2001 (S.I. No. 400 of 2001)

These Regulations set maximum limits for certain contaminants in foodstuffs and give effect to the main EU Directives. In particular, they give effect to the provisions of **Regulation 315/93/EEC**, **Regulation 194/97/EEC** as amended and **Directive 466/2001/EC**, thus facilitating the consolidation of the EU legislation on maximum levels of contaminants for foods. They also transpose **Regulation 1525/98/EC**, **Regulation 864/1999/EC** and **Regulation 1566/99/EC**

These Regulations give effect to most of the limits for the different categories of contaminants as outlined in the subsequent sections.

Nitrates

• EU LEGISLATION

Commission Regulation (EC) No 466/2001 (OJ L77, p1, 16/03/2001) of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs

Amended by:

- **Council Regulation (EC) No 2375/2001** (OJ L321, p1, 06/12/2001) of 29 November 2001

- **Commission Regulation (EC) No 221/2002** (OJ L37, p4, 07/02/2002) of 6 February 2002
- **Commission Regulation (EC) No 257/2002** (OJ L41, p12, 13/02/2002) of 12 February 2002
- **Commission Regulation (EC) No 472/2002** (OJ L75, p18, 16/03/2002) of 12 March 2002
- **Commission Regulation (EC) No 563/2002** (OJ L86, p5, 03/04/2002) of 2 April 2002

Commission Regulation (EC) No 194/97 (OJ L31, p48, 01/02/1997) of 31 January 1997 setting maximum levels for certain contaminants in foodstuffs (note this regulation was repealed by **Regulation 466/2001** on the 5th April 2002)

Amended by:

- **Commission Regulation (EC) No 257/2002** (OJ L41, p12, 13/02/2002) of 12 February 2002

Sampling/Method of Analysis

Commission Directive 79/700/EEC (OJ L207, p26, 15/08/1979) of 24 July 1979 establishing Community methods of sampling for the official control of pesticide residues in and on fruit and vegetables

• NATIONAL LEGISLATION

- **European Communities (Certain Contaminants in Foodstuffs) Regulations, 2001** (S.I. No. 400 of 2001)

The EU rules for maximum levels of nitrates in foods were originally set out in **Regulation 194/97**. They are transposed by **S.I. No. 400 of 2001**. As mentioned above, since April 2002, **Regulation 194/97** has been repealed and the levels as set out in **Directive 466/2001** as amended are now applicable. Incidentally, the levels have remained the same in the consolidated legislation. The sampling methods for nitrates are set out in **Directive 79/700/EC**.

Discussions are ongoing at present within the EU to set a limit for nitrate in infant foods. The proposed level at present is 250mg/kg.

Arsenic

• EU LEGISLATION

Sampling/Method of Analysis

Commission Decision 2002/657/EC (OJ L221, p8, 17/08/2002) of 12 August 2002 implementing **Council Directive 96/23/EC** concerning the performance of analytical methods and the interpretation of results

Commission Regulation (EC) No 466/2001 (OJ L77, p1, 16/03/2001) of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs

Amended by:

- **Council Regulation (EC) No 2375/2001** (OJ L321, p1, 06/12/2001) of 29 November 2001
- **Commission Regulation (EC) No 221/2002** (OJ L37,p4, 07/02/2002) of 6 February 2002
- **Commission Regulation (EC) No 257/2002** (OJ L41, p12, 13/02/2002) of 12 February 2002
- **Commission Regulation (EC) No 472/2002** (OJ L75, p18, 16/03/2002) of 12 March 2002
- **Commission Regulation (EC) No 563/2002** (OJ L86, p5, 03/04/2002) of 2 April 2002

• NATIONAL LEGISLATION

- **Health (Arsenic & Lead in Food) Regulations, 1972** (S.I. No. 44 of 1972)
- **Health (Arsenic & Lead in Food) (Amendment) Regulations, 1992** (S.I. No. 72 of 1992)

The levels of arsenic in food is covered at a national level, with the analytical procedures for the detection of arsenic set down in the **EU Decision 90/515/EEC**.

The Regulations prohibit the sale and importation of any food intended for human consumption which contains more than the specified amount of arsenic. Where a sample of food has been certified by a public analyst not to comply with these Regulations, an authorised officer may seize, remove and detain such food as being food which is unfit for human consumption and in certain circumstances, destroy it.

Discussions are on going on the setting of EU-wide levels for arsenic.

Lead, cadmium and mercury

• EU LEGISLATION

Council Directive 80/778/EEC (OJ L229, p11, 30/08/1980) of 15 July 1980 relating to the quality of water for human consumption

Council Directive 83/417/EEC (OJ L237, p25, 26/08/1983) of 25 July 1983 on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption

Commission Regulation (EC) No 466/2001 (OJ L77, p1, 16/03/2001) of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs

Amended by:

- **Council Regulation (EC) No 2375/2001** (OJ L3212, p1, 06/12/2001) of 29 November 2001
- **Commission Regulation (EC) No 221/2002** (OJ L37, p4, 07/02/2002) of 6 February 2002
- **Commission Regulation (EC) No 472/2002** (OJ L75, p18, 16/03/2002) of 12 March 2002
- **Commission Regulation (EC) No 563/2002** (OJ L86, p5, 03/04/2002) of 2 April 2002

Commission Decision 2002/657/EC (OJ L221, p8, 17/08/2002) of 12 August 2002 implementing **Council Directive 96/23/EC** concerning the performance of analytical methods and the interpretation of results

Sampling/Method of Analysis

Commission Directive 2001/22/EC (OJ L77, p14, 16/03/2001) of 8 March 2001 laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs

Amended by:

- **Commission Decision 2001/873/EC** (OJ L325, p.34, 08/12/2001) of 4 December 2001
- **Commission Decision 2002/657/EC** (OJ L221, p8, 17/08/2002) of 12 August 2002 implementing **Council Directive 96/23/EC** concerning the performance of analytical methods and the interpretation of results
- **Commission Regulation (EC) No 466/2001** (OJ L77, p1, 16/03/2001) of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs

Amended by:

- **Council Regulation (EC) No 2375/2001** (OJ L3212, p1, 06/12/2001)
- **Commission Regulation (EC) No 221/2002** (OJ L37, p4, 07/02/2002) of 6 February 2002
- **Commission Regulation (EC) No 472/2002** (OJ L75, p18, 16/03/2002) of 12 March 2002
- **Commission Regulation (EC) No 563/2002** (OJ L86, p5, 03/04/2002) of 2 April 2002

• NATIONAL LEGISLATION

- **Health (Arsenic & Lead in Food) Regulations, 1972** (S.I. No. 44 of 1972)
- **Health (Arsenic & Lead in Food) (Amendment) Regulations, 1992** (S.I. No. 72 of 1992)
- **European Communities (Certain Contaminants in Foodstuffs) Regulations, 2001** (S.I. No. 400 of 2001)

- **European Communities (Sampling methods and the methods of analysis for the official control of the levels of certain contaminants in foodstuffs) Regulations, 2001 (S.I. No. 401 of 2001)**

The Regulations, **S.I. No. 400 of 2001**, give effect to the maximum levels for Lead, Cadmium and Mercury as set out in **Directive 466/2001/EC** as amended

Certain maximum limits are set for Lead in specified foods in the national legislation. Some but not all of these limits, have been superseded by **Regulation 466/2001/EC**. Therefore it is necessary to consult both pieces of legislation.

In addition to Lead, maximum limits for Mercury and Cadmium are given in **Regulation 466/2001/EC** as amended. Foods, as specified, must not contain levels of Lead or Cadmium higher than the maximum levels specified. The appropriate analytical methods are set out in **Directive 2001/22/EC** which is transposed by **S.I. No. 401 of 2001**. Additional analytical measures are included in **Decision 90/515/EEC**.

Limits for Lead (1mg/kg) in Casein and Caseinates are set as are limits for Cadmium, Lead, Mercury and other metals in drinking water.

The levels for Mercury in fish are set out in **466/2001/EC** and the average limit is increased to 1mg/kg of fresh product for the edible parts of certain fish species.

Tin

• NATIONAL LEGISLATION

- **Health (Tin in Food) Regulations, 1993 (S.I. No. 389 of 1993)**

These Regulations prohibit the sale and importation of any food intended for human consumption which contains more than 200 milligrams of Tin per kilogram of such food. Where a sample of food has been certified by a public analyst not to comply with these Regulations, an authorised officer may seize, remove and detain such food as being food which is unfit for human consumption and in certain circumstances, destroy it.

Discussions are on-going on the setting of EU-wide levels for Tin.

3-MCPD

• EU LEGISLATION

Commission Regulation (EC) No 466/2001 (OJ L77, p1, 16/03/2001) of **8 March 2001** setting maximum levels for certain contaminants in foodstuffs

Amended by:

- **Council Regulation (EC) No 2375/2001** (OJ L321, p1, 06/12/2001) of **29 November 2001**
- **Commission Regulation (EC) No 221/2002** (OJ L37,p4, 07/02/2002) of **6 February 2002**
- **Commission Regulation (EC) No 257/2002** (OJ L41, p12, 13/02/2002) of **12 February 2002**
- **Commission Regulation (EC) No 472/2002** (OJ L75, p18, 16/03/2002) of **12 March 2002**
- **Commission Regulation (EC) No 563/2002** (OJ L86, p5, 03/04/2002) of **2 April 2002**

Sampling/Method of Analysis:

Commission Directive 2001/22/EC (OJ L77, p14, 16/03/2001) of **8 March 2001** laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs

Amended by:

Commission Decision 2001/873/EC (OJ L325 p34, L325, 08/12/2001) of **4 December 2001** correcting Directive 2001/22/EC laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs

• NATIONAL LEGISLATION

- **European Communities (Certain Contaminants in Foodstuffs) Regulations, 2001 (S.I. No. 400 of 2001)**
- **European Communities (Sampling methods and the methods of analysis for the official control of the levels of certain contaminants in foodstuffs) Regulations, 2001 (S.I. No. 401 of 2001)**

The maximum levels for 3-MCPD as set out in **466/2001/EC** are transposed by **S.I. No. 400 of 2001**. Methods of sampling and analysis for 3-MCPD are outlined. Levels are set for 3-MCPD in hydrolysed vegetable protein and soy sauce at 0.02mg/kg. This level is currently under review with a view to increasing the level due to a re-evaluation by the Scientific Committee for Food.

Aflatoxins

• EU LEGISLATION

Commission Regulation (EC) No 466/2001 (OJ L77, p1, 16/03/2001) of **8 March 2001** setting maximum levels for certain contaminants in foodstuffs

Amended by:

- **Council Regulation (EC) No 2375/2001** (OJ L321, p1, 06/12/2001) of **29 November 2001**
- **Commission Regulation (EC) No 221/2002** (OJ L37,p4, 07/02/2002) of **6 February 2002**
- **Commission Regulation (EC) No 257/2002** (OJ L41, p12, 13/02/2002) of **12 February 2002**
- **Commission Regulation (EC) No 472/2002** (OJ L75, p18, 16/03/2002) of **12 March 2002**
- **Commission Regulation (EC) No 563/2002** (OJ L86, p5, 03/04/2002) of **2 April 2002**

Sampling/Method of Analysis:

Commission Directive 98/53/EC (OJ L201, p93, 17/07/1998) of **16 July 1998** laying down the sampling methods and the methods of analysis for the official control of the levels for certain contaminants in foodstuffs.

Amended by:

- **Commission Directive 2002/27/EC** (OJ L75, p44, 16/03/2002) of **13 March 2002** amending **Directive 98/53/EC** laying down the sampling methods and the methods of analysis for the official control of the levels for certain contaminants in foodstuffs.

- **NATIONAL LEGISLATION**

- **European Communities (Certain Contaminants in Foodstuffs) Regulations, 2001 (S.I. No. 400 of 2001)**
- **European Communities (Sampling Methods and the Methods of Analysis for the Official control of the levels of certain contaminants in foodstuffs) Regulations, 2001 (S.I. No. 401 of 2001)**

The maximum levels for aflatoxins as set out in **466/2001/EC** as amended are transposed by **S.I. No. 400 of 2001**.

In addition, the second set of Regulations transposes **Directive 98/53/EC** on the methods of sampling and analysis for aflatoxins in foods in accordance with the maximum levels set out in **Directive 466/2001/EC**.

Maximum levels are set for aflatoxins in cereals and cereal products, groundnuts, nuts and dried fruit and milk and milk products. These levels were previously contained in **Regulation 1525/98/EEC** (amending **Regulation 194/97/EC**) but are now part of **Regulation 466/2001/EC** as amended. The levels however, remain the same.

The methods of analysis for aflatoxins are given in **Directive 98/53/EC**.

Ochratoxin A

- **EU LEGISLATION**

Commission Regulation (EC) No 472/2002 (OJ L75, p18, 16/03/2002) of **12 March 2002** amending **Regulation (EC) No 466/2001** setting maximum levels for certain contaminants in foodstuffs

This amendment sets levels for Cereals and Dried Vine Fruits. Currently under discussion are levels in baby food as well as for Green and Roasted Coffee, Wine, Beer, Grape Juice, Cocoa, Spices.

Sampling/Method of Analysis:

Commission Directive 2002/26/EC (OJ L75, p38, 16/03/2002) of **13 March 2002** laying down the sampling methods and the methods of analysis for the official control of the levels of ochratoxin A in foodstuffs

Dioxins

'Dioxins' encompass a group of 75 polychlorinated dibenzo-p-dioxins, (PCDD) and 135 polychlorinated dibenzofuran (PCDF) congeners.

The European Commission is working towards a comprehensive policy on control of dioxins in food and feed. The levels set for dioxins and PCBs in foods that were in place during the dioxin crisis of 1999 have been revoked and there are, at present, no limits set for these contaminants at Community level.

The approach being adopted to control dioxins in both food and feed is the setting of maximum limits for dioxins in foodstuffs/feedstuffs and action and target levels which form part of a more proactive approach. In the future, it is envisaged that limits will also be set for dioxin-like PCBs. Simultaneously, efforts are being made to develop source directed measures focusing on the environment.

- **EU LEGISLATION**

Commission Regulation (EC) No 466/2001 (OJ L77, p1, 16/03/2001) of **16 March** setting maximum levels for certain contaminants in foodstuffs

Amended by:

- **Council Regulation (EC) No 2375/2001** (OJ L321, p1, 6/12/2001) of **29 November**
- **Commission Recommendation of 4 March 2002 on the reduction of the presence of dioxins, furans and PCBs in feedingstuffs and foodstuffs (notified under document number C(2002) 836)**

The above Regulation, **No.2375/2001**, sets levels for dioxins in the following food group: meat, fish, eggs, milk, fats and oils. The separate Recommendation deals with action and target levels designed to further reduce dioxin levels throughout the food chain. No specific levels have been set for food groups such as cereals and fruit and vegetables, as they are generally accepted to have low levels of contamination. However, they will be monitored and areas for concern will be highlighted. A draft Commission Recommendation concerning on the monitoring of background levels of dioxins and dioxin-like PCBs in foodstuffs makes definitive proposals for Member States to perform random monitoring of the presence of dioxins, furans and dioxin-like PCBs in foodstuffs, proportionate to their production and consumption of foodstuffs, as anticipated in **Commission Recommendation 2002/201/EC**.

Sampling/Method of Analysis:

Commission Directive 2002/69/EC (OJ L252, p40, 20/09/2002) of **26 July 2002** laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs

Amended by:

- **Corrigendum to Commission Directive 2002/69/EC** (OJ L209, 6/8/2002) of **July 2002** laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs

• NATIONAL LEGISLATION

- **European Communities (Certain Contaminants in Foodstuffs) Regulations, 2001** (S.I. No. 400 of 2001)
- **European Communities (Sampling Methods and the Methods of Analysis for the Official control of the levels of certain contaminants in foodstuffs) Regulations, 2001** (S.I. No. 401 of 2001)

The maximum levels for dioxins as set out in **Regulation No 2375/2001** are transposed in principle by the framework **Regulations S.I. No. 400 of 2001**. A future amendment of these Regulations will specifically encompass the EU legislation.

Erucic Acid

• EU LEGISLATION

Council Directive 76/621/EEC (OJ L202, p35 28/07/1976) of **20 July 1976** relating to the fixing of the maximum level of erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils or fats.

Commission Directive 91/321/EEC (OJ L175, p35, 04/07/1991) of **14 May 1991** on infant formulae and follow-on formulae

Amended by:

- **Commission Directive 96/4/EC, Euratom** (OJ L49, p12, 28/02/1996) of **16 February 1996** amending **Directive 91/321/EEC** on infant formulae and follow-on formulae
- **Commission Directive 1999/50/EC** (OJ L139, p29, 02/06/1999) of **25 May 1999** amending **Directive 91/321/EEC** on infant formulae and follow-on formulae

Methods of Analysis:

Commission Directive 80/891/EEC (OJ L254, p35, 27/9/1980) of **25 July 1980** relating to Community method of analysis for determining the erucic acid content in oil and fats intended to be used as such for human consumption and foodstuffs containing added oils and fats

• NATIONAL LEGISLATION

- **Health (Erucic Acid in Food) Regulations, 1978** (S.I. No. 123 of 1978)
- **Health (Erucic Acid in Food) (Amendment) Regulations, 1992** (S.I. No. 67 of 1992)
- **European Communities (Erucic Acid in Food) (Method of Analysis) Regulations, 1982** (S.I. No. 271 of 1982)

These Regulations specify limits for the erucic acid content of oil and fat and of food to which oil or fat has been added. The limit is 5%. The method of analysis determines the erucic acid content of oils, fats and compound foodstuffs to which oils and fats have been added. The Regulations do not apply to food having an overall oil or fat content of less than 5% unless it is described as being specifically prepared for infants and young children or to oil, fat and food intended for manufacturing or catering purposes.

A limit for erucic acid in infant formulae is specified in **Directive 91/321/EEC** as amended.

Mineral Hydrocarbons

• NATIONAL LEGISLATION

- **Health (Mineral Hydrocarbons in Food) Regulations, 1972** (S.I. No. 45 of 1972)
- **Health (Mineral Hydrocarbons in Food) (Amendment) Regulations, 1992** (S.I. No. 71 of 1992)

These Regulations provide (subject to certain exemptions) that the use of any mineral hydrocarbon in the manufacture or preparation of food and the importation, distribution, sale or exposure for sale of any food containing any mineral hydrocarbon is prohibited. The prohibition does not extend to chewing gum and other products, for which maximum limits of mineral hydrocarbon are prescribed. Specifications are set out for mineral hydrocarbon. Where a sample of food has been certified by a public analyst not to comply with these Regulations, an authorised officer may seize, remove and detain such food as being food which is unfit for human consumption and in certain circumstances, destroy it.

Other Undesirable Substances

Vinyl chloride

• EU LEGISLATION

Council Directive 78/142/EEC (OJ L44, p15, 15/02/1978) of **30 January 1978** on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs

Methods of Analysis:

Commission Directive 80/766/EC (OJ L213, p42, 16/08/1980) of **8 July 1980** laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs

Commission Directive 81/432/EEC (OJ L167, p6, 24/06/1981) of **29 April 1981** laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs

• NATIONAL LEGISLATION

- **Health (Vinyl Chloride in Food) Regulations, 1984 (S.I. No. 95 of 1984)**
- **Health (Vinyl Chloride in Food) (Amendment) Regulations, 1992 (S.I. No. 65 of 1992)**
- **European Communities (Vinyl Chloride in Food) (Method of Analysis) Regulations, 1984 (S.I. No. 92 of 1984)**

The Regulations specify a maximum permissible level for vinyl chloride in food of 0.01mg/kg. They transpose the EU Directives on vinyl chloride limits in food.

The method of analysis to be used by a public analyst or person under his direction to determine the content of vinyl chloride in food is specified. Where a sample of food has been certified by a public analyst not to comply with these Regulations, an authorised officer may seize, remove and detain such food as being food which is unfit for human consumption and in certain circumstances, destroy it.

Extraction solvents

• EU LEGISLATION

Council Directive 88/344/EEC (OJ L157, p28, 24/6/1988) of **13 June 1988** on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients

Amended by:

- **Council Directive 92/115/EEC** (OJ L409, p31, 31/12/1992) of **17 December 1992** amending for the first time **Directive 88/344/EEC** on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients

Directive 94/52/EC (OJ L331, p10, 21/12/1994) of **7 December 1994** amending for the second time **Directive 88/344/EEC** on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients

Directive 97/60/EC (OJ L331, p7, 03/12/1997) of **27 October 1997** amending for the third time **Directive 88/344/EEC** on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients

• NATIONAL LEGISLATION

- **European Communities (Extraction Solvents in Foodstuffs and Food Ingredients) Regulations, 2000 (S.I. No. 141 of 2000)**

These Regulations transpose **Council Directive 83/344/EEC** as amended, which lay down specific provisions for extraction solvents used or intended for use in the production of foodstuffs or food ingredients. Solvent and extraction solvent are defined. A list of approved extraction solvents are permitted for the processing of raw materials, foodstuffs, food components and food ingredients. All substances used as extraction solvents must be used in accordance with good manufacturing practices which present no danger to human health and must satisfy certain purity criteria. Some extraction solvents can only be used in accordance with specified conditions.

PESTICIDES

There is extensive legislation in the area of pesticides and it will continue to be developed in the future. The legislation listed sets maximum levels for pesticide residues in and on cereals, fruit, vegetables, foods of animal origin (including dairy and meat products) and feedingstuffs. The aim of establishing these maximum levels is to ensure that the health of consumers is adequately protected and that goods can circulate freely throughout the European Community. Authorisation is given to temporarily reduce the levels if they unexpectedly prove to be dangerous to human or animal health.

Cereals

• EU LEGISLATION

Council Directive 86/362/EEC (OJ L221, p37, 7/8/1986) of 24 July 1988 on the fixing of maximum levels for pesticide residues in and on cereals

Amended by:

- **Council Directive 88/298/EEC** (OJ L126, p53, 20/05/1988) of 16 May 1988
- **Council Directive 93/57/EEC** (OJ L211, p1, 23/8/1993) of 29 June 1993
- **Council Directive 94/29/EC** (OJ L189, p67, 23/7/1994) of 23 June 1994
- **Council Directive 95/39/EC** (OJ L197, p29, 22/8/1995) of 17 July 1996
- **Council Directive 96/33/EC** (OJ L144, p35, 18/6/1996) of 21 May 1996
- **Council Directive 97/41/EC** (OJ L184, p33, 12/07/1997) of 25 June 1997
- **Commission Directive 97/71/EC** (OJ L347, p42, 18/12/1997) of 15 December 1997
- **Commission Directive 98/82/EC** (OJ L290, p25, 29/10/1998) of 27 October 1998
- **Commission Regulation 2000/645/EC** (OJ L78, p7, 29/03/2000) of 28 March 2000
- **Commission Directive 99/65/EC** (OJ L172, p40, 8/07/1999) of 24 June 1999
- **Commission Directive 2000/81/EC** (OJ L326, p56, 22/12/2000) of 18 December 2000
- **Commission Directive 2000/58/EC** (OJ L244, p78, 29/09/2000) of 22 September 2000

- **Commission Directive 2000/48/EC** (OJ L197, p26, 3/08/2000) of 25 July 2000
- **Commission Directive 2000/24/EC** (OJ L107, p28, 4/05/2000) of 28 April 2000
- **Commission Directive 2000/42/EC** (OJ L158, p51, 30/06/2000) of 22 June 2000
- **Commission Directive 2001/39/EC** (OJ L148, p70, 1/06/2001) of 23 May 2001
- **Commission Directive 2001/57/EC** (OJ L208, p36, 1/08/2001) of 25 July 2001
- **Commission Directive 2001/48/EC** (OJ L180, p26, 3/07/01) of 28 June 2001
- **Commission Directive 2001/57/EC** (OJ L208, p36, 01/08/2001) of 25 July 2001
- **Commission Directive 2002/23/EC** (OJ L64, p13, 07/03/2002) of 26 February 2002
- **Commission Directive 2002/42/EC** (OJ L134, p29, 22/05/2002) of 17 May 2002
- **Commission Directive 2002/66/EC** (OJ L192, p47, 20/07/2002) of 16 July 2002
- **Commission Directive 2002/71/EC** (OJ L225, p21, 22/08/2002) of 19 August 2002
- **Commission Directive 2002/76/EC** (OJ L240, p45, 07/09/2002) of 6 September 2002
- **Commission Directive 2002/79/EC** (OJ L291, p1, 28/10/2002) of 2 October 2002
- **Commission Directive 2002/97/EC** (OJ L343, p23, 18/12/2002) of 16 December 2002

• NATIONAL LEGISLATION

- **European Communities (Pesticide Residues) (Cereals) Regulations, 1999** (S.I. No. 181 of 1999)
- **European Communities (Pesticide Residues) (Cereals) (Amendment) Regulations, 1999** (S.I. No. 459 of 1999)
- **European Communities (Pesticide Residues) (Cereals) (Amendment) Regulations, 2000** (S.I. No. 459 of 2000)
- **European Communities (Pesticide Residues) (Cereals) (Amendment) Regulations, 2001** (S.I. No. 138 of 2001)
- **European Communities (Pesticide Residues) (Cereals) (Amendment) (No. 2) Regulations** (S.I. No. 250 of 2001)

In the last few years, new Regulations have been introduced which revoke much of the previous legislation. The **Pesticide Residue (Cereals) Regulations, 1988-1998**

have been revoked by **S.I. No. 181 of 1999**. The Regulations provide that a person shall not put into circulation any cereal, including dried and /or processed products and composite foodstuffs to which these Regulations apply, if it contains the residue of a pesticide specified in the Regulations in a quantity greater than the maximum level laid down. They also substitute new maximum residue levels for a number of substances.

The amendment Regulations transpose EU Directives and introduce maximum residue levels for additional pesticides permitted in cereals.

Foods of Animal Origin

• EU LEGISLATION

Council Directive 86/363/EEC (OJ L221, p43, 7/08/86) of **24 July 1986** on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin

Amended by:

- **Council Directive 93/57/EEC**
(OJ L211, p1, 23/08/1993) of **29 June 1993**
- **Council Directive 94/29/EEC**
(OJ L189, p67, 23/07/1994) of **23 June 1994**
- **Council Directive 95/39/EEC**
(OJ L197, p29, 22/08/1995) of **17 July 1999**
- **Council Directive 96/33/EC**
(OJ L144, p35, 18/06/1996) of **21 May 1996**
- **Council Directive 97/41/EC**
(OJ L184, p33, 12/07/1997) of **25 June 1997**
- **Council Directive 97/71/EC**
(OJ L347, p42, 18/12/1997) of **15 December 1997**
- **Council Directive 98/82/EC**
(OJ L290, p25, 29/10/1998) of **27 October 1998**
- **Council Directive 99/71/EC**
(OJ L194, p36, 27/07/1999) of **14 July 1999**
- **Council Directive 2000/24/EC**
(OJ L107, p28, 4/05/2000) of **28 April 2000**
- **Council Directive 2000/42/EC**
(OJ L158, p51, 30/06/2000) of **22 June 2000**
- **Council Directive 2000/58/EC**
(OJ L244, p78, 29/09/2000) of **22 September 2000**
- **Council Directive 2000/81/EC**
(OJ L326, p56, 22/12/2000) of **18 December 2000**
- **Commission Directive 2001/39/EC**
(OJ L148, p70, 1/06/2001) of **23 May 2001**
- **Commission Directive 2001/57/EC**
(OJ L208, p36, 01/08/2001) of **25 July 2001**

- **Commission Directive 2002/23/EC**
(OJ L64, p13, 07/03/2002) of **26 February 2002**
- **Commission Directive 2002/42/EC**
(OJ L134, p29, 22/05/2002) of **17 May 2002**
- **Commission Directive 2002/66/EC**
(OJ L192, p47, 20/07/2002) of **16 July 2002**
- **Commission Directive 2002/71/EC**
(OJ L225, p21, 22/08/2002) of **19 August 2002**
- **Commission Directive 2002/76/EC**
(OJ L240, p45, 07/09/2002) of **6 September 2002**
- **Commission Directive 2002/79/EC**
(OJ L291, p1, 28/10/2002) of **2 October 2002**
- **Commission Directive 2002/97/EC**
(OJ L343, p23, 18/12/2002) of **16 December 2002**

Note: Many of the amendments to Council Directive 86/363/EC also provide maximum residue levels for cereals, and certain products of plant origin, including fruit and vegetables.

• NATIONAL LEGISLATION

- **European Communities (Pesticide Residues) (Foodstuffs of Animal Origin) Regulations, 1999** (S.I. No. 180 of 1999)
- **European Communities (Pesticide Residues) (Foodstuffs of Animal Origin)(Amendment) Regulations, 1999.** (S.I. No. 460 of 1999)
- **European Communities (Pesticide Residues) (Foodstuffs of Animal Origin) (Amendment) Regulations, 2000** (S.I. No. 460 of 2000)
- **European Communities (Pesticide Residues) (Foodstuffs of Animal Origin) (Amendment) Regulations, 2001** (S.I. No. 137 of 2001)
- **European Communities (Pesticide Residues) (Foodstuffs of Animal Origin) (Amendment) (No. 2) Regulations, 2001** (S.I. No. 249 of 2001)
- **European Communities (Pesticide Residues) (Foodstuffs of Animal Origin) (Amendment) Regulations, 2000** (S.I. No. 460 of 2000)

The Regulations give effect to the EU Directives setting out the maximum pesticide residue limits permitted in foodstuffs of animal origin. A list of the products covered by this legislation is set out and it broadly includes fresh and frozen meats, milk and cream, butter, cheese and curd, sausages and similar products. Products obtained from these products after drying or processing and the composite foods in which they are included. The amendment Regulations allow for the inclusion of additional residue levels for pesticides in foods of animal origin.

Fruit and Vegetables

• EU LEGISLATION

Council Directive 76/895/EEC (OJ L340, p26, 09/12/1976) of 23 November 1976 relating to a fixing of maximum levels for pesticide residues in or on fruit and vegetables

Amended by:

- **Council Directive 80/428** (OJ L 102, p26, 19/4/80) of 28 March 1980
- **Council Directive 81/36/EEC** (OJ L046, p33, 19/2/1981) of 9 February 1981
- **Council Directive 82/528/EEC** (OJ L234, p1, 9/8/1982) of 19 July 1982
- **Council Directive 88/298/EEC** (OJ L126, p53, 20/05/1988) of 16 May 1988
- **Council Directive 89/186/EEC** (OJ L66, p36, 10/3/1989) of 6 March 1989
- **Council Directive 93/58/EEC** (OJ L211, p6, 23/8/1993) of 29 June 1993
- **Commission Directive 79/700/EEC** (OJ L207, p26, 15/8/1979) of 24 July 1979
- **Council Directive 96/32/EC** (OJ L144, p12, 18/06/1996) of 21 May 1996
- **Council Directive 97/41/EC** (OJ L184, p33, 12/07/1997) of 25 June 1997
- **Commission Directive 2000/24/EC** (OJ L107, p28, 4/05/2000) of 24 April 2000
- **Commission Directive 2000/57/EC** (OJ L244, p76, 29/09/2000) of 22 September 2000
- **Commission Directive 2002/66/EC** (OJ L192, p47, 20/07/2002) of 16 July 2002
- **Commission Directive 2002/71/EC** (OJ L225, p21, 22/08/2002) of 19 August 2002
- **Commission Directive 2002/79/EC** (OJ L291, p1, 28/10/2002) of 2 October 2002

• NATIONAL LEGISLATION

- **European Communities (Pesticide Residues) (Fruit and Vegetables) Regulations, 1989** (S.I. No. 105 of 1989)
- **European Communities (Pesticide Residues) (Fruit and Vegetables) Regulations, 1997** (S.I. No. 218 of 1997)
- **European Communities (Pesticide Residues) (Fruit and Vegetables) (Amendment) Regulations, 1998** (S.I. No. 563 of 1998)
- **European Communities (Pesticide Residues) (Fruit and Vegetables) (Amendment) Regulations, 2000** (S.I. No. 461 of 2000)

- **European Communities (Pesticide Residues) (Fruit and Vegetables) (Amendment) Regulations, 1998** (S.I. No. 136 of 2001)

The Regulations set maximum residue levels for pesticides in the listed fruit and vegetables (fresh and chilled). Permitted pesticides and their maximum residue levels are also listed. Previous regulations were revoked, with the net effect that maximum residue levels in respect of eight pesticides have been reduced and the list has been extended to insert maximum residue levels for additional pesticides. An amendment to the Regulations includes dried and processed products and foodstuffs, and foodstuffs intended for export to third countries are subject to these maximum residue levels.

Products of Plant Origin

• EU LEGISLATION

Council Directive 90/642/EEC (OJ L350, p71, 14/12/1990) of 27 November 1990 on the fixing of maximum levels for pesticide residues in or on certain products of plant origin including fruit and vegetables

Amended by:

- **Council Directive 93/58/EEC** (OJ L211, p6, 23/08/1993) of 29 June 1993
- **Corrigenda to Council Directive 93/58 /EEC** (OJ L219 of 24/08/1994)
- **Council Directive 94/30/EEC** (OJ L189, p70, 23/7/1994) of 23 June 1994
- **Council Directive 95/38/EEC** (OJ L197, p14, 22/08/1995) of 29 June 1995
- **Council Directive 95/61/EC** (OJ L292, p27, 07/12/1995) of 29 November 1995
- **Council Directive 96/32/EEC** (OJ L144, p12, 18/06/1996) of 21 May 1996
- **Council Directive 97/41/EEC** (OJ L184, p33, 12/07/1997) of 25 June 1997
- **Commission Directive 97/71/EC** (OJ L347, p21, 18/12/1997) of 15 December 1997
- **Commission Directive 98/82/EC** (OJ L290, p25, 29/10/1998) of 27 October 1998
- **Commission Directive 99/65/EC** (OJ L172, p40, 8/07/1999) of 24 June 1999
- **Commission Directive 99/71/EC** (OJ L194, p36, 27/07/1999) of 14 July 1999
- **Commission Directive 200/24/EC** (OJ L107, p.28, 4/05/2000) of 28 April 2000
- **Commission Directive 2000/48/EC** (OJ L197, p26, 3/08/2000) of 25 July 2000

- **Commission Directive 2000/57/EC**
(OJ L244, p76, 29/09/2000) **of 22 September 2000**
- **Commission Directive 2000/58/EC**
(OJ L244, p78, 29/09/2000) **of 22 September 2000**
- **Commission Directive 2001/35/EC**
(OJ L136, p42, 18/05/2001) **of 11 May 2001**
- **Commission Directive 2001/57/EC**
(OJ L208, p36, 1/08/2001) **of 25 July 2001**
- **Commission Directive 2001/48/EC**
(OJ L180, p26, 3/07/2001) **of 28 June 2001**
- **Commission Directive 2001/57/EC**
(OJ L208, p36, 01/08/2001) **of 25 July 2001**
- **Commission Directive 2002/5/EC**
(OJ L34, p7, 05/02/2002) **of 30 January 2002**
- **Commission Directive 2002/23/EC**
(OJ L64, p13, 07/03/2002) **of 26 February 2002**
- **Commission Directive 2002/42/EC**
(OJ L134, p29, 22/05/2002) **of 17 May 2002**
- **Commission Directive 2002/66/EC**
(OJ L192, p47, 20/07/2002) **of 16 July 2002**
- **Commission Directive 2002/71/EC**
(OJ L225, p21, 22/08/2002) **of 19 August 2002**
- **Commission Directive 2002/76/EC**
(OJ L240, p45, 07/09/2002) **of 6 September 2002**
- **Commission Directive 2002/79/EC**
(OJ L291, p1, 28/10/2002) **of 2 October 2002**
- **Commission Directive 2002/97/EC**
(OJ L343, p23, 18/12/2002) **of 16 December 2002**

• NATIONAL LEGISLATION

- **European Communities (Pesticide Residues) (Products of Plant origin, including Fruit and Vegetables) Regulations, 1999 (S.I. No. 179 of 1999)**
- **European Communities (Pesticide Residues) (Products of Plant Origin, including fruit and vegetables) (Amendment) Regulations, 1999 (S.I. No. 458 of 1999)**
- **European Communities (Pesticide Residues) (Products of Plant Origin, including fruit and vegetables) (Amendment) Regulations, 2000 (S.I. No. 462 of 2000)**
- **European Communities (Pesticide Residues) (Products of Plant Origin, including fruit and vegetables) (Amendment) Regulations, 2001 (S.I. No. 139 of 2001)**
- **European Communities (Pesticide Residues) (Products of Plant Origin, including Fruit and Vegetables) (Amendment) (No. 2) Regulations, 2001 (S.I. No. 256 of 2001)**

These Regulations pertain to maximum pesticide residue levels in products of plant origin, including fresh fruit and vegetables. The products to which these Regulations apply are listed in detail with the corresponding permitted maximum residue levels. They revoke the previous Regulations regarding pesticide residue levels in products of plant origin, 1997 – 1998. The amendment Regulations include maximum residue levels for additional pesticides that are permitted on plant products.

Co-ordinated Monitoring Programmes for Pesticide Residues

Each year Member States partake in a coordinated Community monitoring programme to ensure compliance for maximum levels of pesticide residues in cereals and certain plants including fruit and vegetables. The main objective is to collect data on pesticide dietary exposure. Specific residues are monitored in certain food groups each year. These programmes are set out in a Commission Recommendation each year.

• EU LEGISLATION

Commission Recommendation 2000/43/EC (OJ L14, p36, 20/01/2000) **of 17 December 1999** concerning a coordinated Community monitoring programme for 2000 to ensure compliance with maximum levels of pesticide residues in and on cereals and certain products of plant origin, including fruit and vegetables

Commission Recommendation 2001/42/EC (OJ L44, p40, 16/01/2001) **of 22 December 2000** concerning a co-ordinated monitoring programme for 2001 to ensure compliance with maximum levels of pesticide residues in and on cereals and certain products of plant origin, including fruit and vegetables

Commission Recommendation 2002/1/EC (OJ L2, p8, 04/01/2002) **of 27 December 2001** concerning a coordinated Community monitoring programme for 2002 to ensure compliance with maximum levels of pesticide residues in and on cereals and certain other products of plant origin including fruit and vegetables

Commission Recommendation 2002/663/EC (OJ L225, p25, 22/08/2002) **of 19 August 2002** concerning a coordinated Community monitoring programme for 2003 to ensure compliance with maximum levels of pesticide residues in and on cereals and certain other products of plant origin including fruit and vegetables

Export and Import of Pesticides

• EU LEGISLATION

Council Regulation 2455/92/EC
(OJ L 251, p13, 29/08/1992) of 23 July 1992

Amended by:

- **Council Regulations 3135/94/EC**
(OJ L 332, p1, 22/12/1994) of 15 December 1994
- **Commission Regulation 1492/96/EC**
(OJ L189, p19, 30/07/1996) of 26 July 1996
- **Commission Regulation (EC) No 300/2002**
(OJ L52, p1, 22/02/2002) of 1 February 2002

• NATIONAL LEGISLATION

- **European Communities (Export and Import of Certain Dangerous Chemicals) (Pesticides) (Enforcement) Regulations, 1995 (S.I. No. 135 of 1995)**
- **European Communities (Export and Import of Certain Dangerous Chemicals) (Pesticides) (Enforcement) (Amendment) Regulations, 1995 (S.I. No. 183 of 1995)**
- **European Communities (Export and Import of Certain Dangerous Chemicals) (Pesticides) (Enforcement) (Amendment) Regulations, 1998 (S.I. No. 88 of 1998)**

These Regulations serve to implement the provisions of **Council Regulation 2455/92/EC** as amended. They introduce enforcement powers which apply to pesticides covered by the Regulation, and make provision for the penalties that may be applied by the Courts in the event of infringement. The Regulations include a schedule of those chemicals banned or severely restricted to certain uses owing to their effect on health and the environment. This list of chemicals results from the "prior informed consent" (PIC) programme operated at an international level, and a list of the participating countries is included in the Regulation. The amendments update the list of participating countries and the import decisions made by them in relation to pesticides.

The designated national authority, for the purpose of the Regulations, is the Pesticide Control Service of the Department of Agriculture and Food.

Analysis of Pesticide Residues

Accreditation of laboratories is set down in **Council Directive 93/99/EC**.

• EU LEGISLATION

- **Council Directive 93/99/EEC** (OJ L290, p14, 24/11/93) of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs
- **Commission Decision 98/536/EC** (OJ L251, p39, 11/09/98) of 3 September 1998 establishing the list of national reference laboratories for the detection of residues
- **Commission Decision 2000/159/EC** (OJ L51, p30, 24/02/2000) on the provisional approval of residue plans of third countries according to **Council Directive 96/23/EC**

Plant Protection

Prohibition of active substances

• EU LEGISLATION

Council Directive 79/117/EEC (OJ L33, p36, 8/2/1979) of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances, as amended by:

- **Commission Directive 83/131/EEC**
(OJ L 91, p35, 9/4/1983) of 14 March 1993
- **Commission Directive 85/298/EEC**
(OJ L 154, p48, 13/6/1985) of 22 May 1985
- **Council Directive 86/214/EEC**
(OJ L152, p45, 6/06/86) of 26 May 1986
- **Council Directive 86/355/EEC**
(OJ L212, p33, 2/8/1986) of 21 July 1986
- **Council Directive 87/181/EEC**
(OJ L71, p33, 14/3/1987) of 9 March 1987
- **Commission Directive 87/477/EEC**
(OJ L273, p40, 26/09/87) of 9 September 1987
- **Council Directive 89/365/EEC**
(OJ L159, p58, 10/06/89) of 30 May 1989
- **Council Directive 90/335/EEC**
(OJ L162, p37, 28/06/90) of 7 June 1990
- **Council Directive 90/533/EEC**
(OJ L296, p63, 27/10/90) of 15 October 1990
- **Commission Directive 91/188/EEC**
(OJ L92, p42, 13/04/91) of 19 March 1991

• NATIONAL LEGISLATION

- **European Communities (Prohibition of Certain Active Substances in Plant Protection Products) Regulations, 1981 (S.I. No. 320 of 1981)**

- **European Communities (Prohibition of Certain Active Substances in Plant Protection Products)(Amendment) (No. 2) Regulations, 1985 (S.I. No. 237 of 1985)**
- **European Communities (Prohibition of Certain Active Substances in Plant Protection Products) (Amendment) (No.2) Regulations, 1987 (S.I. No. 342 of 1987)**
- **European Communities (Prohibition of Certain Active Substances in plant protection products) (Amendment) Regulations, 1990 (S.I. No. 339 of 1990)**

The Regulations also require prior notification of intended importation of certain plant protection products; provide for seizing and detaining products and limit the cases where the marketing and use of prohibited products is permitted. The derogation that allowed for the use of DDT in certain circumstances has also been revoked.

Prohibited Poisons

- **The Poisons (Prohibition of the use of Certain Substances for Agricultural Purposes) Regulations, 1991 (S.I. No. 361 of 1991)**

These Regulations made under the **Poisons Act, 1961 (No. 12 of 1961)** declare the following substances and their isomers- chlordecone, reserpine, strychnine, its salts and quaternary compounds – as poisons and as such prohibit their use or storage with intent for use for agricultural purposes.

Dangerous Substances and Preparations

• EU LEGISLATION

Council Directive 76/769/EEC (OJ L262, p 201, 27/09/1976) of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restriction on the marketing and use of certain dangerous substances and preparations

Amended by:

- **Council Directive 79/663/EEC (OJ L197, p37, 3/08/1979) of 24 July 1979**
- **Council Directive 82/806/EEC (OJ L339, p55, 1/12/1982) of 22 November 1982**
- **Council Directive 83/264/EEC (OJ L147, p9, 6/06/1983) of 16 May 1983**

- **Council Directive 83/478/EEC (OJ L263, p33, 24/09/1983) of 19 September 1983**
- **Council Directive 85/467/EC (OJ L269, p56, 11/10/1985) of 1 October 1985**
- **Council Directive 89/677/EEC (OJ L398, p19, 30/12/89) of 21 December 1989**
- **Council Directive 91/338/EEC (OJ L186, p59, 12/07/1991) of 18 June 1991**
- **Council Directive 91/339/EEC (OJ L186, p64, 12/07/1991) of 18 June 1991**
- **Council Directive 94/27/EC (OJ L188, p1, 22/07/1994) of 30 June 1994**
- **Council Directive 94/60/EC (OJ L365, p1, 31/12/1994) of 20 December 1994**
- **Council Directive 96/55/EC (OJ L231, p20, 12/09/1996) of 4 September 1996**
- **Council Directive 97/10/EC (OJ L68, p24, 8/03/1997) of 26 February 1997**
- **Council Directive 97/16/EC (OJ L116, p31, 6/05/1997) of 10 April 1997**
- **Council Directive 97/56/EC (OJ L333, p1, 4/12/1997) of 20 October 1997**
- **Commission Directive 97/64/EC (OJ L315, p13, 19/11/1997) of 10 November 1997**
- **Council Directive 99/43/EC (OJ L166, p87, 1/07/1999) of 25 May 1999**
- **Commission Directive 99/51/EC (OJ L142, p22, 5/06/1999) of 26 May 1999**
- **Commission Directive 99/77/EC (OJ L207, p18, 6/08/1999) of 26 July 1999**
- **Commission Directive 2001/90/EC (OJ L283, p41, 27/10/2001) of 26 October 2001**
- **Commission Directive 2001/91/EC (OJ L286, p27, 30/10/2001) of 29 October 2001**
- **Directive 2002/45/EC (OJ L177, p21, 06/07/2002) of the European Parliament and of the Council of 25 June 2002**
- **Commission Directive 2002/62/EC (OJ L183, p58, 12/07/2002) of 9 July 2002**
- **Directive 2002/61/EC (OJ L243, p15, 11/09/2002) of the European Parliament and of the Council of 19 July 2002**

• NATIONAL LEGISLATION

- **European Communities (Dangerous Substances and Preparations) (Marketing and Use) Regulations, 1994 (S.I. No. 79 of 1994)**
- **European Communities (Dangerous Substances and Preparations) (Marketing and Use) Regulations, 2000 (S.I. No. 107 of 2000)**

These Regulations lay down the restrictions and conditions which must be observed in the marketing and use of the substances and preparations in the first Schedule to the Regulations and specify the powers available to inspectors in the enforcement of these conditions. They give effect to the relevant EU Directives listed above.

MANUFACTURING AND PROCESSING METHODS

Quick-Frozen Food

• EU LEGISLATION

Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption

Implementing Measures:

- **Commission Directive 92/1/EEC** (OJ L34, p28, 11/2/1992) of 13 January 1992 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption
- **Commission Directive 92/2/EEC** (OJ L34, p30, 11/2/1992) of 13 January 1992 laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption

• NATIONAL LEGISLATION

- **European Communities (Quick-Frozen Foodstuffs) Regulations 1992** (S.I. No. 290 of 1992)
- **European Communities (Monitoring of Temperature in the means of Transport, Warehousing and Storage of Quick-Frozen Foodstuffs and Sampling Procedure and Methods of Analysis for Control of the Temperatures of Quick-Frozen foods intended for human consumption) Regulations, 1995** (S.I. No. 370 of 1995)

These Regulations give effect to **Council Directive 89/108/EEC** and **Commission Directives 92/1/EEC** and **92/2/EEC**. "Quick-frozen" foodstuffs are those which

- have undergone a suitable freezing process known as 'quick-freezing' whereby the zone of maximum crystallization is crossed as rapidly as possible, depending on the type of product, and the resulting temperature of the product (after thermal stabilization) is continuously maintained at a level of -18 C or lower at all points, and
- which are marketed in such a way as to indicate that they possess this characteristic

The Regulations only apply to foodstuffs which have undergone the quick freezing process as specified. Air, nitrogen and carbon dioxide meeting specific purity criteria are the permitted cryogenic agents. The temperatures at which quick-frozen foodstuffs shall be distributed and stored, and the appropriate labelling

requirements and enforcement procedures are set out. An indication must be given as to the minimum durability of the product and the appropriate length of time that the product can be stored by the purchaser. Products should be labelled "quick-frozen". Quick-frozen foods must be packaged in pre-packaging which protects them against external contamination and drying

The Regulations also deal with the monitoring of temperature in the means of transport, warehousing and storage for quick-frozen foodstuffs intended for human consumption. Sampling procedures and methods of analysis for control of the temperatures of quick-frozen foods are also described. Manufacturers, storers, transporters, local distributors and retailers of quick frozen foodstuffs should fit their means of storage or transport with appropriate instruments for monitoring or measuring air temperature and keep appropriate records.

Foodstuffs Treated with Ionising Radiation

• EU LEGISLATION

- **Directive 1999/2/EC** (OJ L66, p16, 13/03/99) of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation
- **Directive 1999/3/EC** (OJ L66, p24, 13/03/99) of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation

• NATIONAL LEGISLATION

- **Radiological Protection Act, 1991 (No. 9 of 1991)**
- **Radiological Protection Amendment Act, 1991 (No. 3 of 2002)**
- **European Communities (Foodstuffs Treated with Ionising Radiation) Regulations, (S.I. No. 297 of 2000)**

These Regulations give effect to **Council Directive 1999/2/EC** and **1999/3/EC** setting out the rules for the irradiation of foodstuffs in Ireland.

Irradiated foods are foodstuffs which have been treated with ionising radiation according to the Regulations. The Regulations apply to the manufacture, marketing and importation of foods and food ingredients treated with ionising radiation.

They do not apply to foodstuffs exposed to ionising radiation generated by measuring or inspection devices within certain specified limits, or to foodstuffs which are prepared for patients requiring sterile diets under medical supervision.

Foods can only be irradiated where there is a reasonable technological need and benefit to the consumer and with a permitted purpose such as reducing the incidence of disease. It cannot be used as a substitute for good hygienic practices. Approved sources of ionising radiation must be used within the maximum limits. The words irradiated or treated with ionising radiation must appear on the label or packaging.

An EU-wide list of products authorised for irradiation within the EU is being developed. Currently, the only authorised group of products is dried aromatic herbs, spices and vegetable seasonings with a permitted dose of 10kiloGray (kGy). Permitted sources of ionising radiation are set down gamma rays, X-rays and electrons of certain characteristics. Foods under consideration for inclusion on the list include, chicken meat, egg white, gum arabic, frog legs and peeled shrimps.

In Ireland, the competent authorities are:

- Food Unit, Department of Health and Children for policy matters
- Radiological Protection Institute of Ireland (RPII) for irradiation facilities
- Food Safety Authority of Ireland (FSAI) for irradiated food.

The three Public Analyst Laboratories in Cork, Galway and Dublin have been identified as 'designated' laboratories for the purpose of food analysis in accordance with these Regulations.

• NATIONAL AUTHORISATIONS

Irradiation facilities used for food irradiation in Ireland must be licensed by the RPII for a licence which is known as a 'food irradiation licence'. The conditions of the licence are mainly concerned with the safety aspects of using a source of radiation and to ensure that the facility is capable of administering the appropriate dosage to the specified food.

In addition to the licence granted by the RPII, a person who proposes to irradiate food must apply to the FSAI for a permit. The 'permit' enables a person to irradiate food at the specified irradiation facility. Conditions for granting the permit will include compliance of the facility with general food hygiene requirements and compliance with the dosage limits for the foodstuffs.

The above permits and licences are valid for a period of three years, with provision for revocation where necessary.

GENETICALLY MODIFIED ORGANISMS (GMOS)

The regulatory agencies responsible for the implementation of GMO Regulations in Ireland are the Department of Agriculture and Food (DAF), the Environmental Protection Agency (EPA) and the Food Safety Authority of Ireland (FSAI). They work together under an agreed Modus Operandi (MO) ensuring the inspection, control and traceability of GMOs and their derived products. The MO makes reference to the individual responsibilities of each agency and the appropriate channels of communication between the agencies to ensure an effective control system.

DAF is the competent authority for animal feedingstuffs as well as seed used for cultivation. The EPA is responsible for regulating GM seed used for field trial evaluation (Part B of **Directive 90/220/EEC**) and for 'live' or unprocessed GM seed (until Novel Feed legislation is adopted by the EU) used for animal feed (Part C of **Directive 90/220/EEC**). The FSAI is the competent authority in Ireland for novel food and novel food ingredients, including GM food and food ingredients, and regulates their marketing and labelling through the relevant EC Regulations. The legislation governing novel foods is described in a separate section.

The State Laboratory (SL) in Abbotstown has been designated as the reference laboratory to carry out GM testing procedures as requested by the different agencies.

Contained use

• EU LEGISLATION

- **Council Directive 90/219/EEC** (OJ L117, p1, 08/05/1990) of **23 April 1990** on the contained use of genetically modified micro-organisms

Amended by:

- **Council Directive 98/81/EC** (OJ L330, p13, 5/12/1998) of **26 October 1998** on the contained use of genetically modified micro-organisms

Supplemented by:

Council Decision 2001/204/EC (OJ L73, p32, 15/03/2001) of **8 March 2001** supplementing **Directive 90/219/EEC** as regards the criteria for establishing the safety, for human health and the environment, of types of genetically modified micro-organisms

Deliberate release into the environment

Council Directive 90/220/EEC (OJ L117, p5, 08/05/90) of **23 April 1990** on the deliberate release into the environment of genetically modified organisms

Repealed from 17th October 2002 by:

Council Directive 2001/18/EC (OJ L106, p1, 17/04/2001) on the deliberate release into the environment of genetically modified organisms and repealing **Council Directive 90/220/EC**

- **Commission Decision 2002/623/EC** (OJ L200, p22, 30/07/2002) of **24 July 2002** establishing guidance notes supplementing Annex II to **Directive 2001/18/EC** of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing **Council Directive 90/220/EEC**
- **Council Decision 2002/811/EC** (OJ L280, p27, 18/10/2002) of **3 October 2002** establishing guidance notes supplementing Annex VII to **Directive 2001/18/EC** of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing **Council Directive 90/220/EEC**
- **Council Decision 2002/812/EC** (OJ L280, p37, 18/10/2002) of **3 October 2002** establishing pursuant to **Directive 2001/18/EC** of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products
- **Council Decision 2002/813/EC** (OJ L280, p62, 18/10/2002) of **3 October 2002** establishing, pursuant to **Directive 2001/18/EC** of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market

• NATIONAL LEGISLATION

- **Environmental Protection Agency Act, 1992** (No. 7 of 1992)
- **Genetically Modified Organisms Regulations, 1994** (S.I. No. 345 of 1994)
- **Genetically Modified Organisms (Amendment) Regulations, 1997** (S.I. No. 332 of 1997)
- **Genetically Modified Organisms (Contained Use) Regulations, 2001** (S.I. No. 73 of 2001)

“Contained Use”

The Regulations, **S.I. No. 73 of 2001**, give effect to **Council Directive 90/219/EEC**, as amended by **Directive 98/81/EC** on the contained use of genetically modified micro-organisms. They replace Part II of the **Genetically Modified Organisms Regulations, 1994 (S.I. No. 345 of 1997)**, and all other provisions and Schedules of those Regulations which relate to contained use activities. The EPA is the competent authority. Provision is also made in the Regulations for the establishment of an advisory committee (“Advisory Committee on Genetically Modified Organisms”) for the purpose of consultation by the EPA, and the payment of application fees and other charges to the Agency. The fundamental objective of the Regulations is to protect people and the environment from any adverse effects arising from the contained use of genetically modified organisms (GMOs). They provide for the application of various procedural matters to contained use activities such as maintaining a register of users, and notification procedures. Part II provides specifically for regulation of the contained use of genetically modified micro-organisms (GMMs), including viruses, viroids, and animal and plant cells in culture. Part III provides an updated framework for the regulation of all contained uses involving GMOs, other than GMMs such as laboratory work on genetically modified plants.

All proposed contained uses are subjected to an environmental risk assessment which must be submitted, or otherwise made available to the EPA for evaluation. Proposed contained uses of GMMs which fall into moderate and high classes of risk (classes 3 and 4 in the Regulations) may not proceed without explicit consent from the Agency.

Specific containment measures apply to all contained uses. In addition, users of GMMs are required to apply principles of good microbiological practice, and good occupational safety and hygiene, and users of GMOs are required, as appropriate, to apply good greenhouse or animal-house practice. All users are required to keep appropriate records and to submit them, or otherwise make them available, to the EPA.

Subject to limited confidentiality requirements, a register of contained uses in Ireland must be maintained by the EPA and made available to the general public.

“Deliberate Release”

The sections of **S.I. No. 345 of 1994** related to the deliberate release of GMOs into the environment, are still in place and give effect to the EU legislation governing measures applicable to the deliberate release of GMOs, namely **90/220/EEC**. Note: that 90/220 was repealed with effect from the 17 October 2002

Deliberate release covers both R & D releases and the placing of genetically modified products on the EU market. Any person wishing to make a deliberate release of a GMO must apply to the EPA for consent.

The provisions of the Regulations include notification and consent requirements, application of principles of good microbiological practice, risk assessment, reviews of consents, accident procedures, a public register of notifications and enforcement procedures. Users of GMOs are required by the Regulations to ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment. Consent to place a product, containing or consisting of GMOs, on the EU market must include conditions on the labelling and packaging of the product.

The 1997 amendment (**S.I. No. 332 of 1997**), inter alia, strengthened the labelling requirements in the case of notifications submitted to the EPA for consent to market genetically modified products.

In the case of crop plants, only ‘live’ seed/grain (i.e. capable of germinating or transferring genetic material to other plants) is regulated under the 1994 Regulations. Where genetically modified seed/grain is totally denatured in the course of processing, the resultant product does not contain viable genetically modified material and is not covered under the Regulations, e.g. oil derived from genetically modified soybeans. Such derived products are regulated under the **EU Novel Foods Regulation 258/97**.

Introduction of Directive 2001/18/EC:

Since 17th October 2002, the provisions of **Directive 2000/18/EC** have applied to the deliberate release of GMOs. The main aim of this Directive is to make the procedure for granting consent to the deliberate release and placing on the market of GMOs more efficient and more transparent. It limits such consent to a period of ten years (renewable) and introduces compulsory monitoring after GMOs have been placed on the market.

It also provides for a common methodology to assess the risks associated with the release of GMOs (set out in Annex II to the Directive), and a mechanism allowing the release of the GMOs to be modified, suspended or terminated where new information becomes available. Public consultation and GMO labelling are made compulsory.

The system of exchange of information contained in notifications, set up under **Directive 90/220/EEC**, is maintained. Under the new Directive, the Commission is obliged to consult the competent scientific committees on any question which may affect human health and/or the environment. It may also consult ethical committees.

The Directive requires registers to be established for the purpose of recording information on genetic modifications in GMOs and on the location of GMOs. Every three years, the Commission must publish a summary of the measures taken in the Member States to implement the Directive. In 2003, and every three years thereafter, the Commission must publish a report on experience with GMOs placed on the market. An annual report on ethical issues will also be published.

NOVEL FOODS AND INGREDIENTS

• EU LEGISLATION

Regulation (EC) 258/97/EC (OJ L43, p1, 14/02/1997) of 27 January 1997 concerning novel foods and novel food ingredients

Council Regulation 1139/98/EC (OJ L159, p4 03/06/1998) of 26 May 1998 concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in **Directive 79/112/EEC**

Amended by:

- **Commission Regulation 49/2000/EC** (OJ L6, p13, 11/1/2000) of 10 January 2000

Commission Recommendation 97/618/EC (OJ L253, p1, 16/09/1997) of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under **Regulation 258/97**

Commission Regulation 50/2000 (OJ L6, p15, 11/1/2000) of 10 January 2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms

Corrected by:

Corrigendum (OJ L47, p34, 19/02/2000) has been published to **Commission Regulation 50/2000** on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms

• NATIONAL LEGISLATION

These regulations have not been transposed into Irish Legislation as yet.

The Food Safety Authority of Ireland is designated as the competent authority and assessment body for the approval of novel foods and implementation of the **Novel Foods Regulation** since 1st January 2001.

The scope of **Regulation 258/97** covers a novel food, novel food ingredient or a manufacturing process, which has not, as of May 15, 1997, been consumed/available to a significant degree within the European Community. However, the European Commission has not advised what constitutes 'a significant degree', nor has the matter been considered by the European Court of Justice as yet. Unless and until this is determined, products will be considered on a case by case basis by the EC.

This Regulation governs the procedure for authorisation to market a novel food within the EU. The general criteria are that foods and food ingredients must not present a danger for the consumer, mislead him/her or be nutritionally disadvantageous compared to the product they replace. The scope of categories covered by the Regulation is described.

This Regulation applies to the placing on the market within the Community of foods and food ingredients which fall under the following categories:

- foods and food ingredients containing or consisting of genetically modified organisms
- foods and food ingredients produced from, but not containing, genetically modified organisms;
- foods and food ingredients with a new or intentionally modified primary molecular structure;
- foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;
- foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;
- foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

The EC Regulation does not apply to:

- food additives falling within the scope of **Directive 89/107/EEC**;
- flavourings for use in foodstuffs falling with the scope of **Directive 88/388/EEC**;
- extraction solvents used in the production of foodstuffs falling within the scope of **Directive 88/344/EEC**;
- processing aids such as enzymes

Novel Food Application Procedure

A company that wishes to market a novel food or food ingredient for the first time in the Community must submit an application (according to **Commission Recommendation 97/618/EC**) to the competent Authority in the relevant Member State. In Ireland, the Food Safety Authority of Ireland is the competent Authority. Once it

has been accepted, the company must also send a copy including a summary of the dossier to the European Commission.

An initial assessment of the dossier is carried out by the competent authority with the help of appropriate committee(s) of scientific experts. In Ireland, the Food Safety Authority of Ireland's scientific sub-committee for genetically modified organisms and novel foods and/or the sub-committee for nutrition are consulted. This initial assessment must be completed and sent to the EC within 90 days.

The summary of the application dossier and the initial assessment are circulated by the Commission to all the Member States for comments (which may include reasoned objections) within the following 60 days. If the initial assessment is favourable and no objections are raised by other Member States, then the applicant is notified by the Member State the product can be marketed.

Where an objection is raised, or further assessment is requested by a Member State, the case is referred to the Standing Committee on Foodstuffs (SCF) for a final decision on the application. If the SCF is unable to decide, the matter is referred to the Council of Ministers to decide on a Commission proposal.

Authorisations to place novel foods on the market

Once a final decision is made on a novel food application, a Decision is introduced, some examples follow:

- **Commission Decision 2000/195/EC** (OJ L61, p12, 8/03/2000) of **22 February 2000** authorising the placing on the market of "phospholipids from egg yolk" as a novel food or novel food ingredient under **Regulation 258/97**
- **Commission Decision 2000/500/EC** (OJ L200, p59, 8/08/2000) of **24 July 2000** on authorising the placing on the market of "yellow fat spreads with added phytosterol esters" as a novel food or novel food ingredient under **Regulation 258/97**
- **Commission Decision 2001/122/EC** (OJ L44, p46, 15/02/2001) of **30 January 2001** on authorising the placing on the market of a dextran preparation produced by *Leuconostoc mesenteroides* as a novel food ingredient in bakery products under **Regulation 258/97**
- **Commission Decision 2001/424/EC** (OJ L151, p42, 7/06/2001) of **23 May 2001** authorising the placing on the market of pasteurised fruit-based preparations produced using high-pressure pasteurisation under **Regulation 258/97**

Labelling Requirements

Novel foods labelling requirements

Article 8 of **Regulation (EC) No. 258/97** provides specific labelling requirements for novel foodstuffs in order to ensure that the final consumer is informed of the characteristics of this new food or food ingredient that renders it no longer equivalent to existing foods. The label of a novel food must declare:

- The composition of the food, its nutritional value as well as the intended use of the food. The labelling must also indicate the properties of the food that were modified and the method by which the particular characteristic was obtained,
- The fact that the novel material is not present in an existing equivalent foodstuff which may have implications for the health of certain sections of the population or which may give rise to ethical concerns,
- The presence of a Genetically Modified Organism

At present, the Commission is preparing a major review of the **Novel Foods Regulation 258/97/EC** which would remove all aspects of GMOs and GM food from 258/97. The revision will cater for GM food and feed and will include labelling rules, as well as thresholds for authorised and unauthorised adventitious contamination. It is possible that a 10-year limit may be applied to authorisations, with the option of applying for extensions.

Labelling requirements for genetically modified food

Council Regulation (EC) No. 1139/98 which was amended by **Commission Regulation (EC) No. 49/2000** contains the main labelling requirements for genetically modified food. **Council Regulation (EC) No.1139/98** Regulation details what should appear on the label of a food containing a genetically modified organism whereas **Commission Regulation (EC) No. 49/2000** details when its presence should be declared on the label

Commission Regulation (EC) No. 49/2000 amending **Council Regulation (EC) No. 1139/98**, establishes a threshold level for the adventitious or accidental contamination of non-genetically modified material below which the labelling of food or ingredients is not required. It aims to ensure that food ingredients from non-genetically modified sources do not need to be labelled as genetically modified if they contain very low levels of genetically modified material as a result of accidental contamination.

Specifically, it establishes a minimum threshold of 1% for the non-intentional introduction of material that is genetically modified. In other words, provided that the genetically modified material is present at levels below 1% and the supplier can provide evidence that the

ingredients are not of a genetically modified origin, then there is no requirement to label. This evidence could take the form of validated documentation or laboratory testing i.e. identity preservation documents at all stages throughout the food chain. This provision does not however, apply to food obtained from sources of unknown origin.

Where manufacturers cannot provide evidence that the ingredients are not genetically modified even if they are at a level of less than 1% the requirement to label according to the conditions of **Council Regulation (EC) No. 1139/98** still apply.

This Regulation also extends the labelling requirements of **Regulation (EC) No. 1139/98** to include pre-packaged foodstuffs for supply to mass caterers as well as foods for sale to the final consumer. Therefore, in the case of supply of food to mass caterers the information, including details of the genetically modified components, should appear on the commercial documents accompanying the foodstuff.

Genetically modified additives and flavourings

Commission Regulation (EC) No. 50/2000 regulates the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or that have been produced from genetically modified organisms. It details specific additional labelling requirements for food and food ingredients intended for final consumers and mass caterers.

The Regulation relates to:

- additives falling within the scope of **Directive 89/107/EEC** and/or
- flavourings for use in foodstuffs falling within the scope of **Directive 88/388/EEC** which are, contain or are produced from genetically modified organisms within the meaning of **Council Directive 90/220/EEC** on the deliberate release of genetically modified organisms.

Additives and flavourings that have been genetically modified or have been produced from genetically modified organisms that are not equivalent to their traditional counterparts are subject to these labelling requirements.

Genetically modified additives and flavourings labelling requirements

The label of the foodstuffs must inform the final consumer or mass caterers of the presence in the additives or flavourings of material which is not present in existing equivalent additives or flavourings and

- which may affect the health of certain sections of the population or
- which gives rise to ethical concerns.

The labelling requirements for additives and flavourings that are genetically modified and additives and

flavourings that contain or are produced from genetically modified organisms, are similar to the labelling rules outlined in **Regulation (EC) No. 1139/98** on the labelling of genetically modified food.

Where the additives and flavourings in a food are genetically modified: The words:

‘produced from genetically modified...’ shall appear in the list of ingredients immediately after the indication of the additive or flavouring. Alternatively this wording may appear in a prominently displayed footnote to the list of ingredients linked to the additive or flavouring concerned by way of an asterisk. The footnote must be the same size as the list of ingredients. Where the food does not contain a list of ingredients this wording shall appear clearly on the products label.

Where the additives or flavourings in a food contain or are produced from a genetically modified organism:

The words ‘genetically modified’ shall appear in the list of ingredients immediately after the indication of the additive or flavouring in question. Alternatively this wording may appear in a prominently displayed footnote to the list of ingredients linked to the additive or flavouring concerned by way of an asterisk. The footnote must be the same size as the list of ingredients. Where the food does not contain a list of ingredients this wording shall appear clearly on the products label.

The EU Commission is expected to examine the possibility of establishing a threshold level for the accidental contamination of non-genetically modified additives and flavourings. Below this level the labelling rules would not apply (similar to the provisions of **Regulation (EC) No. 49/2000**). To date no threshold has been established.

Labelling requirements for foodstuffs produced from genetically modified maize or soya

Specific labelling requirements for foodstuffs produced from genetically modified maize or soya authorised prior to implementation of **Regulation No. 258/97/EC** are set out in **Regulation 1139/98/EE** as amended.

Two indications are provided for:

- “produced from genetically modified soya/maize” (abridged as appropriate, to “genetically modified”). Where a food contains a number of ingredients, the indication must appear in parentheses immediately after the name of the ingredient concerned. Alternatively, these words may appear in a prominently displayed footnote to the list of ingredients, related to the ingredient concerned by an asterisk. In the case of products for which no list of ingredients exists, the words must appear clearly on the label.
- “contains [ingredients] produced from genetically modified soya/maize” is reserved for ingredients designated by the name of a category.

Where there is accidental contamination of non-GM foods with authorised GM material, within the minimum threshold of 1%, the labelling requirements of **1139/98/EC** do not apply. **Regulation 49/2000/EC** establishes the minimum threshold of 1% for the non-intentional contamination of non-GM material and requires the supplier to provide evidence that the ingredients are of non-GM origin. The evidence could take the form of validated documentation or laboratory testing.

This “1% threshold” applies to the individual ingredients (eg. soya and maize) and not to the final food. In cases where the final food comprises a single ingredient (eg. soya beans), the threshold obviously applies to the whole food. There is no requirement to label foods and food ingredients as GM when protein and DNA resulting from genetic modification are not present.

Regulation 49/2000/EC also extends the labelling requirements to include foodstuffs for supply to mass caterers as well as foods for sale to the final consumer.

Commission Regulation 50/2000 provides for similar labelling rules for additives and flavourings that have been genetically modified or have been produced from genetically modified organisms and contain genetically modified protein or DNA. This labelling applies to additives and flavourings in foodstuffs intended for final consumers and mass caterers. The provisions of the Regulation do not apply to additives and flavourings sold as such (in free form/bulk) to the consumer.

The EU Commission is expected to examine the possibility of setting a threshold for adventitious contamination of additives and flavourings but as yet, this has not been established. The words “produced from genetically modified...” or “genetically modified”, as appropriate, must appear in the list of ingredients in parentheses, immediately after the indication of the additive or flavouring in question, or in a prominently displayed footnote to the list of ingredients, linked to the additive or flavouring concerned by an asterisk. For foodstuffs with no list of ingredients, the wording must appear clearly on the product’s label.

• NATIONAL LEGISLATION

- **International Carriage of Perishable Foodstuffs Act, 1987 (No. 20 of 1987)**
- **International Carriage of Perishable Foodstuffs Act, 1987 (Commencement) Order, 1989 (S.I. No. 51 of 1989)**
- **International Carriage of Perishable Foodstuffs Act 1987 (Authorised Person) Order 1989 (S.I. No. 53 of 1989)**
- **International Carriage of Perishable Foodstuffs (Consolidation) Regulations, 1993 (S.I. No. 188 of 1993)**
- **International Carriage of Perishable Foodstuffs Act, 1987, (Transfer of Departmental Administration and Ministerial Functions) Order, 1993 (S.I. No. 397 of 1993)**

The Regulations give effect to the detailed requirements of two international agreements to which Ireland is a signatory, namely the ATP, or more correctly, the 'Agreement on the International Carriage of Perishable Foodstuffs and on the Special Equipment to be Used for such Carriage'. This Agreement dates from Geneva in 1970. The other is the Agreement on the Rules governing the Carriage of Frozen and Deep Frozen Foodstuffs by equipment with thin side walls, to and from Italy. It was signed in 1986.

The Regulations apply to insulated, refrigerated, mechanically refrigerated and heated transport equipment used or intended to be used, for the international carriage of perishable foodstuffs. Foodstuffs and classes of foodstuffs known as perishable foodstuffs are prescribed, as designated in the ATP. Temperature limits, standards for insulation and other requirements for transport equipment of these foods are specified. The Regulations also make provision for testing and examination of transport equipment and certification of compliance and issue of certification plates. The National Standards Authority of Ireland is the Competent Authority for certification of equipment. Additional standards apply for certain transport equipment used for the carriage of frozen or deep-frozen foodstuffs to or from Italy during the summer months each year (April to October).

MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

• EU LEGISLATION

General

Council Directive 89/109/EEC (OJ L040, p38, 11/12/1989) of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs

Implementing measures:

- **Commission Directive 80/590/EEC** (OJ L151, p42, 16/8/80) of 9 June 1980 determining the symbol that may accompany materials and articles intended to come into contact with foodstuffs

Materials Containing Vinyl Chloride Monomer

Council Directive 78/142/EEC (OJ L044, p15, 15/2/1978) of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs

Implementing measures:

- **Commission Directive 80/766/EEC** (OJ L213, p42, 16/8/1980) of 8 July 1980 laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs
- **Commission Directive 81/432/EEC** (OJ L167, p6, 24/6/1981) of 29 April 1981 laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs

Materials Containing Certain Epoxy Derivatives

Commission Directive 2001/61/EC (OJ L215, p26, 9/08/2001) of 8 August 2001 on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs (Repealed by 2002/16/EC)

Commission Directive 2002/16/EC (OJ L051, p27, 28/02/2002) of 20 February 2002 on the use of certain epoxy

derivatives in materials and articles intended to come into contact with foodstuffs

Elastomers or Rubber Teats and Soothers: Release of N-nitrosamines and N-nitrosable Substances

Commission Directive 93/11/EEC (OJ L093, p37 17/4/1993) of 5 March 1993 concerning the release of N-nitrosamines and N-nitrosable substances from elastomer or rubber teats and soothers

Ceramic Articles

Council Directive 84/500/EEC (OJ L277, p12, 20/10/1984) of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs

Plastic Material

Commission Directive 90/128/EEC (OJ L075, p19, 21/3/1990) of 23 February 1990 relating to plastic materials and articles intended to come into contact with foodstuffs (Repealed by 2002/72/EC)

A Corrigendum to **Commission Directive 1990/128/EEC of 23 February 1990** relating to plastics materials and articles intended to come into contact with foodstuffs has been published (OJ L349 , p26, 13/12/1990)

Amended by:

- **Commission Directive 92/39/EEC** (OJ L168, p21, 23/6/1992) of 14 May 1992
- **Commission Directive 93/9/EEC** (OJ L090, p26, 14/4/1993) of 15 March 1993
- **Commission Directive 95/3/EEC** (OJ L041, p44, 23/2/1995) of 14 February 1995
- **Commission Directive 96/11/EEC** (OJ L061, p26, 12/3/1996) of 5 March 1996
- **Commission Directive 99/91/EC** (OJ L310, p41, 4/12/1999) 23 November 1999
- **Commission Directive 2001/62/EC** (OJ L221, p18, 17/08/2001) of 9 August 2001

- **Commission Directive 2002/17/EC** (OJ L058, p19, 28/02/2002) of 21 February 2002

A Corrigendum to **Commission Directive 1999/91/EC** relating to plastic materials and articles intended to come into contact with foodstuffs has been published (OJ L249, p26, 4/10/00).

Repealed by:

Commission Directive 2002/72/EC (OJ L220, p18, 15/08/2002) of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs replaced 90/128/EEC and its seven amendments.

Testing Migration of Plastic Materials

Council Directive 82/711/EEC (OJ L097, p26, 23/10/1982) of 18 October 1982 laying down the basic rules necessary for the testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs.

Amended by:

- **Commission Directive 93/8/EEC** (OJ L090, p22, 14/4/1993) of 15 March 1993
- **Commission Directive 97/48/EC** (OJ L222, p10, 12/8/1997) of 29 June 1997.

Implementing measures:

- **Council Directive 85/572/EEC** (OJ L372, p14, 31/12/1985) of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs

Regenerated Cellulose Film

Commission Directive 93/10/EEC (OJ L093, p27, 17/4/1993) of 15 March 1993 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.

Amended by:

- **Commission Directive 1993/111/EC** (OJ L310, p41 14/12/1993) of 10 December 1993

• NATIONAL LEGISLATION

- **European Communities (Materials and Articles Intended to come into Contact with Foodstuffs) Regulations, 1991** (S.I. No. 307 of 1991)

- **European Communities (Materials and Articles Intended to come into Contact with Foodstuffs) (Amendment) Regulations, 1993** (S.I. No.295 of 1993)
- **European Communities (Materials and Articles Intended to come into Contact with Foodstuffs) (Amendment) (No.2) Regulations, 1994** (S.I. No. 93 of 1994)
- **European Communities (Materials and Articles Intended to come into Contact with Foodstuffs) (Amendment) Regulations, 1996** (S.I. No. 226 of 1996)
- **European Communities (Materials and Articles Intended to come into Contact with Foodstuffs) (Amendment) Regulations, 1997** (S.I. No. 335 of 1997)
- **European Communities (Materials and Articles Intended to come into Contact with Foodstuffs) (Amendment) Regulations, 1998** (S.I. No. 278 of 1998)
- **European Communities (Materials and Articles Intended to come into contact with Foodstuffs) (Amendment) Regulations, 2000** (S.I. No. 475 of 2000)
- **European Communities (Materials and Articles intended to come into contact with foodstuffs) Regulations, 2002** (S.I. No. 542 of 2002)

The foundation of the food contact materials and articles legislation is the so-called 'framework' **Directive 89/109/EEC** which sets out the scope of the legislation, the general requirements and provides for the development of directives on specific food contact materials, such as plastics, ceramics, regenerated cellulose etc. The Directive applies to all food contact materials and articles which are intended to come into contact with food and is transposed by **S.I. No. 307 of 1991**.

The general principle is that all food contact materials and articles should be manufactured using good manufacturing practices, so that in normal use they will not transfer their constituents to food in quantities which could endanger health or cause unacceptable changes in the composition of food, or a deterioration in its organoleptic properties (taste, texture, aroma and appearance).

The Regulations deal with the importation and sale of materials intended to come into contact with food, the descriptions which must accompany them and specifies labelling requirements for when materials and articles are sold for food contact use but are not already in contact with food. The Regulations can be enforced by officers of the Minister for Enterprise, Trade and Employment an officer of the Director of Consumer Affairs or a person designated by the Minister for Health and Children (usually environmental health officers (EHOs) in the health boards).

In addition to the general requirements for food contact materials, specific Directives impose more detailed restrictions for regenerated cellulose film, ceramics and plastics, vinyl chloride monomer. These more detailed requirements may include a positive list of substances, purity standards for such substances, limits on migration, appropriate methods of sampling and analysis. As EU legislation is introduced, corresponding national Regulations transpose them into Irish legislation.

Plastics

There is a 'positive list' of monomers and starting substances for use in the manufacture of food contact plastics. Plastics are broadly defined as 'organic polymers'. Many of the substances have either a prescribed 'specific migration limit' (SML) or a prescribed limit on the residual quantity left in the material or article after manufacture (QMA). Procedures for testing the migration from plastic materials have been set down. In 1995, an 'incomplete list' of additives that may be used in the manufacture of food contact plastics was compiled. Additives not on this list may be used but with the general proviso that they do not endanger health. In the longer term it is considered that the EU will arrive at a positive list of additives.

The amending Directive (**Commission Directive 2001/62/EC**) refines 'plastics' and omits silicones from the definition as they should be regarded as elastomeric materials rather than plastics. The verification of compliance with the Directive can be ascertained through the determination of the quantity of a substance in the finished material or article rather than specific migration levels under certain conditions.

The original plastics directive (**Directive 90/128/EEC**) has been amended seven times, mainly to add new substances to the list of approved monomers and starting substances or additives. The legislation was simplified by the introduction of the new plastics directive (**Directive 2002/72/EC**) which consolidated the provisions of the earlier directives.

Regenerated Cellulose Film

Only substances on the 'positive list' of substances can be used in the manufacture of coated and uncoated regenerated cellulose film. Uncoated film must not transfer adhesives or colourants at detectable quantities and coated film must not transfer ethylene glycol or di(ethylene) glycol, by themselves or together, in quantities exceeding 30 milligrams per kilogram of food.

Ceramics

Limits are set for the migration of lead and cadmium from ceramic articles which may be glazed, enamelled and/or decorated. Sampling procedures and methods of analysis are provided.

2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether ('BADGE'), bis(4-hydroxyphenyl)methane bis(2,3-epoxypropyl) ether ('BFDGE') and novolac glycidyl ethers ('NOGE')

Directive 2002/16/EC set migration limits for 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE), bis(4-hydroxyphenyl)methane bis(2,3-epoxypropyl) ether ('BFDGE') and certain derivatives thereof from epoxy coatings. The use of novolac glycidyl ethers (NOGE) is permitted until 31 December 2004. However, in practice, its use will not be possible because a very low maximum migration limit has been set.

Where a specific Directive has not yet been introduced for a given food contact material or article, then it must comply with the general provisions of the framework Directive. In due course, it is proposed to introduce Directives on elastomers and rubbers, paper and board, glass, metal and alloys, wood, including cork, textile products and microcrystalline waxes.

GENERAL PRODUCT SAFETY

• EU LEGISLATION

Council Directive 92/59/EC (OJ L228, p24, 11/08/1992)
of 29 June 1992 on general product safety

Will be repealed from 15th January 2004 by:

Directive 2001/95/EC (OJ L11, p4, 15/01/2002)
of the European Parliament and of the Council
of 3 December 2001 on general product safety

• NATIONAL LEGISLATION

- **European Community (General Product Safety) Regulations, 1997 (S.I. No.197 of 1997)**

These Regulations implement **Council Directive 92/59/EEC** on general product safety. They make it an offence to place unsafe products in the market.

A 'safe product' is defined as "any product which, under normal or reasonably foreseeable conditions of use, including duration, does not present any risk or only the minimum risks compatible with the product's use considered as acceptable and consistent with a high level of protection for the safety and health of persons".

The Regulations specify the duties of producers and distributors in relation to placing safe products in the market.

Member States are required to take measures to prohibit the distribution of products which are deemed unsafe and to organise the effective and immediate withdrawal of a dangerous product or product batch which is already on the market. They shall inform the Commission of any measures taken to prevent distribution or withdraw a product from the market. The criteria for notification to the Commission are knowledge or suspicion that a foodstuff poses a serious risk to the health and safety of consumers and the probability that the foodstuff is on the market in another Member State.

At a Community level, there are systems for the rapid exchange of information in the event of a product recall. In Ireland, the Food Safety Authority of Ireland is the contact point for the coordination of the Rapid Alert System for Food and Feeds (RASFF).

Directive 2001/95/EC enters into force on the 15th January 2004 and aims to ensure that products placed on the market are safe. The obligation to place only safe products on the market rests with producers. The products covered are those intended for consumers or likely to be used by consumers, supplied in the course of a commercial activity

or the provision of a service. Excluded from the scope of the directive are antiques and products sold with a view to being reconditioned before use, provided that the supplier informs the consumer of this. It lays down criteria designed to ensure the general safety requirement, but this does not bar Member States from taking action to withdraw or recall a product if there is evidence that, despite conformity to the criteria, the product is dangerous. The Directive also lays down the procedure for drawing up European standards, reference to which forms part of the criteria for determining product safety.

There are specific obligations placed on producers and distributors, including the obligation to cooperate with the competent authorities on action to avoid the risks posed by products which they supply. Producers must warn consumers of the risks posed by those products already supplied to them, and if necessary, recall products to avoid risks. Distributors must collaborate in tracing the products they supply. The Commission will take part in and promote a European network for product safety. There are specific provisions for exchanges of information and rapid intervention situations, in cases of serious risk.

DEFECTIVE PRODUCTS

• EU LEGISLATION

Council Directive 85/374/EEC (OJ L210 p29 07/08/1985) **of 25 July 1985** on the approximation of the laws, regulations and administrative provisions of the member states concerning liability for defective products

Amended by:

Directive 1999/34/EC (OJ L141, p20, 04/06/1999) **of 10 May 1999** on the approximation of the laws, regulations and administration provisions of the Member States concerning liability for defective products

• NATIONAL LEGISLATION

- **Liability for Defective Products Act, 1991 (No. 28 of 1991)**
- **Liability for Defective Products Act, 1991 (Commencement) Order 1991 (S.I. No. 316 of 1991)**
- **European Communities (Liability for Defective Products) Regulations 2000 (S.I. No. 401 of 2000)**

This Act introduced into Irish law the remedy of damages for negligence based on the principle of no-fault liability. Redress under the Act is by means of High Court actions. The legislation imposes liability on a producer for damage caused wholly or partly by a defect in his/her product, whether or not the producer was negligent. 'Product' means all movables, including primary agricultural products which have not undergone initial processing.

It supplements, in a very substantial way, the existing remedies available under civil law on product liability in tort or contract law, in that the plaintiff is required only to prove that the damage caused is the result of a faulty or defective product. These protections apply not only to finished products but to the producers of raw materials and compounds used in the manufacture or incorporated into the finished products.

Animal Health and Public Health Requirements

Council Directive 64/432/EC (OJ L121, p1977, 29/07/1964) of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine

Amended by:

- **Council Directive 72/462/EEC** (OJ L302, p28, 31/12/1972) of 12 December 1972
- **Council Directive 77/98/EEC** (OJ L26, p81, 31/01/1977) of 21 December 1976
- **Council Directive 75/379/EEC** (OJ L172, p17, 03/07/1975) of 24 June 1975
- **Council Directive 77/98/EEC** (OJ L26, p81, 31/01/1977) of 21 December 1976
- **Council Directive 81/476/EEC** (OJ L186, p20, 08/07/1981) of 24 June 1981
- **Council Directive 84/336/EEC** (OJ L177, p22, 04/07/1984) of 19 June 1984
- **Council Directive 84/643/EEC** (OJ L339, p27, 27/12/1984) of 11 December 1984
- **Council Decision 87/231/EEC** (OJ L99, p18, 11/04/1987) of 7 April 1987
- **Council Directive 87/489/EEC** (OJ L280, p28, 03/10/1987) of 22 September 1987
- **Council Directive 89/662/EEC** (OJ L395, p13, 30/12/1989) of 11 December 1989
- **Council Directive 90/425/EEC** (OJ L224, p29, 18/08/1990) of 25 June 1990
- **Council Directive 91/687/EEC** (OJ L377, p16, 31/12/1991) of 11 December 1991
- **Council Directive 92/65/EEC** (OJ L268, p54, 14/09/1992) of 13 July 1992
- **Council Directive 92/102/EEC** (OJ L355, p32, 5/12/1992) of 27 November 1992
- **Council Directive 98/46/EC** (OJ L198, p22, 15/07/1998) of 24 June 1998
- **Commission Regulation (EC) No 535/2002** (OJ L80, p22, 23/03/2002) of 21 March 2002
- **Council Directive 2000/15/EC** (OJ L105, p34, 3/05/2000) of 10 April 2000
- **European Parliament and of the Council Directive 2000/20/EC** (OJ L163, p35, 04/07/2000) of 16 May 2000
- **Commission Decision 2001/298/EC** (OJ L102, p63, 12/04/2001) of 30 March 2001

Council Directive 92/118/EEC (OJ L62, p49, 15/03/1993) of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to **Directive 89/662/EEC** and, as regards pathogens, to **Directive 90/425/EEC**

Amended by:

- **Commission Decision 1994/466/EC** (OJ L 190, p26 26/07/1994) of 13 July 1994
- **Commission Decision 1994/723/EC** (OJ L288, p48 09/11/1994) of 26 October 1994
- **Commission Decision 95/338/EC** (OJ L200, p35, 24/08/1995) of 26 July 1995
- **Commission Decision 95/339/EC** (OJ L200, p36, 24/08/1995) of 27 July 1995
- **Commission Decision 96/103/EC** (OJ L24, p.28, 31/01/1996) of 25 January 1996
- **Commission Decision 96/405/EC** (OJ L165, p40, 04/07/1996) of 21 June 1996
- **Council Directive 96/90/EC** (OJ L136, p24, 16/01/1997) of 17 December 1996
- **Council Directive 97/79/EC** (OJ L24, p31, 30/01/1998) of 18 December 1997
- **Commission Decision 1999/724/EC** (OJ L290, p14, 19/11/2002) of 28 October 1999
- **European Parliament and Council Directive 2002/33/EC** (OJ L315, p14, 19/11/2002) of 21 October 2002

Veterinary Checks

Third countries

Council Directive 72/462/EEC (OJ L302, p28, 31/12/1972) of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries

Amended by:

- **Council Directive 77/98/EEC** (OJ L26, p81, 31/01/1977) of 21 December 1976
- **Council Directive 83/91/EEC** (OJ L59, p34, 05/03/1983) of 7 February 1983
- **Council Directive 88/289/EEC** (OJ L124, p31, 18/05/1988) of 3 May 1988
- **Council Directive 89/227/EEC** (OJ L93, p25, 06/04/1989) of 21 March 1989

- **Council Directive 89/662/EEC** (OJ L395, p13, 30/12/1989) of **11 December 1989**
- **Council Directive 90/423/EEC** (OJ L224, p13, 18/08/1990) of **26 June 1990**
- **Council Directive 90/425/EEC** (OJ L224, p29, 18/08/1990) of **26 June 1990**
- **Council Directive 91/69/EEC** (OJ L46, p37, 19/02/1991) of **28 January 1991**
- **Council Directive 91/266/EEC** (OJ L134, p45, 29/05/1991) of **21 May 1991**
- **Council Directive 91/496/EEC** (OJ L268, p56, 24/09/1991) of **15 July 1991**
- **Council Directive 91/688/EEC** (OJ L377, p18, 31/12/1991) of **11 December 1991**
- **Council Directive 96/91/EC** (OJ L13, p26, 16/01/1997) of **17 December 1996**
- **Council Directive 97/76/EC** (OJ L10, p25, 16/01/1998) of **16 December 1997**
- **Council Directive 97/79/EC** (OJ L24, p31, 30/01/1998) of **18 December 1997**

Amended and consolidated by:

Council Directive 91/497/EEC (OJ L268, p69, 24/09/1991) of **29 July 1991** amending and consolidating **Directive 64/433/EEC** on health problems affecting intra-Community trade in fresh meat to extend it to the production and marketing of fresh meat

Council Directive 90/675/EEC (OJ L373, p1, 31/12/90) laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries

Amended by:

- **Council Directive 91/496/EEC** (OJ L268, p56, 24/09/1991) of **15 July 1991**
- **Council Decision 92/438/EEC** (OJ L243, p27, 25/08/1992) of **13 July 1992**

Implementing Measures:

Commission Decision 94/360/EC of **20 May 1994** (OJ L158, p4, 25/06/1994) on the reduced frequency of physical checks of consignments of certain products to be implemented from third countries, under Council Directive 1990/675/EEC

Amended by:

- **Commission Decision 97/139/EC** (OJ L55, p13, 25/02/1997) of **3 February 1997**
- **Commission Decision 99/609/EC** (OJ L242, p28, 14/09/1999) of **10 September 1999**

Repealed with effect from 30th June 1999 by:

Council Directive 97/78/EC (OJ L24, p9, 30/01/1998) of **18 December 1997** laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries

Implementing Measures:

Commission Decision 99/609/EC of **10 September 1999** (OJ L242 p28 14/09/1999) amending **Commission Decision 94/360/EC** concerning the reduced frequency of physical checks of consignments of certain products to be imported from third countries, under **Council Directive 97/78/E**

Commission Decision 2001/881/EC (OJ L326, p44, 11/12/2001) of **7 December 2001** drawing up a list of border inspection posts agreed for veterinary checks on animals and animal products from third countries and updating the detailed rules concerning the checks to be carried out by the experts of the Commission

Amended by:

- **Commission Decision 2002/455/EC** (OJ L155, p59, 14/06/2002) of **13 June 2002**

Commission Decision 2000/25/EC of **16 December 1999** (OJ L009, p27, 13/01/2000) establishing the detailed rules for the application of Article 9 of **Council Directive 97/78/EC** concerning the transshipment of products at a Border Inspection Post where the consignments are intended for eventual import into the European Community

Commission Decision 2000/208/EC (OJ L64, p20, 11/03/2000) of **24 February 2000** establishing detailed rules for the application of **Council Directive 97/78/EC** concerning the transit of products of animal origin from one third country to another third country by road only across the European Community

Council Directive 91/496/EEC (OJ L 268, p56, 24/09/1991) of **15 July 1991** laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending **Directives 89/662/EEC, 90/425/EEC** and **90/675/EEC**

Amended by:

- **Council Directive 91/628/EEC** (OJ L340, p17, 11/12/1991) of **19 November 1991**
- **Council Decision 92/438/EEC** (OJ L243, p1, 01/07/1996) of **13 July 1992**
- **Council Directive 96/43/EC** (OJ L162, p1, 01/07/1996) of **26 June 1996**

Implementing Measures:

Commission Decision 92/527/EEC (OJ L332, p22 18/11/1992) of **4 November 1992** laying down the model for the certificate referred to in Article 7 (1) of **Council Directive 1991/496/EEC**

Commission Decision 93/196/EEC (OJ L86, p7, 06/04/1993) of **5 February 1993** on animal health conditions and

veterinary certification for imports of equidae for slaughter

Commission Decision 94/467/EC (OJ L190, p28, 26/07/1994) of **13 July 1994** laying down health guarantees for the transport of equidae from one third country to another in accordance with Article 9 (1) (c) of **Directive 91/496/EEC**

Amended by:

- **Commission Decision 2001/662/EC** (OJ L 232, p28, 30/08/2001) of **7 August 2001**

Commission Decision 97/974/EC (OJ L323, p31, 26/11/1997) of **12 November 1997** laying down certain detailed rules for the application of **Council Directive 91/496/EEC** as regards veterinary checks on live animals to be imported from third countries

Commission Decision 98/140/EC (OJ L38, p14, 12/02/1998) of **4 February 1998** laying down detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in third countries

Intra community trade

Council Directive 89/662/EEC (OJ L395, p13, 30/12/1989) of **11 December 1989** concerning veterinary checks in intra-Community trade with a view to the completion of internal market

Amended by:

- **Council Directive 91/492/EEC** (OJ L268, p1, 24/09/1991) of **15 July 1991**
- **Council Directive 91/493/EEC** (OJ L268, p15, 24/09/1991) of **22 July 1991**
- **Council Directive 91/494/EEC** (OJ L268, p35, 24/09/1991) of **26 June 1991**
- **Council Directive 91/495/EEC** (OJ L268, p41, 24/09/1991) of **27 November 1990**
- **Council Directive 91/496/EEC** (OJ L268, p56, 24/09/1991) of **15 July 1991**
- **Council Directive 92/45/EEC** (OJ L268, p35, 14/09/1992) of **16 June 1992**
- **Council Directive 92/46/EEC** (OJ L268, p1, 14/09/1992) of **16 June 1992**
- **Council Directive 92/118/EEC** (OJ L62, p49, 15/03/1993) of **17 December 1992**

Council Directive 90/425/EEC (OJ L224, p29, 18/08/1990) of **26 June 1990** concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market

Amended by:

- **Council Directive 90/539/EEC** (OJ L303, p6, 31/10/1990) of **15 October 1990**
- **Council Directive 90/667/EEC** (OJ L363, p51, 27/12/1990) of **27 November 1990**
- **Council Directive 91/68/EEC** (OJ L46, p19, 19/02/1991) of **28 January 1991**
- **Council Directive 91/174/EEC** (OJ L85, p37, 05/04/1991) of **25 March 1991**
- **Council Directive 91/496/EEC** (OJ L268, p56, 24/09/1991) of **15 July 1991**
- **Council Directive 91/628/EEC** (OJ L340, p17, 11/12/1991) of **19 November 1991**
- **Council Directive 92/60/EEC** (OJ L268, p75, 14/09/1992) of **30 June 1992**
- **Council Directive 92/65/EEC** (OJ L268, p54, 14/09/1992) of **13 July 1992**
- **Council Directive 92/118/EEC** (OJ L62, p49, 15/03/1993) of **17 December 1992**
- **European Parliament and Council Directive 2002/33/EC** (OJ L315, p14, 19/11/2002) of **21 October 2002**

Implementing measures:

Commission Decision 94/338/EC (OJ L151, p36, 17/06/1994) of **25 May 1994** laying down detailed rules for the application of **Council Directive 90/425/EEC** as regards the taking of samples for the purpose of veterinary inspections at the place of destination

Commission Decision 94/339/EC (OJ L151, p38, 17/06/1994) of **25 May 1994** laying down detailed rules for the application of Article 9.1 of **Council Directive 90/425/EEC** concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market

Commission Decision 98/139/EC (OJ L38, p10, 12/02/1998) of **4 February 1998** laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States

Trade and Imports from Third Countries – Fresh Poultry Meat

Council Directive 91/494/EEC (OJ L26, p35, 24/09/1991) of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultry meat

Amended by:

- **Council Directive 92/116/EEC** (OJ L062, p1, 15/03/1993) of 17 December 1992
- **Council Directive 93/121/EEC** (OJ L340, p39, 31/12/1993) of 22 December 1992
- **Council Directive 99/89/EEC** (OJ L300, p17, 23/11/1999) of 15 November 1999

Implementing measures:

95/117/EC: Commission Decision 95/117/EC (OJ L80, p50, 08/04/1995) of 30 March 1995 fixing the criteria for the testing of poultry for slaughter originating in a surveillance zone for Newcastle disease, in application of Article 5 (3) of **Council Directive 91/494/EEC**

Commission Decision 94/85/EC (OJ L44, p31, 17/02/1994) of 16 February 1994 drawing up a list of third countries from which the Member States authorise imports of fresh poultry meat

Amended by:

- **Commission Decision 94/453/EC** (OJ L187, p11, 22/07/1994) of 29 June 1994
- **Commission Decision 2000/609/EC** (OJ L258, p49, 12/10/2000) of 29 September 2000
- **Commission Decision 2001/733/EC** (OJ L275, p17, 18/10/2001) of 10 October 2001

Commission Decision 94/984/EC (OJ L378 p11, 31/12/1994) of 20 December 1994 laying down animal health conditions and veterinary certificates for the importation of fresh poultry meat from certain third countries

Amended by:

- **Commission Decision 95/302/EC** (OJ L185, p50, 4/08/1995) of 13 July 1995
- **Commission Decision 96/278/EC** (OJ L114, p33, 8/05/1996) of 23 February 1996
- **Commission Decision 96/456/EC** (OJ L188, p52, 27/07/1996) of 22 July 1996
- **Commission Decision 2000/254/EC** (OJ L78, p33, 29/03/2000) of 20 March 2000
- **Commission Decision 2000/352/EC** (OJ L124, p64, 25/05/2000) of 4 May 2000

- **Commission Decision 2001/598/EC** (OJ L210, p37, 03/08/2001) of 11 July 2001

Council Directive 88/409/EEC (OJ L194, p28, 22/07/1988) of 15 June 1988 laying down the health rules applying to meat intended for the domestic market and the levels of the fees to be charged, pursuant to **Directive 85/73/EEC**, in respect of the inspection of such meat

• NATIONAL LEGISLATION

- **European Communities (Fresh Poultry Meat) Regulations, 1996** (S.I. No. 3 of 1996)
- **European Communities (Fresh Poultry Meat) Regulations, 1997** (S.I. No. 125 of 1997)
- **European Communities (Fresh Poultrymeat) (Amendment) Regulations, 2001** (S.I. No. 25 of 2001)
- **European Communities (Marketing Standards for Poultrymeat) Regulations, 2002** (S.I. No. 440 of 2002)

The Regulations, **S.I. No. 3 of 1996**, (transposing **Council Directives 71/118/EEC** and **91/116/EC**) lay down the health rules for the production and placing on the market of fresh poultry meat intended for human consumption. They require premises to comply with set standards of structural and hygienic operation. The Regulations also provide for the health marking of all fresh poultry meat produced in approved establishments and the veterinary supervision of such establishments. The conditions for approval of establishments are detailed. The Regulations do not apply to cutting and storage of fresh poultry meat in retail shops or in premises adjacent to sales points where the cutting and storage are performed solely for the purpose of supplying the consumer directly.

Exemptions, under certain conditions, are also provided for the production of fresh poultry meat by a farmer whose weekly production does not exceed 200 heads of poultry and to establishments whose total input does not exceed 200 heads of poultry. Exemptions are also provided for the annual Christmas and Easter trade in New York Dressed poultry, where the annual production is less than 10,000 head and the poultry is sold in the periods in question.

S.I. No. 125 of 1997 gives effect to **Directive 91/494/EC** covering rules for the export of poultry meat and the health marking of poultry meat and is generally concerned with the control of disease.

S.I. No. 25 of 2001 implements **Council Directive 1999/89/EC** on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultry meat with specific regard to health certificates.

S.I. No. 440 of 2002 requires compliance with European Community legislation on the marketing standards for poultry meat. These standards are set out in **Council**

Regulation No.1906/90/EEC and **Commission Regulation No.1538/91/EEC** as amended Poultry meat marketed in the EU must be graded for quality and weight and marketed, packed, labelled, transported and presented for sale in accordance with the requirements of the EU marketing standards for poultry legislation. Poultry meat may be marketed as 'free range', 'traditional free range', or 'free range total freedom' provided it meets certain criteria.

Import and Export Licences

Beef and veal sector

Commission Regulation (EC) No 1445/95 (OJ L143, p35, 27/06/1995) of **26 June 1995** on rules of application for import and export licences in the beef and veal sector and repealing **Regulation (EEC) No 2377/80**

Amended by:

- **Commission Regulation (EC) No 2365/98** (OJ L293, p49, 31/10/1998) of **30 October 1998**
- **Commission Regulation (EC) No 1659/2000** (OJ L192, p19, 28/07/2000) of **26 July 2000**
- **Commission Regulation (EC) No 24/2001** (OJ L3, p9, 06/01/2001) of **5 January 2001**
- **Commission Regulation (EC) No 2492/2001** (OJ L337, p18, 20/12/2001) of **19 December 2001**
- **Commission Regulation (EC) No 2648/98** (OJ L335, p39, 10/12/98) of **9 December 1998**

Council Directive 91/266/EC (OJ L134, p45, 29/05/1991) of **21 May 1991** on health problems affecting intra-Community trade in fresh meat, and on health and veterinary inspection problems upon importation of bovine, ovine and caprine animals and swine and fresh meat or meat products from third countries

Commission Decision 97/152/EC (OJ L59, p50, 28/02/1997) of **10 February 1997** concerning the information to be entered in the computerized file of consignments of animals or animal products from third countries which are re-dispatched

Egg sector

Commission Regulation (EC) No 1371/95 (OJ L133, p16, 17/06/1995) of **16 June 1995** laying down detailed rules for implementing the system of export licences in the egg sector

Amended by:

- **Commission Regulation(EEC) 2533/95** (OJ L258, p39, 28/10/1995) of **16 June 1995**
- **Commission Regulation (EC) No 2522/95** (OJ L258, p39, 28/10/1995) of **27 October 1995**

- **Commission Regulation 95/2840/EEC** (OJ L296, p5, 9/12/95) of **8 December 1995**
- **Commission Regulation (EC) No 2840/95** (OJ L296, p19, 27/06/1996) of **8 December 1995**
- **Commission Regulation (EC) No 1157/96** (OJ L153, p19, 27/06/1996) of **26 June 1996**
- **Commission Regulation (EC) No 1008/98** (OJ L145, p6, 15/05/1998) of **14 May 1998**
- **Commission Regulation (EC) No 2336/1999** (OJ L281, p16, 04/11/1999) of **3 November 1999**
- **Commission Regulation (EC) No 2260/2001** (OJ L305, p11, 22/11/2001) of **21 November 2001**

Certification of Animal Products

Council Directive of 96/93/EC (OJ L13, p18, 16/01/1997) of **17 December 1996** on the certification of animal products

Commission Decision 97/94/EC (OJ L29, p56, 8/01/1997) of **8 January 1997** concerning measures which are necessary for the implementation of certification rules regarding certain animal products

Border Inspection Posts

Since 1996, a Decision has been introduced which consolidates the list of agreed border inspection posts (BIPs). Veterinary checks on products and animals brought into the Community from third countries shall be carried out by the competent authorities at the agreed BIPs. Each year, every BIP shall be inspected by the Commission veterinary experts in cooperation with the competent national authorities. The amendments to the main Decision update the list of BIPs as necessary.

Commission Decision 2001/881/EC (OJ L326, p44, 11/12/2001) of **7 December 2001** drawing up a list of border inspection posts agreed for veterinary checks on animals and animal products from third countries and updating the detailed rules concerning the checks to be carried out by the experts of the Commission

Amended:

- **Commission Decision 2002/455/EC** (OJ L155, p59, 14/06/2002) of **13 June 2002**

Commission Decision 2001/812/EC (OJ L306, p28, 23/11/2001) of **21 November 2001** laying down the requirements for the approval of border inspection posts responsible for veterinary checks on products introduced into the Community from third countries

Commission Decision 2002/349/EC of 26 April 2002 (OJ L121, p0006, 08/05/2002) laying down the list of products to be examined at border inspection posts under **Council Directive 97/78/EC**

List of Third Countries – Covered by Specific Decision:

The Commission has a system of providing a list of third countries from which imports of animal products are permitted. In certain cases, Decisions are adopted governing the importation of live animals and animal products from specific countries.

Bivalves molluscs, echinoderms, tunicates and marine gastropods

Commission Decision 97/20/EC (OJ L6, p46, 10/01/97) of **17 December 1996** establishing the list of third countries fulfilling the equivalence conditions for the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods

Amended by:

- **Commission Decision 2002/469/EC** (OJ L163, p16, 21/06/2002) of **20 June 2002**

Live poultry and hatching eggs

Commission Decision 95/233/EC (OJ L156, p76, 7/07/1995) of **22 June 1995** drawing up lists of third countries from which the Member States authorise imports of live poultry and hatching eggs

Amended by:

- **Commission Decision 2001/732/EC** (OJ L275, p14, 18/10/2001) of **10 October 2001**
- **Commission Decision 2001/751/EC** (OJ L281, p24, 25/10/2002) of **16 October 2001**
- **Commission Decision 2002/183/EC** (OJ L061, p56, 02/02/2002) of **28 February 2002**

Commission Decision 96/482/EC (OJ L196, p13, 7/08/1996) of **12 July 1996** laying down animal health conditions and veterinary certificates for the importation of poultry and hatching eggs other than ratites and eggs thereof from third countries including animal health measures to be applied after such importation

Amended by:

- **Commission Decision 2002/542/EC** (OJ L176, p43, 05/07/2002) of **4 July 2002** amending **Decision 96/482/EC** as regards the length of the isolation period for imports of live poultry and hatching eggs from third countries and the animal health measures to be applied after such importation

Commission Decision 96/483/EC (OJ L196, p28, 7/08/1996) of **12 July 1996** drawing up the list of third countries entitled to use the model animal health certificates for imports into the Community of live poultry and hatching eggs other than ratites and eggs thereof as laid down by **Decision 96/482/EC**

Amended by:

- **Commission Decision 2002/183/EC** (OJ L061, p56, 09/03/1995) of **28 February 2002**

Meat products

Commission Decision 97/222/EC (OJ L89, p39, 4/04/1997) of **28 February 1997** laying down the list of third countries from which the Member States authorise the importation of meat products

Amended by:

- **Commission Decision 2002/464/EC** (OJ L161, p16, 19/06/2002) of **13 June 2002**

List of Third Countries – Not Yet Covered by Specific Decision:

Bivalves molluscs, echinoderms, tunicates and marine gastropods

Commission Decision 96/333/EC (OJ L127, p33, 25/05/1996) of **3 May 1996** establishing health certification of live bivalve molluscs, echinoderms, tunicates and marine gastropods from third countries which are not covered by a specific decision

Amended by:

- **Commission Decision 2001/65/EC** (OJ L44, p38, 24/01/2001) of **23 January 2001**

Fishery products

Commission Decision 95/328/EC (OJ L191, p32, 12/08/1995) of **25 July 1995** establishing health certification for fishery products from countries which are not yet covered by a specific decision

Amended by:

- **Commission Decision 2001/67/EC** (OJ L 022, p41, 24/01/2001) of **23 January 2001**

Third Country – Authorised Establishments

The Commission has received from certain third countries lists of establishments, with guarantees that they fully meet the appropriate Community health requirements. In the event that an establishment fails to meet these requirements its export activities to the EC will be suspended. Amendments to the main Decisions provide up to date lists.

Animal origin, fishery products or live bivalve molluscs

Commission Decision 97/296/EC (OJ L122, p21, 14/05/1997) of 22 April 1997 drawing up the list of third countries from which the import of fishery products is authorised for human consumption

Amended by:

- **Commission Decision 2002/863/EC** (OJ L301, p53, 05/11/2002) of 29 October 2002

Third Country – List of Provisionally Authorised Establishments

Animal origin, fishery products or bivalve molluscs

Council Decision 1995/408/EC (OJ L 243, p17 10/1995) of 22 June 1995 on the conditions for drawing up, for an interim period, provisional lists of third country establishments from which Member States are authorised to import certain products of animal origin, fishery products or live bivalve molluscs

Amended by:

- **Council Decision 2001/4/EC** (OJ L2, p21, 05/01/2001) of 19 December 2000

Rabbit meat and farmed game meat

Commission Decision 97/467/EC (OJ L199, p57, 26/07/1997) of 7 July 1997 drawing up provisional lists of third country establishments from which the Member States authorise imports of rabbit meat and farmed game meat

Wild game meat

Commission Decision 97/468/EC (OJ L199, p62, 26/07/1997) of 7 July 1997 drawing up provisional lists of third country establishments from which the Member States authorise imports of wild game meat

Meat products

Commission Decision 97/569/EC (OJ L234, p16, 26/08/1997) of 16 July 1997 drawing up provisional lists of third country establishments from which the Member States authorise imports of meat products

Products prepared from meat of bovine animals, swine, equidae, sheep and goats

Commission Decision 97/365/EC (OJ L154, p41, 12/06/1997) of 26 March 1997 drawing up provisional lists of third country establishments from which the Member States authorise imports of products prepared from meat of bovine animals, swine, equidae and sheep and goats

National Legislation – Intra-Community trade in Animal, Animal Products and Agricultural Products

- European Communities (Diseases of Animals Acts, 1996 and 1979 Orders) (General Authorisations for Imports) Regulations, 1985 (S.I. No. 365 of 1985)
- European Communities (General Authorisations for Exports of Agricultural Products) (S.I. No. 266 of 1992)
- European Communities (Trade in Animals and Animal Products) Regulations, 1994 (S.I. No. 289 of 1994)
- European Communities (Trade in certain animal products) Regulations, 1996 (S.I. No. 102 of 1996)
- European Communities (Trade in Bovine Animals and Swine) Regulations, 1997 (S.I. No. 270 of 1997)
- European Communities (Trade in Bovine animals and swine) (Amendment) Regulations (S.I. No. 5 of 2000)
- European Communities (Certification of Animals and Animal Products) Regulations, 1999 (S.I. No. 380 of 1999)
- European Communities (Assembly Centres) Regulations, 2000 (S.I. No. 257 of 2000)
- Diseases of Animals Act, 1966 (Control of Animal Products) Order, 2002 (S.I. No. 390 of 2002)

These Regulations deal with intra community trade, as they provide for the application of EU veterinary and zootechnical legislation to trade with other EU Member States.

Certain animals, poultry and other agricultural products require a licence when imported or exported. The Regulations make provision for the issue of general authorisations where livestock, meat and other agricultural produce are imported or exported. In the interest of disease prevention, general authorisations can include certain conditions or be revoked when necessary.

Additional rules, in the Trade of Animals and Animals Products Regulations, govern the importation and exportation of agricultural products between countries within the EU. It is stipulated that animals and agricultural products cannot be imported or exported unless, at that time, they are in compliance with the veterinary and zootechnical legislation of the European Community.

The Minister for Agriculture and Food will maintain a register of approved persons engaged in the import of animals and or animal products. Only persons on this register can engage in these activities. The powers of authorised officers are outlined. Establishments involved in the production of animal products for import/export must be registered. Specific controls apply to ensure that bovine animals and swine are free from disease to prevent the spread of disease through trade.

Certifying officers must observe certain rules when issuing certificates required by veterinary legislation.

National Legislation – Trade with Third Countries in Animal and Animal Products

- **European Communities (Importation of Animal and Animal Products from Third Countries) Regulations, 1994 (S.I. No. 255 of 1994)**
- **European Communities (Importation of Animal and Animal Products from Third Countries) Regulations, 1996 (S.I. No. 87 of 1996)**
- **European Communities (Importation of Animal and Animal Products from Third Countries) Regulations, 1996 (S.I. No. 12 of 1996)**
- **European Communities (Importation of Animal and Animal Products from Third Countries) Regulations, 1996 (S.I. No. 102 of 1996)**
- **European Communities (Veterinary Checks on Products imported from Third Countries) Regulations, 2000 (S.I. No. 292 of 2000)**

These Regulations deal with the organisation of veterinary checks on products entering Ireland from outside the EU. They also provide for the ports and airports through which agricultural products must be imported, the approval of authorised officers to implement and enforce the Regulations and the creation and prosecution of offences. Parts of **S.I. No. 255 of 1994** are repealed by **S.I. No. 292 of**

2000, in so far as they concern the products covered by the **Directive 97/78/EC**.

National Legislation – Fish

- **European Communities (Trade in Fish) Regulations, 1997 (S.I. No. 191 of 1997)**
- **European Communities (Importation of Fish from Third Countries) Regulations, 1997 (S.I. No. 192 of 1997)**

S.I. No. 191 gives effect to **Council Directives 89/662/EEC, 91/496/EEC** and **90/425/EEC** in so far as fish and fishery products are concerned. They apply to the importation and exportation of fish, bivalve molluscs, aquaculture animals and products and waste of fish and fishery products. Fish may not be imported or exported unless at that time of its importation or exportation, it is or would be in compliance with the veterinary legislation of the European Community. Under these Regulations the Minister of Communications, Marine and Natural Resources maintains a register of persons who have been approved by him as dealers in imported fish or as persons who may accept delivery as consignees of imported fish.

S.I. No. 192 gives effect to **Council Directive 90/675/EEC** and **Council Directive 91/496/EEC** insofar as they relate to fish where “fish” means fish, live bivalve molluscs, aquaculture animals and products, fishery products, waste of fish and fishery products. These regulations set out the rules for importing fish from third countries. Under these Regulations a person shall not import fish unless it is (a) landed at a port or airport specified in the Schedule, and (b) presented at the border inspection post, port or airport at which the fish is landed for the purpose of carrying out the checks required by **Council Directive 90/675** or, as may be appropriate, **Council Directive 91/496**. A person who intends to import fish shall give notice of such intention in writing to the border inspection post at the port or airport at which it is intended to land the fish at least 24 hours before such landing and shall specify in the notice the quantity or number and the type or species, country of origin and estimated date and time of landing or arrival at the inspection post of the fish.

SLAUGHTER OF ANIMALS

• EU LEGISLATION

Council Directive 93/119/EC (OJ L340, p21, 31/12/1993) of **22 December 1993** on the protection of animals at the time of slaughter or killing

• NATIONAL LEGISLATION

- **European Communities (Protection for Animals at Time of Slaughter) Regulations, 1995 (S.I. No. 114 of 1995)**

These Regulations lay down standards for the protection of animals at the time of slaughter or killing and give effect to **Council Directive 93/119/EC**. The Regulations set out the rules for the treatment of animals prior to death and for humane methods of slaughtering and killing animals both within slaughterhouses and in other locations such as farms in order to ensure that animals are spared avoidable pain and suffering.

Other relevant legislation:

- **Agriculture Produce (Fresh Meat) (Beef, Pork and Mutton) Regulations, 1930**

Third schedule lays down general welfare regulations for assembling and penning animals to be slaughtered and for slaughter in a humane manner by stunning by humane killer.

- **Slaughter of Animals Acts, 1935 to 2000**

Provides for the humane treatment of animals in slaughterhouses and for humane methods of slaughtering

- **Slaughter of Animals (Approved Instruments) Order, 1936**

Made compulsory the use of approved instruments for pre-slaughter stunning of cattle, sheep, goats, horses, asses and mules

- **Agriculture Produce (Fresh Meat) (Horse-Flesh) Regulations, 1958**

Article 5(3) provides for the humane slaughter of horses and their stunning before slaughter by means of an approved method.

- **Pigs and Bacon Act, 1935 (Part II) Regulations, 1965**

Second Schedule provides for the assembly and penning of pigs to be slaughtered and for slaughter in a humane manner.

- **Slaughter of Animals (Approved Instruments) (Pigs) Order, 1973**

Made compulsory the use of approved instruments for pre-slaughter stunning of pigs

- **European Communities (Fresh Poultry Meat) Regulations 1976 to 1988**

Give effect to **Directive 71/118/EEC** which inter alia provides for the immediate slaughter of poultry after stunning.

- **Abattoirs Act, 1988 (Abattoirs) Regulations, 1989**

Governs the manner in which animals are to be treated and slaughtered at abattoirs supplying the domestic market.

FRESH MEAT

There is a large body of legislation, both old and new applicable to the fresh meat sector. Trade in fresh meat is largely governed by **Council Directive 64/433/EEC**, now consolidated by **Directive 91/497/EEC** and amended by **Directive 95/23/EC**. These Directives have been instrumental in establishing rules for the production and marketing of fresh meat and also the import and movement of meat from various kinds of animals. (These Directives do not refer to manufactured products).

• EU LEGISLATION

Council Directive 64/433/EEC (OJ L121, p2012, 29/7/1964) of **26 June 1964** on health problems affecting intra-Community trade in fresh meat

Amended by:

- **Council Directive 66/601/EEC** (OJ L192, p3302, 27/10/1966) of **25 October 1966**
- **Council Directive 72/461/EEC** (OJ L302, p24, 31/12/1972) of **12 December 1972**
- **Council Directive 72/462/EEC** (OJ L302, p28, 31/12/1972) of **12 December 1972**
- **Council Directive 75/379/EEC** (OJ L172, p17, 03/07/1975) of **24 June 1975**
- **Council Directive 83/90/EEC** (OJ L59, p10, 05/03/1983) of **7 February 1983**
- **Council Directive 85/586/EEC** (OJ L372, p44, 05/05/1983) of **20 December 1985**
- **Council Directive 89/662/EEC** (OJ L395, p13, 30/12/1989) of **11 December 1989**
- **Council Directive 91/497/EEC** (OJ L26, p68, 24/09/1991) of **29 July 1991**
- **Council Directive 92/5/EEC** (OJ L57, p1, 02/03/1992) of **10 February 1992**
- **Council Directive 95/23/EEC** (OJ L243, p7, 11/10/1995) of **22 June 1995**

Council Directive 72/461/EEC (OJ L302, p24, 31/12/1972) of **12 December 1972** on health problems affecting intra-Community trade in fresh meat

Council Directive 88/409/EEC (OJ L 194, p28, 22/07/1988) of **15 June 1988** laying down the health rules applying to meat intended for the domestic market and the levels of the fees to be charged, pursuant to **Directive 85/73/EEC**, in respect of the inspection of such meat

Commission Decision 2001/471/EC (OJ L165, p1, 21/06/2001) of **8 June 2001** laying down rules for the regular checks on the general hygiene carried out by the operator in

establishments according to **Directive 64/433/EEC** on health conditions for the production and marketing of fresh meat and **Directive 71/118/EEC** on health problems affecting the production and placing on the market of fresh poultry meat.

Amended and consolidated by:

Council Directive 91/497/EEC (OJ L268, p69, 24/09/1991) of **29 July 1991** amending and consolidating **Directive 64/433/EEC** on health problems affecting intra-Community trade in fresh meat to extend it to the production and marketing of fresh meat

Amended by:

- **Council Directive 95/23/EC** (OJ L57, p1, 02/03/1992) of **22 June 1995**

Implementing measures:

Commission **Decision 98/139/EC** (OJ L38, p10, 12/02/1998) of **4 February 1998** laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States

Council Directive 91/498/EEC (OJ L268, p105, 24/09/1991) of **29 July 1991** on the conditions for granting temporary and limited derogations from specific Community health rules on the production and marketing of fresh meat

Corrected by:

Corrigendum (OJ L73, p29, 19/03/1992) to **Council Directive 91/498/EEC of 29 July 1991** on the conditions for granting temporary and limited derogations from specific Community health rules on the production and marketing of fresh meat

Meat plants may not operate without the approval of the Minister for Agriculture and Food. Even abattoirs producing for the domestic market must be so approved, although they fall for inspection by the veterinary officers from the local authorities. Nonetheless, the descriptions below may be of some assistance.

Fresh meat plants can be classified as follows:

- a) Slaughtering Premises: slaughter and trade in carcass or boneless form. Cutting/Boning Halls and/or cold stores are attached to many of the slaughtering premises
- b) Cutting Plants/Boning Halls: buy carcasses from slaughtering premises for cutting up as vac-pac or frozen boneless beef
- c) Cold Stores.

With the completion of the Internal Market, new rules came into force for all premises involved in the production and marketing of fresh meat and meat products. The rules apply equally to the export market and the domestic market. The new rules on fresh meat are contained in **Directives 91/497/EEC, 91/498/EEC and 95/23/EC**. The EU rules are transposed into national legislation through **S.I. No. 434 of 1997. Directive 91/497/EEC** lays down the health conditions applicable to the production and placing on the market of fresh meat intended for human consumption from domestic bovine animals, pigs, sheep, goats and domestic solipeds. The purpose of **Directive 95/23/EEC** is to simplify the rules applicable to low-capacity establishments to take account of their particular circumstances and to reduce the burden of administration (simplification of the rules governing accompanying documents).

The Regulations require premises to comply with set standards of structural and hygienic operation. All fresh meat must be produced in veterinary supervised approved establishments with appropriate health marking. Specific facilities are required for the cold storage and packaging of meat.

Cattle presented at the abattoir for slaughter must have an ear-tag affixed to its ear and be accompanied by an identity card in relation to the identity of the animal. This is to be checked by the veterinary officer prior to commencing the ante-mortem examination.

These new arrangements do not apply to the preparation and storage in retail shops or in premises adjacent to sale points of fresh meat and meat products where the preparation and storage are performed solely for the purpose of supplying the consumer directly.

Under the fresh meat Directive (**91/497/EEC**), premises are classified on throughput:

Low capacity establishments

These are abattoirs slaughtering less than 1,000 livestock units per annum; cutting plants not attached to a slaughterhouse, receiving not more than 5 tonnes of meat per week for cutting up and for placing on the wholesale market and/or dispatch to retail outlets. These outputs may trade on the domestic market.

Large scale establishments

These abattoirs slaughtering over 1,000 livestock units per annum; cutting plants, not attached to a slaughterhouse receiving over 5 tonnes of meat per week for cutting up and for placing on the wholesale meat market and/or for dispatch to retail outlets. These plants may trade on the export market.

Both low capacity and large scale establishments must comply with the operational and hygiene standards set out in the Directive. However, modified structural

requirements also apply to low capacity establishments. These establishments may operate under permanent derogation and can only trade on the national market.

Plants meeting full Directive requirements and so approved

Plants engaged in the production of meat for intra-Community trade for export must be registered by the Department of Agriculture and Food under the **Agricultural Produce (Fresh Meat) Act, 1930**, (as amended). They comply with the provisions of the aforementioned Act and the **European Communities (Fresh Meat) Regulations, 1987**.

Premises engaged in fresh meat trade

Each premises approved for intra-Community trade, (slaughterhouse, cutting plant and cold store) is under constant veterinary supervision. The Veterinary Inspector at the plant is responsible for overseeing:

- a) ante-mortem and post-mortem inspections
- b) hygiene standards in slaughtering procedures and practices
- c) the hygiene of the meat
- d) maintenance of plant and equipment.

Once satisfied that the requirements have been met, the meat is stamped with the plants Veterinary Control Number and the official veterinarian issues a health certificate.

• NATIONAL LEGISLATION

- **Agricultural Produce (Meat) (Miscellaneous Provisions) Act, 1954 (No. 33 of 1954)**
- **Agricultural Produce (Meat) (Miscellaneous Provisions) Act, 1978 (No. 13 of 1978)**
- **Agricultural Produce (Fresh Meat) Act, 1930 (No. 10 of 1930)**
- **Agricultural Produce (Fresh Meat) Act, 1931 (No. 45 of 1931)**
- **Agricultural Produce (Fresh Meat), (Amendment) Act, 1935 (No. 36 of 1935)**
- **Agricultural Produce (Fresh Meat) (Amendment) Act, 1938 (No. 1 of 1938)**
- **Agricultural Produce (Fresh Meat) (Beef Pork and Mutton), (Amendment) Regulations 1942 (S.I. No. 268 of 1942)**
- **Agricultural Produce (Fresh Meat) (Beef, Pork and Mutton) (Amendment) Regulations, 1954 (S.I. No. 145 of 1954)**
- **European Communities (Fresh Meat) Regulations, 1997 (S.I. No. 434 of 1997)**

- European Communities (Fresh Poultry Meat) Regulations, 1996 (S.I. No. 3 of 1996)
- European Communities (Fresh Poultry Meat) Regulations, 1997 (S.I. No. 125 of 1997)
- European Communities (Fresh Poultrymeat) (Amendment) Regulations, 2001 (S.I. No. 25 of 2001)

Domestic plants

- Abattoirs Act, 1988 (No. 8 of 1988)
- Abattoirs Act, 1988 (Commencement) Order, 1989 (S.I. No. 150 of 1989)
- Abattoirs Act, 1988 (Commencement) Order, 1992 (S.I. No. 88 of 1992)
- Abattoirs Act, 1988 (Amendment) Regulations, 1997 (S.I. No. 422 of 1997)
- Abattoirs Act, 1988 (Section 62(2)) (Repeal of Bye Laws) Order, 1989 (S.I. No. 151 of 1989)
- Abattoirs Act, 1988 (Abattoirs) Regulations 1989 (S.I. No. 152 of 1989)
- Abattoirs Act, 1988 (Abattoirs) (Amendment) Regulations, 1999 (S.I. No. 328 of 1999)
- Abattoirs Act, 1988 (Abattoirs) (Amendment) Regulations, 1997 (S.I. No. 424 of 1997)
- Abattoirs Act, 1998 (Abattoirs) (Amendment) Regulations, 1998 (S.I. No. 12 of 1998)
- Abattoirs (Health Mark) Regulations, 1992 (S.I. No. 90 of 1992)
- Abattoirs Act, 1988 (Health Mark) (Amendment) Regulations, 1997 (S.I. No. 423 of 1997)
- Abattoirs Act, 1988 (Veterinary Examination) Regulations, 1992 (S.I. No. 89 of 1992)
- Abattoirs Act, 1988 (Veterinary Examination) Regulations, 1997 (S.I. No. 425 of 1997)
- Abattoirs Act, 1998 (Veterinary Examination) (Amendment) Regulations, 1998 (S.I. No. 6 of 1998)
- Abattoirs Act, 1998 (Veterinary Examination) (Amendment) (No.2) Regulations, 1998 (S.I. No. 512 of 1998)
- Abattoirs Act, 1988 (Veterinary Examination) (Amendment) Regulations, 1999 (S.I. No. 327 of 1999)
- Abattoirs Act, 1988 (Veterinary Examination) (Amendment) Regulations, 2002 (S.I. No. 165 of 2002)
- Pigs and Bacon Act, 1935 (No. 24 of 1935)
- Pigs and Bacon Act, 1937 (No. 23 of 1937)
- Pigs and Bacon (Amendment) Act, 1939 (No. 35 of 1939)
- Pigs and Bacon Act, 1940 (No. 24 of 1940)
- Pigs and Bacon Act (Amendment) Act, 1956 (No. 37 of 1956)
- Pigs and Bacon Act (Amendment) Act, 1961 (No. 14 of 1961)
- Pigs and Bacon Act, 1935 (Part II) (Amendment) Regulations, 1985 (S.I. No. 259 of 1985)

National Beef Assurance Scheme

- National Beef Assurance Scheme Act, 2000 (S.I. No. 2 of 2000)
- National Beef Assurance Scheme Act, 2000 (Commencement) Order, 2000 (S.I. No. 130 of 2000)
- National Beef Assurance Act, 2000 (Commencement) Order (No.2) of 2000 (S.I. No. 414 of 2000)
- National Beef Assurance Scheme Act 2000 (Commencement) Order 2001 (S.I. No. 394 of 2001)
- National Beef Assurance Scheme Act 2000 (First Schedule) (Amendment) Order 2001
- National Beef Assurance Act, 2000 (Census) Regulations, 2000 (S.I. No. 415 of 2000)
- National Beef Assurance Scheme Act 2000 (Approval) Order 2002 (S.I. No. 422 of 2002)

The framework for a National Beef Assurance Scheme is set out in the **National Beef Assurance Scheme Act, 2000**. The purpose is to establish standards under which animals, carcasses and meat shall be produced, processed, traded and under which feedingstuffs shall be manufactured or traded. It governs the further development of the animal tracing system through the collection of data on animal movements. The scope includes the granting of certificates to persons involved in the meat business, seizure and detention of animals, identification and registration of animals and provisions for conducting a cattle census.

Fresh meat labelling

Council Directive 64/433/EEC as amended lays down the health rules for the production and placing on the market of fresh meat intended for human consumption for intra-Community trade in meat. The **European Communities (Fresh Meat) Regulations, 1997 (S.I. No. 434 of 1997)** implements these rules.

These rules contain labelling requirements for fresh meat including the requirement to indicate a health mark. However, this is not necessary where the fresh cut meat is unwrapped. For wrapped fresh cut meat produced for the domestic market a national health mark stamp may be provided instead.

HORSE MEAT

• EU LEGISLATION

Commission Decision 93/196/EEC (OJ L86, p7, 06/04/1993) of 5 February 1993 on animal health conditions and veterinary certification for imports of equidae for slaughter

Amended by:

- **Commission Decision 94/453/EC**
(OJ L187, p11, 22/07/1994) of 29 June 1994
- **Commission Decision 95/322/EC**
(OJ L190, p9, 11/08/1995) of 25 July 1995
- **Commission Decision 96/81/EC**
(OJ L19, p53, 25/01/1996) of 12 January 1996
- **Commission Decision 96/82/EC**
(OJ L19, p56, 25/01/1996) of 12 January 1996
- **Commission Decision 96/279/EC**
(OJ L107, p1, 30/04/1996) of 26 February 1996
- **Commission Decision 97/36/EC**
(OJ L14, p57, 17/01/1997) of 18 December 1996
- **Commission Decision 2001/117/EC**
(OJ L43, p38, 14/02/2001) of 26 January 2001
- **Commission Decision 2001/611/EC**
(OJ L214, p49, 08/08/2001) of 20 July 2001

• NATIONAL LEGISLATION

- **Agricultural Produce (Fresh Meat) Act, 1930 (Horse-Flesh) (Commencement) Order 1958 (S.I. No. 83 of 1958)**
- **Agricultural Produce (Fresh Meat) (Horse-Flesh) Regulations, 1958 (S.I. No. 84 of 1958)**
- **Agricultural Produce (Fresh Meat) (Horse-Flesh) (Amendment) Regulations, 1967 (S.I. No. 17 of 1967)**

These Regulations provide for the control of the slaughtering of horse, the preparation of horse-flesh for human consumption and related matters.

POULTRY AND POULTRY MEAT

Trade and Imports from Third Countries – Fresh Poultry Meat

Council Directive 91/494/EEC (OJ L26, p35, 24/09/1991) of **26 June 1991** on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultry meat

Amended by:

- **Council Directive 92/116/EEC** (OJ L062, p1, 15/03/1993) of **17 December 1992**
- **Council Directive 93/121/EEC** (OJ L340, p39, 31/12/1993) of **22 December 1992**
- **Council Directive 99/89/EEC** (OJ L300, p17, 23/11/1999) of **15 November 1999**

Implementing measures:

95/117/EC: Commission Decision 95/117/EC (OJ L80, p50, 08/04/1995) of **30 March 1995** fixing the criteria for the testing of poultry for slaughter originating in a surveillance zone for Newcastle disease, in application of Article 5 (3) of **Council Directive 91/494/EEC**

Commission Decision 94/85/EC (OJ L44, p31, 17/02/1994) of **16 February 1994** drawing up a list of third countries from which the Member States authorise imports of fresh poultry meat

Amended by:

- **Commission Decision 94/453/EC** (OJ L187, p11, 22/07/1994) of **29 June 1994**
- **Commission Decision 2000/609/EC** (OJ L258, p49, 12/10/2000) of **29 September 2000**
- **Commission Decision 2001/733/EC** (OJ L275, p17, 18/10/2001) of **10 October 2001**

Commission Decision 94/984/EC (OJ L378 p11, 31/12/1994) of **20 December 1994** laying down animal health conditions and veterinary certificates for the importation of fresh poultry meat from certain third countries

Amended by:

- **Commission Decision 95/302/EC** (OJ L185, p50, 4/08/1995) of **13 July 1995**
- **Commission Decision 96/278/EC** (OJ L114, p33, 8/05/1996) of **23 February 1996**
- **Commission Decision 96/456/EC** (OJ L188, p52, 27/07/1996) of **22 July 1996**

- **Commission Decision 2000/254/EC** (OJ L78, p33, 29/03/2000) of **20 March 2000**
- **Commission Decision 2000/352/EC** (OJ L124, p64, 25/05/2000) of **4 May 2000**
- **Commission Decision 2001/598/EC** (OJ L210, p37, 03/08/2001) of **11 July 2001**

Fresh Poultry Meat – Health Problems Affecting Trade

• EU LEGISLATION

Council Directive 71/118/EEC (OJ L55, p23, 8/3/1971) of **15 December 1971** on health problems affecting trade in fresh poultry meat

Amended and updated by:

- **Council Directive 92/116/EEC** (OJ L62, p1, 15/03/1993) of **17 December 1992** amending and updating **Directive 71/118/EEC** on health problems affecting trade in fresh poultrymeat

Amended by:

- **Council Directive 97/79/EC** (OJ L24, p31, 30/01/1998) of **18 December 1997** amending **Directives 1971/118/EEC, 1972/462/EEC, 85/73/EEC, 91/67/EEC, 1991/492/EEC, 1991/493/EEC, 1992/45/EEC** and **1992/118/EEC** as regards the organisation of veterinary checks on products entering the Community from third countries
- **Council Directive 94/65/EC** (OJ L368, p10, 31/12/1994) of **14 December 1994** laying down the requirements for the production and placing on the market of minced meat and meat preparations

Implementing Measure:

Commission Decision 2001/471/EC (OJ L165, p1, 21/06/2001) of **8 June 2001** laying down rules for the regular checks on the general hygiene carried out by the operator in establishments according to **Directive 64/433/EEC** on health conditions for the production and marketing of fresh meat and **Directive 71/118/EEC** on health problems affecting the production and placing on the market of fresh poultry meat.

Council Regulation 1906/90/EEC (OJ L173, p1, 06/07/1990) of **26 June 1990** on certain marketing standards for poultry meat in particular to classification by quality and weight, packaging, storage, transport, presentation and marketing of certain types of poultry meat

Amended by:

- **Council Regulation (EEC) 93/317**
(OJ L37, p8, 13/02/1993) of 9 February 1993
- **Council Regulation (EC) 3204/93**
(OJ L289, p3, 24/11/1993) of 16 November 1993
- **Council Regulation (EC) 1101/98**
(OJ L157, p12, 30/05/1998) of 25 May 1998

Implementing Measures:

Commission Regulation (EEC) 1538/91 (OJ L143, p11, 07/06/1991) of 5 June 1991 introducing detailed rules for implementing **Regulation 1906/90/EEC** on certain marketing standards for poultry meat

Amended by:

- **Commission Decision 2988/91/EEC**
(OJ L284 p26, 12/10/1991) of 11 October 1991
- **Commission Regulation (EEC) 315/92**
(OJ L34, p23, 11/02/1992) of 10 February 1992
- **Commission Regulation (EEC) 1980/92**
(OJ L198, p31, 17/07/1992) of 16 July 1992
- **Commission Regulation (EEC) 2891/93**
(OJ L263 p12, 22/10/1993) of 21 October 1993
- **Commission Regulation (EC) 1026/94**
(OJ L112, p32, 3/05/1994) of 2 May 1994
- **Commission Regulation (EC) 2390/95**
(OJ L244 p60, 12/10/1995) of 11 October 1995
- **Commission Regulation (EC) 205/96**
(OJ L27 p6, 3/2/1996) of 2 February 1996
- **Commission Regulation (EC) 1000/96**
(O.J L134 p9, 5/6/1996) of 4 June 1996
- **Commission Regulation (EC) 2067/96**
(OJ L277 p11 30/10/1996) of 29 October 1996
- **Commission Regulation (EC) 1072/2000**
(OJ L119, p21, 20/05/2000) of 19 May 2000
- **Commission Regulation (EC) No 1321/2002**
(OJ L194, p17, 23/07/2002) of 22 July 2002

Monitoring and control of salmonella in fowl:

Commission Decision 96/389/EC (OJ L155, p60, 28/06/1996) of 17 June 1996 approving the plan for the monitoring and control of salmonella in fowl presented by Ireland

- NATIONAL LEGISLATION

- **European Communities (Fresh Poultry Meat) Regulations, 1996** (S.I. No. 3 of 1996)
- **European Communities (Fresh Poultry Meat) Regulations, 1997** (S.I. No. 125 of 1997)

- **European Communities (Fresh Poultrymeat) (Amendment) Regulations, 2001** (S.I. No. 25 of 2001)
- **European Communities (Marketing Standards for Poultrymeat) Regulations, 2002** (S.I. No. 440 of 2002)

The Regulations, S.I. No. 3 of 1996, (transposing **Council Directives 71/118/EEC** and **91/116/EC**) lay down the health rules for the production and placing on the market of fresh poultry meat intended for human consumption. They require premises to comply with set standards of structural and hygienic operation. The Regulations also provide for the health marking of all fresh poultry meat produced in approved establishments and the veterinary supervision of such establishments. The conditions for approval of establishments are detailed. The Regulations do not apply to cutting and storage of fresh poultry meat in retail shops or in premises adjacent to sales points where the cutting and storage are performed solely for the purpose of supplying the consumer directly.

Exemptions, under certain conditions, are also provided for the production of fresh poultry meat by a farmer whose weekly production does not exceed 200 heads of poultry and to establishments whose total input does not exceed 200 heads of poultry. Exemptions are also provided for the annual Christmas and Easter trade in New York Dressed poultry, where the annual production is less than 10,000 head and the poultry is sold at the periods in question.

S.I. No. 125 of 1997 gives effect to **Directive 91/494/EC** covering rules for the export of poultry meat and the health marking of poultry meat and is generally concerned with the control of disease.

S.I. No. 25 of 2001 implements **Council Directive 1999/89/EC** on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultry meat with specific regard to health certificates.

- MARKETING STANDARDS FOR POULTRY MEAT

S.I. No. 440 of 2002 requires compliance with European Community legislation on the marketing standards for poultry meat. These standards are set out in **Council Regulation No.1906/90/EEC** and **Commission Regulation No.1538/91/EEC** as amended. Poultry meat marketed in the EU must be graded for quality and weight and marketed, packed, labelled, transported and presented for sale in accordance with the requirements of the EU marketing standards for poultry legislation. Poultry meat may be marketed as 'free range', 'traditional free range', or 'free range total freedom' provided it meets certain criteria.

Poultry chicks and hatching eggs – production and marketing

Council Regulation (EEC) No 2782/75 (OJ L282, p100, 01/11/1975) of 29 October 1975 on the production and marketing of eggs for hatching and of farmyard poultry chicks

Amended by:

- **Council Regulation (EEC) No 3494/86** (OJ L323, p1, 18/11/1996) of 13 November 1986

Implemented by:

Commission Regulation (EEC) 1868/77 (OJ L209, p1, 17/08/1977) of 29 July 1977 laying down detailed rules of application for **Regulation 2782/75** on the production and marketing of eggs for hatching and of farmyard poultry chicks

Amended by:

- **Commission Regulation (EEC) 1351/87** (OJ L127, p18, 16/05/1987) of 15 May 1987
- **Commission Regulation (EEC) 3239/94** (OJ L338, p48, 28/12/1994) of 21 December 1994

Laying hens

• EU LEGISLATION

Council Directive 88/166/EEC (OJ L74, p83, 19/03/1988) of 7 March 1988 laying down the minimum standards for the protection of laying hens kept in battery cages

Repealed by: (Repealed with effect from 1 January 2003)

Council Directive 1999/74/EC (OJ L203, p53, 03/08/1999) of 19 July 1999 laying down minimum standards for the protection of laying hens

Poultry and hatching eggs – Health conditions

Council Directive 90/539/EEC (OJ L303, p6, 31/10/1990) of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries, of poultry and hatching eggs

Amended by:

- **Council Directive 91/494/EEC** (OJ L26, p35, 24/09/1991) of 26 June 1991

- **Council Directive 91/496/EEC** (OJ L268, p56, 24/09/1991) of 15 July 1991
- **Commission Decision 92/369/EEC** (OJ L195, p25, 14/07/1992) of 24 June 1992
- **Council Directive 92/65/EEC** (OJ L268, p54, 14/09/1992) of 13 July 1992
- **Council Directive 93/120/EEC** (OJ L340, p35, 31/12/1993) of 22 December 1993
- **Council Directive 99/90/EC** (OJ L300, p19, 23/11/1999) of 15 November 1999
- **Commission Decision 2000/505/EC** (OJ L201, p8, 9/08/2000) of 25 July 2000
- **Commission Decision 2001/867/EC** (OJ L323, p29, 07/12/2001) of 3 December 2001

Commission Decision 92/140/EEC (OJ L58, p28, 3/03/1992) of 12 February 1992 approving the plan for the approval of establishments for the purposes of intra-Community trade in poultry and hatching eggs submitted by Ireland

Breeding poultry and day old chicks

Commission Decision 95/160/EC (OJ L105, p40, 9/05/1995) of 21 April 1995 establishing additional guarantees regarding salmonella for consignments to Finland and Sweden of breeding poultry and day-old chicks for introduction into flocks of breeding poultry or flocks of productive poultry

Amended by:

- **Commission Decision 97/278/EC** (OJ L110, p77, 26/04/1997) of 11 April 1997

• NATIONAL LEGISLATION

- **Poultry Hatcheries Act, 1947 (No. 49 of 1947)**
- **Fowl Pest Order, 1950 (S.I. No. 15 of 1950)**
- **Poultry Hatcheries Regulations, 1959 (S.I. No. 122 of 1959)**
- **Care and Welfare of Poultry (Laying Hens) Regulations, 1990 (S.I. No. 238 of 1990)**
- **European Communities (Live Poultry and Hatching Eggs) Regulations, 1992 (S.I. No.362 of 1992)**
- **European Communities (Live Poultry and Hatching Eggs) (Amendment) Regulations, 1995 (S.I. No. 45 of 1995)**
- **European Communities (Live Poultry and Hatching Eggs) (Amendment) Regulations, 2001 (S.I. No. 26 of 2001)**

The main Regulations, **S.I. No. 362 of 1992**, implement **Directive 90/539/EEC** on animal health conditions governing intra-Community trade in and imports from third countries of poultry and hatching eggs. These rules provide for the control and operation of poultry hatcheries, their licensing and approval and the exemption of certain classes of poultry hatcheries from the Regulations and the records to be kept at poultry hatcheries and supply farms.

The amendment Regulations provide additional provisions for the control of Newcastle disease in intra-Community trade of hatching eggs, transposing the EU **Directives 93/120/EEC** and **1999/90/EC**. All poultry hatcheries and supply farms involved in EU trade in live poultry and hatching eggs require approval from the Department. Each consignment for export must be inspected and accompanied by a health certificate signed by an official veterinarian.

Recommended Codes of Practice are set out in **S.I. No. 238 of 1990** for the minimum requirements for laying hens kept in a battery system or in an intensive unit and give effect to **Council Directive 88/166/EEC**. The Regulations also include a recommended Code of Practice for laying hens kept in a free-range system.

Eggs may also be marketed as 'free range' or as eggs produced from one of the other systems defined in the Regulation (namely, 'semi-intensive', 'deep litter' and 'perchery barn') provided they meet the criteria as defined in **Commission Regulation 1274/91/EEC**.

Eggs for the table

• EU LEGISLATION

Council Regulation 1907/90/EEC (OJ L173, p5, 6/7/1990) of **26 June 1990** on certain marketing standards for eggs

Amended by:

- **Council Regulation (EEC) 2617/93** (O.J. L240, p1, 25/9/1993) of **21 September 1993**
- **Council Regulation (EC) No 3117/94** (OJ L330, p4, 21/12/1994) of **12 December 1994**
- **Council Regulation (EC) 818/96** (OJ L111, p1, 4/05/1996) of **29 April 1996**
- **Council Regulation (EC) 5/2001** (OJ L2, p1, 5/01/2001) of **19 December 2000**

Implemented by:

Commission Regulation 1274/91/EEC (L121, p11, 16/5/1991) of **15 May 1991** and Corrigendum

Amended by:

- **Commission Regulation(EEC) 2221/92** (OJ L218, p81, 1/8/1992) of **31 July 1992**
- **Commission Regulation (EC) 3300/93** (OJ L296, p52, 1/12/1993) of **30 November 1993**
- **Commission Regulation (EC) 786/95** (OJ L79, p12, 07/04/1995) of **6 April 1995**
- **Commission Regulation (EC) 2401/95** (OJ L246, p6, 13/10/1995) of **12 October 1995**
- **Commission Regulation (EC) No 1511/96** (OJ L63, p16, 4/03/1998) of **29 July 1996**
- **Commission Regulation (EC) 505/98** (OJ L63, p16, 4/03/1998) of **3 March 1998**
- **Commission Regulation (EC) 1651/2001** (OJ L220, p1, 15/08/2001) of **14 August 2001**

• NATIONAL LEGISLATION

- **European Communities (Marketing Standards for Eggs) Regulations 1992** (S.I. No. 254 of 1992)

These Regulations implement EU Directives and provide for approved establishments for egg production purposes or as a packing centre. Collectors and collector's premises may also be approved. Approval is granted only where the conditions detailed in the EU Directives are complied with. Hen eggs marketed in the EU must be graded for quality and weight and marketed, packed, labelled, transported and presented for sale, in accordance with the Regulations. The powers of authorised officers to enforce the Regulations and the fees payable in respect of approved establishments are set down. All registered egg packing centres must pay the annual fee on 1 October each year.

Egg products

• EU LEGISLATION

Council Directive 89/437/EEC (OJ L211, p87, 22/7/1989) of **20 June 1989** on hygiene and health problems affecting the production and placing on the market of egg products

Amended by:

- **Council Directive 89/662/EEC** (OJ L395, p13, 30/12/1989) of **11 December 1989**
- **Council Directive 91/684/EEC** (OJ L376, p38, 31/12/1991) of **19 December 1991**

Commission Decision 97/38/EC (OJ L14, p61, 17/01/1997) of **18 December 1996** laying down public health requirements for the importation of egg products intended for human consumption.

- NATIONAL LEGISLATION

- **European Communities (Egg Products) Regulations, 1991 (S.I. No. 293 of 1991)**
- **European Communities (Egg Products) Regulations 1992 (S.I. No. 419 of 1992)**

These Regulations implement **Council Directive 89/437/EC** on hygiene and health problems affecting the production and placing on the market of egg products. They provide for the approval of establishments, the authorisation of officers and the prosecution of offences. The production of eggs, egg products or the packaging of eggs is prohibited except in approved premises. The Regulations do not apply to egg products that are obtained in small-scale enterprises, where the daily production does not involve the use in foodstuffs of more than 7 kilos of whole eggs. In effect, liquid eggs must be pasteurised and come from an approved premises.

The main Regulations are amended by **S.I. No. 419 of 1992** which implement **Council Directive 91/684/EEC** which refers to analytical specifications to reflect scientific and technological progress since the Directive was adopted in 1989.

GAME

Wild Game

• EU LEGISLATION

Council Directive 92/45/EEC (OJ L268, p35, 14/09/1992) of 16 June 1992 on public health and animal health problems relating to the killing of wild game and the placing on the market of wild game meat

Amended by:

- **Council Directive 92/116/EEC** (OJ L62, p1, 15/3/1993) of 17 December 1995
- **Council Directive 96/23/EC** (OJ L125, p10, 23/05/1996) of 29 April 1996
- **Council Directive 97/79/EC** (OJ L24, p31, 30/01/1998) of 18 December 1997

Commission Decision 97/468/EC (OJ L199, p62, 26/07/1997) drawing up provisional lists of third country establishments from which the Member States authorise imports of wild game meat

Amended by:

- **Commission Decision 98/369/EC** (OJ L165, p30, 10/06/1998) of 19 May 1998
- **Commission Decision 99/343/EC** (OJ L131, p70, 27/05/1999) of 25 May 1999
- **Commission Decision 2000/76/EC** (OJ L30, p33, 04/02/2000) of 17 December 1999
- **Commission Decision 2002/672/EC** (OJ L228, p26, 24/08/2002) of 21 August 2002 amending Decision 97/468/EC

• NATIONAL LEGISLATION

- **European Communities (Wild Game Meat) Regulations, 1995 (S.I. No. 298 of 1995)**

The purpose of these Regulations is to implement **EU Directive 92/45/EEC** which lays down standards for the hygienic production of wild game in approved and officially supervised establishments so as to safeguard public and animal health. The conditions for approval of establishments by the Minister for Agriculture and Food are prescribed, as are the conditions for placing game meat on the market. Health marking conditions are set down. The Regulations also deal with the condition of processing houses, imports from third countries, powers of inspection, certification, offences, penalties and enforcement. The Regulations do not apply, under certain

conditions, to a small number of wild game supplied directly by the hunter to the consumer or retailer, nor to small quantities of wild game meat supplied directly to the final consumer, nor to the cutting and storage of wild game meat in retail shops.

Farmed Game and Rabbit Meat

• EU LEGISLATION

Council Directive 91/495/EEC (OJ L268, p41, 24/9/1991) of 27 November 1990 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat

Amended by:

- **Council Directive 92/65/EEC** (OJ L268, p54, 14/09/1992) of 13 July 1992
- **Council Directive 92/116/EEC** (OJ L62, p1, 15/03/1992) of 17 December 1992
- **Council Directive 94/65/EEC** (OJ L368, p10, 31/12/1994) of 14 December 1994

Commission Decision 97/41/EC (OJ L17, p34, 21/01/1997) of 18 December 1996 establishing health conditions and a public health certificate for the importation from third countries of meat products obtained from poultry meat, farmed game meat, wild game meat and rabbit meat

Commission Decision 2000/585/EC (OJ L251, p1, 6/10/2000) of 7 September 2000 laying down animal and public health conditions and veterinary certificates for import of wild and farmed game meat and rabbit meat from third countries and repealing **Commission Decisions 97/217, 97/218, 97/219, 97/220**.

Amended by:

- **Commission Decision 2001/640/EC** (OJ L223, p28, 18/08/2001) of 2 August 2001
- **Commission Decision 2001/736/EC** (OJ L275, p32, 18/10/2001) of 17 October 2001
- **Commission Decision 2002/219/EC** (OJ L72, p27, 14/03/2002) of 7 March 2002
- **Commission Decision 2002/646/EC** (OJ L211, p23, 07/08/2002) of 31 July 2002

• NATIONAL LEGISLATION

- **Agriculture and Fishery Products (Regulation of Export) Act 1947 (Export of Poultry and Rabbits) Order 1950 (S.I. No. 302 of 1950)**
- **European Communities (Rabbit Meat and Farmed Game Meat) Regulations, 1995 (S.I. No. 278 of 1995)**

The Regulations implement **EU Directive 91/495/EEC** and cover the standards to be met in the hygienic production and marketing of farmed game meat and rabbit meat. Rabbit meat and farmed game meat establishments must be approved by the Minister for Agriculture and Food. Health marking conditions are prescribed. In certain conditions the regulations do not apply to the direct supply of rabbit meat by a small producer to a private individual for his own consumption, or to the supply of small quantities by farmers. Similar exemptions are provided for farmed game birds.

MINCED MEAT AND MEAT PREPARATIONS

• EU LEGISLATION

Council Directive 94/65/EC (OJ L368, p10, 31/12/1994) of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations

Commission Decision 2000/572/EC (OJ L240, p19, 23/09/2000) of 8 September 2000 laying down animal and public health conditions and veterinary certification for imports of minced meat and meat preparations from third countries and repealing **Decision 97/29/EC**

Commission Decision 99/710/EC (OJ L281, p82, 4/11/99) of 15 October 1999 drawing up provisional lists of third country establishments from which the Member States authorise imports of minced meat and meat preparations

Amended by:

- **Commission Decision 2000/79/EC** (OJ L30, p39, 4/02/2000) of 20 December 1999
- **Commission Decision 2000/252/EC** (OJ L78, p28, 29/03/2000) of 17 March 2000
- **Commission Decision 2000/430/EC** (OJ L170, P?? 11/07/2000) of 6 July 2000
- **Commission Decision 2001/336/EC** (OJ L120, p39, 28/04/2001) of 18 April 2001
- **Commission Decision 2002/920/EC** (OJ L321, p49, 26/11/2002) of 25 November 2002

Council Directive 97/76/EC (OJ L10, p25, 16/01/1998) of 16 December 1997 amending **Directive 77/99/EEC** and **Directive 72/462/EEC** with regard to the rules applicable to minced meat, meat preparations and certain other products of animal origin.

• NATIONAL LEGISLATION

- **European Communities (Minced Meat and Meat Preparations) Regulations, 1996 (S.I. No. 243 of 1996)**

These Regulations implement **Council Directive 94/65/EC** which deals with the requirements necessary to prepare and market minced meat. They set standards of hygiene and operation for premises producing minced meat or meat preparations either for the domestic or export market. The requirements however do not apply to minced meat prepared in retail shops and sold directly to the consumer. The Regulations prescribe the conditions which must be fulfilled before a plant can be approved, the source of meat to be minced, health marking, composition standards, (fat content, collagen to meat protein ratio),

microbiological criteria and wrapping, packing and storage conditions.

For the importation of minced meat and meat preparations from third countries, a new format for the health certificate was introduced in **Decision 2000/572/EC**. At Community level, a provisional list of establishments which comply with EU rules is maintained, imports from these establishments is authorised into the EU.

Labelling of minced meat and meat preparations

Council Directive 94/65/EC regulating the production and placing on the market of minced meat and meat preparations was implemented by **European Communities (Minced meat and meat preparations) Regulations, 1996 (S.I. No. 243 of 1996)**. These rules detail additional marking, labelling, wrapping and packaging requirements for minced meat and meat preparations.

MEAT PRODUCTS

• EU LEGISLATION

Council Directive 77/99/EEC (OJ L26, p85, 31/01/1977) of **21 December 1976** on health problems affecting intra-Community trade in meat products of **21 December 1976**

Amended by:

- **Council Directive 81/476/EEC** (OJ L186, p20, 08/07/1981) of **24 June 1981**
- **Council Directive 85/327/EEC** (OJ L168, p49, 28/06/1985) of **12 June 1985**
- **Council Directive 89/227/EEC** (OJ L93, p25, 06/04/1989) of **21 March 1989**
- **Council Directive 89/662/EEC** (OJ L395, p13, 30/12/1989) of **11 December 1989**
- **Council Directive 92/5/EEC** (OJ L57, p1, 02/03/1992) of **10 February 1992**
- **Council Directive 92/45/EEC** (OJ L268, p35, 14/09/1992) of **16 June 1992**
- **Council Directive 92/116/EEC** (OJ L62, p1, 15/03/1993) of **17 December 1992**
- **Council Directive 92/118/EEC** (OJ L62, p49, 15/03/1993) of **17 December 1992**
- **Council Directive 95/68/EEC** (OJ L332, p10, 30/12/1995) of **22 December 1995**
- **Council Directive 97/76/EC** (OJ L10, p25, 16/01/1998) of **16 December 1997**

Exceptions from Council Directive 77/99/EEC

Commission Directive 83/201/EEC (OJ L112, p28, 28/04/1983) of **12 April 1983** establishing exceptions from **Council Directive 77/99/EEC** for certain products which contain other foodstuffs and only a small percentage of meat or meat product

Amended by:

Commission Directive 83/577/EEC (OJ L334, p21, 29/11/1983) of **15 November 1983**, **Council Directive 85/327/EEC** (OJ L168, p49, 28/06/85) of **12 June 1985** amending **Directive 77/99/EEC** on health problems affecting intra-Community trade in meat products

Establishments manufacturing meat products without having an industrial structure or an industrial production capacity

Commission Decision 94/383/EC (OJ L174, p33, 8/07/1994) of **3 June 1994** on the criteria to be applied to

establishments manufacturing meat products without having an industrial structure or an industrial production capacity

Re-wrapping centres

Commission Decision 94/837/EC (OJ L352, p15, 31/12/1994) of **16 December 1994** laying down special conditions for the approval of the re-wrapping centres referred to in **Council Directive 77/99/EEC** and rules for the marketing of the products therefrom.

Council Directive 80/215/EEC (OJ L47, p4, 21/02/1980) of **22 January 1980** on animal health problems affecting intra-Community trade in meat products

• NATIONAL LEGISLATION

- **European Communities (Meat Products and Other Products of Animal Origin) Regulations, 1995** (S.I. No. 126 of 1995)
- **European Communities (Meat Products and Other Products of Animal Origin) (Amendment) Regulations, 1997** (S.I. No. 175 of 1997)
- **European Communities (Meat Products and Other Products of Animal Origin) (Amendment) Regulations, 2000** (S.I. No. 93 of 2000)
- **European Communities (Meat Products and Other Products of Animal Origin) (Amendment) Regulations, 2002** (S.I. No. 391 of 2002)
- **European Communities (Meat Products and Other Products of Animal Origin) (Amendment) (No. 2) Regulations, 2002** (S.I. No. 484 of 2002)

These Regulations transpose the EU Directives which lay down the health rules for the production and marketing of meat products and other products of animal origin intended for human consumption or for the preparation of other foodstuffs. They cover the standards of manufacturing premises and the operational procedures for hygienic production. The amendment Regulations give additional provisions on the health marking of meat products, the production conditions for stomachs, bladders and intestines and prescribe additional labelling rules.

Premises manufacturing meat products

Premises which engage in the manufacture of meat products for intra-Community trade must comply with **Directive 77/99/EEC** as amended, on health problems affecting intra-Community trade in meat products.

Meat used in the manufacture of meat products intended for intra-Community trade must have originated in a registered slaughtering premises approved under **Directive 64/433/EEC** as amended. The premises on which the product is manufactured must also be approved under **Directive 77/99/EEC** on intra-Community trade in meat products.

All meat and meat products being traded in the Community must be accompanied by a health certificate issued by a Veterinary Inspector of the Department which guarantees the fitness of the meat/products for human consumption; that the meat was derived from animals showing no evidence of infectious diseases and that random samples did not contain residues of antibiotics, hormones or other substances detrimental to human health. The meat should also be loaded and transported in hygienic conditions.

A manufacturing licence to manufacture each product is required. In this regard, the formulation/ composition of all products intended for export must be submitted to the Department of Agriculture and Food (DAF) for approval before production.

Samples of each product are taken at regular intervals and undergo micro-biological examination at DAF's Central Meat Control Laboratory at Abbotstown, Castleknock, Dublin 15.

Meat products labelling

Council Directive 77/99/EEC as amended regulates the health rules for the production and marketing of meat products and other products of animal origin intended for human consumption. The **European Communities (Meat Products and Other Products of Animal Origin) Regulations, 1995, 1997 and 2000 (S.I. No. 126 of 1995, S.I. No. 175 of 1997 and S.I. No. 93 of 2000)** implement these rules.

The 1997 amendment Regulation provides some provisions for the wrapping, packing and labelling of meat products. In addition, it details that meat products must carry a health mark and the manner and other particulars in which this marking is carried out although there are some exemptions.

- **Commission Directive 2001/101/EC** (OJ L310, p19, 28/11/2001) **of 26 November 2001**
- **Commission Directive 2002/86/EC of 6 November 2002** (OJ L 305, p.19, 07/11/2002) amending **Directive 2001/101/EC** as regards the date from which trade in products not in conformity with **Directive 2000/13/EC** of the European Parliament and of the Council is prohibited

Directive 2001/101/EC defines meat as "Skeletal muscles of mammalian and bird species recognised as fit for human consumption with naturally included or adherent tissue", where the total fat and connective tissue content does not exceed the values set out in the directive and "where it is an ingredient of another foodstuff". The definition does not apply therefore to the labelling of meat cuts and anatomical parts which are sold without further processing.

Directive 2002/86/EC allows for a transitional period of 6 months (i.e. up to 1st July 2003) to allow for operators to make the necessary changes to their labels.

Labelling of beef and beef products (including minced beef)

• EU LEGISLATION

Regulation (EC) No 1760/2000 (OJ L204, p1, 11/08/2000) **of the European Parliament and of the Council of 17 July 2000** establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing **Council Regulation (EC) No 820/97**

Implemented by:

Commission Regulation (EC) No 1825/2000 (OJ L216, p.8, 26/08/2000) **of 25 August 2000** laying down detailed rules for the application of **Regulation (EC) No 1760/2000** of the European Parliament and of the Council as regards the labelling of beef and beef products

• NATIONAL LEGISLATION

- **European Communities (Labelling of Beef and Beef Products) Regulations, 2000 (S.I. No. 435 of 2000)**
- **EC (Labelling of Beef & Beef Products) (Amendment) Regulations, 2002 (S.I. No. 485 of 2002)**

These Regulations provide that operators or organisations involved in the production or marketing of beef or veal must label their product with certain compulsory indications of traceability. The Regulations also provide for approval of additional voluntary labelling claims.

Compulsory beef labelling system

Operators or organisations are required to label beef with the following information:

- The reference number or code of the animal or group of animals from which the beef was derived
- The country of the slaughterhouse and approval number. The indication should read: 'Slaughtered in (name of country) (approval number)'.
- The country of the de-boning hall and approval number. The indication should read: 'Cutting in (name of country) (approval number)'.
- Country of birth
- All countries where fattening took place
- All countries where slaughter took place.

However, where the beef is derived from animals born, raised and slaughtered in the same country (i.e. in the same Member State or third country), the indication on the label may be given as "Origin: (name of Member State)" or "Origin: (name of third country)".

However, there is an exception to the compulsory beef labelling system for minced beef.

An operator or organisation preparing minced beef can indicate on the label:

- 'prepared in (name of country)' depending on where the meat was prepared
- 'origin (name of country)' where the country or countries of origin are not the same as the country of preparation
- a reference number or reference code ensuring the link between the meat and the animal or group of animals and
- the name of the country where the animal was slaughtered.

In addition, an operator or organisation preparing minced beef may add the following to the label:

- one or more of the compulsory indications above for beef if they wish, such as where fattening took place and
- the date on which it was prepared.

Council Directive 94/65/EC specifically regulates the production and placing on the market of minced meat and meat preparations and also contains some labelling provisions.

Operators and organisations involved in the production and marketing of beef, should arrange to implement the requirements of the compulsory beef labelling system, ensuring that a system is in place to guarantee the accuracy of the information on the labels.

Voluntary beef labelling

Council Regulation (EC) No. 1760/2000 incorporates the voluntary labelling provisions of the now repealed **Council Regulation (EC) No. 820/97** which permitted operators to put additional information on labels.

Operators wishing to place information on the label additional to the requirements of the compulsory labelling system must first submit an application for approval to the competent authority where the sale or production of the beef takes place. In Ireland it is the responsibility of DAF.

The competent authority is obliged to examine the application thoroughly, particularly to ensure that the traceability system is capable of verifying the information on the label. The costs of the controls carried out by an independent control body must be borne by the operators.

Approval by DAF of the information to be provided on the label will depend on the application submitted by the operator or organisation indicating:

- the information to be included on the label;
- the measures to be taken by the operator or organisation to ensure the accuracy of the information;
- the control system to be applied at all stages from production through to the point of sale including checks to be carried out by an independent control body designated by the applicant for this purpose. These bodies must comply with the criteria set out in European Standard EN/45011.

For example, labels wishing to contain the following type of information, relating to the animals from which the beef was produced, must be approved:

- Farm Assured / Quality Assured,
- identification number and sex,
- method of fattening,
- information on slaughtering (e.g. age at slaughter or date of slaughter)
- method or length of maturation of beef
- breed
- other information not easily checked at point of sale.

MILK

Milk and Milk Products

• EU LEGISLATION

Council Directive 92/46/EEC (OJ L 268, p1, 14/9/92) of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products

Amended by:

- **Council Directive 92/118/EEC** (OJ L62, p49, 15/03/1993) of 17 December 1992
- **Council Directive 96/23/EC** (OJ L125, p10, 23/05/1996) of 29 April 1996
- **Council Decision 94/330/EEC** (OJ L146, p23, 11/06/1994) of 25 May 1994
- **Commission Directive 94/71/EEC** (OJ L368, p33, 31/12/1994) of 13 December 1994

Council Regulation (EC) 97/2597 (OJ L351, p13, 23/12/1997) of 18 December 1997 laying down additional rules on the common organization of the market in milk and milk products for drinking milk

Amended by:

- **Council Regulation (EC) 1999/1602** (OJ L189, p43, 22/07/1999) of 19 July 1999 laying down additional rules on the common organisation of the market in milk and milk products for drinking milk.

Commission Decision 96/360/EC (OJ L138, p25, 11/06/1996) of 5 June 1996 authorising Ireland to adjust the method for calculating the somatic cell count in cows' milk

Corrected by Corrigendum to:

Commission Decision 96/360/EC (OJ L257, p44, 10/10/1996) of 5 June 1996 authorizing Ireland to adjust the method for calculating the somatic cell count in cows' milk

Council Regulation (EC) 1255/1999/EC (OJ L160, p48, 26/06/1999) of 17 May 1999 on the common organisation of the market in milk and milk products

• NATIONAL LEGISLATION

- **Milk and Dairies Act, 1935 (No. 22 of 1935)**
- **Milk and Dairies (Amendment Act), 1956 (No. 42 of 1956)**
- **Milk and Dairies Regulations, 1936 (S.I. No. 30 of 1936)**

- **Milk (Percentage of Milk-Fat and Milk-Solids) (No.2) Regulations, 1936 (S.I. No. 321 of 1936)**
- **Milk and Dairies (Special Designation) Regulations, 1938 (S.I. No. 148 of 1938)**
- **Milk and Dairies (Special Designation) (Amendment) Regulations, 1939 (S.I. No. 20 of 1939)**
- **Milk and Dairies Regulations 1936 (Amendment) Regulations, 1957 (S.I. No. 162 of 1957)**
- **European Communities (Hygienic Production and Placing on the Market of Raw Milk, Heat-Treated Milk and Milk-Based Products), Regulations, 1996 (S.I. No. 9 of 1996)**

The 1996 Regulations, S.I. No. 9 of 1996, are the cornerstone of public health protection legislation in the dairying sector. These Regulations give legal effect to **Council Directive 92/46/EEC** and its associated Directives. They are a comprehensive measure governing health protection in every aspect of the dairying industry from the animal health status of the milk yielding animals to the labelling of finished products leaving the processing plant. They apply to the milk of sheep and goats as well as that of cows. They make provision for the official inspection of milking animals, on-farm dairying facilities, processing establishments and transport and storage facilities. They also lay down microbiological criteria for milk and milk based products.

It should be noted that the standards for heat-treated drinking milk are now included in the 1996 Regulations. The additional rules set out in **Regulation 2597/97/EC** replace **S.I. No. 321 of 1986**.

These Regulations apply in lieu of those provisions of the **Dairy Produce Acts, 1924 – 1984, the Creamery Acts, 1928-1934** and the **Milk and Dairies Acts, 1935 -1956** which relate to the hygienic production and marketing of milk and milk based products.

Accordingly, only the provisions of the above Acts which do not touch on matters covered by the Regulations, (mainly administrative and commercial aspects) are now enforced. It is intended in due course to replace all outdated legislation with measures dovetailed with the Regulations.

In the meantime, the following measures remain on the Statute Books:

- **Dairy Produce Act, 1924 (No. 58 of 1924)**
- **Dairy Produce Act, 1931 (No. 29 of 1931)**
- **Dairy Produce (Amendment) Act, 1934 (No. 34 of 1934)**

- Dairy Produce (Amendment) Act, 1941 (No. 10 of 1941)
- Dairy Produce (Amendment) Act, 1947 (No. 16 of 1947)
- Dairy Produce Act, 1924 (Regulations under Part 1) Order, 1925 (S.I. No. 28 of 1924)
- Dairy Produce Act, 1924 (Regulations under Part I) (Amendment) Order, 1933 (S.I. No. 72 of 1933)
- Dairy Produce Act, 1924 (Regulations under Part III) Order No.1, 1925 (S.I. No. 51 of 1924)
- Dairy Produce Act, 1924 (Regulations under Part III) (Amendment) Order 1928 (S.I. No. 22 of 1928)
- Dairy Produce Act, 1924 (Regulations under Part III) (Amendment) Order, 1933 (S.I. No. 73 of 1933)
- Dairy Produce Act, 1924 (Regulations under Part III) (Amendment) Order, 1939 (S.I. No.129 of 1939)
- Dairy Produce Act, 1924 (Regulations under Part III) (Amendment) (No.2) Order, 1939 (S.I. No. 400 of 1939)
- Dairy Produce Act, 1924 (Regulations under Part III) (Amendment) Order, 1940 (S.I. No. 241 of 1940)
- Dairy Produce Act, 1924, (Regulations under Part III) (Amendment) Order, 1950 (S.I. No. 129 of 1950)
- Dairy Produce Act, 1924 (Regulations under Part III) (Amendment) (No.2) Order, 1950 (S.I. No. 223 of 1950)
- Dairy Produce Act, 1924 (Regulations under Part III) (Amendment) Order, 1955 (S.I. No. 129 of 1955)
- Dairy Produce Act, 1924 (Regulations under Part V) Order No.1, 1925 (S.I. No. 29 of 1925)
- Dairy Produce Act, 1924 (Regulations under Part V) Order No.2, 1924 (S.I. No. 15 of 1927)
- Dairy Produce (Price Stabilisation) Act, 1935 (S.I. No. 21 of 1935)
- Dairy Produce (Butter Returns) Regulations, 1931 (S.I. No. 56 of 1931)
- Pasteurising (Separated Milk) Regulations, 1957 (S.I. No. 196 of 1957)
- Pasteurising (Separated Milk) (Temporary Amendment) Regulations, 1959 (S.I. No. 112 of 1959)
- Creamery Act, 1928 (No. 26 of 1928)
- Creamery (Amendment) Act, 1934 (No. 33 of 1934)
- Butter Exporting (Examination) Order, 1931 (S.I. No. 44 of 1931)
- Sale of Food and Drugs (Milk) Act, 1935 (No. 3 of 1935)
- Sale of Food and Drugs (Milk Sampling) Regulations, 1936 (S.I. No. 312 of 1936)
- Sale of Food and Drugs (Milk) Act, 1936 (No. 44 of 1936)
- Milk & Dairies Act, 1935 (No. 22 of 1935)
- Milk & Dairies (Amendment) Act, 1956 (No. 42 of 1956)
- Milk & Dairies (Date of Commencement) (No.1) Order, 1936 (S.I. No. 360 of 1936)
- Milk & Dairies (Amendment) Act, 1956 (Commencement) Order, 1957 (S.I. No. 135 of 1957)
- Milk & Dairies (Amendment) Act, 1957 (Commencement) (No.2) Order, 1957 (S.I. No. 177 of 1957)
- Milk & Dairies (Amendment) Act, 1956 (Commencement) (No.3) Order, 1957 (S.I. No. 212 of 1957)
- Milk & Dairies Regulations, 1936 (S.I. No. 310 of 1936)
- Milk & Dairies Regulations, 1936 (Amendment) Regulations, 1953 (S.I. No. 108 of 1953)
- Milk & Dairies Regulations, 1936 (Amendment) Regulations, 1957 (S.I. No. 162 of 1957)
- Milk & Dairies (Amendment) Regulations, 1941 (S.I. No. 234 of 1941)
- Milk & Dairies Regulations, 1957 (S.I. No. 138 of 1957)
- Milk & Dairies (Prohibition Order), 1936 (S.I. No. 300 of 1936)
- Milk & Dairies (Milk Sampling) Regulations, 1936 (S.I. No. 38 of 1937)
- Milk & Dairies (Bacteriological Examination) Regulations, 1936 (S.I. No. 37 of 1937)
- Milk & Dairies (General Designations) Regulations, 1938 (S.I. No. 146 of 1938)
- Milk & Dairies (Special Designations) Regulations, 1938 (S.I. No. 148 of 1938)
- Milk & Dairies (Special Designations) Amendment) Regulations, 1938 (S.I. No. 20 of 1939)
- Milk & Dairies (Special Designations) (Amendment) Regulations, 1955 (S.I. No. 136 of 1955)
- Milk & Dairies (Temporary Special Designations License) Regulations, 1957 (S.I. No. 161 of 1957)

- Milk & Dairies (Infectious Diseases) Order, 1948 (S.I. No. 321 of 1948)
- Milk & Dairies (Infectious Diseases) Order, 1947 (S.I. No. 169 of 1947)
- Milk & Dairies (Application for Restriction of Sale) (Form of Notice) Regulations, 1950 (S.I. No. 39 of 1950)
- Milk & Milk Products (Restriction of Export) Order 1964 (S.I. No. 25 of 1964)
- Milk & Milk Products (Restriction of Export) (Amendment) Order, 1971 (S.I. No. 304 of 1971)
- Milk Products (Regulations of Import) Order, 1966 (S.I. No. 149 of 1966)
- Pasteurising (Separated Milk) Regulations, 1957 (S.I. No. 16 of 1957)
- Milk (Percentage of Milk-Fat and Milk-Solids) Regulations, 1935 (S.I. No. 77 of 1936)
- Milk (Percentage of Milk-Fat and Milk-Solids) (No.2) Regulations, 1936 (S.I. No. 321 of 1936)
- Processed Cheese Order, 1936 (S.I. No. 382 of 1936)
- Whey (Concentration or Condensation) Order, 1935 (S.I. No. 644 of 1935)
- Registration of Dairymen Regulations, 1936 (S.I. No. 299 of 1936)
- Creamery Butter and Butter Boxes Order, 1947 (S.I. No. 157 of 1947)
- Cooling of Creamery Butter Order, 1947 (S.I. No. 220 of 1947)
- Creamery Butter (Packaging Order), 1971 (S.I. No. 40 of 1971)
- Dairy Produce Marketing Act, 1961 (No. 1 of 1961)
- Dairy Produce Marketing Act, 1961 (Commencement) (No.2) Order, 1961 (S.I. No. 46 of 1961)
- Dairy Produce Marketing Act, 1961 (Commencement) (No.2) Order, 1961 (S.I. No. 145 of 1961)
- Dairy Produce Marketing Act, 1961 (Transfer Day) Order, 1961 (S.I. No. 146 of 1961)
- Dairy Produce (Price Stabilisation) Act, 1935 (Section 41) (Suspending) Order, 1965 (S.I. No. 47 of 1965)
- Agricultural Products (Restriction of Export) Order, 1964 (S.I. No. 26 of 1964)
- Agricultural Products (Restriction of Export of unsweetened milk powder commodities) Order, 1972 (S.I. No. 70 of 1972)
- European Communities (Dehydrated Preserved Milk) Regulations, 1980 (S.I. No. 152 of 1980)
- European Communities (Dehydrated Preserved Milk) (Amendment) Regulations, 1987 (S.I. No. 68 of 1987)
- European Communities (Dehydrated Preserved Milk) Regulations, 1990 (S.I. No. 167 of 1990)
- Milk (Regulation of Supply) Act, 1994 (No. 25 of 1994)
- Milk (Regulation of Supply) (Amendment) Act, 1995 (No. 36 of 1995)
- Milk (Regulation of Supply) (Amendment) Act, 1996 (No. 41 of 1996)

Labelling (raw milk, heat-treated milk and milk based products)

European Communities (Hygienic Production and Placing on the Market of Raw Milk, Heat-Treated Milk and Milk-Based Products) Regulations, 1996 (S.I. No. 9 of 1996) contains provisions and the conditions governing Health Marking and labelling of the products covered by the Directive. All such products carry a Health Mark. Marking must be carried out during or immediately after manufacture. The Marks must be legible, indelible and its characters easily distinguishable. The Health Marks may be applied to the product or to the wrapping if the product is individually wrapped or to a label affixed to the wrapping

Preserved Milk

• EU LEGISLATION

Council Directive 76/118/EEC (OJ L24, p49, 30/01/1976) of 18 December 1975 on the approximation of the laws of the Member States relating to the certain partly or wholly dehydrated preserved milk for human consumption

Amended by:

- Council Directive 78/630/EEC (OJ L206, p12, 29/07/1978) of 19 June 1978
- Council Directive 83/635/EEC (OJ L357, p37, 21/12/1983) of 13 December 1983.

Repealed with effect from 17 July 2003 by:

Council Directive 2001/114/EC (OJ L15, p19, 17/01/2002) of 20 December 2001 relating to certain partly or wholly dehydrated preserved milk for human consumption

First Commission Directive 79/1067/EEC (OJ L327, p29, 24/12/1979) **of 13 November 1979** laying down Community methods of analysis for testing certain partly or wholly dehydrated preserved milk for human consumption

First Commission Directive 87/524/EEC (OJ L306, p24, 28/10/1987) **of 6 October 1987** laying down Community methods of sampling for chemical analysis for the monitoring of preserved milk products.

• NATIONAL LEGISLATION

- **European Communities (Dehydrated Preserved Milk) Regulations, 1980 (S.I. No. 152 of 1980)**
- **European Communities (Dehydrated Preserved Milk) (Amendment) Regulations, 1987 (S.I. No. 68 of 1987)**
- **European Communities (Dehydrated Preserved Milk) (Amendment) Regulations, 1990 (S.I. No. 167 of 1990)**

The Regulations set down the rules relating to partly or wholly dehydrated preserved milk for human consumption. It details compositional requirements for different types of dehydrated milk, the use of reserved descriptions, manufacturing specifications and the labelling of products. Products which do not comply with these Regulations may not be marketed.

AQUACULTURE ANIMALS AND PRODUCTS

Production and Placing on the Market

Aquaculture animals and products

• EU LEGISLATION

Council Directive 91/67/EEC (OJ L76, p1, 19/02/1991) of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products

Amended by:

- **Council Directive 93/54/EC** (OJ L175, p34 19/7/1994) of 24 June 1993
- **Council Directive 95/22/EC** (OJ L243, p33 11/10/1995) of 22 June 1995
- **Council Directive 97/79/EC** (OJ L24, p31, 30/01/1998) of 18 December 1997
- **Council Directive 98/45/EC** (OJ L189, p12, 3/07/1998) of 24 June 1998

Implementing Measures:

Commission Decision 93/22/EEC (OJ L16, p8, 25/01/1993) of 11 December 1992 laying down the model of the movement documents referred to in Article 14 of **Council Directive 91/67/EEC**

Commission Decision 1999/567/EC (OJ L216, p13, 14/08/1999) of 27 July 1999 laying down the model of the certificate referred to in Article 16(1) of **Council Directive 91/67/EEC**

• NATIONAL LEGISLATION

- **European Communities (Aquaculture Animals and Fish) (Placing on the Market and Control of Certain Diseases) Regulations, 1996** (S.I. No. 253 of 1996)
- **European Communities (Aquaculture animals and fish) (Placing on the market and control of certain diseases) Regulations, 2000** (S.I. No. 377 of 2000)

S.I. No. 253 gives full effect to **Council Directive 91/67/EEC** (as amended by **Council Directive 93/54/EEC**) and **Council Directive 93/53/EEC**. **Directive 91/67/EEC** "means **Council Directive 91/67/EEC** concerning the animal health conditions governing the placing on the market of aquaculture animals and products, as amended by **Council Directive 93/54/EEC** and **95/22/EC** and read with the decisions made under that Directive referred to in Schedule 6".

Bivalve molluscs

• EU LEGISLATION

Council Directive 91/492/EEC (OJ L268, p1, 24/09/91) of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs

Amended by:

- **Council Directive 97/61/EC** (OJ L295, p35, 29/10/1997) of 20 October 1997
- **Council Directive 97/79/EC** (OJ L24, p31, 30/01/1998) of 18 December 1997

Implementing Measures:

Marine biotoxins

Commission Decision 96/77/EC (OJ L15, p46, 20/01/1996) of 18 January 1996 establishing the conditions for the harvesting and processing of certain bivalve molluscs coming from areas where the paralytic shellfish poison level exceeds the limit laid down by **Council Directive 91/492/EEC**

Commission Decision 2002/225/EC (OJ L75, p62, 16/03/2002) of 15 March 2002 laying down detailed rules for the implementation of **Council Directive 91/492/EEC** as regards the maximum levels and the methods of analysis of certain marine biotoxins in bivalve molluscs, echinoderms, tunicates and marine gastropods.

Commission Decision 2002/226/EC (OJ L75, p65, 16/03/2002) of 15 March 2002 establishing special health checks for the harvesting and processing of certain bivalve molluscs with a level of amnesic shellfish poison (ASP) exceeding the limit laid down by **Council Directive 91/492/EEC**

Microbiological criteria

Commission Decision 93/51/EEC (OJ L13, p11, 21/01/1993) of 15 December 1992 concerning the microbiological criteria applicable to the production of cooked crustacea and molluscs

Pathogenic micro organisms

Commission Decision 93/25/EEC (OJ L16, p22, 25/01/1993) of 11 December 1992 approving certain treatments to inhibit the development of pathogenic micro-organisms in bivalve molluscs and marine gastropods

Amended by:

- **Commission Decision 97/275/EC**
(OJ L108, p52, 25/04/1997) of 9 April 1997

- **NATIONAL LEGISLATION**

- **European Communities (Live Bivalve Molluscs) (Health Conditions for Production and Placing on the Market) Regulations, 1996** (S.I. No. 147 of 1996)
- **European Communities (Live Bivalve Molluscs) (Health Conditions for Production and placing on the market) (Amendment) Regulations, 2000** (S.I. No. 390 of 2000)
- **Live Bivalve Molluscs (Production Areas) (No. 2) Designation, 2002**

These Regulations give effect to **Council Directive 91/492/EEC** as amended or replaced by any regulation, directive or decision of the European Union. A person shall not place on the market live bivalve molluscs for immediate human consumption or for further processing unless they comply with the conditions specified in the Directive. The Directive is applicable whether the bivalve molluscs are of Community origin or imported from third countries. The directive also applies to echinoderms, tunicates and marine gastropods with the exceptions of the provisions on purification.

A person shall not operate a dispatch centre or a purification centre unless the centre has been approved by the Minister for Communications, Marine and Natural Resources under the process set out in the Regulations. Provision is made for the designation of production areas and their approval, the operation of laboratories and their official approval.

Under the regulations a person shall not operate a laboratory for use by a person operating a dispatch centre or a purification centre unless the laboratory has been approved by the Minister.

The Production Area Designation is made pursuant to Regulation 8(1) of **S.I. No.147 of 1996** and sets out production areas, their classification and the species to be harvested from that area. As Designations are made on average twice a year, please contact the Sea Fisheries Administration and Harbour Division of the Department of Communications, Marine and Natural Resources (DCMNR) for the most up to date Designation.

Under **S.I. No. 390 of 2000**, the Minister for Communications, Marine and Natural Resources can prohibit the production or harvesting of live bivalve molluscs from a designated area or any other area of the sea which the Minister considers is unsuitable for these activities for health reasons. The Statutory Instrument sets out the provisions for the publication of an approval or withdrawal or restriction of a designated area.

Labelling of fishery and aquaculture products

Council Regulation (EC) No. 104/2000 regulates the common organisation of the markets in fishery and aquaculture products. **Commission Regulation (EC) No. 2065/2001** lays down the rules for the application of **Council Regulation (EC) No. 104/2000** as regards informing consumers about fishery and aquaculture products.

These Regulations have been applicable in Ireland since 1st January 2002. National Regulations to impose penalties and give enforcement powers to particular authorities for the implementation of these EU Regulations are currently being drafted.

A guidance document to these Regulations entitled 'Guidance Note No.7 – The labelling of Fish and Aquaculture Products according to Council Regulation (EC) No. 104/2000 and Commission Regulation (EC) No. 2065/2001' was drawn up by the Food Safety Authority of Ireland in conjunction with DCMNR and Bord Iascaigh Mhara. The guide which specifically details the labelling and packaging requirements for fishery and aquaculture products and the traceability of such products should be consulted for a more detailed guide to the legislation.

There is a minimum amount of information that must be provided on the label where fishery products are sold at retail level to consumers. In addition, for the purposes of traceability this information must be included on the commercial documents for the fishery products throughout the marketing chain, such as during processing, at wholesale level and for use by mass caterers.

FISHERY PRODUCTS

Production and Placing on the Market

• EU LEGISLATION

Council Directive 91/493/EEC (OJ L268, p15, 24/09/1991) of 22 July 1991 laying down the health conditions for the production and placing on the market of fishery products.

Amended by:

- **Council Directive 95/71/EC** (OJ L332, p40, 30/12/1995) of 22 December 1995
- **Council Directive 97/79/EC** (OJ L24, p31, 30/01/1998) of 18 December 1997

Implementing Measures:

- **Council Directive 92/48/EEC** (OJ L187, p41, 07/07/1992) of 16 June 1992 laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with Article 3(1)(a)(i) of **Directive 91/493/EEC**
- **Council Decision 93/140/EEC** (OJ L56, p42, 09/03/1993) of 19 January 1993 laying down the detailed rules relating to the visual inspection of detecting parasites in fishery products
- **Commission Decision 94/356/EEC** (OJ L1, p220, 03/01/1994) of 20 May 1994 laying down detailed rules for the application of **Council Directive 91/493/EEC** as regards own health checks on fishery products
- **Council Directive 95/71/EEC** (OJ L332, p40, 30/12/1995) of 22 December 1995 fixing sanitary rules governing the production and placing on the market of fishery products
- **Commission Decision 95/149/EC** (OJ L97, p84, 29/04/1995) of 8 March 1995 fixing the total volatile basic nitrogen (TVB-N) limit values for certain categories of fishery products and specifying the analysis methods to be used
- **Commission Regulation (EC) No 466/2001** (OJ L77, p1, 16/03/2001) of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs

Corrected by:

Corrigendum (OJ L313, p60, 30/11/2001) to **Council Regulation (EC) No 466/2001 of 8 March 2001** setting maximum levels for certain contaminants in foodstuffs

- **European Communities (Fishery Products) (Health Conditions and Hygiene Rules for Production and Placing on the Market) Regulations, 1996** (S.I. No. 170 of 1996)

These Regulations give effect to **Council Directive 91/493/EEC** and **92/48/EEC** as amended or replaced by any regulation, directive or decision of the EC. Fishery products must not be placed on the market except in compliance with these Regulations. **Directive 91/493/EEC** applies to products of Community origin or those imported from third countries.

A person may not engage in activities associated with the placing on the market of fishery products for human consumption unless the premises from which the activities are undertaken consist of an establishment or factory vessel approved or an auction market or wholesale market registered pursuant to the Regulations. The conditions for official approval are set out in the Regulations. A person responsible for an establishment must carry out a system of own checks in accordance with Article 6 of **Directive 91/493/EC**.

Regulation 13 of S.I. No. 170 of 1996 details the process for the approval of laboratories for use by a person operating an establishment, factory vessel, wholesale market, auction market or vessel engaged in the cooking of shrimps and molluscs on board or a fishing vessel to which **Council Directive 91/493/EC** applies. Only detergents, disinfectant and similar substances which have been approved of by the Minister of Communications, Marine and Natural Resources may be used in these premises.

Conditions applicable to factory vessels, requirements during and after landing, conditions for establishments on land, handling fishery products on shore, health control and monitoring of production conditions, packaging, identification marks, storage and transport are set out in Annex 1 of the Directive.

BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) /SPECIFIED RISK MATERIALS (SRM)

• EU LEGISLATION

Regulation (EC) No 999/2001 (OJ L147, p1, 31/05/2001) of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

Amended by:

- **Commission Regulation (EC) No 1248/2001** (OJ L173, p12, 27/06/2001) of 22 June 2001 Annexes III, X and XI to **Regulation (EC) No 999/2001** of the European Parliament and of the Council as regards epidemic-surveillance and testing of transmissible spongiform encephalopathies
- **Commission Regulation (EC) No 1326/2001** (OJ L177, p60, 30/06/2001) of 29 June 2001 laying down transitional measures to permit the changeover to the Regulation of the European Parliament and of the Council **(EC) No 999/2001** laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, and amending Annexes VII and XI to that Regulation
- **Commission Regulation (EC) No 270/2002** (OJ L45, p4, 15/05/2002) of 14 February 2002 amending **Regulation (EC) No 999/2001** of the European Parliament and of the Council as regards specified risks material and epidemic-surveillance for transmissible spongiform encephalopathies and amending **Regulation (EC) No 1326/2001** as regards animal feeding and the placing on the market of ovine and caprine animals and products thereof
- **Commission Regulation (EC) No 1494/2002** (OJ L225, p3, 22/08/2002) of 21 August 2002 amending Annexes III, VII and XI to **Regulation (EC) No 999/2001** of the European Parliament and the Council as regards monitoring of bovine spongiform encephalopathy, eradication of transmissible spongiform encephalopathy, removal of specified risk materials and rules for importation of live animals and products of animal origin

• IRISH LEGISLATION

- **Diseases of Animals (BSE) (Specified Risk Material) (Amendment) Order 1998** (S.I. No. 144 of 1998)
- **Diseases of Animals (BSE) Order, 1996 (Revocation) Order, 1998** (S.I. No. 174 of 1998)

- **Diseases of Animals (Bovine Spongiform Encephalopathy) (Specified Risk Material) Order, 2000** (S.I. No. 331 of 2000)
- **EC (Specified Risk Material) Regulations, 2000** (S.I. No. 332 of 2000)
- **EC (Specified Risk Material) Regulations, 2001** (S.I. No. 24 of 2001)
- **Diseases of Animals (Bovine Spongiform Encephalopathy) (Specified Risk Material) Order, 2001** (S.I. No. 31 of 2001)

Regulation (EC) 999/2001 has been applicable as of 1 July 2001. It provides for measures (a) targeting all animal and public health risks resulting from all animal transmissible spongiform encephalopathies (TSEs), and (b) governing the entire chain of production and placing on the market of live animals and products of animal origin.

It consolidates the rules for the monitoring of TSEs in bovine, ovine and caprine animals, the removal of specified risk material and prohibitions concerning animal feeding. It also provides for the procedure, criteria and categories for the classification of countries according to BSE status.

• REMOVAL OF SPECIFIED RISK MATERIALS

Specified risk materials (SRM) are defined as the animal tissues being most at risk of harbouring the TSE agent. By way of precaution, these tissues must be removed from the food and feed chains to avoid the risk of recycling the TSE agent.

Commission Regulation (EC) No. 270/2002, Annex XI as amended by **Commission Regulation (EC) No 1494/2002** defines the following tissues as specified risk material:

- i) the skull including the brain and eyes, the tonsils, the vertebral column excluding the vertebrae of the tail, the transverse processes of the lumbar and thoracic vertebrae and the wings of the sacrum, but including dorsal root ganglia and spinal cord, of bovine animals aged over 12 months, and the intestines from the duodenum to the rectum and the mesentery of bovine animals of all ages.
- ii) the skull including the brain and eyes, the tonsils and the spinal cord of ovine and caprine animals aged over 12 months or which have a permanent incisor erupted through the gum, and the spleen of ovine and caprine animals of all ages.

All specified risk material shall be stained with a dye or, as appropriate, marked immediately on removal, and completely destroyed:

- a) by incineration without pre-processing, or
- b) after pre-processing:
 - i. in accordance with the systems described in Chapters I to IV, VI and VII of the Annex to **Decision 92/562/EEC**:
 - by incineration
 - by co-incineration;
 - ii. in accordance at least with the standards set out in Annex I to **Decision 1999/534/EC**, by burial in an approved landfill site.

The pre-processed material shall be re-stained or, as appropriate, re-marked if the dye is no longer visible or the marker no longer detectable.

These measures also apply to the production and placing on the market of a wide range of animal products.

WATER

Drinking water

• EU LEGISLATION

- **Council Directive 80/778/EEC** (OJ L229, p11, 30/08/1980) of 15 July 1980 relating to the quality of water for human consumption

Amended by:

- **Council Directive 91/692/EEC** (OJ L377, p48, 31/12/1991) of 23 December 1991 standardising and rationalising reports on the implementation of certain Directives relating to the environment

Repealed from January 2004 by:

- **Council Directive 98/83/EC** (OJ L330, p32, 5/12/1998) on the quality of water intended for human consumption.
- **Commission Recommendation of 20 December 2001** (OJ L344, p85, 28/12/2001) on the protection of the public against exposure to radon in drinking water supplies

• NATIONAL LEGISLATION

- **European Communities (Quality of Water intended for Human Consumption) Regulations, 1988** (S.I. No. 81 of 1988)
- **European Communities (Quality of Water intended for Human Consumption) (Amendment) Regulations, 1999** (S.I. No. 350 of 1999)
- **European Communities (Quality of Water intended for Human Consumption) (Amendment) Regulations, 2000** (S.I. No. 177 of 2000)

This will be revoked in January 2004 by:

- **European Communities (Drinking Water) Regulations, 2000** (S.I. No. 439 of 2000).

The basic standards governing the quality of drinking water intended for human consumption are set out in **EU Directive 80/778/EEC**, which is transposed by **S.I. No. 81 of 1988**. All water for human consumption, whether in its original state or after treatment, regardless of origin is covered. It includes water used in the food industry. Natural mineral waters and medicinal waters are excluded. The Regulations specify standards in respect of 55 water quality parameters. Minimum frequencies of sampling and analysis for the respective groups of parameters are also defined.

The Environmental Protection Agency prepares and publishes annual reports on the results of the monitoring programmes carried out.

In EU food law, where there is a reference to potable water, it is usually defined as water which meets the standards of this Directive.

Where the water quality does not meet the specified standards, remedial measures are outlined in **S.I. No. 350 of 1999** for public and private water supplies. Additional measures for private supplies, including time limits for compliance with the standards, were introduced in **S.I. No.177 of 2000**.

It should be noted that **Council Directive 98/83/EC** has introduced new controls relating to the quality of water for human consumption. It will entail significant changes in all aspects of implementation sample numbers, parameters, parameter classes, extent of coverage and so on.

The Directive has been transposed by **S.I. No. 439 of 2000** and will come into operation on 1 January 2004, when they will revoke and replace **EC (Quality of Water intended for Human Consumption) Regulations, 1988** as amended. The Regulations prescribe a total of 48 parametric values which are grouped into three categories, i.e. microbiological, chemical and indicator parameters. More stringent standards will be introduced for Lead, Ammonium and Fluoride. Provisions for temporary departures from a standard and requirements for the provision of information to consumers are described.

Bottled waters

There are three types of water which can be bottled (or packaged):

- Natural mineral water
- Spring water
- All other water

Currently there is different legislation governing the different types of water.

Natural mineral water

For a water to be declared a natural mineral water it must comply with the following legislation:

• EU LEGISLATION

Council Directive 80/777/EEC (OJ L229, p1, 30/08/1980) of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of Natural Mineral Waters

Amended by:

Directive 96/70/EC of the European Parliament and of the Council (OJ L299, p26, 23/11/1996) of 28 October 1996

• NATIONAL LEGISLATION

- **European Communities (Natural Mineral Waters) Regulations, 1986** (S.I. No.11 of 1986)
- **European Communities (Natural Mineral Waters) (Amendment) Regulations, 1998** (S.I. No. 461 of 1998)

This water must be recognised as a natural mineral water by the responsible authority which in Ireland is the National Standards Authority of Ireland (NSAI).

Spring water

Water which does not meet the requirements of a natural mineral water but is a spring water must comply with the natural mineral waters legislation above and with the rules on drinking water.

All other water

Water which is not a natural mineral water must comply with the drinking water regulations as follows:

• EU LEGISLATION

Council Directive 80/778/EEC (OJ L229, p11, 30/08/1980) of 15 July 1980 relating to the quality of water for human consumption

Amended by:

Council Directive 91/692/EEC (OJ L377, p48, 31/12/1991) of 23 December 1991 standardising and rationalising reports on the implementation of certain Directives relating to the environment

Repealed from January 2004 by:

Council Directive 98/83/EC (OJ L330, p32, 5/12/1998) on the quality of water intended for human consumption

• NATIONAL LEGISLATION

- **European Communities (Quality of Water intended for Human Consumption) Regulations, 1988** (S.I. No. 81 of 1988)

This will be revoked in January 2004 by:

- **European Communities (Drinking Water) Regulations, 2000** (S.I. No. 439 of 2000)

Forthcoming changes to the legislation

1. The Department of Health and Children is due to publish a new Statutory Instrument which will govern all bottled waters whether natural mineral water, spring water or other water. The current Statutory Instruments governing natural mineral waters will then be revoked.
2. The Department of the Environment published S.I. No. 439 of 2000, which transposes Council Directive 98/83/EC on quality of water intended for human consumption. This legislation comes into force in January 2004 at which time, the existing Regulations (S.I. No. 81 of 1988) will be revoked. However S.I. No. 439 of 2000 does not apply to bottled water. The new Regulations on Bottled Water to be published by the Department of Health and Children will fill this gap.
3. The European Commission is working on proposals for a revised Commission Directive on natural mineral water with three purposes
 - Setting maximum limits for certain natural contaminants
 - Prescribing conditions for the use of ozone and related labelling
 - Labelling the presence of fluoride

VETERINARY MEDICINES AND CONTROL OF ILLEGAL SUBSTANCES

• EU LEGISLATION

Council Regulation (EEC) 2377/90 (OJ L224, p1, 18/08/90) of 26 June 1993 establishing community procedures for fixing maximum limits for veterinary drug residues in foodstuffs of animal origin (note this Regulation has been amended on numerous occasion, listed below are the amendments for 2002 only)

Amended by:

- **Commission Regulation (EC) No 77/2002** (OJ L16, p9, 18/01/2002) of 17 January 2002
- **Commission Regulation (EC) No 868/2002** (OJ L137, p6, 25/05/2002) of 24 May 2002
- **Commission Regulation (EC) No 869/2002** (OJ L137, p10, 25/05/2002) of 24 May 2002
- **Commission Regulation (EC) No 1181/2002** (OJ L172, p13, 02/07/2002) of 1 July 2002
- **Commission Regulation (EC) No 1530/2002** (OJ L230, p3, 28/08/2002) of 27 August 2002
- **Commission Regulation (EC) No 1752/2002** (OJ L264, p18, 02/10/2002) of 1 October 2002
- **Commission Regulation (EC) No 1937/2002** (OJ L297, p3, 31/10/2002) of 30 October 2002

Council Regulation 2309/93/EEC (OJ L214, p1, 24/08/1993) of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

Amended by:

- **Commission Regulation (EC) No 649/98** (OJ L88, p7, 24/03/1998) of 23 March 1998

Implemented by:

Commission Regulation (EC) No 1662/95 (OJ L158, p4, 08/07/1985) of 7 July 1995 laying down certain detailed arrangements for implementing the Community decision-making procedures in respect of marketing authorizations for products for human or veterinary use

Council Directive 96/22/EC (OJ L125, p3, 23/05/1996) of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC

Council Directive 96/23/EEC (OJ L125, p10, 23/05/1996) of 29 April 1996 on measures to monitor certain

substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

Directive 2001/82/EC (OJ L311, p1, 28/11/2001) of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

Commission Decision 2002/657/EC (OJ L221, p8, 17/08/2002) of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results

• NATIONAL LEGISLATION

The thrust of the legislation listed below is to control residues of hormones, growth promoters or other undesirable substances in meat or animal products.

- **Control of Animal Remedies and their Residues Regulations, 1998** (S.I. No. 507 of 1998)

These Regulations replace a number of earlier Regulations and transpose the provisions of Council Directives 96/22/EC and 96/23/EC. They prohibit the import, manufacture, sale, supply, administration or possession of substances having oestrogenic, androgenic, gestagenic or thyrostatic action and beta-agonists. Limited exceptions are made in respect of authorised animal remedies containing these substances, insofar as these exceptions are provided for in Council Directive 96/22/EC.

Animals or foods which have been treated, either with a prohibited substance or illegally treated with an authorised product are deemed to be unfit for human consumption and the Regulations provide for the destruction of animals in such cases. A register of persons engaged in the trade of farm animals and for measures to be taken by processors to assure consumers that animals and meat are free of illegal residues.

Aspects of the legislation listed below include the control of prohibited substances and prevention of excess residues in animal products through appropriate residue programmes.

- **Animal Remedies Act 1993** (No. 23 of 1993)
- **Animal Remedies Act 1993 (Commencement) Order, 1993** (S.I. No. 283 of 1993)
- **Animal Remedies Regulations, 1996** (S.I. No. 179 of 1996)
- **Animal Remedies (Amendment) Regulations, 2002** (S.I. No. 44 of 2002)

For the control of illegal substances, the **Animal Remedies Act, 1993**, sets out a full range of enforcement powers to authorised officers of the Department of Agriculture and Food, to the Garda and customs services, including powers to enter and search premises/lands, examine and take samples, detain/seize animals, records, substances etc. Where evidence of the use of hormones or other prohibited substances is found in an animal or its carcass, the carcass will be condemned and live animals found to be illegally treated will be permanently excluded from the food chain.

Penalties, in the event of a conviction are also provided for in the 1993 Act; these range from a fine of €1,000 and/or up to one year's imprisonment on summary conviction, to a fine of up to €250,000 and/or up to ten years' imprisonment in the event of conviction on indictment for a second or subsequent offence. The 1993 Act also provides for the possibility of a person, who is convicted on indictment, being disqualified from keeping animals or animal remedies.

The Animal Remedies Regulations of 1996 provide a code of legislation relating to the authorisation, manufacture, sale and administration of animal remedies. The Regulations govern animal remedies from the stage of manufacture up to use on farm and include all stages of the intervening commercial chain.

Each year, the Department of Agriculture and Food administers a National Residues Monitoring Plan as required in the Control of Animal Remedies and their **Residues Regulations, 1998 (S.I. No. 507 of 1998)**. The Plan is designed to safeguard consumers from illegal residues and therefore the samples are generally taken in accordance with criteria designed to target animals or products which are more likely to contain illegal residues.

The permitted residue levels for veterinary medicinal products in foodstuffs of animal origin are set out in **Council Regulation 2377/90/EEC** as amended.

In 1993, Community procedures were established for the authorisation and supervision of medicinal products for human and veterinary use and to establish a European Agency for the Evaluation of Medicinal Products.

ANIMAL REMEDIES

• EU LEGISLATION

Council Directive 90/167/EEC (OJ L92, p42, 07/04/1990) of **26 March 1990** laying down the conditions governing the preparation, placing on the market and use of medicated foodstuffs in the Community

Council Regulation (EEC) 2377/90 (OJ L224, p1, 18/08/90) of **26 June 1993** establishing community procedures for fixing maximum limits for veterinary drug residues in foodstuffs of animal origin (note this Regulation has been amended on numerous occasions, listed below are the amendments for 2002 only)

Amended by:

- **Commission Regulation (EC) No 77/2002** (OJ L16, p9, 18/01/2002) of **17 January 2002**
- **Commission Regulation (EC) No 868/2002** (OJ L137, p6, 25/05/2002) of **24 May 2002**
- **Commission Regulation (EC) No 869/2002** (OJ L137, p10, 25/05/2002) of **24 May 2002**
- **Commission Regulation (EC) No 1181/2002** (OJ L172, p13, 02/07/2002) of **1 July 2002**
- **Commission Regulation (EC) No 1530/2002** (OJ L230, p3, 28/08/2002) of **27 August 2002**
- **Commission Regulation (EC) No 1752/2002** (OJ L264, p18, 02/10/2002) of **1 October 2002**
- **Commission Regulation (EC) No 1937/2002** (OJ L297, p3, 31/10/2002) of **30 October 2002**

Council Regulation 2309/93/EEC (OJ L214, p1, 24/08/1993) of **22 July 1993** laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

Amended by:

- **Commission Regulation (EC) No 649/98** (OJ L88, p7, 24/03/1998) of **23 March 1998**

Implemented by:

Commission Regulation (EC) No 1662/95 (OJ L158, p4, 08/07/1985) of **7 July 1995** laying down certain detailed arrangements for implementing the Community decision-making procedures in respect of marketing authorizations for products for human or veterinary use

• NATIONAL LEGISLATION

- **Animal Remedies Act, 1993 (No. 23 of 1993)**
- **European Communities (Animal Remedies and Medicated Feedingstuffs) Regulations, 1994**

(S.I. No. 176 of 1994)

- **Animal Remedies Regulations, 1996 (S.I. No. 179 of 1996)**

The **Animal Remedies Act, 1993** governs the field of authorised and prohibited veterinary medicines. An animal remedy is defined as any substance or combination of substances administered to animals for the purpose of treating, preventing or modifying disease, making a medical or surgical diagnosis in animals or correcting or modifying physiological functions in animals. More detailed provisions for animal remedies are contained in the secondary legislation made under this Act.

These Regulations, **S.I. No. 176 of 1994**, implement **Council Directive 90/167/EEC** and provide for the control of the manufacture, availability and use of medicated feedingstuffs. The manufacture, distribution and sale of medicated feedingstuffs and intermediate products for the manufacture thereof is subject to licensing by the Minister for Agriculture and Food. The use of medicated feedingstuffs is prohibited except under and in accordance with the terms of a veterinary written directive.

The Regulations of 1996, lay down detailed rules regarding the authorisation of animal remedies and the manufacture, wholesale and retail sale of animal remedies. They include rules for the administration of animal remedies and certain matters relating to veterinary practice in relation to animal remedies. These Regulations give effect to the aspects of the EU legislation listed below of relevance to the authorised use of animal remedies.

The competent authority for approval of medicines covered by **Directive 81/851/EEC** is the Irish Medicines Board, (except for vaccines where the Minister for Agriculture and Food is the competent authority). All animal remedies are required to be authorised by either the Irish Medicines Board or by the Minister for Agriculture and Food as appropriate. Animal remedies may only be used in accordance with the conditions attached to the product authorisation. It is an offence not to observe the proper dose rate and withdrawal period stated on the product label.

All premises involved in the wholesale or retail sale require to be licensed by the Minister for Agriculture and Food, (with the exception of pharmacies and veterinary surgeons professional practices).

DESIGNATIONS OF ORIGIN

Protection of Geographical Indications and Designations of Origin for Agricultural Products and Foodstuffs

• EU LEGISLATION

Council Regulation (EEC) 2081/92 (OJ L208, p3, 25/03/97) of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products

Amended by:

- **Council Regulation (EC) 535/97** (OJ L083, p3, 25/03/97) of 17 March 1997
- **Commission Regulation (EC) 1068/97** (OJ L156, p10, 13/06/97) of 12 June 1997
- **Commission Regulation (EC) 2796/2000** (OJ L324, p26, 21/12/2000) of 20 December 2000

Implementing measures:

Commission Regulation 2037/93/EEC (OJ L185, p5, 28/07/93) of 27 July 1993 laying down detailed rules of application of Council Regulation 2081/92/EEC

Amended by:

- **Commission Regulation (EC) 1428/97** (OJ L196, p39, 24/07/97) of 23 July 1997
- **Commission Regulation (EC) 1726/98** (OJ L224, p1, 11/08/98) of 22 July 1998

Commission Regulation (EC) 1107/96 (OJ L148, p1, 21/06/96) of 12 June 1996 on the registration of geographical indications and designations of origin under the procedure laid down in Article 17 of Council Regulation 2081/92/EEC

Supplemented by:

- **Commission Regulation (EC) 1263/96** (OJ L163, p19, 2/07/96) of 1 July 1996
- **Commission Regulation (EC) 123/97** (OJ L22, p19, 24/01/97) of 23 January 1997
- **Commission Regulation (EC) 1065/97** (OJ L156, p5, 13/06/97) of 12 June 1997
- **Commission Regulation (EC) 2325/97** (OJ L322, p33, 25/11/97) of 24 November 1997

- **Commission Regulation (EC) 134/98** (OJ L15, p6, 21/01/98) of 20 January 1998
- **Commission Regulation (EC) 644/98** (OJ L87, p8, 21/03/98) of 20 March 1988
- **Commission Regulation (EC) 1549/98** (OJ L202, p25, 18/07/98) of 17 July 1998
- **Commission Regulation (EC) 83/99** (OJ L8, p17, 14/01/99) of 13 January 1999
- **Commission Regulation (EC) 590/99** (OJ L74, p8, 19/03/99) of 18 March 1999
- **Commission Regulation (EC) 2317/99** (OJ L280, p66, 30/10/99) of 29 October 1999
- **Commission Regulation (EC) 1070/99** (OJ L130, p18, 26/05/99) of 25 May 1999
- **Council Regulation (EC) 813/2000** (OJ L100, p5, 20/04/2000) of 17 April 2000
- **Commission Regulation (EC) 2703/2000** (OJ L311, p25, 12/12/2000) of 11 December 2000
- **Commission Regulation (EC) 913/2001** (OJ L129, p8, 11/05/2001) of 10 May 2001
- **Council Regulation (EC) 1347/2001** (OJ L182, p3, 05/07/2001) of 28 June 2001
- **Commission Regulation (EC) No 1778/2001** (OJ L240, p6 08/09/2001) of 7 September 2001

Amended by:

- **Commission Regulation (EC) No 564/2002** (OJ L086, p7, 03/04/2002) of 2 April 2002
- **Commission Regulation (EC) No 1829/2002** (OJ L277, p10 15/10/2002) of 14 October 2002

Commission Regulation (EC) 2400/96 (OJ L327, p11, 18/12/96) of 17 December 1996 on the entry of certain names in the 'Register of protected designations of origin and protected geographical indications' provided for in Council Regulation 2081/92/EC

Supplemented by:

- **Commission Regulation (EC) 1875/97** (OJ L265, p26, 27/09/97) of 25 September 1997
- **Commission Regulation (EC) 2396/97** (OJ L331, p3, 3/12/97) of 2 December 1997
- **Commission Regulation (EC) 195/98** (OJ L20, p20, 27/01/98) of 26 January 1998
- **Commission Regulation (EC) 1265/98** (OJ L175, p7, 19/06/98) of 18 June 1998
- **Commission Regulation (EC) 1576/98** (OJ L206, p15, 23/07/98) of 22 July 1998

- **Commission Regulation (EC) 2088/98**
(OJ L266, p24, 1/10/98) of **30 September 1998**
- **Commission Regulation (EC) 2139/98/EC**
(OJ L270, p7, 7/10/98) of **6 October 1998**
- **Commission Regulation (EC) 2784/98**
(OJ L347, p19, 23/12/98) of **22 December 1998**
- **Commission Regulation (EC) 38/99**
(OJ L5, p62, 9/01/99) of **8 January 1999**
- **Commission Regulation (EC) 378/99**
(OJ L46, p13, 20/02/99) of **19 February 1999**
- **Commission Regulation (EC) 872/99**
(OJ L110, p4, 28/04/99) of **27 April 1999**
- **Commission Regulation (EC) 1645/99**
(OJ L195, p7, 28/07/99) of **27 July 1999**
- **Commission Regulation (EC) 2107/99**
(OJ L258, p3, 5/10/99) of **4 October 1999**
- **Commission Regulation (EC) 547/2000**
(OJ L67, p8, 15/03/2000) of **14 March 2000**
- **Commission Regulation (EC) 1187/2000**
(OJ L133, p19, 6/06/2000) of **5 June 2000**
- **Commission Regulation (EC) 1338/2000**
(OJ L154, p5, 27/06/2000) of **26 June 2000**
- **Commission Regulation (EC) 1576/2000**
(OJ L181, p35, 20/07/2000) of **19 July 2000**
- **Commission Regulation (EC) 1651/2000**
(OJ L189, p15, 27/07/2000) of **26 July 2000**
- **Commission Regulation (EC) 1903/2000**
(OJ L228, p55, 8/09/2000) of **7 September 2000**
- **Commission Regulation (EC) 1904/2000**
(OJ L228, p57, 8/09/2000) of **7 September 2000**
- **Commission Regulation (EC) 2446/2000**
(OJ L281, p12, 7/11/2000) of **6 November 2000**
- **Commission Regulation (EC) 138/2001**
(OJ L23, p17, 25/01/2001) of **24 January 2001**
- **Commission Regulation (EC) 464/2001**
(OJ L66, p29, 8/03/2001) of **7 March 2001**
- **Commission Regulation (EC) 509/2001**
(OJ L76, p7, 16/03/2001) of **15 March 2001**
- **Commission Regulation (EC) 898/2001**
(OJ L126, p18, 8/05/2001) of **7 May 2001**
- **Commission Regulation (EC) 1356/2001**
(OJ L182, p25 05/07/2001) of **4 July 2001**
- **Commission Regulation (EC) 1971/2001**
(OJ L269, p5 10/10/2001) of **9 October 2001**
- **Commission Regulation (EC) 2036/2001**
(OJ L275, p9, 18/10/2001) of **17 October 2001**
- **Commission Regulation (EC) 2372/2001**
(OJ 320, p9, 05/12/2001) of **4 December 2001**
- **Commission Regulation (EC) 2601/2001**
(OJ L345, p47, 29/12/2001) of **28 December 2001**

- **Commission Regulation (EC) 245/2002**
(OJ L039, p12, 09/02/2002) of **8 February 2002**
- **Commission Regulation (EC) 538/2002**
(OJ L082, p4, 26/03/2002) of **25 March 2002**
- **Commission Regulation (EC) 905/2002**
(OJ L142, p27, 31/05/2002) of **30 May 2002**
- **Commission Regulation (EC) 1018/2002**
(OJ L155, p25, 14/06/2002) of **13 June 2002**
- **Commission Regulation (EC) 1097/2002**
(OJ L166, p8, 25/06/2002) of **24 June 2002**
- **Commission Regulation (EC) 1241/2002**
(OJ L 181, p4, 11/07/2002) of **10 July 2002**
- **Commission Regulation (EC) 1495/2002**
(OJ L225, p11, 22/08/2002) of **21 August 2002**

Certificates of specific character for agricultural products and foodstuffs

Council Regulation (EC) 2082/92 (OJ L208, p9, 24/07/92) of **14 July** on certificates of specific character for agricultural products and foodstuffs

Implementing measures:

Commission Regulation (EC) 1848/93 (OJ L168, p35, 10/07/93) of **9 July 1993** laying down detailed rules for the application of **Council Regulation 2082/92/EEC** on certificates of specific character for agricultural products and foodstuffs

Amended by:

- **Commission Regulation 2515/94/EC**
(OJ L275, p94, 26/10/94) of **9 September 1994**
- **Commission Regulation 2182/98/EC**
(OJ L275, p18, 10/10/98) of **9 October 1998**

Commission Regulation 2301/97 (OJ L319, p8, 21/11/97) of **20 November 1997** on the entry of certain names in the 'Register of certificates of specific character' provided for in **Council Regulation 2082/92/EEC** on certificates of specific character for agricultural products and foodstuffs

Corrected by:

- Corrigendum (OJ L153, p18, 27/05/1998) to **Commission Regulation (EC) No 2301/97 of 20 November 1997** on the entry of certain names in the 'Register of certificates of specific character' provided for in **Council Regulation (EEC) No 2082/92** on certificates of specific character for agricultural products and foodstuffs

Amended by:

- **Commission Regulation 954/98/EC**
(OJ L133, p10, 7/05/98) of **6 May 1998**
- **Commission Regulation 2527/98/EC**
(OJ L317, p14, 26/11/98) of **25 November 1998**

- **Commission Regulation 2419/99/EC**
(OJ L291, p25, 13/11/99) of 12 November 1999
- **Commission Regulation 1482/2000/EC**
(OJ L167, p8, 7/07/2000) of 6 July 2000

• NATIONAL LEGISLATION

- **European Communities (Protection of Geographical Indication and Designations of Origin for Agricultural Products and Foodstuffs) Regulations, 1995 (S.I. No.148 of 1995)**
- **European Communities (Certificates of Specific Character for Agricultural Products and Foodstuffs) Regulations, 1995 (S.I. No.149 of 1995)**
- **European Communities (Protection of Geographical Indications and Designations of Origin for Agricultural Products and Foodstuffs) (Amendment) Regulations, 1999 (S.I. No. 275 of 1999)**

A large body of EU legislation exists governing the areas of Protection of Geographical Indications and Designations of Origin and Certificates of Specific Character for Agricultural Products and Foodstuffs. The provisions adopted allow producers to register and in that way protect the names of certain agricultural products and foodstuffs. 'Protected' foodstuffs exhibit special characteristics derived, in cases where the name is geographical, from the specific area in which the product is produced and in other cases from a traditional composition or method of production. The following classifications exist and corresponding registers are maintained:

Protected Designation of Origin (PDO)

Foodstuffs and agricultural products whose names are protected and prepared within a particular geographical environment and must have qualities or characteristics exclusive to that area with its inherent natural and human factors.

Protected Geographical Indication (PGI)

Products bearing the name of a particular geographical area which are produced or processed or prepared within that area and which have a reputation, features or certain qualities attributable to that area can be registered under the PGI designation.

Certificate of Specific Character or Traditional Speciality Guaranteed (TSG)

This type of registration relates to the traditional character of a foodstuff or agricultural product by either its composition or by means of its production, rather than to its origin. The registered designation is open to all Community producers producing the product to the registered specification.

Applications for registration under the above designations should be submitted to the Food Division, Department of Agriculture and Food, Kildare Street, Dublin 2.

The principal effect of the Irish Regulations, **S.I. No.148 and 149 of 1995** is to provide for penalties for breaches of certain provision of **EU Regulation 2081/92/EEC and 2082/92** and confer power of entry on authorised officers. Sampling procedures for authorised officers are prescribed.

The amendment to **S.I. No. 148 of 1995** gives effect to **Council Regulation 535/97/EC**, on the protection of geographical indications and designations of origin for agricultural products and foodstuffs.

APPENDIX 1 : FOOD SAFETY AUTHORITY OF IRELAND (FSAI)

The Food Safety Authority of Ireland (FSAI) was formally established as an independent statutory science-based body on 1st January 1999 under the Food Safety Authority of Ireland Act, 1998 (herein referred to as “The Act”) and is dedicated to protecting public health and consumer interests in the area of food safety and hygiene.

Mission of the Authority:

The principal function of the Authority is to take all reasonable steps to ensure that all food consumed, distributed, marketed and produced in the state meets the highest standard of food safety and hygiene reasonably available. Responsibilities of the FSAI include:

- a) ensuring the co-ordinated and seamless delivery of food safety services to an agreed high standard by the various state agencies involved,
- b) ensuring that food complies with legal requirements, or where appropriate, with recognised codes of good practice
- c) the provision of advice to regulators in relation to food safety issues, and
- d) working with industry to gain their commitment in the production of safe food

The FSAI has specific responsibility for the:

- processing of novel food applications
- coordination of the Rapid Alerts System
- approval of food irradiation facilities.

THE AUTHORITY STRUCTURE AND OPERATION:

The Board of the Authority

The Board of the Authority consists of 10 members and is appointed by the Minister for Health and Children. The Board direct and carry out the functions of the Authority in accordance with the Food Safety Authority of Ireland Act, 1998.

Scientific Committee

The Authority has a Scientific Committee comprising of not more than fifteen members, who provide advice to the Board. Under the Act, sub-committees may be established to provide scientific advice and expertise on a particular topic, for example, GMOs and novel foods, BSE, Microbiology etc.

Consultative Council

The Council, which currently comprises of 22 members representing the key stakeholders in Ireland in relation to food production and consumption. Meeting on a quarterly basis the Council acts as a forum for debate on food safety issues and may also provide advice to the FSAI Board on areas of relevance.

Food Safety Legislation:

The Food Safety Authority of Ireland Act, 1998 transfers responsibility for the enforcement of all food legislation to the Food Safety Authority of Ireland. The food legislation for which the FSAI has responsibility for is set down in the First Schedule of the FSAI Act; this schedule is updated periodically through orders made by the Minister of Health and Children.

While the Authority may enforce food legislation in its own right, it manages its enforcement role through a series of service contracts with official agencies. Copies of these Service Contracts are available on the Authority's website (www.fsai.ie). These Service Contracts specify an agreed level and standard of food safety activity that the official agencies will undertake under contract to the Authority. Official agencies for the purposes of the FSAI Act are:

- the Director of Consumer Affairs,
- a health board,
- a local authority,
- the Marine Institute,
- the Minister for Agriculture and Food,
- the Minister for Health and Children,
- the Minister for the Environment and Local Government,
- the Minister for Communications, Marine and Natural Resources,
- the Radiological Protection Institute of Ireland,
- the State Laboratory.

Authorised officers have an enhanced range of powers under the FSAI Act. These additional powers allow for the serving of Improvement Notices, Improvement Orders, Closure Orders and Prohibition Orders, which can apply to all or part of a food business.

These new enforcement options enable the Authority's agents to take quicker and more decisive action than previously afforded, when confronted with situations posing a risk to public health. Details of Closure, improvement and Prohibition Orders served are published on the Authority's website (www.fsai.ie)

In addition to the enforcement of legislation and the promotion of higher standards, the FSAI has functions in relation to research, advice, co-ordination of services and certification of food. It also promotes, in conjunction with industry and producer groups, food safety assurance schemes.

Food Safety Surveillance

The FSAI continually monitors the safety of food in the Irish food chain, in conjunction with its official agencies and associated laboratories. Monitoring and surveillance of food for chemical and microbiological contaminants is essential for the protection of public health.

The objectives of the Authority in relation to surveillance of foodstuffs include: identifying contaminated product and removing it from the market, assisting outbreak investigators in targeting food for sampling, as well as comparing microbiological quality of imported and domestic foods. Investigation of foodborne illness is an important component of the Authority's role in protecting public health and the Authority works with the National Disease Surveillance Centre (NDSC) and official agents to enhance the surveillance system.

Certification of Food for Export

The Authority administers the Certification of Food for Export (which was previously administered by the Department of Health and Children). These certificates relate to specific food premises, and state that the food production processes are to a certain standard, and the food product complies with all Irish Regulations.

Rapid Alerts

Another aspect of food safety surveillance under the control of the FSAI is that of the European Rapid Alert System for Food and Feed (RASFF). The purpose of RASFF which is operated by the EU, is to send urgent information to Competent Authorities in the Member States of the presence of a serious risk to the health of the consumer presented by a food product. The FSAI is the Irish contact point, and a list of alerts issued is available on the FSAI website (www.fsai.ie)

Food Safety Training

The ultimate responsibility for the production of safe food rests primarily with the food industry. The Authority endeavours to raise awareness within the food industry that the legal obligation to produce safe food rests with the food industry and that there is also a requirement that industry have appropriate systems in place to ensure that food produced, processed, distributed and marketed is safe.

Every food business has a legal obligation to ensure that staff working in a food environment are adequately

trained and/or supervised commensurate with their work activity. The Authority as part of its' role in fostering the establishment and maintenance of high standards of food hygiene, established the Food Safety Training Council (FSTC).

The Council brings together enforcement officers, industry, food safety training providers and the Authority, with the aim of establishing agreed levels of skills required by employees working in the food industry. Training standards which must be demonstrated at various stages of employment in order to produce safe food in accordance with current legislation are outlined in a series of guides published by the FSAI in consultation with the FSTC.

Communication and Information

A large constituent of the Authority's work focuses on the provision of appropriate information and advice on food safety practices to distinct food industry audiences. Thus, the role of the Authority in this area is geared towards key sectors of the food chain to highlight the risks of foodborne disease, provide information on outbreaks and advise how these risks should be prevented and controlled.

The Authority's support channels include a food safety helpline service, information centre, library and website which act as a resource for all interested parties to source information and have their queries answered.

Official Agencies

The Food Safety Authority of Ireland oversees the work of Government Departments and other State agencies that historically comprised the nation's food control and enforcement system. It is the role of the Authority to co-ordinate the activities of these agencies so as to achieve the most effective use of these State resources in protecting consumer health and continually improving standards, both within the agencies and within the food industry.

Department of Health and Children (DoHC)

The mission statement of the Department of Health and Children is "In a partnership with the providers of health care, and in co-operation with other government departments, statutory and non-statutory bodies, to protect promote and restore the health and well-being of people by ensuring that health and personal social services are planned, managed and delivered to achieve measurable health and social gain and provide the optimum return on resources invested."

The DoHC has an overall responsibility for the development of food safety legislation and policy this role is developed and coordinated by the Food Unit of the DoHC.

Health Boards

Health boards are funded by the DoHC and are involved in implementing a range of legislation in relation to food safety and hygiene. Environmental health officers (EHOs) are employed by the health boards and implement national and EU laws on food safety and hygiene. This function is carried out mainly through the inspection of food establishments, responding to rapid alerts, investigation of foodborne disease outbreaks and food incidents and participation on Zoonoses committees.

Under the food safety legislation enforced by the EHOs, foodstuffs can be recalled, withdrawn and destroyed. Business must also have a food safety management system in place, and this can be inspected by the EHO.

Department of Agriculture and Food (DAF)

In relation to its service contract with the FSAI, the work carried out by DAF focuses mainly on control of foods of animal origin. The responsibility can be divided into 4 main areas:

- meat and meat products,
- milk and milk products,
- egg and egg products and
- pesticide control.

Authorised officers carry out food safety inspections in large abattoirs, meat manufacturing and processing plants, milk plants, egg and egg products premises. These inspections can involve the examination of standards relating to structures and equipment, inspections of animals, operational programmes and staff training. A full laboratory service is provided to support the inspections carried out by the DAF inspectorate.

Food Safety Liaison Unit

During 2001, the DAF established a food safety liaison unit to coordinate the food safety activities of the DAF. The aim of the unit is to highlight the food safety control activity and food safety related research being undertaken and funded by DAF. It also aims to assist in the development of close working relationships between all agencies involved in food safety in Ireland.

Local Authorities

Under its service contract with the Food Safety Authority of Ireland, each County Council is responsible for the supervision of domestic abattoirs and small meat manufacturing within its area. The local authority veterinary officer carries out regular inspections on hygiene and operational/structural matters in the abattoir, as well as post mortem and ante mortem checks.

Department of Communications, Marine and Natural Resources (DCMNR)

The Sea Fisheries Control Division of the DCMNR is responsible for the implementation and enforcement of National and EU legislation which deal with the health conditions for the production and placing on the market of fish, fishery products and aquaculture products through a service contract with the FSAI. The sea fisheries officers ensure compliance with health and hygiene regulations through inspection, sampling and audit of vessels and processing plants, dispatch centres and purification centres, auction centres and wholesale markets.

In addition to the inspection activities the DCMNR send samples of fish, water, seaweed and sediments to the Radiological Protection Agency of Ireland for analysis. The Marine Institute take shellfish samples for analysis for the parameters outlined under EU Legislation.

Office of the Director of Consumer Affairs (ODCA)

One of the primary tasks of the ODCA is to ensure that there is full compliance with consumer legislation. Under the Service Contract with the FSAI, the ODCA is responsible for enforcing the European Communities (Labelling, Presentation and Advertising of Foodstuffs) Regulations, 2002 in relation to pre-packaged foodstuffs. Along with acting on complaints received by consumers, the ODCA also carries out pro-active visits and investigations, calling into premises and looking at various products in order to ensure that the requirements of the Regulations are met.

Radiological Protection Institute (RPII)

The Radiological Protection Institute of Ireland (RPII) monitors radioactivity levels in all parts of the Irish marine and terrestrial environment; with regard to food, it arranges the sampling and analysis of seafood, crops, animals and drinking water. The RPII and FSAI are also involved in a dual licensing system for food irradiation facilities. During 2001, the FSAI and the RPII signed a Memorandum of Understanding, a formal agreement to co-operate in the area of monitoring radioactivity levels in foods and foodstuffs. The agreement respects the statutory duties of both bodies to maintain their independence.

APPENDIX 2 : THE EUROPEAN FOOD SAFETY AUTHORITY (EFSA)

In January 2000, following extensive consultation, the Commission issued a white paper on food safety. In November of the same year a proposal for a regulation laying down the general principles and requirements of food law and establishing a European Food Safety Authority was issued by the European Parliament and the Council of Ministers. This became "Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food"

The primary responsibility of the European Food Safety Authority will be to provide independent scientific advice on all matters with a direct or indirect impact on food safety. The Authority has been given a wide brief, so that it can cover all stages of food production and supply, from primary production to the safety of animal feed, right through to the supply of food to consumers

The Authority will have six main tasks:

- 1 provide independent scientific advice on food safety issues and other related matters such as animal health/welfare, plant health, GMOs and nutrition at the request of the Commission, the European Parliament (EP) and the Member States as a basis for risk management decisions;
- 2 advice on technical food issues to underpin policy development and legislation related to the food chain;
- 3 collection and analysis of data on dietary, exposure and other information
- 4 relevant to any potential risks necessary to monitor safety along the food chain in the EU;
- 5 identification and early warning of emerging risks;
- 6 support to the Commission in case of crisis;
- 7 communication to the general public on all matters within its mandate.

EFSA was established in early 2002 and is located temporarily in Brussels. It is a separate legal entity, independent from other Community institutions and comprises of:

A Management Board

The Management Board is responsible for ensuring that the Authority functions effectively and efficiently. Within this objective, it is responsible for establishing the Authority's draft budget and work programmes, monitoring their implementation, and agreeing to internal rules and regulations. It is also responsible for

appointing the Executive Director of the Authority and the members of the Scientific Committee and Panels.

Executive Director and Staff

The Executive Director is responsible for the day to day management of the Authority and is answerable to the Management Board. The Executive Director is responsible for the appointment of the Authority's technical, scientific, administrative and communications personnel.

Mr Geoffrey Podger has been appointed as the first Executive Director of the European Food Safety Authority. Mr Podger has been Chief Executive of the UK Food Standards Agency since it was set up in 2000. He will take up the position of Executive Director on 1st February 2003.

Advisory Forum

The Executive Director will be assisted by an Advisory Forum composed of representatives from the competent bodies in the Member States, which undertake tasks similar to those of the Authority, on the basis of one representative per Member State.

Scientific Committee and Panels

A Scientific Committee and several Scientific Panels will be responsible for the scientific opinions of the Authority.

A Scientific Committee will be responsible for the general co-ordination necessary to ensure the consistency in the scientific opinions of the different panels. This Committee will be composed of the chairpersons of the Scientific Panels and six independent experts who do not belong to any panel.

The Scientific Panels will be composed of independent scientific experts selected following an open call for expressions of interest and appointed by the Management Board. They will be selected on the basis of criteria of competence, knowledge, independence and experience.

The following 8 panels will be established:

- Panel on food additives, flavourings, processing aids and materials in contact with food;
- Panel on additives and products or substances used in animal feed;
- Panel on plant health, plant protection products and their residues;
- Panel on genetically modified organisms;
- Panel on dietetic products, nutrition and allergies;

- Panel on biological hazards (including TSE/BSE issues);
- Panel on contaminants in the food chain;
- Panel on animal health and welfare.

In accordance with the Regulation, until these Committee and Panels are established scientific advice on matters falling within the competence of the Authority will continue to be provided by the existing scientific committees established by Commission Decisions and supported by the Commission's civil servants. These existing committees are:

- Scientific Steering Committee
- Scientific Committee on Food
- Scientific Committee on Animal Nutrition
- Scientific Committee on Animal Health and Animal Welfare
- Scientific Committee on Veterinary Measures relating to Public Health
- Scientific Committee on Plants
- Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers
- Scientific Committee on Medicinal Products and Medical Devices
- Scientific Committee on Toxicity, Ecotoxicity and the Environment

APPENDIX 3 : CODEX ALIMENTARIUS

An intergovernmental organisation, Codex Alimentarius Commission (generally referred to as Codex) with 167 members represents more than 97% of the world's population. Created in 1963 by the FAO and WHO, the CACs' principal purpose is to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. It aims to protect consumers whilst facilitating fair trading practices in food.

The day-to-day functions of the Commission are conducted by a Secretariat located in Rome, Italy. The CAC meets every two years, alternating between Rome and Geneva (i.e. FAO and WHO headquarters respectively). An Executive Committee, that meets annually, is responsible for making recommendations about the general direction of Codex work.

Codex Committees

To accomplish its work, Codex has established a number of different committees and ad hoc intergovernmental task forces. Codex Committees are classified as either General Subject Committees or Commodity Committees and they generate two types of Standards – general standards and specific commodity standards. General standards are those standards which apply to all Codex bodies such as food hygiene, labelling etc and are managed by corresponding general subject committees.

There are nine general subject Codex committees. These committees work closely with scientific bodies in developing standards and recommendations. The committees and their host countries are:

- Food Additives and Contaminants (The Netherlands)
- Food Hygiene (United States)
- Food Import and Export Inspection and Certification Systems (Australia)
- Food Labelling (Canada)
- General Principles (France)
- Methods of Analysis and Sampling (Hungary)
- Nutrition and Foods for Special Dietary Uses (Germany)
- Pesticide Residues (The Netherlands)
- Veterinary Drugs in Foods (United States)

Commodity standards on the other hand relate to a specific food commodity, and commodity committees develop or expand standards, guidelines and related text for that commodity e.g. cocoa products and chocolate, fish and fishery products, milk and milk products etc. Commodity committees must follow guidelines

established by general committees on their area of expertise.

Development of Standards

Standards are developed through the work of the various committees, who follow an eight-step or accelerated five-step procedure from proposal to adoption. The procedure provides for input from various interested parties.

The steps in a full eight-step procedure:

- 1 The Commission decides taking into account "Criteria for the Establishment of Work Priorities", to elaborate a Standard and assigns the work to a Committee.
- 2 The Codex Secretariat arranges preparation of a Proposed Draft Standard
- 3 The Draft is sent to Governments and international Organizations for comments
- 4 The Secretariat forwards comments to the responsible Committee
- 5 The Committee reviews the comments and the Proposed Draft Standard is sent to the Commission through the Secretariat for adoption as a Draft Standard
- 6 The Commission sends the Draft to governments and international Organizations for comments
- 7 Secretariat forwards comments to the Committee
- 8 After consideration of the comments, the Draft Standard is returned to the Commission for adoption as a Codex Standard, which is then sent to Governments for acceptance

In the accelerated process, steps 6 and 7 (i.e. the second round of input from stakeholders) are omitted. In order for a standard to be elaborated using the accelerated process, a two-thirds majority of the Commission must agree.

Codex Contact Point (CCP)

Input to the work of Codex is facilitated through an established consultation process, with each country nominating a designated Codex Contact Point (CCP). The contact point in Ireland is the Department of Agriculture and Food (DAF).

All the Codex final texts (standards, codes of practice, guidelines and other advisory texts) and working documents of Codex sessions are first received by the CCP and are disseminated to all concerned parties for reference and comments. Parties which have comments on the working Codex documents provide feedback to the

CCP.

A National Codex Committee – the Irish Codex Advisory Committee has been in existence for the past few years. This Committee which meets on a regular basis, provides a forum for discussions and for responses to Codex proposals.

For further information on current Active Codex Committees and Task Forces please refer to Appendix 3

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For further information on Codex contact:

Secretariat of the Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla
00100 Rome
Italy

Telephone: +39(06)5705.1

Fax: +39(06)5705.4593

E-mail: Codex@fao.org

Website: <http://www.codexalimentarius.net/>

IRELAND

Codex Contact Point
Department of Agriculture and Food
Agriculture House
Kildare Street
Dublin 2

Email: codex@agriculture.gov.ie

APPENDIX 4 : ACTIVE CODEX COMMITTEES AND TASK FORCES

The following is a list of current active Committees and Task Forces and their terms of reference:

GENERAL SUBJECT COMMITTEES

List of Active Codex Alimentarius Committees and Task Forces

ACRONYM	NAME AND TERMS OF REFERENCE
CCFICS	<p>Codex Committee on Food Import and Export Inspection and Certification Systems</p> <p>Terms of Reference</p> <p>(a) to develop principles and guidelines for food import and export inspection and certification systems with a view to harmonising methods and procedures which protect the health of consumers, ensure fair trading practices and facilitate international trade in foodstuffs; (b) to develop principles and guidelines for the application of measures by the competent authorities of exporting and importing countries to provide assurance where necessary that foodstuffs comply with requirements, especially statutory health requirements; (c) to develop guidelines for the utilisation, as and when appropriate, of quality assurance systems to ensure that foodstuffs conform with requirements and to promote the recognition of these systems in facilitating trade in food products under bilateral/multilateral arrangements by countries; (d) to develop guidelines and criteria with respect to format, declarations and language of such official certificates as countries may require with a view towards international harmonization; (e) to make recommendations for information exchange in relation to food import/export control; (f) to consult as necessary with other international groups working on matters related to food inspection and certification systems; and, (g) to consider other matters assigned to it by the Commission in relation to food inspection and certification systems. Quality assurance means all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality (ISO-8402 Quality - Vocabulary)</p>
CCFH	<p>Codex Committee on Food Hygiene</p> <p>Terms of Reference</p> <p>(a) to draft basic provisions on food hygiene applicable to all food; (b) to consider, amend if necessary and endorse provisions on hygiene prepared by Codex commodity committees and contained in Codex commodity standards, and (c) to consider, amend if necessary, and endorse provisions on hygiene prepared by Codex commodity committees and contained in Codex codes of practice unless, in specific cases, the Commission has decided otherwise, or (d) to draft provisions on hygiene applicable to specific food items or food groups, whether coming within the terms of reference of a Codex commodity committee or not; (e) to consider specific hygiene problems assigned to it by the Commission; (f) to suggest and prioritize areas where there is a need for microbiological risk assessment at the international level and to develop questions to be addressed by the risk assessors; and, (g) to consider microbiological risk management matters in relation to food hygiene and in relation to the risk assessment of FAO and WHO. (The term "hygiene" includes, where necessary, microbiological specifications for food and associated methodology.)</p>
CCFL	<p>Codex Committee on Food Labelling</p> <p>Terms of Reference</p> <p>(a) to draft provisions on labelling applicable to all foods; (b) to consider, amend if necessary, and endorse draft specific provisions on labelling prepared by the Codex Committees drafting standards, codes of practice and guidelines; (c) to study specific labelling problems assigned to it by the Commission; and, (d) to study problems associated with the advertisement of food with particular reference to claims and misleading descriptions.</p>

ACRONYM	NAME AND TERMS OF REFERENCE
CCGP	<p>Codex Committee on General Principles</p> <p>Terms of Reference</p> <p>To deal with such procedural and general matters as are referred to it by the Codex Alimentarius Commission. Such matters have included the establishment of the General Principles which define the purpose and scope of the Codex Alimentarius, the nature of Codex standards and the forms of acceptance by countries of Codex standards; the development of Guidelines for Codex Committees; the development of a mechanism for examining any economic impact statements submitted by governments concerning possible implications for their economies of some of the individual standards or some of the provisions thereof; the establishment of a Code of Ethics for the International Trade in Food.</p>
CCMAS	<p>Codex Committee on Methods of Analysis and Sampling</p> <p>Terms of Reference</p> <p>(a) to define the criteria appropriate to Codex Methods of Analysis and Sampling; (b) to serve as a coordinating body for Codex with other international groups working in methods of analysis and sampling and quality assurance systems for laboratories; (c) to specify, on the basis of final recommendations submitted to it by the other bodies referred to in (b) above, Reference Methods of Analysis and Sampling appropriate to Codex Standards which are generally applicable to a number of foods; (d) to consider, amend, if necessary, and endorse, as appropriate, methods of analysis and sampling proposed by Codex (Commodity) Committees, except that methods of analysis and sampling for residues of pesticides or veterinary drugs in food, the assessment of micro biological quality and safety in food, and the assessment of specifications for food additives, do not fall within the terms of reference of this Committee; (e) to elaborate sampling plans and procedures, as may be required; (f) to consider specific sampling and analysis problems submitted to it by the Commission or any of its Committees; and, (g) to define procedures, protocols, guidelines or related texts for the assessment of food laboratory proficiency, as well as quality assurance systems for laboratories.</p>
CCNFSDU	<p>Codex Committee on Nutrition and Foods for Special Dietary Uses</p> <p>Terms of Reference</p> <p>(a) to study specific nutritional problems assigned to it by the Commission and advise the Commission on general nutrition issues; (b) to draft general provisions, as appropriate, concerning the nutritional aspects of all foods; (c) to develop standards, guidelines or related texts for foods for special dietary uses, in cooperation with other committees where necessary; and, (d) to consider, amend if necessary, and endorse provisions on nutritional aspects proposed for inclusion Codex standards, guidelines and related texts.</p>
CCPR	<p>Codex Committee on Pesticide Residues</p> <p>Terms of Reference</p> <p>(a) to establish maximum limits for pesticide residues in specific food items or in groups of food; (b) to establish maximum limits for pesticide residues in certain animal feeding stuffs moving in international trade where this is justified for reasons of protection of human health; (c) to prepare priority lists of pesticides for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR); (d) to consider methods of sampling and analysis for the determination of pesticide residues in food and feed; (e) to consider other matters in relation to the safety of food and feed containing pesticide residues; and, (f) to establish maximum limits for environmental and industrial contaminants showing chemical or other similarity to pesticides, in specific food items or groups of food.</p>
CCRVDF	<p>Codex Committee on Residues of Veterinary Drugs in Foods</p> <p>Terms of Reference</p> <p>(a) to determine priorities for the consideration of residues of veterinary drugs in foods; (b) to recommend maximum levels of such substances; (c) to develop codes of practice as may be required; and, (d) to consider methods of sampling and analysis for the determination of veterinary drug residues in foods.</p>

List of Active Codex Alimentarius Committees and Task Forces

ACRONYM	NAME AND TERMS OF REFERENCE
CCCPC	Codex Committee on Cocoa Products and Chocolate Terms of Reference To elaborate world wide standards for cocoa products and chocolate
CCFAC	Codex Committee on Food Additives and Contaminants Terms of Reference (a) to establish or endorse permitted maximum or guideline levels for individual food additives, for contaminants (including environmental contaminants) and for naturally occurring toxicants in foodstuffs and animal feeds; (b) to prepare priority lists of food additives and contaminants for toxicological evaluation by the Joint FAO/WHO Expert Committee on Food Additives; c) to recommend specifications of identity and purity for food additives for adoption by the Commission; (d) to consider methods of analysis for their determination in food; and, (e) consider and elaborate standards or codes for related subjects such as the labelling of food additives when sold as such, and food irradiation.
CCFFP	Codex Committee on Fish and Fishery Products Terms of Reference To elaborate world wide standards for fresh, frozen (including quick frozen) or otherwise processed fish, crustaceans and molluscs.
CCFFV	Codex Committee on Fresh Fruits and Vegetables Terms of Reference (a) to elaborate world wide standards and codes of practice as may be appropriate for fresh fruits and vegetables; (b) to consult with the UN/ECE Working Party on Standardization of Perishable Produce in the elaboration of world wide standards and codes of practice with particular regard to ensuring that there is no duplication of standards or codes of practice and that they follow the same broad format; and, (c) to consult, as necessary, with other international organizations which are active in the area of standardization of fresh fruits and vegetables.
CCFO	Codex Committee on Fats and Oils Terms of Reference To elaborate world wide standards for fats and oils of animal, vegetable and marine origin including margarine and olive oil
CCMMP	Codex Committee on Milk and Milk Products Terms of Reference To elaborate world-wide standards, codes and related texts for milk and milk products.
CCMPH	Codex Committee on Meat and Poultry Hygiene Terms of Reference To elaborate world wide standards and/or codes of practice as may seem appropriate for meat and poultry hygiene.

ACRONYM	NAME AND TERMS OF REFERENCE
CCPFV	<p>Codex Committee on Processed Fruits and Vegetables</p> <p>Terms of Reference</p> <p>To elaborate world wide standards for all types of processed fruits and vegetables including dried products, canned dried peas and beans, jams and jellies, but not dried prunes, or fruit and vegetable juices. The Commission has also allocated to this Committee the work of revision of standards for quick frozen fruits and vegetables.</p>

AD HOC INTERGOVERNMENTAL TASK FORCES

List of Active Codex Alimentarius Committees and Task Forces

ACRONYM	NAME AND TERMS OF REFERENCE
TFAF	<p>Ad Hoc Intergovernmental Task Force on Animal Feeding</p> <p>Terms of Reference</p> <p>(a) To complete and extend the work already done by relevant Codex Committees on the Draft Code of Practice for Good Animal Feeding; (b) To address other aspects which are important for food safety, such as problems related to toxic substances, pathogens, microbial resistance, new technologies, storage, control measures, traceability, etc.; and, (c) To take full account of and collaborate with, as appropriate, work carried out by relevant Codex Committees, and other relevant international bodies, including FAO, WHO, OIE and IPPC.</p>
TFFBT	<p>Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology</p> <p>Terms of Reference</p> <p>(a) To elaborate standards, guidelines, or other principles, as appropriate, for foods derived from biotechnology; (b) To coordinate and closely collaborate, as necessary, with appropriate Codex Committees within their mandate as relates to foods derived from biotechnology; and, (c) To take full account of existing work carried out by national authorities, FAO, WHO, other international organizations and other relevant international fora.</p>
TFFJ	<p>Ad Hoc Intergovernmental Task Force on Fruit and Vegetable Juices</p> <p>Terms of Reference</p> <p>(a) revise and consolidate the existing Codex standards and guidelines for fruit and vegetable juices and related products, giving preference to general standards; (b) revise and up-date the methods of analysis and sampling for these products; and, (c) complete its work prior to the 26th Session of the Commission (2005).</p>

List of Active Codex Alimentarius Committees and Task Forces

ACRONYM	NAME AND TERMS OF REFERENCE
CCAFRICA	<p>FAO/WHO Coordinating Committee for Africa</p> <p>Terms of Reference</p> <p>(a) defines the problems and needs of the region concerning food standards and food control; (b) promotes within the Committee contacts for the mutual exchange of information on proposed regulatory initiatives and problems arising from food control and stimulates the strengthening of food control infrastructures; (c) recommends to the Commission the development of world wide standards for products of interest to the region, including products considered by the Committee to have an international market potential in the future; (d) develops regional standards for food products moving exclusively or almost exclusively in intra regional trade; (e) draws the attention of the Commission to any aspects of the Commission's work of particular significance to the region; (f) promotes coordination of all regional food standards work undertaken by international governmental and non-governmental organizations within the region; (g) exercises a general coordinating role for the region and such other functions as may be entrusted to it by the Commission; and, (h) promotes the acceptance of Codex standards and maximum limits for residues by member countries.</p>
CCASIA	<p>FAO/WHO Coordinating Committee for Asia</p> <p>Terms of Reference</p> <p>(a) defines the problems and needs of the region concerning food standards and food control; (b) promotes within the Committee contacts for the mutual exchange of information on proposed regulatory initiatives and problems arising from food control and stimulates the strengthening of food control infrastructures; (c) recommends to the Commission the development of world wide standards for products of interest to the region, including products considered by the Committee to have an international market potential in the future; (d) develops regional standards for food products moving exclusively or almost exclusively in intra regional trade; (e) draws the attention of the Commission to any aspects of the Commission's work of particular significance to the region; (f) promotes coordination of all regional food standards work undertaken by international governmental and non-governmental organizations within the region; (g) exercises a general coordinating role for the region and such other functions as may be entrusted to it by the Commission; and, (h) promotes the acceptance of Codex standards and maximum limits for residues by member countries.</p>
CCEURO	<p>FAO/WHO Coordinating Committee for Europe</p> <p>Terms of Reference</p> <p>(a) defines the problems and needs of the region concerning food standards and food control; (b) promotes within the Committee contacts for the mutual exchange of information on proposed regulatory initiatives and problems arising from food control and stimulates the strengthening of food control infrastructures; (c) recommends to the Commission the development of world wide standards for products of interest to the region, including products considered by the Committee to have an international market potential in the future; (d) develops regional standards for food products moving exclusively or almost exclusively in intra regional trade; (e) draws the attention of the Commission to any aspects of the Commission's work of particular significance to the region; (f) promotes coordination of all regional food standards work undertaken by international governmental and non-governmental organizations within the region; (g) exercises a general coordinating role for the region and such other functions as may be entrusted to it by the Commission; and, (h) promotes the acceptance of Codex standards and maximum limits for residues by member countries.</p>

CCLAC

FAO/WHO Coordinating Committee for Latin America and the Caribbean

Terms of Reference

(a) defines the problems and needs of the region concerning food standards and food control; (b) promotes within the Committee contacts for the mutual exchange of information on proposed regulatory initiatives and problems arising from food control and stimulates the strengthening of food control infrastructures; (c) recommends to the Commission the development of world wide standards for products of interest to the region, including products considered by the Committee to have an international market potential in the future; (d) develops regional standards for food products moving exclusively or almost exclusively in intra regional trade; (e) draws the attention of the Commission to any aspects of the Commission's work of particular significance to the region; (f) promotes coordination of all regional food standards work undertaken by international governmental and non-governmental organizations within the region; (g) exercises a general coordinating role for the region and such other functions as may be entrusted to it by the Commission; and, (h) promotes the acceptance of Codex standards and maximum limits for residues by member countries.

CCNASWP

FAO/WHO Coordinating Committee for North America and South West Pacific

Terms of Reference

(a) defines the problems and needs of the region concerning food standards and food control; (b) promotes within the Committee contacts for the mutual exchange of information on proposed regulatory initiatives and problems arising from food control and stimulates the strengthening of food control infrastructures; (c) recommends to the Commission the development of world wide standards for products of interest to the region, including products considered by the Committee to have an international market potential in the future; (d) develops regional standards for food products moving exclusively or almost exclusively in intra regional trade; (e) draws the attention of the Commission to any aspects of the Commission's work of particular significance to the region; (f) promotes coordination of all regional food standards work undertaken by international governmental and non-governmental organizations within the region; (g) exercises a general coordinating role for the region and such other functions as may be entrusted to it by the Commission; and, (h) promotes the acceptance of Codex standards and maximum limits for residues by member countries.

CCNEA

FAO/WHO Coordinating Committee for Near East

Terms of Reference

(a) defines the problems and needs of the region concerning food standards and food control; (b) promotes within the Committee contacts for the mutual exchange of information on proposed regulatory initiatives and problems arising from food control and stimulates the strengthening of food control infrastructures; (c) recommends to the Commission the development of world wide standards for products of interest to the region, including products considered by the Committee to have an international market potential in the future; (d) develops regional standards for food products moving exclusively or almost exclusively in intra regional trade; (e) draws the attention of the Commission to any aspects of the Commission's work of particular significance to the region; (f) promotes coordination of all regional food standards work undertaken by international governmental and non-governmental organizations within the region; (g) exercises a general coordinating role for the region and such other functions as may be entrusted to it by the Commission; and, (h) promotes the acceptance of Codex standards and maximum limits for residues by member countries.

List of Active Codex Alimentarius Committees and Task Forces

ACRONYM	NAME AND TERMS OF REFERENCE
CAC	Codex Alimentarius Commission Terms of Reference Cf. Statutes of the Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission Terms of Reference See the Rules of Procedure of the Codex Alimentarius Commission. The membership of the Executive Committee consists of the Chairperson and Vice-Chairpersons of the Commission together with seven further members, elected by the Commission at regular sessions from among the Members of the Commission, one each coming from the following geographic locations: Africa, Asia, Europe, Latin America and the Caribbean, Near East, North America, South-West Pacific; it being understood that not more than one delegate from any one country shall be a member of the Executive Committee. The 18th Session of the Commission (1989) agreed that Members elected on a regional basis may be accompanied by not more than two advisors from the same geographical location. Regional Coordinators are invited to attend meetings of the Executive Committee as observers.

APPENDIX 5 : CODEX ALIMENTARIUS – LIST OF VOLUMES

The Codex Alimentarius has an extensive compilation of Food Standards, Codes of Practice, Guidelines and Recommendations which are contained in the following 13 volumes:

VOLUME	TITLE
Vol. 1A	General requirements 2nd edition 1999. ISBN 92-5-104472-4
Vol. 1B	General requirements (food hygiene) 1995. ISBN 103766 <ul style="list-style-type: none"> • Supplement to volume 1B - General Requirements (Food hygiene) 2nd edition Second Edition 1997, 47 pp. ISBN 92-5-104029-X
Vol. 2	Pesticide residues in food 2nd edition 1993. ISBN 103271-8
Vol. 2A	Part 1 - Pesticide Residues in Food - Methods of analysis and sampling 2nd edition 2000. ISBN 92-5-104496-1
Vol. 2B	Pesticide residues in food - Maximum residue limits 2nd edition 2000. ISBN 92-5-004495-X
Vol. 3	Residues of veterinary drugs in foods 2nd edition 1996. ISBN 103822-8
Vol. 4	Foods for special dietary uses including food for infants and children 1994. ISBN 103510-5
Vol. 5A	Processed and quick frozen fruits and vegetables 1995. ISBN 92-5-103629-2
Vol. 5B	Tropical Fresh Fruits and Vegetables 2nd edition 1993. ISBN 103414-1 <ul style="list-style-type: none"> • Supplement 1 to volume 5B - Fresh fruits and vegetables 2nd Edition 1996. ISBN 92-5-103848-1
Vol. 6	Fruit juices and related products 2nd edition 1992. ISBN 103221-1
Vol.7	Cereals, pulses, legumes and derived products and vegetable proteins 2nd edition 1996. ISBN 92-5-103850-3
Vol. 8	Fats, oils and related products 2nd edition 1993. ISBN 103268-8

VOLUME	TITLE
Vol. 9	Fish and fishery products 2nd edition 2001. ISBN 92-5-1046603
Vol. 10	Meat and meat products including soups and broths 2nd edition 1993. ISBN 103425-7
Vol. 11	Sugars, cocoa products and chocolate and miscellaneous products 1994. ISBN 103508
Vol. 12	Milk and milk products 2nd edition 2000. ISBN 92-5-104497-X
Vol. 13	Methods of analysis and sampling 1994. ISBN 103612

APPENDIX 6 : FOOD SAFETY AUTHORITY OF IRELAND PUBLICATIONS

LEAFLETS

- Food Safety Authority of Ireland Corporate Leaflet
- Safe Food To Go
- Food Safety and Genetically Modified Foods
- Understanding Food Labelling
- Organic Food
- *E.coli* O157 Leaflets
- Reducing the Risk of *E.coli* O157 on the Farm
- *E.coli* O157 Preventing the Spread of Infection in the Abattoir
- *E.coli* O157 Preventing the Spread of Infection in the Food Factory
- *E.coli* O157 Protecting Yourself & Your Family
- *E.coli* O157 Protecting Vulnerable Groups

FACT SHEETS

- Guidance on the Use and Handling of Frying Fats and Oils
- Labelling of Genetically Modified Foods
- Salmonella
- Salmonella and Eggs – Advice for Caterers
- Salmonella enteritidis
- *E.coli* O157: H7
- Campylobacter
- Unpasteurised Milk
- Business Start-Up Information
- Food Safety Management System Based on the Principles of HACCP

POSTERS

- Food Labels – What Do They Mean?

REPORTS

- The Prevention of *E.coli* O157:H7 Infection: A Shared Responsibility
- Food Safety and Genetically Modified Foods
- Recommendations for a National Infant Feeding Policy
- Recommended Dietary Allowances for Ireland 1999
- Recommendations for a National Food and Nutrition Policy for Older People
- Legislation, Intake and Usage of Food Additives in Ireland
- The Labelling of Food in Ireland 2002
- Control of Campylobacter Species in the Food Chain
- A Compendium of Food Law in Ireland, 1998

- Annual Report 1999
- Annual Report 2000
- Food Safety Consultative Council Annual Report 2001
- The Introduction of Service Contracts: Reaction and Response (April 2000)

TRAINING GUIDES

- Guide to Food Safety Training – Level 1: Induction Skills
- Guide to Food Safety Training – Level 2: Additional Skills

CODES OF PRACTICE

- No. 1 Risk Categorisation of Food Businesses to Determine Priority for Inspection
- No. 2 Inspection of Food Operations Run by Health Boards
- No. 3 Risk Categorisation, Inspection and Sampling Frequencies of Meat Manufacturing Premises Producing Solely for the Domestic Market
- No. 4 Food Safety in the Fresh Produce Supply Chain in Ireland

GUIDANCE NOTES

- No. 1 Inspection of a Food Business
- No. 2 EU Classification of Food
- No. 3 Interpretation of Results of Microbiological Analysis of Some Ready-to-Eat Foods Sampled at Point of Sale
- No. 4 Approval and Operation of Independent Meat Production Units Under EC Meat Legislation: Meat Products, Minced Meat and Meat Preparations
- No. 5 Approval and Operation of Independent Meat Production Units Under EC Fresh Meat Legislation
- No. 6 Implementation of European Communities (Infant Formulae) Regulations, 1998 to 2000
- No. 7 The Labelling of Fish and Aquaculture Products According to Council Regulation (EC) No. 104/2000 and Commission Regulation (EC) No. 2065/2001
- No. 8 The Implementation of Food Safety Management Systems in Beef and Lamb Slaughter Plants based on HACCP Principles
- No. 9 Flavourings Legislation in Ireland
- No. 10 Product Recall and Traceability
- No. 11 Compliance with Regulation 4.2 of the European Communities (Hygiene of Foodstuffs) Regulations 2000 (S.I. No. 165 of 2000)

To order publications

Publications can be ordered from:

Food Safety Authority of Ireland, Abbey Court, Lower Abbey St., Dublin 1,
Tel: 1890 33 66 77
Fax: 01 – 8171301
Email: info@fsai.ie

APPENDIX 7 : NATIONAL STANDARDS AUTHORITY OF IRELAND (NSAI)

NSAI operates under the National Standards Authority of Ireland Act, 1996, on behalf of the Minister for Enterprise, Trade and Employment for the publication of national standards.

The Mission of NSAI Standards is to further the social and economic interests of the consumer and industry through the development and promotion of Irish, European and international Standards for products and services.

The following standards are of interest in the area of food hygiene:

NATIONAL REF:	TITLE:
I.S. 340:1994	Hygiene in the Catering Sector
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
I.S. 341:1998	Hygiene in food retailing and wholesaling
I.S. 344:2002	Hygiene for domestic-scale food production
I.S. 3219:1990	Code of Practice for Hygiene in the Food and Drink Manufacturing Industry

FOOD PROCESSING MACHINERY

I.S. EN 453:2000	Food processing machinery – Dough mixers – Safety and hygiene requirements
I.S. EN 454:2000	Food processing machinery – Planetary mixers – Safety and hygiene requirements
I.S. EN 1672-2:1997	Food processing machinery – Basic concepts – Part 2: Hygiene requirements
I.S. EN 1673:2000	Food processing machinery – Rotary rack ovens Safety and hygiene requirements
I.S. EN 1674:2000	Food processing machinery – Dough and pastry brakes Safety and hygiene requirements
I.S. EN 1678:1998	Food processing machinery – Vegetable cutting machines – Safety and hygiene requirements
I.S. EN 1974:1998	Food processing machinery – Slicing machines – Safety and hygiene requirements
I.S. EN 12041:2000	Food processing machinery Moulders – Safety and hygiene requirements
I.S. EN 12043:2000	Food processing machinery – Intermediate provers – Safety and hygiene requirements
I.S. EN 12505:2000	Food processing machinery – Centrifugal machines for processing edible oils and fats – Safety and hygiene requirements

NATIONAL REF:	TITLE:
I.S. EN 12852:2001	Food processing machinery – Food processors and blenders – Safety and hygiene requirements
I.S. EN 12853:2001	Food processing machinery – Hand-held blenders and whisks – Safety and hygiene requirements
I.S. EN 13390:2002	Food processing machinery – Pie and tart machines – Safety and hygiene requirements

PASTA PROCESSING PLANTS

I.S. EN 13289:2001	Pasta processing plants – Dryers and coolers – Safety and hygiene requirements
I.S. EN 13378:2001	Pasta processing plants – Pasta presses – Safety and hygiene requirements
I.S. EN 13379:2001	Pasta processing plants – Spreader, stripping and cutting machine, stick return conveyor, stick magazine – Safety and hygiene requirements

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