Agriculture and Agri-Food Canada | Agriculture et Agroalimentaire Canada

Canada

Canadian Exporters' Guide to Food Labelling & Packaging Requirements of the European Union

Canadian Mission to the European Union
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0. INTRODUCTION

0.1 EU FOOD LEGISLATION - OVERVIEW

The free movement of goods within a customs union lies at the heart of the Treaty of Rome forming the European Community (now commonly referred to as the European Union, or EU). This freedom, along with the free movement of persons, services and capital, was considered necessary to establish a common market, the Treaty's primary goal. Any barrier to internal trade is strictly regulated by the Treaty and the case law of the European Court of Justice.

The process of building a common EU market in foodstuffs, which began with the first Community directive on food in 1962, has been long and difficult but is now well advanced. Prior to 1985 the approach to foodstuffs legislation was implicitly based on the assumption that all specific requirements in national legislation necessarily met an essential public need. EU-level legislation was limited to so-called "recipe laws" applicable to certain special foodstuffs and some horizontal directives on additives, labelling and test methods, often of an optional nature. Barriers to internal trade were considerable.

Motivated by an important case law precedents (especially the famous Cassis de Dijon case), the European Commission issued Communications in 1985 and 1989 that began a process of important change in foodstuffs legislation. The strategy was to combine the adoption of harmonized rules at Community level, applicable to all foodstuffs marketed in the EU, with the principle of mutual recognition of national regulations and standards for matters where EU-level regulation was deemed unnecessary. Thus "vertical legislation" dealing with specific foodstuffs was supplemented with an increasing volume of "horizontal legislation" designed to establish common rules in the areas of public health protection, provision of consumer information (e.g. labelling), fair trading and official control. Virtually all the legislation set out in the mid-1980's (covering such areas as food hygiene, sweeteners, colours, contaminants, etc., but excluding food irradiation) has now been adopted. As well, member states must now notify all draft technical regulations concerning foodstuffs (including labelling) so that their compliance with EU legislation can be confirmed.

EU food legislation is constantly evolving. As suggested by a "green paper" on EU food law published in April 1997, new efforts are underway to simplify and rationalize legislation, taking a "stable to table" approach. Food safety is a major preoccupation in the wake of Europe's "mad cow" crisis. New legislation concerning novel foods has been adopted and a review of the nutritional labelling directive is pending.

Responsibility for proposing, debating and adopting EU legislation falls to the *European Commission, the Council of Ministers* and the *European Parliament*. The two main legal instruments for implementation of Community law are *directives* and *regulations*. A directive "directs" the 15 member states to implement the measure in national law usually by a specific deadline. A regulation is directly applicable and binding in its entirety without any legislative action by the member state.

The European Commission's White Paper on Food Safety, which was released 13 January 2000, seeks to reform EU food legislation and proposes the establishment of an independent EU Food Authority. The action plan includes a range of proposals concerning: a general food law directive, novel foods, labelling of GMO-free foodstuffs, hygiene, contaminants and residues, additives, flavourings, packaging and irradiation. Principles such as traceability, risk analysis, and the precautionary principle are part of the comprehensive and integrated approach to food safety. The

Commission plans to review food legislation and adopt the majority of changes by the end of 2002. While this objective is optimistic, it will have an impact on the regulations mentioned in this guide.

0.2 THE GENERAL APPROACH TO LABELLING

Council Directive 79/112/EEC on the labelling, presentation and advertising of foodstuffs was explicitly designed to constitute a single legislative framework for the compulsory rules on the labelling of foodstuffs. The Directive has now been amended many times, the most recent amendment was adopted in 1999.

Directive 79/112/EEC is based on the principle of functional labelling. The objective of the Directive is to ensure that consumers are provided with the essential information as regards the composition of the product, its manufacturer, and its methods of storage and preparation which are necessary to ensure consumer safety and fair competition. Producers and manufacturers are free to provide whatever additional information they wish, provided that this is accurate and does not mislead the consumer.

In addition to the rules laid down in *Directive 79/112/EEC*, a number of vertical texts contain specific mandatory labelling provisions, such as the Community rules on wine, fresh fruit and vegetables, eggs and the specific directives on foodstuffs for particular nutritional purposes. There is also legislation governing the provision of additional information by manufacturers on a voluntary basis. For example, nutritional labelling is not obligatory but if manufacturers wish to make nutritional claims they must do so in accordance with a standardized format. Similarly, *Council Regulation (EEC) 2092/91* sets out rules governing the use of the organic label on products. The responsibility for verifying claims made on labels lies with the Member States.

0.3 PURPOSE OF THIS GUIDE

After the US, the EU is the world's largest market for agri-food products. In 1997, the EU imported agri-food products worth US $80.8 billion from the rest of the world and exported US $62.3 billion outside the EU.(1) Canadian agri-food exports to the EU totalled Cdn $1.55 billion in 1998.(2) Value added, often consumer-ready products now make up half of this total and are expected to grow further. In order to achieve this growth, and noting that imports from third countries generally have to meet the same standards that are imposed on national products circulating within the Community, an understanding of EU labelling and packaging requirements is essential for export success.

This guide is intended to provide detailed and practical information on EU legislation governing the sale and marketing of packaged foodstuffs within the EU. In some cases, information is also provided on EU rules and requirements as regards composition and manufacturing of the foodstuff. As noted above, in some cases EU Member States may derogate from or supplement certain aspects of EU food legislation in their national legislation. Where this is the case the letters "MS" will appear at the end of the section and the reader will have to seek additional information through one of the information sources in the member states as listed in Annex III.

The Table of Contents should be consulted to determine what legislation is relevant to a given foodstuff. Sections 1 to 8 cover the "horizontal legislation" applicable to the full range of foodstuffs whereas Section 9 covers "vertical legislation" dealing with individual foodstuff categories. If a given foodstuff is not mentioned in Section 9 then only the horizontal legislation is

relevant.

The legislation has been analyzed and then the main provisions described in practical terms. The reader should note that *Council Directive 79/112/EEC*, known as the "Framework Directive on Labelling", is outlined in Sections 1.1 to 1.4 and provides the reader with the basic overview of EU labelling requirements. Similarly, *European Parliament and Council Directive 94/62/EEC*, known as the "Framework Directive on Packaging", is outlined in Section 3 and provides the basic overview of EU packaging requirements.

Annex I is a glossary covering terms mentioned throughout the guide, including references to where the definition was obtained.

The reader will notice that each section concludes with a reference to the EU legislation that imposes the requirements. Annex II provides the reader with an updated list of the EU legislation mentioned in the guide as well as the appropriate reference from the *Official Journal.*

Annex III lists the key points-of-contact in the EU-15 for Canadian exporters. The Commercial/Economic Division of the Canadian Embassies offer practical assistance regarding investment and trade opportunities.

Terms or phrases bolded and within quotations ("example") refer to particulars that should be indicated on the label. These are drafted in English throughout the guide, however, they must normally be written in the national language(s) of the country where the product is being sold.

Requirements listed in the format (a), (b), (c), etc., or (1), (2), (3), etc., and separated by semi-colons (;), must ALL be included to be in conformance with the legislation. Where a bullet ("•") precedes each item in a list, or each item is followed by "or", only ONE of the items must be included to be in conformance with the legislation.

Every effort has been made to make this guide as accurate as possible. However, it remains only a guide to a complex and continually changing subject. Before any Canadian agri-food exporter acts on information in this guide, they should seek professional advice to ensure they are in compliance with current EU legislation and any relevant national legislation in the member state to which they intend to export. Local agents and distributors will normally assist in seeking confirmation that a given label or type of packaging is acceptable.

Finally, the Canadian Mission and Canada's agri-food exporters are extremely grateful to **Ms. Stephanie Burnett** who, as a stagiaire at the Canadian Mission to the EU from January -March 1997, diligently researched and wrote this guide. We are also grateful to many officials of the European Commission for their expert advice and review of relevant sections. We believe this is the first comprehensive and detailed guide to EU food labelling and packaging requirements from any source. Comments on the guide are most welcome.

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Counsellor (Agriculture)
Canadian Mission to the EU
May 1997

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1. HORIZONTAL LEGISLATION - LABELLING-GENERAL PRINCIPLES

1.1 LEGISLATIVE FRAMEWORK

Foodstuffs for sale to the consumer or intended for supply to restaurants, hospitals, canteens and mass caterers in the EU must be labelled, presented and advertised correctly.

Directive 79/112 and its subsequent amendments are referred to as the "framework legislation" laying down general rules on labelling. However, it is possible that other EU directives and regulations or Member Statesï provisions applicable to certain specified foodstuffs supplement these general guidelines or derogate from them.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

1.2 NATURE OF LABELLING

All labelling and methods used must:

(a) be easy to understand;
(b) be marked in such a way as to be easily visible, clearly legible and indelible;
(c) protect public health;
(d) prevent fraud in trade;
(e) protect industrial and commercial property rights;
(f) appear in a language easily understood by the consumer.

For prepackaged foodstuffs, the compulsory labelling particulars should appear on the packaging or a label attached to it. For prepackaged foodstuffs intended for mass caterers (foodstuffs sold in bulk), the compulsory labelling particulars should appear on commercial documents while the name under which it is sold, the date of durability or use-by-date and the name of manufacturer should appear on the external packaging.

MS- Member States may adopt rules for labelling of products offered for sale to the ultimate consumer or mass caterers without packaging, or which will be packaged at the time of sale.
Member States may provide specific labelling rules for products in fancy packages.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

1.3 LANGUAGE USED FOR LABELLING

Labelling should be drafted in or at least translated into, the official language(s) of the country of marketing, permitting the use of foreign terms and expressions on the condition that this does not impair the consumer's understanding.

MS- Member States may require that the labelling be given in the national language(s).

Council Directive 79/112 of 18 December 1978 and subsequent amendments
Commission Communication 93/C 345/03 of 23 December 1993

1.4 GENERAL LABELLING REQUIREMENTS

The following shall be COMPULSORY on the labelling of foodstuffs:

(a) The **name** under which the product is sold.

(b) The **list of ingredients** including all the ingredients in descending order of weight as recorded at the time of their use in the manufacture of the foodstuff, preceded by a suitable heading which includes the word "**ingredients**".

(c) The **net quantity** of prepackaged foodstuffs in metric units (litre, centilitre, millilitre) for liquids and (kilogram, gram) for non-liquids.

(d) The **date of minimum durability** consisting of day, month and year in that order and preceded by the words "**best before**" or "**best before end**" or the "**use by**" **date** for highly perishable goods.

(e) Any special **storage conditions** or **conditions of use.**

(f) The **name or business name and address** of the manufacturer, packer or EU seller.

(g) Particulars of the **place of origin or provenance** in the cases where failure to give such particulars might mislead the consumer as to the true origin or provenance of the foodstuff.

(h) **Instructions of use** when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions.

(i) For beverages containing more than 1.2 % by volume of alcohol, the **actual alcoholic strength** by volume.

(j) **Lot marking** on pre-packaged foodstuffs with the marking preceded by the letter "**L**", except in cases where it is clearly distinguishable from other indications on the label.

MS- Member States may require additional labelling requirements.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments

1.4.1 THE NAME OF THE PRODUCT (GENERIC NAME)

Foodstuffs must be labelled with their generic name. No trademark, brand name or fancy name may be substituted for the name but rather may be used in addition. The name under which the product is sold shall include or be accompanied by particulars as to the physical condition of the foodstuff or the specific treatment to which it has undergone (powdered, freeze-dried, deep-frozen, concentrated, smoked) where omission of such may confuse the purchaser.

Any foodstuff that has been treated with ionizing radiation must indicate either "irradiated" or "treated with ionizing radiation".

The name must appear on the external packaging in which the foodstuffs are presented for

marketing along with the date of minimum durability or the use-by-date and the manufacturer's name. The name must appear in the same field of vision as the net quantity, the date of minimum durability or the use-by-date and the volume of alcohol.

In absence of EU recognition of a generic name, the name under which the product is sold shall be the name which has received Member State recognition. It is possible that a description of the foodstuff and if necessary, its use may be required where omission of such may confuse the consumer.

MS- Member States may require that the generic name be accompanied by an indication of a specific ingredient which characterises the product.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Commission Communication 91/C 270/02 provides conditions where an importing Member State may change the name of a product from that which it is marketed in order to alert the consumer the real nature of the product (vinegar, yoghurt, caviar).

1.4.2 LIST OF INGREDIENTS

All ingredients should be listed in descending order of weight preceded by the word "ingredients".

Compound ingredients constituting less than 25 % of the product (except in the case of additives) need only be labelled under their own name, whereas compound ingredients constituting more than 25 % of the product may be included in the list of ingredients under its own designation in terms of its overall weight, provided that it is immediately followed by a list of ingredients.

If an ingredient or category of ingredients appears in the name under which the foodstuff is sold, the quantity of that ingredient must be expressed as a percentage or the category must be mentioned in the list.

Water and volatile products are to be listed in order of their weight in the finished product. Water content need not be specified where water is used during the manufacturing process for reconstitution of ingredients in concentrated or dehydrated form or in the case of a liquid medium not normally consumed. Ingredients used in concentration or dehydration are to be listed in order of weight as recorded before concentration or dehydration and those reconstituted by the addition of water should be accompanied by an expression such as "ingredients of the reconstituted product" or "ingredients of the ready-to-use product".

In a mixture of fruits or vegetables or in a mixture of spices or herbs where no particular one dominates, the list should be accompanied by an expression like "in variable proportion".

The quantity of an ingredient or category of ingredients used in the manufacture or preparation of a foodstuff shall be compulsory on the labelling:

- where the ingredient or category of ingredients concerned appears in the name under which the foodstuff is sold or is usually associated with that name by the consumer, or
- where the ingredient or category of ingredients concerned is emphasized on the labelling in words, pictures or graphics, or
- where the ingredient or category of ingredients concerned is essential to characterize a foodstuff and to distinguish it from products with which it might be confused because of its name or appearance.

This requirement does not apply in the first two cases where the wording "with sweetener" or "with sugar(s) and sweetener(s)" accompanies the name or if vitamins and minerals are added which are subject to nutrition labelling.

The indication of quantity is not required for:

- ingredients whose drained net weight is already indicated, or
- ingredients whose quantities are already required under Community provisions, or
- ingredients used in small quantities for flavouring, or
- ingredients whose quantity is not essential to characterize the foodstuff or does not distinguish it from similar foods, or ingredients whose quantity has been stipulated by community provisions without providing for its indication on the labelling.

The indication of quantity should appear as a percentage in or next to the name of the foodstuff or in the list of ingredients.
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

1.4.2a SUBSTANCES NOT REGARDED AS INGREDIENTS

The following shall NOT be regarded as ingredients:

• the constituents of an ingredient which have been temporarily separated during the manufacturing process and later reintroduced but NOT in excess of their original proportions, or
• additives whose presence in a given foodstuff is solely due to the fact that they were contained in one or more ingredients of that foodstuff, provided that they serve no technological function in the finished product, or
• additives which are used as processing aids, or
• substances used in the quantities strictly necessary as solvents or media for additives or flavouring.
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

1.4.2b INGREDIENTS DESIGNATED BY INGREDIENT CATEGORY

The following categories of ingredients (listed under **DEFINITION**) may be designated by the name of the category (listed under **DESIGNATION**) rather than the specific name:

DEFINITION	DESIGNATION
refined oils other than olive oil	"vegetable oil" or "animal oil" with specific indication of origin "hydrogenated" must be indicated with hydrogenated oil or fat
refined fats	"vegetable fat" or "animal fat" with specific indication of origin
mixtures of flour from 2 or more cereal species	"flour" with list of cereals from which it was obtained in decreasing order of weight
starches/modified starches	"starch" with indication of specific vegetable origin when ingredient may contain gluten
species of fish as ingredient	"fish", if not a specific species
types of cheese as ingredient	"cheese"
spices less than 2 % of weight of foodstuff	"spice(s)" or "mixed spices"

herbs less than 2 % of weight of foodstuff	"herb(s)"of "mixed herbs"
gum preparation for gum base	"gum base"
crumbed baked cereal products	"crumbs" or "rusks"
types of sucrose	"sugar"
anhydrous dextrose/dextrose monohydrate	"dextrose"
(anhydrous) glucose syrup	"glucose syrup"
milk proteins (caseins, caseinates and whey proteins)/milk mixtures	"milk proteins"
various forms of cocoa butter	"cocoa butter"
crystallized fruit less than 10 % of weight	"crystallized fruit"
mixtures of vegetables less than 10 % of weight	"vegetables"
wine(3)	"wine"

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

1.4.2c CATEGORIES OF INGREDIENTS DESIGNATED BY NAME OF CATEGORY

The following categories of ingredients must be designated by the name of their category followed by their specific name or EEC number:

colours	preservatives	anti-oxidants
emulsifiers	thickeners	gelling agents
stabilizers	flavour enhancers	acids
acidity regulators	anti-caking agents	modified starches(5)
sweeteners	raising agents	anti-foaming agents
glazing agents	emulsifying salts(4)	flour treatment agents
firming agents	humectants	bulking agents
propellent gases		

If an ingredient belongs to more than one of the categories, the category appropriate to the principal function of the foodstuff in question shall be indicated.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

1.4.2d FOODSTUFFS FOR WHICH THE LIST OF INGREDIENTS NEED NOT BE MANDATORY

The following foodstuffs do NOT require a list of ingredients:

- fresh fruit and vegetables, or
- carbonated water, or
- fermentation vinegars derived from a single basic product, provided that no other ingredient has been added, or
- cheese, butter, fermented milk and cream, provided that no ingredient has been added other than lactic products, enzymes and micro-organism cultures essential to manufacture, or
- products consisting of a single ingredient where the trade name is identical or enables the nature of the ingredient to be identified.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

1.4.3 NET QUANTITY

The net quantity of prepackaged foodstuffs should be expressed in metric units (litre, centilitre,

millilitre) for liquids and (kilogram, gram) for non-liquids. However, this labelling is **NOT** compulsory for foodstuffs:

• which are subject to considerable losses in their volume or mass, or
• which are sold by number or weighed in the presence of the purchaser, or
• which has a net quantity less than 5 g or 5 ml (except herbs and spices).

Where a solid foodstuff is presented in a liquid medium, the drained net weight of the foodstuff shall also be indicated on the labelling.

If a prepackage item consists of two or more individual packages which are available as separate units containing the same quantity of the same product, the net quantity of each package plus the number of packages must be indicated unless this can be clearly seen from the outside. If a prepackage item consists or two or more individual packages which are **NOT** regarded as units of sale containing the same quantity of the same product, the net quantity shall be given by indicating the total net quantity and the total number of individual packages.

If the package is a measuring container and if the indication of its nominal capacity is visible under normal conditions of presentation, it is NOT necessary to indicate the nominal volume of contents.

MS- Member States may exempt specific foodstuffs from having to mention the total number of individual units.

Council Directive 71/316/EEC of 26 July 1971 and subsequent amendments
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

1.4.3a MARKINGS AND INSCRIPTIONS

Prepackaged foodstuffs must have the following markings:

(a) the indication of the quantity (also known as nominal weight or nominal volume) must be marked in figures of specific sizes (see chart below), depending upon the quantity of the contents and must be followed by the symbol for the unit of measurement (l, cl, ml or kg, g) or the name of the unit;

SIZE OF INDICATION	VOLUME OF CONTENTS
at least 6 mm high	if greater than 100 cl or 1000 g
at least 4 mm high	between 100 cl or 1000 g and 20 cl or 200 g
at least 3 mm high	between 20 cl or 200 g and 5 cl or 50 g
at least 2 mm high	less than 5 cl or 50 g

(b) a mark or description must identify the packer or the EU seller;
(c) a small "**e**", at least 3 mm high, must accompany the nominal weight or nominal volume (this letter should have the same form shown in the drawing contained in section 3 of Annex II to Directive 71/316/EEC).

Council Directive 71/316/EEC of 26 July 1971 and subsequent amendments
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 79/112/EEC of 12 December 1978 and subsequent amendments

1.4.4 DATE OF MINIMUM DURABILITY

The date of minimum durability shall be the date until which the foodstuff retains its specific properties when properly stored. The date of minimum durability must be indicated or a reference to where the date is given on the labelling and should be preceded by "best before" (when the date includes a indication of the day) or "best before end" (in other cases).

The date should consist of the day, month and year in this order however, for foodstuffs which:

• will NOT keep longer than three months, day and month must be indicated, or
• will keep within three and eighteen months, month and year must be indicated, or
• will keep for more than 18 months, year must be indicated.

If need be, a description of the storage conditions should follow the date of minimum durability if the storage influences the durability of the product. The date of minimum durability should appear in the same field of vision as the generic name and net quantity.

The date of durability is NOT required for:

• fresh fruit and vegetables, or
• wines; liqueur wines; sparkling wines; aromatized wines, or
• beverages containing 10 % or more by volume of alcohol; soft drinks; fruit juices; fruit nectars and alcoholic beverages in individual containers of more than 5 litres, or
• bakers' and pastry cooks' wares normally consumed within 24 hours of manufacture, or
• vinegar, or
• cooking salt, or
• solid sugar, or
• confectionary products of flavoured and/or coloured sugars, or
• chewing gums, or
• individuals portions of ice-cream.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

1.4.4a USE BY DATE (for highly perishable foodstuffs)

The phrase "**use by**" along with the date shall replace the date of minimum durability in foodstuffs that are highly perishable and therefore likely after a short period to constitute danger to human health. The use by date should consist of the day, month and possibly the year in uncoded form or a reference to where the date is given on the labelling. The "**use by**" phrase should by followed by a description of the storage conditions if the storage influences the durability of the product.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

1.4.5 STORAGE CONDITIONS AND CONDITIONS OF USE

Storage conditions and conditions of use should be indicated anywhere on the label however, they must follow the date of durability if storage influences the durability of the foodstuff.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

1.4.6 MANUFACTURER'S NAME

The name or business name and address of the manufacturer or packer or the EU seller must indicated.

MS- Member States may require that the indication of the factory or packaging centre in respect of domestic production be indicated.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

1.4.7 PLACE OF ORIGIN OR PROVENANCE

The place of origin or provenance must be stated in cases where failure to include such particulars might mislead the consumer.
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

1.4.8 INSTRUCTIONS OF USE

Instructions of use shall be indicated in such a way as to enable appropriate use of the foodstuff.
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

1.4.9 ACTUAL ALCOHOLIC STRENGTH

The figure for alcoholic strength shall be given to not more than one decimal place followed by the "**% vol**" symbol and may be preceded by the term "**alcohol**" or "**alc**". The actual alcoholic strength should be in the same field of vision as the product name, net quantity and minimum durability or use by date.
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Commission Directive 87/250/EEC of 15 April 1987

1.4.10 LOT MARKING

Foodstuffs must be accompanied by indication of the lot to which the foodstuff belongs and shall be preceded by the letter "**L**" except in cases where it is clearly distinguishable from the other indications on the label.

For prepackaged foodstuffs, the lot marking shall appear on the prepackaging or on a label attached to it. For non prepackaged foodstuffs, the lot marking shall appear on the packaging or on the container or on the relevant commercial documents that accompany the foodstuffs.

Lot marking is NOT necessary for:

• agricultural products sold or delivered to temporary storage, preparation or packaging stations, transported to producers' organizations or collected for immediate integration into an operational preparation or processing system, or
• foodstuffs sold in bulk to the consumer, or
• packages or containers with the largest side having an area less than 10 cm^2, or
• individual portions of ice cream, though it must appear on the combined package, or
• foodstuffs whose lot size is determined by the date of minimum durability or use-by-date, provided that date consists of a specified day and month.
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments

1.5 NUTRITIONAL LABELLING

Nutritional labelling is NOT compulsory except when a nutrition claim is made in the labelling, presentation or advertising of the product or when it is required by another EU directive.
MS- Member States may require that products for sale to the ultimate consumer or mass caterers without packaging or which will be packaged at the time of sale provide nutritional labelling.

Council Directive 90/496/EEC of 24 September 1990

1.5.1 DECLARATIONS

The labelling must consist of a numerical declaration of nutrients expressed per 100 g or per 100 ml or per serving (as quantified on the label) or per portion (provided that the number of portions contained in the package is stated). The information should be presented in tabular form, with the numbers aligned if space permits or where space does NOT permit, in linear form. The amounts should be those of the foodstuff as sold and this information may relate to the foodstuff after preparation, provided that sufficiently detailed preparation instructions are given and the information relates to the foodstuff as prepared for consumption.

Where nutritional labelling is provided, the information to be given shall consist of either group (1) or group (2) plus the claims' nutrients should be declared.

group 1	***group 2***
For a nutritional claim relating to energy, protein, carbohydrate or fat: energy value in kJ and kcal protein content in g carbohydrate content in g fat content in g	**For a nutritional claim made for sugars, saturates, fibre or sodium:** energy value in kJ and kcal protein content in g carbohydrate content in g sugars content in g fat content in g saturates content in g fibre content in g sodium content in g

Details concerning quantities of the following may also be included:

- starch content in g, or
- polyols content in g, or
- mono-unsaturates content in g, or
- polyunsaturates content in g, or
- cholesterol content in mg, or
- minerals or vitamins as listed in the Vitamins and Mineral Declarations section (see below).

Where sugars and/or polygols and/or starch are declared, this declaration shall immediately follow the declaration of the carbohydrate content in the following manner:

carbohydrate content in g	of which	sugars content in g polyols content in g starch content in g

Where the amount and/or type of fatty acid and/or the cholesterol rate is declared, this declaration shall immediately follow the declaration of the total fats in the following manner:

fat content in g	of which	saturates content in g mono-unsaturates in g polyunsaturates in g cholesterol content in mg

Where a nutritional claim is made referring to a substance of which belongs to or is a component of one of the following categories, the substance must also be mentioned separately:

- energy, or
- protein, or
- carbohydrate, or
- sugars, or
- fat, or
- saturates, or
- fibre, or
- sodium, or
- starch, or
- polyols, or
- mono-unsaturates, or
- polyunsaturates, or
- cholesterol, or
- vitamins and minerals.

Where the amount of polyunsaturates and/or mono-unsaturates and/or the cholesterol rate is given, the amount of saturates shall also be given.
Council Directive 90/496/EEC of 24 September 1990

1.5.2 VITAMIN AND MINERAL DECLARATIONS

Information on vitamins and minerals must be expressed as a percentage of the recommended daily allowance (RDA) and this percentage may be given in graphical form, however in the following manner:

NUT.	UNIT	RDA	NUT.	UNIT	RDA
Vitamin A	µg	800	Vit. B12	µg	1
Vitamin D	µg	5	Biotin	mg	0.15
Vitamin E	mg	10	Pantothenic Acid	mg	6
Vitamin C	mg	60	Calcium	mg	800
Thiamin	mg	1.4	Phosphorus	mg	800
Riboflavin	mg	1.6	Iron	mg	14
Niacin	mg	18	Magnesium	mg	300
Vitamin B6	mg	2	Zinc	mg	15
Folacin	µg	200	Iodine	µg	150

In deciding what constitutes a significant amount, as a rule 15 % of the RDA supplied by 100 g or 100 ml or per package if the package contains only a single portion should be taken into consideration.
Council Directive 90/496/EEC of 24 September 1990

1.5.3 DECLARATION OF ENERGY

The energy value should be calculated using the following conversion factors with the kJ preceding the kcal:

Carbohydrate (except polyols): 17 kJ/g - 4 kcal/g
Polyols: 10 kJ/g - 2.4 kcal/g
Protein: 17 kJ/g - 4 kcal/g
Fat: 37 kJ/g - 9 kcal/g
Alcohol (ethanol): 29 kJ/g - 7 kcal/g
Organic acid: 13 kJ/g - 3 kcal/g
Council Directive 90/496/EEC of 24 September 1990

1.5.4 CALCULATION OF DECLARED VALUES

The declared values for nutrients, micronutirents and fibre shall be average values based on:

(a) the manufacturer's analysis of the food;
(b) a calculation from the known or actual average values of the ingredients used;
(c) a calculation from generally established and accepted data.

MS- Member States may provide for determining the definition and fibre content.

Council Directive 90/496/EEC of 24 September 1990

2. FOOD ADDITIVES

2.1. LEGISLATIVE FRAMEWORK

Various EU directives and regulations lay down positive lists of food additives which apply to all foodstuffs to be consumed within the EU; set general purity criteria which the additives have to meet; and impose specific rules on labelling that supplement or amend Directive 79/112/EEC. Directive 89/107/EEC outlines a flexible framework for future legislation of this type.

Food additives of the following categories may be used or are intended to be used as ingredients during the manufacture or preparation of a foodstuff:

colours	preservatives	anti-oxidants
emulsifiers	thickeners	gelling agents
stabilisers	flavour enhancers	acids
acidity regulators	anti-caking agents	modified starches
sweeteners	raising agents	anti-foaming agents
glazing agents	emulsifying salts	flour treatment agents
firming agents	humectants	bulking agents
propellent gases	sequestrants	enzymes
packaging gases		

EU methods of analysis exist for verifying that additives satisfy general and specific criteria of purity.

Directive 95/2/EC regulates the authorization and conditions of use of food additives which are not colours, sweeteners or flour treatment agents. Directive 96/77/EC lays down specific criteria of purity for food additives other than colours or sweeteners.

MS- Member States may maintain prohibition of some additives in the production of foodstuffs considered as traditional, subject to certain conditions.

Commission Directive 81/712/EEC of 28 July 1981
Council Directive 89/107/EEC of 21 December 1988 and subsequent amendments
European Parliament and Council Directive 95/2/EC of 20 February 1995 and subsequent amendments
Commission Directive 96/77/EC of 2 December 1996 and subsequent amendments

2.1.1 ADDITIVES NOT INTENDED FOR SALE

Food additives from the above list NOT intended for sale to the ultimate consumer may be marketed only if their packaging or containers bear the following requirements:

(a) the name of the additive(s) used as laid down by EU provisions and its EEC number with other substances incorporated in the additive indicated, in descending order of the proportion by weight in the total;
(b) the statement "**for use in food**" or "**restricted use in food**" or a more specific reference to its intended food use;
(c) if necessary, special conditions of storage and use;
(d) if necessary, directions for use;
(e) lot marking;
(f) the name and address of the manufacturer or packer or the EU seller;
(g) compositional information to enable the purchaser to comply with EU provisions;
(h) the net quantity.
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/107/EEC of 21 December 1988 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments

2.1.2 ADDITIVES INTENDED FOR SALE

Food additives from the above list intended for sale to the ultimate consumer may be marketed only if their packaging or containers bear the following requirements:

(a) the name and EEC number under which the product is sold or a precise description of the product;
(b) the name of the additive(s) used as laid down by EU provisions and its EEC number with other substances incorporated in the additive indicated, in descending order of the proportion by weight in the total;
(c) the statement "**for use in food**" or "**restricted use in food**" or a more specific reference to its intended food use;
(d) if necessary, special conditions of storage and use;
(e) if necessary, directions for use;
(f) lot marking;
(g) the name and address of the manufacturer or packer or the EU seller;
(h) the net quantity;
(i) the date of durability.
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/107/EEC of 21 December 1988 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments

2.2 AUTHORIZED COLOURING MATTERS

Authorized colouring matters of Annex I to 62/2645/EEC satisfying EU general or specific purity criteria may be placed on the market only if their packaging or containers bear:

(a) the name and address of the manufacturer or EU seller;
(b) the number of colour matter(s) according to the EU numbering system listed in Annex I to Directive 62/2645/EEC;
(c) the words "**colour matter for foodstuffs**".
Council Directive 62/2645/EEC and subsequent amendments
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
European Parliament and Council Directive 94/36/EC of 30 June 1994

Commission Directive 95/45/EC of 26 July 1995 and subsequent amendments

2.3 DESIGNATION OF FLAVOURINGS

Specific labelling requirements for flavourings do NOT apply to:

• edible substances and products intended to be consumed as such, with or without reconstitution, or
• substances which have exclusively a sweet, sour or salt taste, or
• materials of vegetable or animal origin, having inherent flavouring properties, where they are NOT used as flavouring sources.
Council Directive 88/388/EEC of 22 June 1988 and subsequent amendments

2.3.1 FLAVOURINGS NOT INTENDED FOR SALE

Flavourings NOT intended for sale to the consumer may be marketed only if their packaging or containers bear:

(a) the name and address of the manufacturer, packer or EU seller;
(b) the sales description: either the word "**flavouring**" or a more specific name or description of the flavouring;
(c) either the statement "**for foodstuffs**" or a more specific reference to the foodstuff for which the flavouring is intended;
(d) a list in descending order of weight of the categories of flavouring substances and flavouring preparations present as follows (natural flavouring substances; flavouring substances identical to natural flavouring substances; artificial flavouring substances; flavouring preparations; process flavourings; smoke flavourings);
(e) in the case of a mixture of flavourings with other substances or materials, a list in descending order of weight in the mixture of:
• the categories of flavourings as mentioned in (4), or
• the names and where appropriate, EEC numbers of the other substances or materials
(f) an indication of the maximum quantity of each component or group of components subject to quantitative limitation in a foodstuff;
(g) lot marking;
(h) the net quantity.

The above markings (d) to (f) may appear on the trade documents relating to the consignment provided the indication "**intended for the manufacture of foodstuffs and not for retail**" appears in a conspicuous part of the packaging or container of the products in question.

"**Natural**" or any other word having substantially the same meaning may be used only for flavourings in which the flavouring component contains exclusively flavouring substances or flavouring preparations. If the name of the flavouring contains a reference to the vegetable or animal nature or origin of the incorporated substance, "**natural**" CANNOT be used unless the flavouring component has been isolated by appropriate physical processes, enzymatic or microbiological processes or traditional food-preparation processes solely or almost solely from the foodstuff or the flavouring sources concerned.
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 88/388/EEC of 22 June 1988 and subsequent amendments

2.3.2 FLAVOURINGS INTENDED FOR SALE

Flavourings intended for sale to the consumer may be marketed only if their packaging or containers bear:

(a) the name and address of the manufacturer, packer or EU seller;
(b) the sales description: either the word "**flavouring(s)**" or a more specific name or description of the flavouring;
(c) either the statement "**for foodstuffs**" or a more specific reference to the foodstuff for which the flavouring is intended;
(d) the date of minimum durability;
(e) where necessary, the special conditions for storage and use;
(f) where necessary, the instructions for use;
(g) in the case of a mixture of flavourings with other substances or materials, a list in descending order of weight in the mixture of:
• the flavouring(s), or
• the names and where appropriate, EEC numbers of the other substances or materials
(h) lot marking;
(i) the net quantity.

"**Natural**" or any other word having substantially the same meaning may be used only for flavourings in which the flavouring component contains exclusively flavouring substances or flavouring preparations. If the name of the flavouring contains a reference to the vegetable or animal nature or origin of the incorporated substance, "**natural**" CANNOT be used unless the flavouring component has been isolated by appropriate physical processes, enzymatic or microbiological processes or traditional food-preparation processes solely or almost solely from the foodstuff or the flavouring sources concerned.
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 88/388/EEC of 22 June 1988 and subsequent amendments

2.4 AUTHORIZED SWEETENERS

Authorized sweeteners listed in the Annex to Directive 94/35/EC that satisfy EU specific criteria of purity with a view to sale to the ultimate consumer or use in the manufacture of foodstuffs may be placed on the market only if details and warnings concerning the presence of certain sweeteners on foodstuffs are labelled. Sweeteners can not be used in food for infants or young children, unless otherwise laid down in specific provisions.

"**With no added sugar**" should be labelled if the foodstuff contains no added mono- or disaccharides or any other foodstuff used for its sweetening properties.

"**Energy-reduced**" should be labelled if the foodstuff has an energy value reduced by at least 30 % compared with the original foodstuff or a similar product.

The sales description of a tabletop sweetener must include the term "**... based table-top sweetener**" using the name(s) of the sweetening substance(s) used in its composition.

If the foodstuff contains polyols and/or aspartame, the labelling must bear the following warnings:

polyols: "**excessive consumption may induce laxative effects**"
aspartame: "**contains a source of phenylalanine**"

The following is a list of foodstuffs for which the labelling must include one or more additional

particulars which should accompany the name under which the product is sold:

TYPE OR CATEGORY OF FOODSTUFF	PARTICULARS
• foodstuffs containing a sweetener or sweeteners[(6)]	"**with sweetener(s)**"
• foodstuffs containing both added sugar(s) and sweetener(s)[(7)]	"**with sugar(s) and sweetener(s)**"

European Parliament and Council Directive 94/35/EC of 30 June 1994 and subsequent amendments
Commission Directive 94/54/EC of 18 November 1994 and subsequent amendments
Commission Directive 95/31/EC of 5 July 1995 and subsequent amendments

3.PACKAGING

3.1 LEGISLATIVE FRAMEWORK

Directive 94/62/EC lays down measures aimed at preventing the production of packaging waste; reusing packaging; recycling and other forms of recovering packaging waste; and reducing the final disposal of such waste.

Note: At the time of writing, there is a proposal for additional legislation in this area. The European Commission has proposed a Directive which will harmonize the use of symbols on packaging in order to promote reuse and recycling. It also includes a compliance assessment procedure which will be applicable to all packaging covered by Directive 94/62/EC.
European Parliament and Council Directive 94/62/EC of 20 December 1994 and subsequent amendments

3.1.1 IDENTIFICATION SYSTEM

Packaging shall bear the appropriate marking either on the packaging itself or on the label. It shall be clearly visible and easily legible. The marking shall be appropriately durable and lasting including when the packaging is opened.

The numbering shall be from:

(a) 1 to 19 for plastic;
(b) 20 to 39 for paper and cardboard;
(c) 40 to 49 for metal;
(d) 50 to 59 for wood;
(e) 60 to 69 for textiles;
(f) 70 to 79 for glass.

The identification system may also use the abbreviation for the relevant materials such as HDPE: high density polyethylene. Materials may be identified by a numbering system and/or abbreviation. The identification marks shall appear in the centre of or below the graphical marking indicating the reusable or recoverable nature of the packaging.
European Parliament and Council Directive 94/62/EC of 20 December 1994 and subsequent amendments

3.1.2 EU STANDARDS

Essential requirements on the composition and the reusable and recoverable, including recyclable, nature of packaging exist relating to:

(a) criteria and methodologies for life-cycle analysis of packaging;
(b) methods for measuring and verifying the presence of heavy metals and other dangerous substances in the packaging and their release into the environment from packaging and packaging waste;
(c) criteria for a minimum content of recycled material in packaging for appropriate types of packaging;
(d) criteria for recycling methods;
(e) criteria for composting methods and produced compost;
(f) criteria for the marking of packaging.
European Parliament and Council Directive 94/62/EC of 20 December 1994 and subsequent amendments

3.1.2a MANUFACTURING AND COMPOSITION REQUIREMENTS FOR PACKAGING

(a) packaging shall be so manufactured that the packaging volume and weight be limited to the minimum adequate amount to maintain the necessary level of safety, hygiene and acceptance for the packaged product and for the consumer;
(b) packaging shall be designed, produced and commercialized in such a way to permit its reuse or recovery, including recycling, and to minimize its impact on the environment when packaging waste or residues from packaging waste management operations are disposed of;
(c) packaging shall be so manufactured that the presence of noxious and other hazardous substances and materials as constituents of the packaging material or of any of the packaging components is minimized with regard to their presence in emissions, ash or leachate when packaging or residues from management operations or packaging waste are incinerated or landfilled.
European Parliament and Council Directive 94/62/EC of 20 December 1994 and subsequent amendments

3.1.2b REQUIREMENTS SPECIFIC TO THE REUSABLE NATURE OF PACKAGING

(a) the physical properties and characteristics of the packaging shall enable a number of trips or rotations in normally predictable conditions of use;
(b) possibility of processing the used packaging in order to meet health and safety requirements for the workforce;
(c) fulfil the requirements specific to recoverable packaging when the packaging is no longer reused and thus becomes waste.
European Parliament and Council Directive 94/62/EC of 20 December 1994 and subsequent amendments

3.1.2c REQUIREMENTS SPECIFIC TO THE RECOVERABLE NATURE OF PACKAGING

• MATERIAL: packaging must be manufactured in such a way as to enable the recycling of a certain percentage by weight of the material used into the manufacture of marketable products, in compliance with current standards in the EU
• ENERGY: packaging waste processed for the purpose of energy recovery shall have a minimum inferior calorific value to allow optimization of energy recovery
• COMPOSTING: packaging waste processed for the purpose of composting shall be of such biodegradable nature that it should NOT hinder the separate collection and the composting process or activity into which it is introduced
• BIODEGRADABLE MATERIAL: biodegradable packaging waste shall be of such a nature that it is capable of undergoing physical, chemical, thermal or biological decomposition such that most of the finished compost ultimately decomposes into carbon dioxide, biomass and water.
European Parliament and Council Directive 94/62/EC of 20 December 1994 and subsequent amendments

3.1.3 PREPACKAGED LIQUIDS

All liquid prepackages must bear an indication of volume of liquid, called the nominal volume of contents that satisfy the following requirements:

(a) the actual volume of the contents shall NOT be less, on average, than the nominal volume of the contents according to statistical controls as laid down in the Annexes;
(b) the proportion of the prepackages having a negative error greater than the tolerable negative error laid down in Annex I to Directive 75/106/EEC shall be sufficiently small for batches of prepackages to satisfy the requirements of tests listed in Annex II to Directive 75/106/EEC;
(c) no prepackage having a negative error greater than twice the tolerable negative error given in the Annex I to Directive 75/106/EEC may be marked with the EEC mark outlined in section 1.4.3a.

As well, basic conditions are laid down:

(a) the nominal volume of the content of a prepackage is the volume indicated on the prepackage;
(b) the actual volume of the contents of a prepackage is the volume of liquid it in fact contains; in all checking operations, the value employed for actual volume of the contents shall be measured at or corrected at a temperature of 20C;
(c) the negative error is the quantity by which the actual volume of the contents is less than the nominal volume of the contents of the package;
(d) the tolerable negative error shall be fixed according to the table in Annex I to Directive 75/106/EEC.

The markings and inscriptions are described in section 1.4.3a.

The quantities of liquids contained in prepackages shall be measured and checked on the responsibility of the packer or EU seller. This condition is fulfilled if the packer or EU sellercarries out production checks in accordance with procedures recognized by the competent authorities in the Member States. For imports, the EU seller may instead of measuring and checking, provide evidence that he is in possession of all the necessary guarantees enabling him to assume responsibility.

In principle the nominal volumes of the contents indicated in Annex III to Directive 75/106/EEC is mandatory for liquids such as wine of fresh grapes, 1(a), sparkling wines , 2(a) and spirits (4). For other liquids itemised in Annex III the shown nominal volume of content is not mandatory. Annex III to Directive 80/232/EEC lays down the volumes of the liquid phase for such products and, in the case of metal containers, the capacity of the container.

For multipacks made up of two or more individual prepackages, the standard ranges apply to the individual prepackages. For multipacks made up of two or more individual packages which are NOT intended to be sold individually, the prescribed ranges apply.
Council Directive 75/106/EEC of 19 December 1974 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments

3.1.4 PREPACKAGED NON-LIQUIDS

All non-liquid prepackages must bear an indication of weight , called the nominal volume of contents that satisfy the following requirements:

(a) the actual quantity of the contents shall NOT be less, on average, than the nominal quantity of

the contents;
(b) the proportion of the prepackages having a negative error greater than the tolerable negative error laid down in Annex I to Directive 76/211/EEC shall be sufficiently small for batches of prepackages to satisfy the requirements of tests listed in Annex II to Directive 76/211/EEC;
(c) no prepackage having a negative error greater than twice the tolerable negative error given in the Annex I to Directive 76/211/EEC may be marked with the EEC mark outlined in section 1.4.3a.

As well, basic conditions are laid down:

(a) the nominal quantity of the contents of a prepackage is the weight or volume indicated on the prepackage;
(b) the actual volume of the contents of a prepackage are the quantity (weight or volume) of product which it in fact contains; in all checking operations, the value employed for actual volume of the contents shall be measured at or corrected at a temperature of 20C, whatever the temperature at which packaging or checking is carried out; thisrule shall NOT apply to deep frozen or frozen products - the quantity of which is expressed in units of volume;
(c) the negative error is the quantity by which the actual volume of the contents is less than the nominal volume of the contents of the package;
(d) the tolerable negative error shall be fixed according to the table in Annex I to Directive 76/211/EEC.

The markings and inscriptions are described in section 1.4.3a.

The quantities of products contained in prepackages shall be measured and checked on the responsibility of the packer or EU seller. This condition is fulfilled if the packer or EU seller carries out production checks in accordance with procedures recognized by the competent authorities in the Member States. For imports, the EU seller may instead of measuring and checking, provide evidence that he is in possession of all the necessary guarantees enabling him to assume responsibility.

Annex I to Directive 80/232/EEC lays down for each of certain products the range of nominal quantities for the contents of prepackages. These ranges are not mandatory except for knitting yarn. Annex II to Directive 80/232/EEC lays down for such products the range of capacities for such containers.

For multipacks made up of two or more individual prepackages, the standard ranges apply to the individual prepackages. For multipacks made up of two or more individual packages which are NOT intended to be sold individually, the prescribed ranges apply.
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments

3.1.5 CONCENTRATION OF HEAVY METALS

The sum of concentration levels of lead, cadmium, mercury and hexavelant chromium present in packaging or packaging components shall NOT exceed:

(a) 600 ppm by weight after 30 June 1998;
(b) 250 ppm by weight after 30 June 1999;
(c) 100 ppm by weight after 30 June 2001.

Derogations apply to plastic crates and plastic pallets manufactured in a controlled recycling process. The recycled material must originate from other plastic crates or pallets and the

introduction of external material should be the minimum technically feasible, up to a maximum of 20% by weight.
European Parliament and Council Directive 94/62/EC of 20 December 1994 and subsequent amendments

3.2 MATERIALS AND ARTICLES

Materials and articles must be manufactured in compliance with good manufacturing practice (GMP) so that, under their normal or foreseeable conditions of use, they do NOT transfer their constituents to foodstuffs in quantities which could:

• endanger human health, or
• bring about an unacceptable change in the composition of the foodstuff, or
• bring about a deterioration in the organoleptic characteristics of the foodstuff.

However, covering or coating substances such as substances covering cheese rinds, prepared meat products or fruit, which form part of the foodstuffs and may be consumed together with those foodstuffs shall NOT be subject to the above condition.

If materials are NOT subject to specific EU legislation, materials and articles NOT already in contact with foodstuffs must when placed on the market be accompanied by:

(a) the words "**food use**" or a specific indication as to their use or an authorized symbol as in the Annex to Directive 80/590/EEC;
(b) where necessary, conditions to be observed when they are being used;
(c) the name or business name and the address of the registered office of the manufacturer, packer or EU seller or the registered trade mark of the manufacturer, packer or EU seller.

These particulars shall be labelled in a conspicuous, clearly legible and indelible manner and shall NOT be compulsory if by their nature are clearly intended to come into contact with the foodstuffs.

At the retail stage, these particulars should be:

• on the materials and articles or on the packaging, or
• on the labels affixed to the material and articles or to their packaging, or
• on a notice in the immediate vicinity of the materials and articles and clearly visible to purchasers.

At the marketing stage other than retail, these particulars should be:

(a) on the accompanying documents;
(b) on the labels or packaging or on the materials and articles themselves.

At the marketing stage other than retail, specific directives such as those concerning vinyl chloride monomer, plastics, regenerated cellulose film, ceramics, etc., shall require that such materials and articles be accompanied by a written declaration attesting that they comply with the rules applicable to them.
Commission Directive 80/590/EEC of 9 June 1980
Council Directive 89/109/EEC of 21 December 1988

3.2.1 VINYL CHLORIDE MONOMER

EU rules govern that materials and articles intended to come into contact with foodstuffs must NOT contain vinyl chloride monomer in a quantity exceeding 1 milligram per kilogram in the final product.

Criteria to determine the quantity released:

(a) the level of vinyl chloride in materials and articles and the level of vinyl chloride released by materials and articles to foodstuffs are determined by means of gas-phase chromatography using the "headspace" method;
(b) for the purposes of determining vinyl chloride released by materials and articles to foodstuffs, the detection limit shall be 0 01mg/kg;
(c) vinyl chloride released by materials and articles to foodstuffs is in principle determined in the foodstuff.

The Annex to Directive 80/766/EEC lays down the EU 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.

The Annex to Directive 81/432/EEC lays down the EU method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs.

MS- When the determination of vinyl chloride monomer in certain foodstuffs is shown to be impossible for technical reasons, Member States may permit determination by simulants for these particular foodstuffs.

Council Directive 78/142/EEC of 30 January 1978
Commission Directive 80/766/EEC of 8 July 1980
Commission Directive 81/432/EEC of 29 April 1981

3.2.2 PLASTICS

EU rules govern plastic materials and articles and parts:

• consisting exclusively of plastics which, in the final product are intended to come into contact with foodstuffs, or
• composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by other means which, in the final product are intended to come into contact with foodstuffs.

However these rules do NOT govern:

• varnished or unvarnished regenerated cellulose film., or
• elastomers and natural and synthetic rubber, or
• paper and paperboard, or
• surface coatings obtained from paraffin wax, micro-crystalline wax, mixtures of waxes, or
• ion-exchange resins.

EU rules govern the migration level of constituents from these materials and articles into or onto foodstuffs. Generally, plastics materials and articles shall NOT transfer their constituents to foodstuffs in quantities exceeding 10 mg/dm2 (overall migration limit) of the total surface area of material or article. However, this limit shall be 60 milligrams of the constituents released per kilogram of foodstuff (mg/kg) in:

• articles which are containers or are comparable to containers or which can be filled, with a capacity not less than 500 ml and not more than 10 L, or
• articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs, or
• caps, gaskets, stoppers or similar devices for sealing.

Only those monomers and other starting substances listed in Annex II, Section A and B to Directive 90/128/EEC and only those additives listed in Annex III to Directive 90/128/EEC may be used for the manufacture of plastic materials and articles subject to the migration limits.

The Annex to Directive 97/48/EC lays down the basic rules necessary for testing migration of the constituents of plastic material and articles intended to come into contact with foodstuffs. The Annex to Directive 85/572/EEC lays 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.
Council Directive 82/711/EEC of 18 October 1982 and subsequent amendments
Council Directive 85/572/EEC of 19 December 1985
Commission Directive 90/128/EEC of 23 February 1990 and subsequent amendments

3.2.3 REGENERATED CELLULOSE FILM

EU rules govern regenerated cellulose film that:

• constitutes a finished product in itself intended to come into contact with foodstuffs, or
• forms part of a finished product containing materials intended to come into contact with foodstuffs.

However these rules do NOT govern:

• regenerated cellulose film which on the side intended to come into contact with foodstuffs has a coating exceeding 50 mg/dm2, or
• synthetic casings of regenerated cellulose.

Substances or groups of substances listed in Annex II to Directive 93/10/EEC may be used for the manufacture of regenerated cellulose film and only under the conditions laid down therein. Substances employed as colouring matters (dyes/pigments) or as adhesives are also permitted, provided that there is no trace of migration of the substances into or onto the foodstuffs. Printed surfaces of regenerated cellulose film shall NOT come into contact with foodstuffs.

Where special conditions of use are indicated, the material or article of regenerated film shall be labelled accordingly.
Commission Directive 93/10/EEC of 15 March 1993 and subsequent amendments

3.2.4 CERAMIC

EU rules govern the quantities of lead and cadmium transferred from ceramic articles. These quantities are determined by means of a test, the conditions of which are specified in Annex I to Directive 84/500/EEC, using the method of analysis described in Annex II to Directive 84/500/EEC.

Three categories are defined:

• articles which CANNOT be filled and articles which can be filled, the internal depth of which,

measured from the lowest point to the horizontal plane passing through the upper rim does NOT exceed 25 mm, or

lead: 0,8 mg/dm2
cadmium: 0,07 mg/dm2

• all other articles which can be filled, or

lead: 4,0 mg/l
cadmium: 0,3 mg/l

• cooking ware; packaging and storage vessels having a capacity of more than 3 litres:

lead: 1,5 mg/l
cadmium: 0.1 mg/l.

Where a ceramic article consists of a vessel fitted with a ceramic lid, the lead and/or cadmium limits which may NOT be exceeded shall be that which applies to the vessel alone. The vessel alone and the inner surface of the lid shall be tested separately and under the same conditions. The sum of the two lead and/or cadmium extraction levels thus obtained shall be related as appropriate to the surface area of the volume of the vessel alone.

Where a ceramic article does NOT exceed the above quantities by more than 50 %, that article has satisfied the requirements if at least three other articles with the same shape, dimensions, decorations and glaze meet the necessary limits, with none of those articles exceeding those limits by more than 50 %.
Council Directive 84/500/EEC of 15 October 1984

3.3 PACKAGING GASES

Foodstuffs whose durability has been extended by means of packaging gases, must be labelled "**packaged in a protective atmosphere**".
Council Directive 89/107/EEC of 21 December 1988 and subsequent amendments
Commission Directive 94/54/EC of 18 November 1994 and subsequent amendments

4. FOODSTUFFS FOR PARTICULAR NUTRITIONAL USES

4.1 LEGISLATIVE FRAMEWORK

Directive 89/398/EEC lays down general criteria to which foodstuffs have to conform before being marketed. It defines and determines measures to protect the consumer against fraud and sets down rules for labelling the products in question. Products for particular nutritional uses are listed, as are the particular requirements they must fulfil. It also envisages the adoption of specific directives for certain groups of foodstuffs listed in Annex I to Directive to 89/398/EEC, some of which have already been adopted. In addition to these and other specific directives, dietetic products must also comply with any mandatory provisions applicable to foodstuffs for normal consumption.

Specific directives such as those relating to infant formulae, baby food, and weight- reduction foods cover:

(a) essential requirements as to the nature and composition of the products;

(b) provisions regarding the quality of raw materials;
(c) hygiene requirements;
(d) permitted changes that ensure that products conform to the particular nutritional requirements;
(e) a list of additives;
(f) provisions regarding labelling, presentation and advertising;
(g) sampling procedures and methods of analysis necessary for checking compliance with the requirements of specific directives.
Council Directive 89/398/EEC of 3 May 1989 and subsequent amendments

4.1.1 PARTICULAR NUTRITIONAL REQUIREMENTS

A particular nutritional use must fulfill the particular nutritional requirements:

• of certain categories of persons whose digestive processes or metabolism are distributed, or
• of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs, or
• of infants or young children in good health.
Council Directive 89/398/EEC of 3 May 1989 and subsequent amendments

4.1.2 LABELLING

With reference to section 1.4, the following must appear on the labelling for dietetic foods:

(a) generic name;
(b) list of ingredients;
(c) for packaged foodstuffs, the net quantity;
(d) date of minimum durability or use by date;
(e) storage conditions or conditions of use;
(f) the name or business name of the manufacturer, packer or EU seller;
(g) place of origin or provenance;
(h) instructions for use;
(i) lot marking.

In addition, products that refer to the first two of the requirements in section 4.1.1 may be labelled "**dietetic**" or "**dietary**". A procedure exists whereby foodstuffs for normal consumption may also indicate such suitability. Nutritional labelling is compulsory.

It is foreseen to adopt a list of substances such as vitamins, mineral salts, amino acids and other substances intended to be added to the foodstuff intended for particular nutritional uses, together with the purity criteria applicable to them, and, where appropriate, the conditions under which they should be used.

Conditions exist under which reference may be made in labelling, presentation and advertising to a diet or to a category of persons for which a product is intended. The labelling and labelling methods used, the presentation and the advertising of the products for particular nutritional uses must NOT attribute properties for the prevention, treatment, or cure of human disease unless a specific derogation has been adopted (none to date). This provision should not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition or pharmacy.

MS- Member States may require additional labelling particulars.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments
Council Directive 89/398/EEC of 3 May 1989 and subsequent amendments

4.1.2a GENERIC NAME

In addition to section 1.4.1, the designation under which the product is sold shall be accompanied by an indication of its particular nutritional characteristics. However, in the case of the products intended to fulfil the nutritional requirements of infants or young children in good health, the above reference shall be replaced by a reference to the purpose for which they are intended.
MS- Member States may require that the generic name be accompanied by an indication of a specific ingredient which characterizes the product.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/398/EEC of 3 May 1989 and subsequent amendments

4.1.2b NUTRITIONAL CHARACTERISTICS

The labelling of products for which NO specific directive has been adopted must also include:

(a) the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the product its particular nutritional characteristics;
(b) the available energy value expressed in kilojoules or kilocalories and the carbohydrate, protein and fat content per 100 grams or 100 millilitres of the product as marketed and, where appropriate, per specified quantity of the product as proposed for consumption. However, if the energy value is less than 50 kilojoules (12 kilocalories) per 100 grams or 100 millilitres of the product as marketed, these particulars may be replaced either by the words "**energy value less than 50 kilojoules (12 kilocalories) per 100 grams**" or by the words "**energy value less than 50 kilojoules (12 kilocalories) per 100 millilitres**".
Council Directive 89/398/EEC of 3 May 1989 and subsequent amendments

4.1.3 PACKAGING

In addition to packaging requirements outlined in section 3 and section 6, dietetic foodstuffs shall only be allowed on the retail market in pre-packaged form, and the packaging shall

completely cover the products unless the necessary labelling requirements accompany the product at the time when the product is put on sale.

Prepackaged liquid and non-liquid dietary foodstuffs must be prepackaged according to the rules outlined in section 3.1.3 and section 3.1.4.
Council Directive 75/106/EEC of 19 December 1974 and subsequent amendments
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments
Council Directive 89/398/EEC of 3 May 1989 and subsequent amendments

4.1.4 OFFICIAL MONITORING FOR FIRST-TIME PRODUCTS

Dietetic products that are NOT covered by a specific directive or do NOT belong to a group listed in Annex I to Directive 89/398/EEC may be placed on the market for the first time if an official monitoring within a Member State is conducted. To permit this official monitoring specific provisions must be followed:

(a) when a product is placed on the market for the first time, the manufacturer or EU seller shall notify the competent authority of the Member State where the product is being marketed by forwarding it a model of the label used for the product;
(b) where the same product is subsequently placed on the market in another Member State, the manufacturer or EU seller shall provide the competent authority of that Member State with the same information, together with an indication of the recipient of the first notification;
(c) where necessary, the competent authority shall be empowered to require the manufacturer or the EU seller to produce scientific work and the data establishing the product's compliance with the rules governing foodstuffs for particular nutritional uses.

Member States shall communicate to the Commission the identity of the competent authorities monitoring the products and other useful information which will then be published in the Official Journal of the European Communities (C series).
Council Directive 89/398/EEC of 3 May 1989 and subsequent amendments

4.2 INFANT FORMULAE AND FOLLOW-ON FORMULAE

EU rules govern the compositional and labelling requirements for infant formulae and follow-on formulae intended for use by infants in good health. They aim to provide health protection for the mother and the infant respecting their nutritional requirements and to ensure that only products that conform to the EU definitions and rules laid down may be marketed.
Commission Directive 91/321/EEC of 14 May 1991 and subsequent amendments

4.2.1 COMPOSITION AND MANUFACTURING

Infant formulae and follow-on formulae shall be manufactured from protein sources defined in the Annexes to Directive 91/321/EEC. Other foods ingredients whose suitability for particular nutritional use by infants from birth (infant formulae) or by infants aged over four months (follow-on formulae) that have been established within the EU are also permitted, according to the annexes to Directive 91/321/EEC. Infant formulae and follow-on formulae shall not contain any substance in such quantities (such as pesticide residues) which could endanger the health of infants and young children.
Commission Directive 91/321/EEC of 14 May 1991 and subsequent amendments

4.2.2 LABELLING

With reference to section 1.4, the following must appear on the labelling of infant-formulae and follow-on formulae:

(a) generic name;
(b) list of ingredients;
(c) for packaged foodstuffs, the net quantity;
(d) date of minimum durability;
(e) storage conditions or conditions of use;
(f) the name or business name of manufacturer, packer or EU seller;
(g) place of origin or provenance;
(h) instructions for use;
(i) lot marking.

The labelling of infant formulae and follow-on formulae shall be designed to provide the necessary information about the appropriate use of the products so as NOT to discourage breast-

feeding.

The use of terms "**humanized**", "**maternalized**", or similar terms shall be prohibited. The term "**adapted protein**" can only be used if the protein content is lower than 0.6 g/100 kJ (2.5 g/100 kcal) and the whey protein/casein ratio is NOT less than 1,0.

MS- Member States may require additional labelling particulars.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments
Commission Directive 91/321/EEC of 14 May 1991 and subsequent amendments

4.2.2a GENERIC NAME

In addition to section 1.4.1, the name under which the product is sold shall be, respectively "**infant formulae**" and "**follow-on formulae**".

MS- Member States may require that the generic name be accompanied by an indication of a specific ingredient which characterises the product.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Commission Directive 91/321/EEC of 14 May 1991 and subsequent amendments

4.2.2b SPECIFICALLY FOR INFANT FORMULAE

In addition to the compulsory labelling requirements outlined in section 4.2.2, the labelling of infant formulae shall bear the following mandatory particulars:

(a) a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are NOT breast-fed;
(b) in the case of infant formulae that do NOT contain added iron, a statement to the effect that, when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources;
(c) the available energy value, expressed in kJ and kcal, and the content of proteins, lipids and carbohydrates expressed in numerical form, per 100 ml of the product ready for use;
(d) the average quantity of each mineral substance and of each vitamin mentioned in the Annexes I and II to Directive 91/321/EEC respectively, and where applicable of choline, inositol, carnitine, taurine expressed in a numerical form, per 100 ml of the product ready to use;
(e) instructions for appropriate preparation of the product and a warning against the health hazards of inappropriate preparation;
(f) a statement concerning the superiority of breast-feeding;
(g) a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care.

The particulars in (f) and (g) are to be preceded by the words "**Important Notice**" or their equivalent.

The labelling of infant formulae shall NOT include pictures of infants, nor shall it include other pictures or text which may idealize the use of the product. It may, however, have graphic representation for easy identification of the product and for illustrating methods of preparation.

Claims about the particular composition of an infant formulae are made under the following conditions:

• "**adapted protein**" if the protein content is lower than 0.6 g/100 kJ (2.5 g/100 kcal) and the whey protein/casein ratio is NOT less than 1.0, or
• "**low sodium**" if the sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal), or
• "**sucrose free**" if NO sucrose is present, or
• "**lactose only**" if lactose is the only carbohydrate present, or
• "**lactose free**" if NO lactose is present, or
• "**iron enriched**" if iron is added, or

• "**reduction of risk to allergy to milk proteins**" (may include terms referring to reduced allergen or reduced antigen properties) if formulae satisfies provisions of Annex I and other conditions in Annex IV to Directive 91/321/EEC.
Commission Directive 91/321/EEC of 14 May 1991 and subsequent amendments

4.2.2c SPECIFICALLY FOR FOLLOW-ON FORMULAE

In addition to the compulsory labelling requirements outlined in section 4.2.2, the labelling of follow-on formulae shall bear the following mandatory particulars:

(a) a statement to the effect that the product is suitable for particular nutritional use by infants over the age of four months, that it should form only part of a diversified diet and that it is NOT to be used as a substitute for breast milk during the first four months of life;
(b) the available energy value, expressed in kJ and kcal, and the content of proteins, lipids and carbohydrates expressed in numerical form, per 100 ml of the product ready for use;
(c) the average quantity of each mineral substance and of each vitamin mentioned in the Annexes I and II to Directive 91/321/EEC respectively, and where applicable of choline, inositol, carnitine, taurine expressed in a numerical form, per 100 ml of the product ready to use;
(d) instructions for appropriate preparation of the product and a warning against the health hazards of inappropriate preparation.

In addition, the labelling may bear other information on nutrients according to the Annexes to Directive 91/321/EEC.
Commission Directive 91/321/EEC of 14 May 1991 and subsequent amendments

4.2.3 PACKAGING AND ADVERTISING

Liquid and non-liquid infant formulae and follow-on formulae must be prepackaged according to the rules outlined in section 3.1.3 and section 3.1.4. In addition to the packaging requirements outlined in section 3 and section 6, the EU requirements, prohibitions and restrictions on infant formulae and follow-on formulae mentioned above, shall also apply to the presentation of products concerned (packaging) and advertising.

Advertising of infant formulae is restricted to publications specializing in baby care and scientific publications. Such information shall NOT imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding. NO point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formulae directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales shall be permitted. Manufacturers and distributors of infant formulae shall NOT provide to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or other promotional gifts, either directly or indirectly via the health care system or health workers.

Informational and educational materials, whether written or audiovisual, dealing with the feeding

of infants and intended to reach pregnant women and mother of infants and young children shall include the clear information on all the following points:

(a) the benefits and superiority of breast-feeding;
(b) maternal nutrition and the preparation for and maintenance of breast-feeding;
(c) the possible negative effect on breast-feeding of introducing partial bottle-feeding;
(d) the difficulty of reversing the decision NOT to breast-feed;
(e) where needed, the proper use of infant formulae, whether manufactured industrially or home-prepared.

When such materials contain information about the use of infant formulae, they shall include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods, and, in particular, the health hazards of improper use of infant formulae. Such material shall NOT use any pictures which may idealize the use of infant formulae.

MS- Member States may require more specific rules concerning the information on baby feedings to which packages and advertising need abide.

Council Directive 75/106/EEC of 19 December 1974 and subsequent amendments
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments
Commission Directive 91/321/EEC of 14 May 1991 and subsequent amendments

4.3. PROCESSED CEREAL-BASED FOODS AND BABY FOODS

EU rules govern products intended for use by infants while they are being weaned, and by young children as a supplement to their diet and/or for their progressive adaptation to ordinary food. Nutritional labelling is compulsory.

Processed cereal-based foods and baby foods shall be manufactured from ingredients whose suitability for particular nutritional use by infants and young children has been established bygenerally accepted scientific data. Processed cereal-based foods shall comply with the compositional criteria specified in Annex I to Directive 96/5/EC while baby foods shall comply with the compositional criteria specified in Annex II to Directive 96/5/EC. Only the nutritional substances listed in Annex IV to Directive 96/5/EC may be added in the manufacture of processed cereal-based foods and baby foods. These products shall not contain any substance in such quantity as to endanger the health of infants and young children, including residues of pesticides.
Commission Directive 96/5/EC of 16 February 1996 and subsequent amendments

4.3.1 LABELLING

With reference to section 1.4, the following must appear on the labelling of cereal-based foods and baby foods:

(a) generic name;
(b) list of ingredients;
(c) for packaged foodstuffs, the net quantity;
(d) date of minimum durability or use by date;
(e) storage conditions or conditions of use;
(f) name or business name of manufacturer, packer or EU seller;
(g) place of origin or provenance;
(h) instructions for use;
(i) lot marking.

In addition, the labelling of processed cereal-based foods and baby foods should include the following particulars:

(a) a statement as to the appropriate age from which the product may be used, regard being had to its composition, texture or other particular properties. The stated age shall NOT be less than four months for any product;
(b) information as to the presence or absence of gluten if the indicated age from which the product may be used is below six months;
(c) the available energy value expressed in kJ and kcal, and the protein, carbohydrate and lipid content, expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption;
(d) the average quantity of each mineral substance and of each vitamin governed by a specific level in Annex I and II to Directive 96/5/EC respectively, expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption;
(e) instructions for appropriate preparation, when necessary, and a statement as to the importance of following those instructions.

The labelling may bear :

• the average quantity of the nutrients set out in Annex IV to Directive 96/5/EC, expressed in numerical form, per 100 g or 100 ml of the products as sold and, where appropriate, per specified quantity of the product as proposed for consumption
• in addition to the numerical information on vitamins and minerals, information on vitamins and minerals as shown in Annex V to Directive 96/5/EC, expressed as a percentage of the reference values given per 100g or 100 ml of the product as sold and where appropriate, per specified quantity of the product as proposed for consumption.

MS- Member States may require additional labelling particulars.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments
Commission Directive 96/5/EC of 16 February 1996 and subsequent amendments

4.3.2 PACKAGING

In addition to the packaging requirements outlined in section 3 and section 6, prepackaged baby food and cereal-based foods for infants and young children must be packaged according to the rules outlined in section 3.1.3 and section 3.1.4.
Council Directive 75/106/EEC of 19 December 1974 and subsequent amendments
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments

4.4 WEIGHT-REDUCTION FOODSTUFFS

EU rules govern compositional (Annex 1 to Directive 96/8/EC) and labelling requirements for foods for particular nutritional uses intended for use in energy restricted diets for weight reduction and presented as such. Nutritional labelling is compulsory.

The labelling, advertising and presentation of all products concerned for weight reduction shall NOT make any reference to the rate or amount of weight loss which may result from the use or to

a reduction in the sense of hunger or an increase in the sense of satiety.
Commission Directive 96/8/EC of 26 February 1996

4.4.1 LABELLING

With reference to section 1.4, the following must appear on the labelling for foods for use in energy-restricted diets for weight reduction:

(a) generic name;
(b) list of ingredients;
(c) the net quantity;
(d) date of minimum durability or use by date;
(e) storage conditions or conditions of use;
(f) name or business name of manufacturer, packager or EU seller;
(g) place of origin or provenance;
(h) instructions for use;
(i) lot marking.

The nature and destination of products intended for use in energy-restricted diets for weight reduction require additional nutritional labelling for the energy and principle nutrients they contain.

MS- Member States may require additional labelling particulars.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments
Commission Directive 96/8/EC of 26 February 1996

4.4.1a GENERIC NAME

In addition to section 1.4.1, "**total diet replacement for weight control**" shall accompany the name under which the product is sold for products presented as a replacement for the whole of the daily diet.

"**Meal replacement for weight control**" shall accompany the name under which the product is sold for products presented as a replacement for one or more meals of the daily diet.
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Commission Directive 96/8/EC of 26 February 1996

4.4.1b SPECIFICALLY FOR TOTAL DIET REPLACEMENT

In addition to the labelling requirements listed in section 4.4.1, the labelling of foods intended for use in energy-restricted diets for weight reduction should include the following particulars:

(a) the available energy value expressed in kJ and kcal and the content of proteins, carbohydrates and fat, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption;
(b) the average quantity of each mineral and each vitamin according to paragraph 5 of Annex 1 to Directive 96/8/EC, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption;
(c) when necessary instructions for appropriate preparation , a statement as to the importance of following those instructions;
(d) when necessary, a statement to the effect that the food may have a laxative affect if intake of

polyols is in excess of 20 g per day;
(e) a statement on the importance of maintaining adequate daily fluid intake;
(f) a statement that the product provides adequate amounts of all essential nutrients for the day;
(g) a statement that the product should NOT be used for more than three weeks without medical advice.
Commission Directive 96/8/EC of 26 February 1996

4.4.1c SPECIFICALLY FOR MEAL REPLACEMENT

In addition to the labelling requirements listed in section 4.4.1, the labelling of foods intended for use in energy-restricted diets for weight reduction should include the following particulars:

(a) the available energy value expressed in kJ and kcal and the content of proteins, carbohydrates and fat, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption;
(b) the average quantity of each mineral and each vitamin according to paragraph 5 of Annex 1 to Directive 96/8/EC, expressed in numerical form and as a percentage of the values outlined in section 1.5.2, per specified quantity of the product ready for use as proposed for consumption;
(c) when necessary instructions for appropriate preparation, a statement as to the importance of following those instructions;
(d) when necessary, a statement to the effect that the food may have a laxative affect if intake of polyols is in excess of 20 g per day;
(e) a statement on the importance of maintaining adequate daily fluid intake;
(f) a statement to the effect that the product is useful for the intended use only as part of an energy-restricted diet and that other foodstuffs should be a necessary part of such diet.
Commission Directive 96/8/EC of 26 February 1996

4.4.2 PACKAGING

In addition to the packaging requirements outlined in section 3 and section 6, all components of products intended for use in energy-restricted diets for weight reduction must be contained in the same package.

Prepackaged liquid and non-liquid foods intended for use in energy-restricted diets for weight-reduction must be packaged according to the rules outlined in section 3.1.3 and section 3.1.4.
Council Directive 75/106/EEC of 19 December 1974 and subsequent amendments
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments
Commission Directive 96/8/EC of 26 February 1996

4.5 DIETARY FOODS FOR SPECIAL MEDICAL PURPOSES

Directive 1999/21/EC governs the composition and labelling of dietary foods for special medical purposes. These foods are classified into three categories:

- nutritionally complete foods with a standard nutrient formulation which may constitute the sole source of nourishment for the intended consumer, or
- nutritionally complete foods with a nutrient-adapted formulation specific for a disease, disorder or medical condition which may constitute the sole source of nourishment for the intended consumer or may be used as a partial replacement or supplement to the patient's diet, or
- nutritionally incomplete foods with a standard formulation or a nutrient-adapted

formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment but may be used as a partial replacement or supplement to the patient's diet.

Commission Directive 1999/21/EC of 25 March 1999

4.5.1 COMPOSITION

Formulation of dietary foods for special medical purposes shall be based on sound medical and nutritional principles. These food products must comply with the compositional criteria specified in the Annex to Directive 1999/21/EC. The use of these foodstuffs, in accordance with the manufacturer's instructions, must be safe, beneficial, and effective in meeting the nutritional requirements of the intended consumers.
Commission Directive 1999/21/EC of 25 March 1999

4.5.2 LABELLING

With reference to section 1.4, the following must appear on the labelling of foods for special medical purposes:

(a) generic name;
(b) list of ingredients;
(c) the net quantity;
(d) date of minimum durability or use by date;
(e) storage conditions or conditions of use;
(f) name or business name of manufacturer, packager or EU seller;
(g) place of origin or provenance;
(h) instructions for use;
(i) lot marking.

Dietary foods for special medical purposes shall be sold under the name "**Food(s) for special medical purposes**". In addition, the following labelling particulars are required:

- the available energy value expressed in kJ and kcal, and the content of protein, carbohydrate and fat, expressed in numerical form per 100g or per 100ml of the product as sold and where appropriate, per 100g or per 100ml of the product ready for use in accordance with the manufacturer's instructions;
- the average quantity of each mineral substance and vitamin mentioned in the Annex to Directive 1999/21/EC which are present in the product. This should be expressed in numerical form as described in point (a) above;
- selectively the content of components of protein, carbohydrate and fat and/or of other nutrients and their components, the declaration of which would be necessary for the appropriate intended use of the product. These details should also be expressed in numerical form as described in point (a) above;
- information on the osmolality or the osmolarity of the product where appropriate;
- information on the origin and the nature of the protein and/or protein hydrolysates contained in the product.

(f) a statement that the product must be used under medical supervision;

(g) a statement whether the product is suitable for use as the sole source of nourishment;

(h) a statement that the product is intended for a specific age group, as appropriate;

(i) where appropriate, a statement that the product poses a health hazard when consumed by persons who do not have the diseases, disorders or medical conditions for which the product is intended.

Points (f) to (i) should be preceded by the words "**important notice**" or their equivalent.

The labelling shall also include:

- the statement "**For the dietary management of...**" with an indication of the diseases, disorders or medical conditions for which the product is intended;
- where appropriate, a statement concerning adequate precautions and contra-indications;
- a description of the properties and/or characteristics that make the product useful, in particular relating to the nutrients which have been increased, reduced, eliminated, or otherwise modified, and the rationale of the use of the product;
- where appropriate, a warning that the product is not for parenteral use.

The labelling shall bear instructions for the appropriate preparation, use and storage of the product after the opening of the container.
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Commission Directive 1999/21/EC of 25 March 1999

4.5.3 PACKAGING

In addition to the packaging requirements outlined in section 3 and section 6, prepackaged dietary foods for special medical purposes must be packaged according to the rules outlined in section 3.1.3 and section 3.1.4.
Council Directive 75/106/EEC of 19 December 1974 and subsequent amendments
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments

5. SPECIFIC FOODSTUFFS

5.1 CERTIFICATES OF SPECIFIC CHARACTER

The European Commission administers a register of certificates of specific character which lists the names of agricultural products and foodstuffs of which the specific character has been recognized at the EU level. Provision is made for allowing trade with third countries offering equivalent guarantees for the issue and inspection of certificates of specific character in their territory. Producers will be able to have unique characteristics of their products certified throughout the EU and protected from imitation.

EU recognition is obtained once the foodstuff has met **specific production criteria** and a **registration procedure** is completed. The certified specific character is subject to **official inspection.** Once a producer can prove that the foodstuff complies with the requirements of the relevant specification and the inspection body that has been selected has been approved, upon registration can he or she use a registered trade description or a EU symbol.

Agricultural products intended for human consumption plus certain foodstuffs from the list below

are eligible for certificates:

• beer, or
• chocolate and other food preparations containing cocoa, or
• confectionary, bread, pastry, cakes, biscuits and other baker's wares, or
• pasta, whether or not cooked or stuffed, or
• pre-cooked meals, or
• prepared condiment sauces, or
• soups or broths, or
• beverages made from plant extracts, or
• ice-cream and sorbets.

Council Regulation 2082/92/EEC of 14 July 1992

5.1.1 SPECIFIC PRODUCTION CRITERIA

Foodstuffs can be registered if:

(a) an agricultural product or foodstuff has either been produced using traditional raw materials or by traditional production methods;
(b) if its name is specific in itself and expresses the specific character of the agricultural product or the foodstuff.

Foodstuffs can NOT be registered if:

• the specific character is due to its provenance or geographical origin, or
• the specific character is due solely to the application of a technological innovation, or
• its name refers only to claims of a general nature used for a set of agricultural products or foodstuffs, or to those provided by specific EU legislation, or
• its name is misleading (such as not corresponding to the specification or to the consumer's expectations).

Council Regulation 2082/92 of 14 July 1992

5.1.2 REGISTRATION

In order to qualify for a certificate of specific character, an agricultural product must comply with a product specification. The product specification must include at least:

(a) the name in more than one languages;
(b) a description of the method of production, including the nature and characteristics of the raw material and/or ingredients used and/or the method of preparation of the agricultural product or the foodstuff, referring to its specific character;
(c) aspects allowing appraisal of its traditional character;
(d) a description of the agricultural product or the foodstuff giving its main physical, chemical, microbiological and/or organoleptic characteristics which relate to the specific character;
(e) the minimum requirements and inspection procedures to which specific character is subject.

Only a group can apply for a register. An application comprising of the product specification is submitted to the competent authority of the Member State in which the group is established. If the competent authority believes that the requirements are fulfilled, the application is then forwarded to the Commission. The Commission then forwards the translated application to other Member States. The Commission will then publish the application in the Official Journal and receive letters of opposition. If no opposition is expressed to the Commission within six months, the Commission shall enter the certificate in the EU register. Only then, can a producer use a EU

symbol and/or a prescribed indication in the labelling, presentation and advertising of the foodstuff.

Member States may submit that a criterion laid down in the product specification ceases to be met or can apply for an amendment to the product specification.
Council Regulation 2082/92/EEC of 14 July 1992

5.1.3 INSPECTION

Foodstuffs of specific character are subject to an inspection authority ensuring that the producer complies with the published information (ie. amendments to the application published in the Official Journal) before and while the product is placed on the market.
Council Regulation 2082/92/EEC of 14 July 1992

5.1.4 LISTS OF FOODSTUFFS OF SPECIFIC CHARACTER

The names listed in the Annexes of the following regulations are entered in the register of certificates of specific character:
Commission Regulation 2301/97/EC of 20 November 1997 and subsequent amendments
Council Regulation 2082/92/EEC of 14 July 1992

5.2 PROTECTION OF GEOGRAPHICAL INDICATIONS AND DESIGNATIONS OF ORIGIN

The European Commission administers a register for names indicating the geographic origin of agricultural products and foodstuffs protected at the EU level. For protected geographical indication status (PGI), the product must possess a specific quality, reputation or other characteristics attributable to that geographical area while for protected designation of origin status (PDO), the product's quality or characteristics are essentially or exclusively due to a particular geographical environment. Producers will be able to have the name of the product protected from imitation throughout the EU.

Provision is made for allowing trade agreements with third countries offering equivalent guarantees for the issue and inspection of PGI/PDO certificates in their territory. If a protected name from a third country is identical to a EU protected name, registration shall be granted with due regard for local and traditional usage and the practical risks of confusion. Such names shall be authorized only if the country of origin of the product is clearly and visibly indicated on the label.

EU recognition is obtained once the name of a foodstuff has met **specific criteria** and a **registration procedure** is completed. The certified PGI/PDO is subject to **official inspection.** Once a producer can prove that the foodstuff complies with the requirements of the relevant specification and the inspection body that has been selected has been approved, upon registration can he or she use either a registered protected name.

Agricultural products and certain foodstuffs are eligible PGI/PDO for certificates:

- beer, or
- natural mineral waters and spring waters, or
- beverages made from plant extracts, or
- bread, pastry, cakes, confectionary, biscuits and other baker's wares, or
- natural gums and resins, or
- hay, or

• essential oils, or
• cork, or
• cochineal (raw product of animal origin).
Council Regulation 2081/92 of 14 July 1992 and subsequent amendments

5.2.1 SPECIFIC CRITERIA

Names of foodstuffs may register for a PGI if the name refers to a foodstuff or agricultural product that :

(a) originates in a region, specific place or country;
(b) possesses a specific quality, reputation or other characteristics attributable to that geographical origin;
(c) is produced at least in one of its stages in the defined geographical area.

Names of foodstuffs may register for a PDO if the name refers to a foodstuff or agricultural product that:

(a) originates in a region, specific place or country;
(b) possesses the quality or characteristics which are due to the geographical environment;
(c) is produced at all stages in the defined geographical area.

Certain PGI shall be regarded as PDO where the raw materials of the products concerned come from a geographical area larger than or different from the processing area, provided that:

(a) the production area of the raw material is limited;
(b) special conditions for the production of the raw materials exist;
(c) inspection arrangements are available.

CANNOT be registered:

• generic names, or
• if the name conflicts with the name of a plant variety or an animal breed which is likely to mislead the public as to the true origin of the product.
Council Regulation 2081/92 of 14 July 1992 and subsequent amendments

5.2.2 REGISTRATION

In order to qualify for a PGI or PDO, an agricultural product or foodstuff must comply with a product specification. The product specification must include at least:

(a) the name of the product, including the designation of origin or the geographical indication;
(b) a description of the product including the raw materials, if appropriate, and its principal physical, chemical, microbiological and/or organoleptic characteristics;
(c) the definition of the geographical area;
(d) evidence that the product originates in the geographical area;
(e) a description of the method of obtaining the product;
(f) details bearing out the link with the geographical environment or the geographical origin;
(g) details of the inspection structures;
(h) the specific labelling details relating to the indication PGI or PDO, or the equivalent traditional national indications;
(i) any EU and/or national requirements.

Only a group or a natural or legal person can apply for a register. An application comprising of the product specification is submitted to the competent authority of the Member State in which the group is established. If the competent authority believes that the requirements are fulfilled, the application is then forwarded to the Commission. The Commission then forwards the translated application to other Member States. The Commission will then publish the application in the Official Journal and receive letters of opposition either from Member States or from any legitimately concerned natural or legal person. If no opposition is expressed to the Commission within six months, the Commission shall enter the PGI or PDO in the EU register. Only then, can a registered producer use the protected name and a prescribed indication of the PGI/PDO in the labelling, presentation and advertising of the foodstuff.

Member States may submit that a criterion laid down in the product specification ceases to be met or can apply for an amendment to the product specification. Transitional national protection can also be provided by Member States until registration is granted.
Council Regulation 2081/92/EEC of 14 July 1992 and subsequent amendments

5.2.3 INSPECTION

Names and foodstuffs of PGI and PDO are subject to an inspection authority ensuring that the producer complies with the published information (ie. amendments to the application published in the Official Journal) before and while the product with the protected name is placed on the market. Costs of inspections shall be borne by the producers using the protected name.
Council Regulation 2081/92/EEC of 14 July 1992 and subsequent amendments

5.2.4 PROTECTION OF REGISTERED NAMES

Registered names shall be protected against:

• any direct or indirect use of a registered name for comparable products NOT covered by the registration, or
• any use of a registered name that exploits the reputation of the protected name, or
• any misuse, imitation or evocation even if the true origin of the product is indicated or if the protected name is translated or accompanied by an expression such as "**style**", "**type**", "**method**", "**as produced in**", "**imitation**", etc., or
• any false or misleading indication as to the provenance, origin, nature or essential qualities of the product on packaging, advertising material or related documents, or
• any other practices liable to mislead the public as to the true origin of the product.
Council Regulation 2081/92/EEC of 14 July 1992 and subsequent amendments

5.2.5 USE OF TRADEMARKS

Use of trademarks which is in conflict with registered PGI/PDO is permissable if the trademark was registered in good faith before the date on which application for registration of PDO or PGI was lodged and if they conform with the EU legislation on trademarks.
Council Regulation 2081/92 of 14 July 1992 and subsequent amendments

5.2.6 LISTS of PGIs/PDOs

The names listed in the Annexes of the following regulations shall be registered as PGIs or PDOs:
Commission Regulation 1107/96/EC of 12 June 1996 and subsequent amendments
Commission Regulation 2400/96/EC of 17 December 1996 and subsequent amendments

These registered names shall be used only by producers operating in that region but Member States may continue to authorize the use of the registered names under certain conditions during a transitory period of 5 years after the date of the publication of the said registration.
Council Regulation 2081/92 of 14 July 1992 and subsequent amendments

6. CONTROL AND HYGIENE OF FOODSTUFFS

6.1 OFFICIAL CONTROL

Directive 89/397/EEC lays down the general principles for the performance of official control of foodstuffs. It provides for inspections by competent authorities of:

(a) foodstuffs;
(b) food additives, vitamins, mineral salts, trace elements and other additives intended to be sold as such;
(c) materials and articles intended to come into contact with foodstuffs.
Council Directive 89/397/EEC of 14 June 1989 and subsequent amendments

6.1.1 INSPECTIONS

The inspections must be carried out regularly and especially where non-compliance is suspected. Inspectors with adequate powers shall inspect at the production stage considered the most appropriate by the competent authority. Inspections shall cover all stages of production, manufacture, import into the EU, processing, storage, transport, distribution and trade. The inspections may also comprise of sampling and analysis, examination of the staff, examination of written and documentary material, and examination of any verification systems set up by the company.

The following shall be subject to inspection:

(a) the state and use of the site, premises, offices, plant surroundings, means of transport, machinery and equipment which is made at the different stages of the product's production, manufacture, etc.;
(b) raw materials, ingredients, technological aids and other products used for the preparation and production of foodstuffs;
(c) semi-finished products;
(d) finished products;
(e) materials and articles intended to come into contact with foodstuffs;
(f) cleaning and maintenance products and processes and pesticides;
(g) processes used for manufacture or processing of foodstuffs;
(h) labelling and presentation of foodstuff;
(i) preserving methods.

Inspections may also be supplemented by:

• interviews with the head of the inspected undertaking and with persons working for that undertaking, or
• the reading of the values recorded by measuring instruments installed by the undertaking, or
• inspections carried out by the competent authority, with its own instruments, of measurements taken with the instruments installed by the undertaking.

Samples may be taken for purposes of analysis carried out by official laboratories. Companies subject to an analysis of samples can apply for a second opinion.

List of competent authorities and official laboratories shall be published in the Official Journal ("C" series).
Council Directive 89/397/EEC of 14 June 1989 and subsequent amendments

6.1.2 SAMPLING AND ANALYSIS

EU methods of sampling and analysis to be undertaken to determine the composition, conditions of manufacture, packaging or labelling of a foodstuff shall be adopted by the Commission or Council with respect to criteria found in the Annex to Directive 85/591/EEC:

(a) specificity;
(b) accuracy;
(c) precision; repeatability within laboratory and reproducibility within and between laboratories; variability;
(d) limit of detection;
(e) sensitivity;
(f) practicability and applicability;
(g) other criteria may be selected as required.
Council Directive 85/591/EEC of 20 December 1985

6.2 HYGIENE

Directive 93/43/EEC establishes general rules for the level of food hygiene in the EU and the procedures for verification of compliance with these rules. The preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply of foodstuffs shall be carried out in a hygienic way.
Council Directive 93/43/EEC of 14 June 1993 and subsequent amendments

6.2.1 FOOD BUSINESS OPERATORS' RESPONSIBILITIES

Food business operators shall identify any step in their activities which is critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented, maintained and reviewed on the basis of the following principles used to develop the system of HACCP (Hazard analysis and critical control points):

(a) analyzing the potential food hazards in a food business operation;
(b) identifying the points in those operations where food hazards may occur;
(c) deciding which of the points identified are critical to food safety;
(d) identifying and implementing effective control and monitoring procedures at those critical points;
(e) reviewing the analysis of food hazards, the critical control points and the control and monitoring procedures periodically and whenever the food business operations change.

Food business operators shall comply with the rules of hygiene as listed in the Annex to Directive 93/43/EEC with the following outlined in detail:

(a) general requirements for food premises;
(b) specific requirements in rooms where foodstuffs are prepared, treated or processed;

(c) requirements for moveable and/or temporary premises; premises used primarily as a private dwelling house; premises used occasionally for catering purposes; vending machines;
(d) equipment requirements;
(e) transport requirements;
(f) food waste requirements;
(g) water supply requirements;
(h) personal hygiene requirements;
(i) production requirements;
(j) training requirements.
Council Directive 93/43/EEC of 14 June 1993 and subsequent amendments

6.2.2 GUIDES TO GOOD HYGIENE PRACTICE

MS- Member States may adopt guides to good hygiene practice which may be used voluntarily by food businesses as a guide to compliance with the rules of hygiene for foodstuffs. If there is a need for guides to be developed on a European basis, the Commission will do so through consultation with Member States. The titles and references shall then be published in the Official Journal ("C" Series).

Council Directive 93/43/EEC of 14 June 1993 and subsequent amendments

6.2.3 INSPECTIONS

Competent authorities shall carry out controls ensuring that foodstuffs including those imported into the EU are complying to the necessary hygiene requirements. Inspections shall include a general assessment of the potential food safety hazards associated with the business. Competent authorities shall pay particular attention to critical control points identified by food businesses to assess whether the necessary monitoring and verification controls are being operated.

If while carrying out the controls the competent authorities ascertain that failure to comply with the hygiene requirements might result in risks to the safety or wholesomeness of foodstuffs, they shall take appropriate measures which may extend to the withdrawal and/or destruction of the foodstuff or to the closure of all or part of the undertaking for an appropriate period of time. Those affected by the control have a right of appeal against the measures taken by the competent authority following the control.

If a hygiene problem likely to pose a serious risk to human health arises or spreads in the territory of a third country, the Commission, either on its own initiative or at the request of a

Member State, shall take the following measures without delay:

• suspend imports from all or part of the third country concerned and, where necessary, from the transit third country, and/or
• lay down special conditions for foodstuffs from all or part of the third country concerned.

Normally this would be done through consultation with Member States except in an emergency, the Commission may take interim protective measures regarding the foodstuff concerned.
Council Directive 93/43/EEC of 14 June 1993 and subsequent amendments

6.3 FOODSTUFFS TREATED WITH IONIZING RADIATION

The conditions for authorization of foodstuffs treated with ionizing radiation are given in Annex I

to Directive 1999/2/EC. Irradiation may be carried out by the sources listed in Annex II in accordance with the dosage and procedures in Annex III to Directive 1999/2/EC.

Directive 1999/3/EC lists the foodstuffs which may be treated with ionizing radiation and the maximum radiation doses authorized:

Category of foodstuff	**Maximum overall average absorbed radiation dose (kGy)**
Dried aromatic herbs, spices and vegetable seasonings	10

Labels on foodstuffs treated with ionizing radiation shall include the words "**irradiated**" or "**treated with ionizing radiation**". These words are also required for irradiated ingredients used in compound ingredients in foodstuffs even if these constitute less than 25 % of the finished product. The indication of treatment shall in all cases be given on documents which accompany or refer to irradiated foodstuffs.

Imports of foodstuffs treated with ionizing radiation must comply with the conditions for irradiated foodstuffs. Accompanying documents must show the name and address of the facility which carried out the treatment and provide the following information:

(a) nature and quantity of foodstuffs irradiated;
(b) the batch number;
(c) the person ordering the irradiation treatment;
(d) the recipient of the treated foodstuffs;
(e) date of irradiation;
(f) the packaging materials used during treatment;
(g) data for control of irradiation process as provided for in Annex III of Directive 1999/2/EC, the dosimetric checks and results, with details in particular of the lower and upper limits of the dose absorbed and the type of ionizing radiation;
(h) reference to the initial dose validation measurements.

Imports must be treated in an irradiation facility approved by the Community and appearing on a list of approved facilities.
European Parliament and Council Directive 1999/2/EC of 22 February 1999
European Parliament and Council Directive 1999/3/EC of 22 February 1999

7. CONTAMINATION

Foodstuffs containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall NOT be placed on the market.

Contaminant levels shall be kept as low as can reasonably be achieved during all stages of production, manufacture, processing, packaging, transport, etc.

Maximum tolerances for certain contaminants such as radioactive contamination, extraction solvents, pesticide residues have been established including:

(a) limits for the same contaminant in different foods;
(b) analytical detection limits;
(c) a reference to the sampling and analysis methods to be used.

MS- When EU rules do NOT govern, Member States may adopt new legislation in consultation with the Commission and other Member States.

Council Regulation 315/93 of 8 February 1993

7.1 RADIOACTIVE CONTAMINATION

EU rules govern the maximum permitted limits of radioactive contamination of foodstuffs which may be placed on the market following a nuclear accident or any other case of radiological emergency.

The maximum permitted levels for baby foods, dairy produce, liquid foodstuffs and other foodstuffs except minor foodstuffs (foodstuffs considered to be of minor dietary importance and account for only a small proportion of the average food intake) are listed in the Annex to Regulation 3954/87/EURATOM. The maximum levels for minor foodstuffs are listed in the Annex to Regulation 944/89/EURATOM.

The procedure of informing the Commission and Member States about significant increases in the level of radioactivity or about nuclear accidents in non-EU countries is outlined in Decision 87/600/EURATOM.

Importing foodstuffs from third countries that have undergone a nuclear accident shall be considered to be placed on the market if, on the customs territory of the EU, they undergo a customs procedure other than a transit procedure.
Council Regulation 3954/87/EURATOM of 22 December 1987 and subsequent amendments
Council Decision 87/600/EURATOM of 14 December 1987
Commission Regulation 944/89/EURATOM of 12 April 1989

7.2 EXTRACTION SOLVENTS

EU rules govern the use of extraction solvents in the manufacture of foodstuffs or food ingredients. However, they do not apply to extraction solvents used in the production of food additives, vitamins and other nutritional additives unless such are listed in the Annex to Directive 88/344/EEC.

Substances and materials listed in the Annex to Directive 88/344/EEC are authorized for use as extraction solvents in the manufacture of foodstuffs. However, they are subject to conditions of use, purity criteria and maximum residue limits. Substances listed in the Annex to Directive 88/344/EEC and intended for use as extraction solvents may NOT be marketed unless their packaging, containers, or labels carry the following information in an easily visible, clearly legible and indelible manner:

(a) the name as given in the Annex to Directive 88/344/EEC;
(b) a clear indication that the material is of a quality suitable for use for the extraction of food and food ingredients;
(c) lot marking:
(d) the name or business name and address of the manufacturer, packer or EU seller;
(e) the net quantity given as units of volume;
(f) when necessary, any special storage condition or conditions of use.

The particulars listed from (c) to (f) may appear merely on the trade documents relating to the batch or lot which are to be supplied with or prior to the delivery of the foodstuffs.

Council Directive 88/344/EEC of 13 June 1988 and subsequent amendments

7.3 PESTICIDES RESIDUES

EU rules govern the use of chemical pesticides in the production of plants, plant products and livestock. Maximum levels for certain pesticide residues in and on certain foodstuffs such as cereals, fruits and vegetables and certain products of animal origin have been fixed. Procedures for reducing specified levels and methods of sampling and analysis for monitoring levels are outlined in Directive 86/362/EEC, Directive 86/363/EEC and Directive 76/895/EEC.

Cereals listed in Annex I of Directive 86/362/EEC may NOT contain from the time they are put into circulation, levels of pesticide residues greater than those specified in Annex II to Directive 86/362/EEC. Authorization for the presence of pesticide residues listed in Part B of Annex II to Directive 86/362/EEC in or on cereals may extend the specified limits if theseproducts are NOT intended for immediate consumption and an appropriate control system ensures that they cannot be made available to the end user.

Foodstuffs of animal origin listed in Annex I to Directive 86/363/EEC may NOT contain from the time they are put into circulation, levels of pesticide greater than those specified in Annex II to Directive 86/363/EEC.

Fruits and vegetables listed in Annex I to Directive 76/895/EEC may NOT contain from the time they are put into circulation, levels of pesticide greater than those specified in Annex II to Directive 76/895/EEC unless Member States consider the foodstuffs justified.

Directive 90/642/EEC also applies maximum pesticide limits on products of plant origin as defined in Annex I. These products shall NOT contain from the time they are put into circulation, pesticide residue levels higher than those specified in Annex II to Directive 90/642/EEC.
Council Directive 76/895/EEC of 23 November 1976 and subsequent amendments
Council Directive 86/362/EEC of 24 July 1986 and subsequent amendments
Council Directive 86/363/EEC of 24 July 1986 and subsequent amendments
Council Directive 90/642/EEC of 27 November 1990 and subsequent amendments

8. MANUFACTURING AND PROCESSING PROCEDURES

8.1 QUICK-FROZEN FOODS

EU rules cover the composition, preparation, storage, labelling and packaging of quick-frozen foodstuffs.
Council Directive 89/108/EEC of 21 December 1988

8.1.1 COMPOSITION, PREPARATION, STORAGE

Raw materials used in the manufacture of quick-frozen foodstuffs must be of sound, genuine and merchantable quality and be of a degree of freshness.

Preparation and quick-freezing of products must be carried out promptly, using appropriate technical equipment, in order to limit chemical, biochemical and microbiological changes to a minimum.

The cryogenic media authorized for use in direct contact with quick-frozen foodstuffs must be of

air, nitrogen and carbon dioxide.

EU rules govern temperature controls in the means of transport, warehousing and storage of quick-frozen foodstuffs as well as official checks (Annex I and II to Directive 92/2/EEC) to monitor that these temperatures are met. Temperatures must be stable and maintained, at all points in the product, at - 18C or lower, with possibly brief upward fluctuations of no more than 3C during transport. The means of transport, warehousing and storage must be fitted with suitable recording instruments to monitor at frequent and regular intervals, the air temperatures to which quick-frozen foods intended for human consumption are subjected. In the case of transport, the measuring instruments must be approved by the competent authorities of the country in which means of transport is registered. Temperature recordings obtained in this manner must be dated and stored by the operator for at least one year or longer according to the nature of the food.
Council Directive 89/108/EEC of 21 December 1988
Commission Directive 92/1/EEC of 13 January 1992
Commission Directive 92/2/EEC of 13 January 1992

8.1.2 ADDITIONAL LABELLING REQUIREMENTS

In addition to the labelling requirements outlined in section 1.4, the following must appear on quick-frozen foodstuffs intended for supply to the ultimate consumer:

(a) "**quick-frozen**";
(b) in addition to the date of minimum durability, the period during which quick-frozen products may be stored by the purchaser and the storage temperature and/or type of storage equipment required;
(c) lot marking;
(d) a clear message of the type "**do not refreeze after defrosting**".

Quick-frozen products NOT intended for sale to the ultimate consumer or to mass caterers shall only contain the following mandatory information on the packaging, container or wrapper or on a label attached thereto:

(a) the sales name accompanied with the words "**quick-frozen**";
(b) the net quantity expressed in units of mass;
(c) lot marking;
(d) the name or business name and address of the manufacturer or packager or the EU seller.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/108/EEC of 21 December 1988
Council Directive 89/396/EEC of 14 June 1989

8.1.3 PACKAGING

In addition to the packaging requirements outlined in section 3 and section 6, quick-frozen foodstuffs intended for supply to the ultimate consumer must be packed by the manufacturer or packer in suitable pre-packaging which protects them from microbial or other forms of external contamination and against drying.
Council Directive 89/108/EEC of 21 December 1988

8.2 ORGANIC PRODUCTS

Products bearing the indication "**organic**", that is referring to organic production methods, may be:

• unprocessed agricultural crop products or livestock and unprocessed livestock products that comply with specific production and inspection rules in Annex I and III to Regulation 2092/91, or
• processed agricultural crop and livestock products intended for human consumption prepared essentially from one or more ingredients of plant and/or animal origin, or
• feedingstuffs, compound feedingstuffs and feed materials not covered by the first point above.

Council Regulation 2092/91 of 24 June 1991 and subsequent amendments

8.2.1 SPECIFIC PRODUCTION METHODS

8.2.1a PRODUCTS WITH AT LEAST 95% DERIVING FROM ORGANIC METHODS

A product bearing indications referring to organic production methods shall be labelled "**organic**" where:

- at least 95 % of the ingredients of agricultural origin contained in the product are derived from products obtained in accordance with the rules for organically produced products or are imported from third countries according to requirements in Regulation 2092/91;
- all other ingredients of agricultural origin are listed in Annex VI, section C of Regulation 2092/91 or have been provisionally authorized by a Member State;
- the product contains only substances listed in Annex VI, section A of Regulation 2092/91 (non-agricultural products);
- the product or its ingredients have NOT been subjected to treatments involving the use of substances NOT listed in Annex VI, section B of Regulation 2092/91;
- the product or its ingredients have NOT been subjected to treatments involving the use of ionizing rays;
- the product has been prepared or imported by an operator who is subject to inspection measures;
- the name and/or the code number of the inspection body to which the operator is subject is labelled;
- the product has been produced without the use of genetically modified organisms and/or any products derived from such organisms.

The indications referring to organic production methods must make it clear that they relate to a method of agricultural production and must be accompanied by a reference to the ingredients of agricultural origin concerned, unless such reference is clearly given in the list of ingredients.
Council Regulation 2092/91 of 24 June 1991 and subsequent amendments

8.2.1b PRODUCTS WITH AT LEAST 70% DERIVING FROM ORGANIC METHODS

A product bearing indications referring to organic production methods shall be labelled "**X % of the agricultural ingredients were produced in accordance with the rules of organic production**" where:

- at least 70% of the ingredients of agricultural origin contained in the product are derived from products obtained in accordance with the rules for organically produced products or are imported from third countries according to requirements in Regulation 2092/91;
- all other ingredients of agricultural origin are listed in Annex VI, section C of Regulation 2092/91 or have been provisionally authorized by a Member State;

- the indications referring to organic production methods appear in the list of ingredients in the same colour and with an identical size and style of lettering as the other ingredients;
- the indications referring to organic production methods also appear in a separate statement ("**X % of the agricultural ingredients were produced in accordance with the rules of organic production**") set in the same visual field as the sales description;
- the product contains only substances listed in Annex VI, section A of Regulation 2092/91 (non-agricultural products);
- the product or its ingredients have NOT been subjected to treatments involving the use of substances NOT listed in Annex VI, section B of Regulation 2092/91;
- the product or its ingredients have NOT been subjected to treatments involving the use of ionizing radiation;
- the product has been prepared or imported by an operator who is subject to inspection measures;
- the name and/or the code number of the inspection body to which the operator is subject is labelled;
- the product has been produced without the use of genetically modified organisms and/or any products derived from such organisms.

Council Regulation 2092/91 of 24 June 1991 and subsequent amendments

8.2.2 CONVERSION PERIOD

Crop products bearing the indication that farms are converting to organic production methods should be labelled as "**product under conversion to organic farming**" and must appear in a colour, size and style of lettering which is NOT more prominent than the product's sales description. The indication "**organic farming**" may NOT be more prominent that the words "**product under conversion to**". These products must meet the necessary production methods as described above and have been produced after a conversion period of 12 months even though the status of "**organic**" is normally granted after a two or three year conversion period.

These products may contain only one crop ingredient of agricultural origin. The product cannot be produced with the use of genetically modified organisms and/or products derived from such organisms.

The name and/or the code number of the inspection authority or body to which the operator who has carried out the most recent production or preparation operation is subject, must also appear on the labelling.
Council Regulation 2092/91 of 24 June 1991 and subsequent amendments

8.2.3 ORGANIC IMPORTS

Provisions are made for organic products from third countries where the third country has been recognized by the EU and where the products comply with production and inspection rules equivalent to those in the EU. The list of approved third countries is found in the Annex to Regulation 94/92. This regulation gives the requirements for application for inclusion in the list.

The competent authority or body in the third country must issue a certificate of inspection stating that the lot was obtained within these rules. A model of the inspection certificate is provided in Regulation 3457/92. The certificate must accompany the goods in the original copy to the premises of the first consignee.

Products shall be imported from a third country in appropriate packages or containers, which are closed in order to prevent subsitution of the contents. The products must show identification of

the exporter and any marks and numbers which identify the lot with the inspection certificate.

Canadian organic producers can be certified under the National Standard of Canada for Organic Agriculture developed by the Canadian Organic Advisory Board (COAB). However, this standard has not yet been approved to be equivalent to EU standards so Canada is not included on the list in Regulation 94/92. At the time of writing, Canada is planning to submit the organic standard to the Commission and will indicate that an inspection and accreditation system is being developed (COAB is applying to be an accredited certification body in Canada). The EU approval process involves an evaluation of the Canadian standard, the inspection system, and the certification organization. In order to be approved, the production and inspection standards must be equivalent to the EU standards and the inspection body in the third country should satisfy requirements of the EU standard EN45011 or the international standard ISO 65.

In the meantime, Canadian producers can export to the EU until 31 December 2005, subject to certain conditions. The importer must provide evidence to the Member State authority that the products are manufactured according to the EU production rules and are subject to inspection measures equivalent to the EU inspection scheme. Essentially, Canadian producers must conform with EN45011 or the equivalent ISO 65 to be eligible to export to Member States. The European standard was established in 1995, based on ISO 65, to ensure compliance of all certification organizations including those in third countries. It is the Member State's responsibility to assess third country compliance. This can be done by: (1) an official accreditation body in the third country or in the Member State; (2) a government authority in the third country; or (3) an authority in the Member State granting authorization.
Council Regulation 2092/91 of 24 June 1991 and subsequent amendments
Commission Regulation 94/92 of 14 January 1992 and subsequent amendments
Commission Regulation 3457/92 of 30 November 1992

8.2.4 INSPECTION SCHEME

Organic products which are covered by the inspection scheme may have an indication such as the phrase "**Organic Farming - EC Control System**" on the label if the products:

- satisfy the requirements of section 8.2.1a;
- have been subject to inspection arrangements throughout the production and preparation process;
- are sold directly by the producer/preparer to the ultimate consumer in sealed packaging, or are placed on the market as prepackaged foodstuffs;
- show on the labelling the name and/or business name of the producer, preparer or vendor with the name or code number of the inspection authority or body and other labelling requirements.

No claim may be made on the label or advertising material that suggests to the purchaser that the inspection logo constitutes a guarantee of superior organoleptic, nutritional or salubrious quality.
Council Regulation 2092/91 of 24 June 1991 and subsequent amendments

8.3 NOVEL FOODS

Specific additional labelling requirements are required for novel foods or novel food ingredients (including additives and flavourings) which fall under the following categories:

- foods and food ingredients containing or consisting of genetically modified organisms, or
- foods and food ingredients produced from genetically modified organisms, or

- foods and food ingredients with a new or intentionally modified primary molecular structure, or
- foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae, or
- foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals except those obtained by traditional propagating or breeding practices, or
- food and food ingredients which during production undergo significant changes in the composition or structure which affect their nutritional value, metabolism or level of undesirable substances.

Note: At the time of writing this guide, the European Commission was considering the publication of more detailed guidelines for labelling of novel foods containing genetically modified organisms. It also intends on developing a regulation concerning novel feeds. Directive 90/220/EEC is currently being revised to increase traceability and labelling of GMOs and to change the rules of risk assessments. Also, various member states have established national regulations or voluntary guidelines concerning labelling of food products containing GMOs.
European Parliament and Council Regulation 258/97/EC of 27 January 1997
Commission Regulation 50/2000/EC of 10 January 2000

8.3.1 LABELLING

If a novel food or novel food ingredient (including additives and flavourings) has undertaken the necessary safety and environmental assessment procedures and has been authorized within the EU, it can only be marketed if the consumer is informed of:

(a) any characteristic of food property such as composition, nutritional value or nutritional effects or intended use of food which renders a novel food or food ingredient no longer equivalent[(8)] to an existing food or food ingredient;

(b) the presence of material which is not in an existing equivalent[(9)] foodstuff and which may have implications for the health of consumers;

(c) the presence of material which is not in an existing equivalent[(10)] foodstuff and which gives rise to ethical concerns;

(d) the presence of an organism genetically modified by techniques of genetic modification such as those listed in Annex 1A Part 1 to Directive 90/220/EEC.

Novel Foods Regulation 258/97 requires all foods, additives and flavourings which contain genetically modified DNA or protein to be labelled:

- the words "**genetically modified**" or "**produced from genetically modified... (soya, maize, etc)**" as appropriate, shall appear in parentheses after the name of the ingredient in the list of ingredients, or as a footnote to the list of ingredients. Where no list of ingredients exists, the words above shall appear clearly on the label of the foodstuff
- where an ingredient of the foodstuff is designated by the name of an ingredient category, that designation should contain the phrase "**contains... produced from genetically modified soya/genetically modified maize**"
- where an ingredient of a compound ingredient is derived from the foodstuff produced with genetically modified soya or maize, it shall be mentioned on the labelling of the final product with the phrases "**produced from genetically modified soya**" or "**produced from**

genetically modified maize"

Regulation 49/2000 (amending Regulation 1139/98) provides that if the food contains less than 1% GM DNA or protein measured 'as a proportion of the food ingredients individually considered' and the quantity it contains is adventitious, labelling as containing GMOs is not required.

The European Commission intends on developing a negative list of food products which would be exempt from GMO labelling.

European Parliament and Council Regulation 258/97/EC of 27 January 1997
Council Regulation 1139/98/EC of 26 May 1998 and subsequent amendments
Commission Regulation 50/2000/EC of 10 January 2000

8.3.2 APPROVAL

Products containing or consisting of genetically modified organisms which are to be placed on the market must obtain consent from the Community. Before a GMO is placed on the market as or in a product, the manufacturer or the importer must submit a notification to the competent authority of the Member State where the product is to be placed on the market. Directive 90/220/EEC specifies the requirements of this notification with lists of the required information given in Annex II and III. Once the authority has given written consent, the product can be placed on the market throughout the Community.

At the time of writing, the EU has a 'de facto' ban on approval of new GMOs.

There is a separate approval process for Novel Foods which is described in Regulation 258/97. An applicant must submit a request to the Member State and to the Commission with the necessary information on the product, including studies and other material which demonstrate compliance with the regulation and a proposal for presentation and labelling. An initial assessment report is issued within 3 months of the receipt of the request. If objections are raised by the Commission or other Member States, or if an additional assessment is required, an authorization decision must be made which will determine conditions of use, designation of the food, specific labelling requirements, etc.

Commission Recommendation 97/618/EC provides details on the scientific aspects of the information necessary to support applications for placing novel foods and novel food ingredients on the market.

Council Directive 90/220/EEC of 23 April 1990 and subsequent amendments
European Parliament and Council Regulation 258/97/EC of 27 January 1997
Commission Recommendation 97/618/EC of 29 July 1997

9. VERTICAL LEGISLATION - SPECIFIC FOODSTUFF CATEGORY

Many of the regulations and directives in this section will be subject to changes being discussed in the European Parliament and the Council at the time of writing. Legislation concerning the following products is being updated and is at various stages of the approval process:

- sugars
- dehydrated milk products for human consumption
- fruit juices and similar products
- honey

- fruit jams, jellies and marmalade

Proposals for changes were introduced in 1996 in an attempt to simplify vertical legislation which regulates the labelling and composition requirements of certain foodstuffs.

9.1 ERUCIC ACID

The level of erucic acid in oils, fats and mixtures intended for human consumption calculated on the total level of fatty acids in the fat component, may NOT be greater than 5 %. This also applies to compound foodstuffs to which oils, fats or mixtures that have been added and the overall fat content of which exceeds 5 %.

The analysis necessary for the determination of the erucic acid content is outlined in Article 2 and in the Annex to Directive 80/891/EEC.
Council Directive 76/621/EEC of 20 July 1976
Commission Directive 80/891/EEC of 25 July 1980

9.2 COCOA AND CHOCOLATE

EU rules govern composition, labelling and packaging of cocoa and chocolate products defined in Annex I to Directive 73/241/EEC.

Note: At the time of writing, a new directive on the composition of cocoa and chocolate products intended for human consumption was approved by the European Parliament and the Council. Where possible, reference has been made to the provisions of this new directive although it has not yet been published in the Official Journal. This directive will eventually replace Directive 73/241/EEC.
Council Directive 73/241/EEC of 24 July 1973 and subsequent amendments

9.2.1 LABELLING

With reference to section 1.4, the following must appear on the labelling of cocoa and chocolate products:

(a) generic name as defined in the Annex to Directive 73/241/EEC;
(b) indication of cocoa, cocoa butter and vegetable fat content;
(c) type(s) of chocolate used;
(d) specific ingredients of certain products outlined in Annex I to Directive 73/241/EEC;
(e) the net weight;
(f) business name or name and address of manufacturer, packer or EU seller;
(h) lot marking.

MS- Member States may also require indication of:• the factory in respect of national production, or
• the country of origin.

For products put in packages or containers and holding a net weight of more than 10 kg and are NOT retailed, the cocoa content, type(s) of chocolate used, specific ingredients and netweight may appear only in the accompanying documents. The name or business name must also be mentioned for cocoa beans, cocoa nib, cocoa dust or fines, cocoa mass, cocoa press cake, fat-reduced cocoa press cake and expeller cocoa press cake.

MS- Member States may also require additional labelling particulars.

Council Directive 73/241/EEC of 24 July 1973 and subsequent amendments
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments

9.2.1a GENERIC NAME

With reference to section 1.4.1, the name reserved for the cocoa or chocolate products shall be accompanied by an indication to the filling product used.

Chocolate products which are sold in assortments may be labelled as "**assorted chocolates** " or "**assorted filled chocolates** " or similar names. In this case, there may be a single list of ingredients for all of the products in the assortment.

The name "**chocolate**", "**milk chocolate**" and "**couverture chocolate**" may also be supplemented by information or descriptions relating to quality criteria only if:

- the chocolate has a total dry cocoa solids content of at least 43 %, including at least 26 % cocoa butter, or
- the milk chocolate contains at least 30 % total dry cocoa solids and 18 % dry milk solids obtained by dehydration of milk or cream, including at least 4.5 % milk fat.
- the couverture chocolate has at least 16% of dry non-fat cocoa solids.

MS- Some Member States may permit the sale of chocolate products under the names "**cream chocolate**", "**skimmed-milk chocolate**" and "**chocolate familiar a la taza**".

Council Directive 73/241/EEC of 24 July 1973 and subsequent amendments
Council Dirертive 79/112/EEC of 18 December 1978 and subsequent amendments

9.2.1b COCOA CONTENT

The statement "**cocoa solids...% minimum**" must be used to indicate the total dry cocoa solids content for chocolate, powdered chocolate, chocolate in powder, sweetened cocoa, sweetened cocoa powder, drinking chocolate, milk chocolate, family milk chocolate, 'chocolate a la taza', and 'chocolate familiar a la taza'.

The cocoa butter content should also be labelled for fat-reduced cocoa, fat-reduced cocoa powder, fat-reduced drinking chocolate, fat-reduced sweeetened cocoa, and fat-reduced sweetened cocoa powder.

Vegetable fats other than cocoa butter which are defined in Annex II to Directive ( ), may be used in chocolate products within a limit of 5% of the finished product without reducing the minimum content of cocoa butter or total dry cocoa solids. The permitted vegetable fats are: illipe, palm oil, sal, shea, kokum guri and mango kernel.

Products containing the specified vegetable fats may be marketed in Member States, provided that the labelling contains a clearly legible statement "**contains vegetable fats in addition to cocoa butter** ". This statement should be in the same field of vision as the list of ingredients but clearly separated from that list.
Council Directive ( ) of ( ) (Directive not yet published in Official Journal)

9.2.1c TYPE OF CHOCOLATE

For filled chocolate and chocolates obtained from chocolate products other than chocolate and couverture chocolate, an additional indication of the types of chocolate used is mandatory.
Council Directive 73/241/EEC of 24 July 1973 and subsequent amendments

9.2.1d SPECIFIC INGREDIENTS

Cocoa or chocolate products:

- with crystallized glucose (dextrose) should be accompanied by "**with crystallized glucose**" or "**with dextrose**", or
- having a flavouring effect other than ethyl vanillin should have the statement "**...taste**" or "**...flavour**"; where ethyl vanillin is employed, "**with ethyl vanillin**" of "**ethyl vanillin flavour**" should be indicated, or
- with a technically pure vegetable lecithin addition should be accompanied by a declaration of this addition and its percentage, or
- with edible substances with the exception of flour and starches and of fat and fat preparations NOT derived exclusively from milk, a declaration relating to these edible substances should be accompanied by the name of the product.

Council Directive 73/241/EEC of 24 July 1973 and subsequent amendments

9.2.1e NET WEIGHT

With reference to section 1.4.3, in the case of products weighing less than 50 g per unit and presented in packages containing two or more such products, the net weight should be indicated on the outer wrapper or the individual net weight on each unit wrapper. In case of hollow moulded products, this information should be replaced by the minimum net weight.
Council Directive 71/316/EEC of 26 July 1971 and subsequent amendments
Council Directive 73/241/EEC of 24 July 1973 and subsequent amendments
Council Directive 75/106/EEC of 19 December 1974 and subsequent amendments
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments

9.2.2 PACKAGING

With reference to packaging requirements outlined in section 3 and section 6, cocoa and chocolate products should be prepackaged according to section 3.1.3 and section 3.1.4:

- chocolate, plain chocolate, gianduja nut chocolate, milk chocolate, milk chocolate with high milk content, gianduja nut milk chocolate, white chocolate and filled chocolate in the forms of bars or tablets each weighing NOT less than 85 g and NOT more than 500 g shall be marketed in the following individual weights, or

85 g	100 g	125 g	150 g	200 g	250 g	300 g	400 g	500 g

- cocoa powder products such as cocoa, cocoa powder, fat-reduced cocoa, fat-reduced cocoa powder, sweetened cocoa, sweetened cocoa powder, drinking chocolate, sweetened fat-reduced cocoa, sweetened fat-reduced cocoa powder and fat-reduced drinking chocolate when packaged in units having an individual net weight equal to or more than 50 g and

NOT exceeding 1 kg, shall be marketed in the following individual weights:

50 g	75 g	125 g	250 g	500 g	750 g	1 kg

MS- Member States may have rules for the retail sale of various chocolate products without wrapping.

Council Directive 71/316/EEC of 26 July 1971 and subsequent amendments
Council Directive 73/241/EEC of 24 July 1973 and subsequent amendments
Council Directive 75/106/EEC of 19 December 1974 and subsequent amendments
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments

9.3 SUGAR

EU rules govern composition, labelling and packaging of sugars.
Council Directive 73/437/EEC of 11 December 1973
Commission Directive 79/786/EEC of 26 July 1979

9.3.1 COMPOSITION AND MANUFACTURING

All sugar products defined in Article 1 to Directive 73/437/EEC must comply with the composition and manufacturing specifications laid down and are subject to specific testing. Sampling procedures and methods of analysis are set out in Annex I and II to Directive 79/786/EEC.

MS- Member States may permit higher levels in the case of glucose syrup and dried glucose syrup intended for use in sugar confectionary.

Council Directive 73/437/EEC of 11 December 1973
Commission Directive 79/786/EEC of 26 July 1979

9.3.2 LABELLING

With reference to section 1.4, the following must appear on the labelling on sugars:

(a) generic name as defined in Article 1 of Directive 73/437/EEC;
(b) the net weight;
(c) business name or name and address of the manufacturer, packer or EU seller;
(d) lot marking.

In addition, the following must also be mentioned on the labelling:

- indication of the true content of dry matter and invert sugar in the case of sugar solution, invert sugar solution, and invert sugar syrup, or
- the term "**crystallized**" for invert sugar syrup incorporating crystals in the solution, or
- the description of glucose syrup or dried glucose syrup of which the sulphur dioxide content exceeds 20 mg/kg shall be followed by a reference to the foodstuff for the manufacture of which it is intended; the maximum sulphur dioxide content of the product being indicated on the accompanying documents.

For sugar products made up into packages or containers or a net weight equal to or exceeding 10 kg and are NOT offered for retail sale, the last three requirements including the net weight may only appear on the accompanying documents.

MS- Member States may also require additional labelling such as :
• the factory, in respect of home production, or
• the country of origin.
Member States may require additional labelling particulars.

Council Directive 73/437/EEC of 11 December 1973
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments

9.3.2a GENERIC NAME

With reference to section 1.4.1, the names in Article 1 to Directive 73/437/EEC shall be used for the products that comply with the definitions.

The description "**white**" is reserved for:

- sugar solution where the colour in the solution does NOT exceed 25 ICUMSA units determined according to the methods provided for in the Annex to Directive 73/437/EEC, or
- invert sugar solution and for invert sugar syrup of which the ash content does NOT exceed 0.1% and the colour in solution does NOT exceed 25 ICUMSA units determined according to the method provided in the Annex to Directive 73/437/EEC.

The use of the word "**sugar**" without any other qualifying term shall apply only to direct trade in food sugars and NOT to compound products in which sugars have been used.

"**Monohydrate**" and "**anhydrous**" shall be used optionally for the retail trade description for dextrose monohydrate and dextrose anhydrous sugar products. However, the qualifying expression "**includes colouring agents**" shall be obligatory in the description of products containing colouring agents with the term "**white**" prohibited.
Council Directive 73/437/EEC of 11 December 1973
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

9.3.2b NET WEIGHT

The net quantity of sugar products should be according to the rules outlined in section 1.4.3. However, if products weighing less than 50 g each presented in packages containing two or more such products whose net weight inclusive of packaging is NOT less than 50 g, the total net weight of the products contained in the outer package must be indicated therein.

For semi-white sugar, sugar or white sugar, extra white sugar, dextrose monohydrate and dextrose anhydrous, the indication of net weight may be replaced by that of the minimum net weight if the products are offered for sale in pieces of small sachets.
Council Directive 71/316/EEC of 26 July 1971 and subsequent amendments
Council Directive 73/437/EEC of 11 December 1973
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments

9.3.3 PACKAGING

With reference to packaging requirements outlined in section 3 and section 6, prepackaged sugar products should be prepackaged according to section 3.1.3 and section 3.1.4:

• semi-white sugar, sugar or white sugar and extra white sugar when packed at a net individual weight of between 100 g and 5 kg shall be offered for sale only at the following individual net weights:

125g	250g	500g	750g	1kg	1.5kg	2kg	2.5kg	3kg	4kg	5kg

Council Directive 71/316/EEC of 26 July 1971 and subsequent amendments
Council Directive 73/437/EEC of 11 December 1973
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 75/106/EEC of 19 December 1974 and subsequent amendments
Council Directive 80/232/ EEC of 15 January 1980 and subsequent amendments

9.4 HONEY

EU rules govern the composition, labelling and packaging of honey.
Council Directive 74/409/EEC of 22 July 1974

9.4.1 COMPOSITION AND MANUFACTURING

All honey products defined in Article 1 to Directive 74/409/EEC must comply with specific compositional criteria listed in the Annex to Directive 74/409/EEC.

Honey shall be free from organic or inorganic matters foreign to its composition, such as mould, insects, insect debris, brood or grains of sand when the honey is marketed a such or used in any product for human consumption.

Honey shall NOT:

- have any foreign tastes or odours, or
- have begun to ferment or effervesce, or
- have been heated to such an extent that its natural enzymes are destroyed or made inactive, or
- have an artificially changed acidity.

Honey may be marketed as baker's honey or industrial honey if it does not comply with the first three particulars from above or if the diastase activity or hydroxymethylfurfural content do NOT comply with the specifications laid down in the Annex to Directive 74/409/EEC.

MS- Member States may authorize the marketing of heather honey with a maximum moisture content of 25%.
Member States may authorize the marketing of baker's honey in industrial honey with a moisture content of NOT more than 25 %.

Council Directive 74/409/EEC of 22 July 1974

9.4.2 LABELLING

With reference to section 1.4, the following must appear on the labelling on honey:

(a) generic name as defined in Article 1 of Directive 74/409/EEC;
(b) for packaged foodstuffs, the net weight in kg or g;
(c) date of minimum durability;
(d) storage conditions or conditions of use;
(e) the name or business name and address of the manufacturer, packer or EU seller;
(f) origin or provenance;
(g) instructions of use;
(h) lot marking.

Where honey is put in packages or containers of a net weight equal to or exceeding 10 kilograms and is NOT retailed, the net quantity and the manufacturer's name may appear only on the accompanying documents.

MS- Member States may also require additional particulars.

Council Directive 74/409/EEC of 22 July 1974
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments

9.4.2a GENERIC NAME

With reference to section 1.4.1, the term "**honey**" can only be applied to products defined in Article 1 of Directive 74/409/EEC:

• blossom honey, or
• honeydew honey, or
• comb honey, or
• chunk honey, or
• drained honey, or
• extracted honey, or
• pressed honey

In addition, the following may also be labelled:

- a reference to the origin, whether blossom or plant, provided that the product comes predominantly from the source indicated and has the appropriate organoleptic, physio-chemical, and microscopic characteristics, or
- a regional, territorial or topographical name, provided the product originates entirely in the area indicated.

MS- Member States may authorize the use of "**honeydew honey**" for honey which is predominantly honeydew honey, which has the organoleptic, physio-chemical and microscopic characteristics of such honey and for which there is given NO indication of a specific plant origin, such as "pine honey".
Member States may require that the labelling indicate the country of origin.

Council Directive 74/409/EEC of 22 July 1974
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

9.4.3 PACKAGING

With reference to packaging requirements outlined in section 3 and section 6, honey products

should be prepackaged according to section 3.1.3 and section 3.1.4.

MS- Member States may require honey be offered for sale at specific individual net weights.

Council Directive 71/316/EEC of 26 July 1971 and subsequent amendments
Council Directive 74/409/EEC of 22 July 1974
Council Directive 75/106/EEC of 19 December 1974 and subsequent amendments
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments

9.5 FRUIT JUICES AND NECTARS

EU rules govern composition, labelling and packaging of fruit juices and nectars.
Commission Directive 93/45/EEC of 17 June 1993
Council Directive 93/77/EEC of 21 September 1993

9.5.1 COMPOSITION AND MANUFACTURING

All fruit juice and nectar products (fruit juice, concentrated fruit juice, fruit nectar, dried fruit juice) defined in Article 1 to Directive 93/77/EEC must comply with the composition and manufacturing specifications laid down in Articles 4, 5, 6, and 7 of Directive 93/77/EEC and Directive 93/45/EEC.

MS- Member States may permit use of additional vitamins, additional substances and the process of diffusion.

Commission Directive 93/45/EEC of 17 June 1993
Council Directive 93/77/EEC of 21 September 1993

9.5.2 LABELLING

With reference to section 1.4, the following must appear on the labelling of fruit juices and nectars:

(a) generic name as defined in Article 1 to Directive 93/77/EEC;
(b) list of ingredients;
(c) for packaged foodstuffs, the net quantity;
(d) date of minimum durability;
(e) storage conditions or conditions of use;
(f) the name or business name of the manufacturer, packer or EU seller;
(g) place of origin or provenance;
(h) instructions for use;
(i) lot marking.

In addition, the following must also be mentioned on the label (the first three of the list below shall appear in the same vision as the generic name, the net quantity, the date of durability and the actual alcohol strength):

- for fruit juice and nectar obtained wholly or partially from a concentrated product, the declaration "**contains ..... made from concentrate**", plus the name of the concentrated product used; this declaration shall appear in the immediate vicinity of the product name, standing out prominently in bold lettering, or
- for fruit juice, concentrated fruit juice and fruit nectar, the carbon dioxide content of which

is greater than 2 grams per litre, the description "**carbonated**", or
- for fruit nectars, the actual minimum content of fruit juice, fruit purée, or mixture of these ingredients, the declaration "**fruit content: ... % minimum**", or
- for concentrated fruit juice and dried fruit juice, an indication of the quantity of water to be added to restore the product.

The addition of L-ascorbic acid shall not authorize any reference to Vitamin C.

MS- Member States may also require additional labelling particulars.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments
Council Directive 93/77/EEC of 21 September 1993

9.5.2a GENERIC NAME

With reference to section 1.4.1, the names under which the products defined in Article 1 to Directive 93/77/EEC are sold shall be the name reserved for them.

If the product comes from a single variety of fruit, the name of the latter shall be substituted for the word "**fruit**" or shall accompany any descriptions NOT containing the word "**fruit**".

For dried fruit juice, the adjective "**dried**" may be replaced by the adjective "**powdered**" and may be accompanied or replaced by particulars of the specific process (e.g. freeze-dried).

The name under which the products are sold may be supplemented by:

- for products manufactured from two or more kinds of fruit, a list of the fruits used in descending order of the weight of the fruit juices or purées included, where appropriate after restoration; the use of the term "**fruit**" shall then be optional in this case (this is not the case of lemon juice replacing citric acid in a quantity not greater than 5 g per litre in a fruit nectar obtained from apples, pears or peaches), or
- in case of fruit juices other than pear and grape with added sugar not greater than 5 g per litre, by the description "**sweetened**", followed by an indication of the maximum quantity of sugars added, calculated as dry matter and expressed in g per litres; the quantity indicated may NOT exceed the actual quantity added by more than 15 %, or
- for the fruit nectars obtained exclusively from fruit purée and/or concentrated fruit purée or from fruit juice and fruit purée and/or concentrated fruit purée which are NOT designated by the description "**succo e polpa**" alone, by the description contains "**fruit pulp**" or an equivalent description.

The following descriptions shall be reserved for the products defined therein and be used in trade to describe them:

- "**Vruchtendrank**", for fruit nectars, or
- "**Süßmost**", for fruit nectars obtained exclusively from fruit juices, concentrated fruit juices or a mixture of these products inedible in the natural state because of their high natural acidity, or
- "**succo e polpa**", for fruit nectars obtained exclusively from fruit purée and/or concentrated fruit purée or "**sumo e polpa**" for fruit nectars obtained exclusively from fruit juice and fruit purée and/or concentrated fruit juice, or
- "**æblemost**", for apple juice with NO added sugars, or
- "**Sur ... saft**", together with the name (in Danish) of the fruit used, for juices with NO added

sugar and obtained from blackcurrants, cherries, redcurrants, whitecurrants, raspberries, strawberries or elderberries, or

- "**sød ... saft**" or "**sødet ... saft**", together with the name of the fruit used, in Denmark to describe a product consisting of juices obtained from blackcurrants, cherries, redcurrants, whitecurrants, raspberries, strawberries or elderberries and added sugars in a quantity exceeding 200 g per litre

MS- Member States may permit the use of the description "fruit nectar" for certain products where the descriptions listed therein are used to designate these products.
Member States may require that the generic name be accompanied by an indication of a specific ingredient which characterises the product.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 93/77/EEC of 21 September 1993

9.5.2b INGREDIENTS LIST

With reference to section 1.4.2, the obligation to declare the list of ingredients shall NOT involve ingredients subject to:

(a) the restoration to its original state, by means of the substances strictly necessary for the operation of fruit juice from a concentrated fruit juice or of a fruit purée from concentrated fruit purée;
(b) the restoration of the flavour to concentrated fruit juice and to dried fruit juice

As well, the following shall NOT be considered as ingredients of grape juice in fruit juice, concentrated fruit juice, fruit nectar and dried fruit juice where the sulphur dioxide content of these products, as determined by analysis, does NOT exceed 10 mg per litre:

• sulphur dioxide (E 220), or
• sodium sulphite (E 221), or
• acid sodium sulphite (sodium bisulphite) (E 222), or
• sodium disulphate (sodium pyrosulphate or sodium metabisulphite) (E 223), or
• potassium disulphate (potassium pyrosulphate or potassium metabisulphite) (E 224), or
• calcium sulphite (E 226), or
• acid calcium sulphite (e 227).

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 93/77/EEC of 21 September 1993

9.5.2c DATE OF MINIMUM DURABILITY

The date of minimum durability is NOT required for fruit juices and fruit nectars in individual containers of more than 5 litres for supply to mass caterers.
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

9.5.3 PACKAGING

With reference to packaging requirements outlined in section 3 and section 6, fruit juices and fruit nectars should be prepackaged according to section 3.1.3 and section 3.1.4.

Fruit juices (including grapes) or vegetable juices, whether or NOT containing added sugar, but unfermented and NOT containing spirit, and fruit nectar should be put up for sale only in

packages of the following nominal volumes in litres:

0.125	0.20	0.25	0.33	0.50	0.7	0.75	1	1.5	2

In case of cans, the following nominal volume in litres are permitted:

.125	.18	.20	.25	.33	.35	.50	.7	.75	1	1.5	2

Council Directive 71/316/EEC of 26 July 1971 and subsequent amendments
Council Directive 75/106/EEC of 19 December 1974 and subsequent amendments
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments
Council Directive 93/77/EEC of 21 September 1993

9.6 FRUIT JAMS, JELLIES AND MARMALADES

EU rules govern composition, labelling and packaging of fruit jams, jellies and marmalades.
Council Directive 79/693/EEC of 24 July 1979 and subsequent amendments

9.6.1 COMPOSITION AND MANUFACTURING

All fruit jams, jellies and marmalades defined in Annex I to Directive 79/693/EEC must comply with the compositions and manufacturing specifications laid down. Only raw materials corresponding to the definitions given in Annex II to Directive 79/693/EEC may be used in the manufacture of the products defined in Annex I. Only the substances listed in Annex III to Directive 79/693/EEC may be added, and only in the manner prescribed therein, to these products. Products defined in Annex I may NOT, in particular, contain sulphur dioxide in amounts exceeding the limits fixed in Annex IV to Directive 79/693/EEC.

MS- Member States may also permit the addition of certain substances and the total or partial replacement of sugars.

Council Directive 79/693/EEC of 24 July 1979 and subsequent amendments

9.6.2 LABELLING

With reference to section 1.4, the following must appear on the labelling of fruit jams, jellies and marmalades:

(a) generic name as defined in Annex I to Directive 79/693/EEC;
(b) list of ingredients;
(c) for packaged foodstuffs, the net quantity;
(d) date of minimum durability;
(e) storage conditions or conditions of use;
(f) name of manufacturer, packer or EU seller;
(g) place of origin or provenance;
(h) instructions for use;
(i) lot marking.

In addition, the following is also mandatory on the labelling (in the same field of vision as the generic name, the net quantity and the date of durability):

- the words "**prepared with ... g of fruit per 100g**" for:
  - pulp, purée, juice and aqueous extracts in the manufacture of extra jam, jam, extra jelly, jelly and chestnut purée after deduction of the weight of water used in preparing aqueous extracts,
  - citrus fruit in the manufacture of marmalade, or
- the words "**total sugar content: ... g per 100 g**" where the value of sugar content is determined by refractometer at 20C for the finished product, subject to a tolerance of +/- 3 refractometer degrees, or
- the words "**keep in a cool place once opened**" for products having a soluble dry matter of less than 63 %; this indication shall NOT, however, be compulsory for products in small containers, the content of which is normally consumed at one time and for products to which preservatives have been added, or
- in the case of marmalade containing peel, an indication of the style of cut of that peel and where it does NOT contain peel, the absence of peel must be mentioned on the label.

The addition of L-ascorbic acid shall NOT authorize reference to be made to vitamin C.

MS- Member States may require additional labelling particulars.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 79/693/EEC of 24 July 1979 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments

9.6.2a GENERIC NAME

With reference to section 1.4.1, the names (extra jam, jam, extra jelly, jelly, marmalade, chestnut purée) under which the products defined in Annex I to Directive 79/693/EEC are sold shall be the name reserved for them in so far as their soluble dry matter content is NOT less than 60 % as determined by refractometer.

The name under which the products are sold shall be supplemented by:

- an indication of the type(s) of fruit used in descending order of importance by weight of the raw materials used; however, for products made from three or more types of fruit, the indication of the types of fruit used may be replaced by the words "**mixed fruit**" or by an indication of the number of types of fruit used, or
- an indication of specific ingredients used.

MS- Member States may permit the name "jelly marmalade".

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 79/693/EEC of 24 July 1979 and subsequent amendments

9.6.2b INGREDIENTS LIST

With reference to section 1.4.2, the following must also appear in the list of ingredients for jams and jellies:

- the words "**dried apricots**", where apricots intended for the manufacture of jam have been dried by a process other than freeze-drying, or
- the words "**red beetroot juice to reinforce the colour**", where beetroot juice has been added to the jam and jelly which have been obtained from one or more of the following:

strawberries, raspberries, gooseberries, redcurrants or plums, or
- "**sulphur dioxide**", where the residual dioxide is more than 30 mg/kg according to the percentage by weight of the residue in the finished product.

MS- Member States may permit the use of the word "**fruit**" replacing the naming of the types of fruit in the list of ingredients, in the case of products made from three or more types of fruit.

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 79/693/EEC of 24 July 1979 and subsequent amendments

9.6.3 PACKAGING

With reference to packaging requirements outlined in section 3 and section 6, fruit jams, jellies, marmalade and chestnut purée should be prepackaged according to section 3.1.4.
Council Directive 71/316/EEC of 26 July 1971 and subsequent amendments
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 79/693/EEC of 24 July 1979 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments

9.7 PRESERVED MILK

EU rules govern the composition, labelling and packaging of preserved milk.
Council Directive 76/118/EEC of 18 December 1975

9.7.1 COMPOSITION AND MANUFACTURING

Definitions and specific compositional rules for certain partly and wholly dehydrated milks are set out in Article 5 and Article 6 and in the Annex to Directive 76/118/EEC. Partly dehydrated milks include: unsweetened condensed milk, unsweetened condensed skimmed milk, unsweetened condensed partly skimmed milk, unsweetened condensed high-fat milk, sweetened condensed milk, sweetened condensed skimmed milk, and sweetened condensed partly skimmed milk. Wholly dehydrated milks include: dried whole milk or whole milk powder, dried skimmed milk or skimmed milk powder, dried partly skimmed milk or partly skimmed milk powder, and dried high-fat or high-fat milk powder.

Preservations of the products shall be achieved for:

- unsweetened condensed milks by sterilization through heat-treatment, or
- sweetened condensed milks by the addition of sucrose (semi-white sugar, sugar or white sugar or extra-white sugar), or
- wholly dehydrated milks by dehydration.

The lactate content of products must NOT be greater than 300 mg per 100 g of milk solids NOT fat.

In addition, sampling procedures and methods of analysis are given to verify the composition of preserved milk products. The verification criteria is listed in Annex I to Directive 79/1067/EEC, the methods are described in Annex II to Directive 79/1067/EEC and the sampling procedures are outlined in the Annex to Directive 87/524/EEC.

MS- Member States may authorize in their territory the use of additional additives for wholly dehydrated milk used in vending machines and clearly labelled as such.
Member States may authorize in their territory the addition of vitamins to partly and wholly dehydrated milk products.
Member States may maintain any ban in their territory on the use of wholly dehydrated milk in the production and marketing of partly dehydrated milk, if the ban existed prior to 1 October 1974.

Council Directive 76/118/EEC of 18 December 1975 and subsequent amendments Commission Directive 79/1067/EEC of 13 November 1979
Commission Directive 87/524/EEC of 6 October 1987

9.7.2 LABELLING

With reference to section 1.4, the following must appear on the labelling of preserved milk products:

(a) generic name as defined in Article 1 and in the Annex to Directive 76/118/EEC;
(b) list of ingredients;
(c) for packaged foodstuffs, the net quantity;
(d) date of minimum durability;
(e) storage conditions or conditions of use;
(f) name of manufacturer, packer or EU seller;
(g) place of origin or provenance;
(h) instructions of use;
(i) lot marking.

In addition, the following shall appear on the packaging, containers or labels of the said products:

- the percentage of milk-fat, expressed by weight in relation to the finished product, except in the case of unsweetened condensed milk, sweetened condensed skimmed milk and dried skimmed milk, or
- the percentage of fat-free dried milk extract in the case of partly dehydrated milk.

For preserved milk products weighing less than 20 g per unit and packed in an outer packaging, the labelling particulars need appear on the outer packaging only, except for the generic name.

For preserved milk products NOT intended for the ultimate consumer, the following must be on the labelling:

(a) generic name as defined in Article 1 and the Annex to Directive 76/118/EEC;
(b) the net quantity;
(c) name or business name and address of manufacturer, packer or EU seller;
(d) for imports, the name of the country of origin;
(e) the date of manufacture or lot marking.

MS- Member States can insist on the inclusion of details of the nature and quantity of the added vitamins.
Member States may require the inclusion of a special warning concerning the use of wholly skimmed products as baby food.

Council Directive 76/118/EEC of 18 December 1975 and subsequent amendments
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments

9.7.2a GENERIC NAME

With reference to section 1.4.1, the names under which the products defined in Article 1 and in the Annex to Directive 76/118/EEC are sold shall be the names reserved for them.

The following particulars must also indicated:

- the word "**instant**" shall be added to products in the case where lecithins (E 322) have been used in the production of dried whole milk, dried partly skimmed milk and dried high-fat milk, or
- the expressions "**UHT**" or "**ultra heat treated**" for unsweetened condensed milks where these products are obtained as a result of such treatment and aseptically packed.

MS- Member States may permit for specific designations to be reserved.

Council 76/118/EEC of 18 December 1975 and subsequent amendments
Council 79/112/EEC of 18 December 1978 and subsequent amendments

9.7.2b NET QUANTITY

With reference to section 1.4.3, in the case of preserved milk products, the net quantity shall be expressed in units of mass and in the case of unsweetened condensed milks packed in tubes or metal tins, the net quantity shall be expressed in units of mass and volume.
Council Directive 76/118/EEC of 18 December 1975 and subsequent amendments
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

9.7.2c INSTRUCTIONS FOR USE

With reference to section 1.4.8, in the case of partly dehydrated milk products, the recommendations on the method of dilution or reconstitution need appear on the label. These particulars may be replaced by relevant information on the use of the products when the latter are intended for use in the unaltered state.

In the case of wholly dehydrated milk products, the recommendations on the method of dilution or reconstitution, including details of the fat content of the product must appear on the label, except for dried skimmed milk.
Council Directive 76/118/EEC of 18 December 1975 and subsequent amendments
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

9.7.3 PACKAGING

Preserved milk products destined for retail sale shall be packed by the manufacturer or packer in sealed containers which protect the product from harmful influence and which must be delivered intact to the consumer.

With reference to the packaging requirements outlined in section 3 and section 6, preserved milks should be prepackaged according to section 3.1.3 and section 3.1.4.

Milk-based beverages and milk, fresh, not concentrated or sweetened, excluding yogurt, kephir, curdled milk, whey and other fermented or acidified milk, should be put up for sale only in packages of the following nominal volumes in litres:

0.10	0.20	0.25	0.50	0.75	1	2

Council Directive 71/316/EEC of 26 July 1971 and subsequent amendments
Council Directive 75/106/EEC of 19 December 1974 and subsequent amendments
Council Directive 76/118/EEC of 18 December 1975 and subsequent amendments
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments

9.8 CASEINS AND CASEINATES

EU rules govern the composition and labelling of foodstuffs containing caseins and/or caseinates.
Council Directive 83/417/EEC of 25 July 1983

9.8.1 COMPOSITION AND MANUFACTURING

Edible caseins and caseinates defined in Annexes I and II to Directive 83/417/EEC must comply with the composition and manufacturing specifications laid down in Annexes I and II to Directive 83/417/EEC.

In addition, sampling procedures and methods of analysis are outlined. The verification criteria is set out in Annex I to Directive 85/503/EEC, the methods of analysis are described in Annex II to Directive 85/503/EEC and the sampling procedures are outlined in the Annex to Directive 86/424/EEC.
Council Directive 83/417/EEC of 25 July 1983
Commission Directive 85/503/EEC of 25 October 1985
Commission Directive 86/424/EEC of 15 July 1986

9.8.2 LABELLING

With reference to section 1.4, the following must appear on foodstuffs containing caseins and/or caseinates NOT intended for sale to the ultimate consumer:

(a) the name reserved for the product listed in the Annexes I and II to Directive 83/417/EEC and in the case of caseinates, an indication of the cation(s);
(b) in the case of mixture of products:

> (1) the words "**mixture of ...**" followed by the names of the different products in decreasing order of weight found;
> (2) an indication of the cation(s) in case of caseinates;
> (3) the protein content in the case of mixtures containing caseinates;

(c) the net quantity expressed in kg or g;
(d) the name or business name and the address of the manufacturer or packager or the EU seller;
(e) in the case of imported products, the name of the country of origin;
(f) the date of manufacture or lot marking.

The protein content, net quantity, name of manufacturer, packer or EU seller need only appear on an accompanying document.
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 83/417/EEC of 25 July 1983
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments

9.9 NATURAL MINERAL WATERS

EU rules govern the composition, labelling and packaging of natural mineral waters. These rules also apply to waters extracted from a third country and imported into the EU, if recognized with a certification as natural mineral waters by the responsible authority of a Member State. These authorities are to be officially published.

The requirements and criteria for applying for a definition, that is a certification, are listed in Annex I, Section II to Directive 80/777/EEC. Supplementary qualifications are listed in Annex I, Section III. Conditions for the exploitation and marketing of natural mineral water are listed in Annex II.
Council Directive 80/777/EEC of 15 July 1980 and subsequent amendments

9.9.1 COMPOSITION AND MANUFACTURING

Natural mineral water springs may be exploited and their waters bottled only in accordance with Annex II to Directive 80/777/EEC.

Natural mineral water may NOT be the subject of any other treatment than:

- the separation of its unstable elements, such as iron and sulphur compounds, by filtration or decanting, possibly preceded by oxygenation, in so far as this treatment does NOT alter the composition of the water as regards the essential constituents which give it its properties, or
- the separation of iron, manganese and sulphur compounds and arsenic from certain natural mineral waters by treatment with ozone-enriched air in so far as such treatment does NOT alter the composition of the water as regards the essential constituents which give it its properties, and provided that the treatment follows EU conditions laid down and is notified to, and specifically controlled by, the competent authorities, or
- the separation of undesirable constituents other than those specified above in so far as such treatment does NOT alter the composition of the water as regards the essential constituents which give it its properties, and provided that the treatment follows EU conditions laid down and is notified to, and specifically controlled by, the competent authorities, or
- the total or partial elimination of free carbon dioxide by exclusively physical methods, or
- the introduction or the reintroduction of carbon dioxide under the conditions laid down is Annex I, Section III to Directive 80/777/EEC.

In particular, any disinfection treatment by whatever means or the addition of bacteriostic elements or any other treatment likely to change the viable colony count of the natural mineral water shall be prohibited.
Council Directive 80/777/EEC of 15 July 1980 and subsequent amendments

9.9.2 HYGIENE

The revival total colony count of a natural mineral water at source should conform to its normal viable colony count and give satisfactory evidence of the protection of the source against all contaminations. This is determined under the conditions laid done in Annex I, Section II, point 1.3.3 to Directive 80/777/EEC.

At source, the total colony count should NOT exceed 20 per ml at 20 to 22C in 72 hours and 5 per

ml at 37 C in 24 hours respectively, on the understanding that they are to be considered as guide figures and NOT as maximum permitted concentrations.

After bottling, the total colony count at source may NOT exceed 100 per ml at 20 to 22C in 72 hours on agar-agar or an agar-gelatine mixture and 20 per ml at 37C in 24 hours on agar-agar. The total colony count shall be measured within the 12 hours following the bottling. The water maintained at 4C plus or minus 1C during this 12 hour-period.

At source and during its marketing, a natural mineral water shall be free from:

(a) parasites and pathogenic micro-organisms;
(b) escherichia coli and other coliforms and faecal streptococci in any 250 ml sample examined;
(c) sporulated sulphite-reducing anaerobes in any 50 ml sample examined;
(d) pseudomonas aeruginosa in any 250 ml sample examined.

As well, at the marketing stage, the revivable total colony count of a natural mineral water may only be that resulting from the normal increase in the bacteria content which it had at source and the natural mineral may NOT contain any organoleptic defects.
Council Directive 80/777/EEC of 15 July 1980 and subsequent amendments

9.9.3 LABELLING

With reference to section 1.4, the following must appear on the labelling of natural mineral waters:

(a) sales description;
(b) a statement of the analytical composition giving its characteristics constituents;
(c) the place where the spring is exploited and the name of the spring;
(d) any treatments referred to in the 2nd and 3rd point described in section 9.9.1;
(e) storage conditions;
(f) name of manufacturer, packer or EU seller;
(g) place of origin;
(h) instructions for use;
(i) lot marking.

It shall be forbidden in the labelling or advertising to use designations, proprietary names, trade marks, brand names, illustrations or other signs which:

- suggest a characteristic which the natural mineral water does NOT possess, in particular as regards its origin, the date of the authorization to exploit it, the results of the analyses or any similar references to guarantees or authenticity
- mislead the consumer to confusion of packaged drinking water with natural mineral water
- attribute properties relating to the prevention, treatment or cure of a human illness.

Indications ("**low mineral content**", "**very low mineral content**", "**rich in mineral salts**", "**contains bicarbonate**", "**contains sulphate**", "**contains chloride**", "**contains calcium**", "**contains magnesium**", "**contains fluoride**", " **contains iron**", "**acidic**", "**contains sodium**", "**suitable for preparation of infant food**", "**suitable for a low-sodium diet**", "**may be laxative**", "**may be diuretic**") listed in Annex III to Directive 80/777/EEC shall be authorized to be indicated on labelling only if they meet the relevant criteria laid down in Annex III to Directive 80/777/EEC or criteria laid down by the Member State, provided that the latter has been drawn up based on various examinations.

MS- Member States may maintain national provisions on the labelling of certain treatments.
Member States may authorize the indication "**stimulates digestion**", " **may facilitate the hepato-biliary functions**" or similar indications.
Member States may adopt provisions regarding information on the advertising and labelling concerning the suitability of a natural mineral water for the feeding of infants**.**

Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 80/777/EEC of 15 July 1980 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments

9.9.3a SALES DESCRIPTION

The sales description shall be "**natural mineral water**" or "**naturally carbonated natural mineral water**" or "**natural mineral water fortified with gas from the spring**" or "**carbonated natural mineral water**" defined in Annex I, Section III to Directive 80/777/EEC. If the natural mineral waters have undergone any of the treatments such as "**fully de-carbonated**" or "**partially de-carbonated**", this shall be added.

The term "**spring water**" shall be reserved for water which is intended for human consumption in its natural state, and bottled at source, which:

(a) satisfies the conditions of exploitation laid down;
(b) satisfies the micro-biological requirements;
(c) satisfies the labelling requirements;
(d) has NOT undergone any treatment other that those permitted.
Council Directive 80/777/EEC of 15 July 1980 and subsequent amendments

9.9.3b PLACE OF ORIGIN

The name of a locality, hamlet or place may occur in the wording of a trade description provided that it refers to a natural mineral water the spring of which is exploited at the place indicated by that description and provided that it is NOT misleading as regards the place of exploitation of the spring.

It shall be forbidden to market natural mineral water from one and the same spring under more than one trade description.

When the labels or inscriptions on the containers or in advertising in which the natural mineral waters are offered for sale include a trade description different from the name of the spring or place of its exploitation, this place or the name of the spring shall be indicated in letters at least one-and-a-half times the height and width of the largest of the letters used for that trade description.

MS- Member States may require the indication of the country of origin for import into the EU.

Council Directive 80/777/EEC of 15 July 1980 and subsequent amendments

9.9.4 PACKAGING

Any containers used for packaging natural mineral waters shall be fitted with closures designed to avoid any possibility of adulteration or contamination.

With reference to the packaging requirements outlined in section 3 and section 6, natural mineral waters should be prepackaged according to section 3.1.3.

Mineral waters, including spa waters and aerated waters should only be put up for sale in packages of the following nominal volumes in litres including volumes below 0.2:

0.2	0.20	0.25	0.33	0.35	0.45	0.46	0.50	0.70	0.75	0.90	1	1.25	1.5	2

Council Directive 71/316/EEC of 26 July 1971 and subsequent amendments
Council Directive 75/106/EEC of 19 December 1974 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments
Council Directive 80/777/EEC of 15 July 1980 and subsequent amendments

9.10 COFFEE & CHICORY

EU rules govern composition, labelling and packaging of coffee and chicory extracts.
Council Directive 77/436/EEC of 27 June 1977 and subsequent amendments

9.10.1 COMPOSITION AND MANUFACTURING

All coffee and chicory extracts (soluble coffee, instant coffee, dried coffee extract, dried extract of coffee, coffee extract paste, liquid coffee extract, dried chicory extract, soluble chicory, instant chicory, chicory extract paste, liquid chicory extract) defined in Article 1 and in the Annex to Directive 77/436/EEC must comply with the composition and manufacturing specifications laid down therein. Only raw materials which are sound, genuine and merchantable quality may be used in the manufacture of the products referred to in the Annex to Directive 77/436/EEC.

In addition, sampling procedures and methods of analysis are laid out in the Annex to Directive 79/1066/EEC as the composition and manufacturing of coffee and chicory extracts are subject to verification.

Blends of coffee extracts and chicory extracts and extracts of blends of roasted coffee and roasted chicory may be offered for sale only if these products comply with the definitions laid down and if a solid paste, be prepackaged according to the requirements in section 9.10.3.

MS- Member States may authorize the use of anti-caking agents in their territory for soluble coffee, instant coffee, dried instant coffee or dried extract of coffee when they are used in vending machines and specifically labelled as such, and for dried chicory extract, soluble chicory or instant chicory.

Council Directive 77/436/EEC of 27 June 1977 and subsequent amendments
Commission Directive 79/1066/EEC of 13 November 1979

9.10.2 LABELLING

With reference to section 1.4, the following must appear on the labelling of coffee and chicory extracts:

(a) generic name as defined in Article 1 and in the Annex to Directive 77/436/EEC;
(b) list of ingredients;
(c) for packaged foodstuffs, the net quantity;
(d) date of minimum durability;

(e) storage conditions or conditions of use;
(f) name of manufacturer, packer or EU seller;
(g) place of origin or provenance;
(h) instructions of use
(i) lot marking.

In addition, the following must also appear on the label in the same field of vision as the sales description:

- the term "**decaffeinated**" in the case of coffee extracts provided that the anhydrous caffeine content does NOT exceed 0.3 % by weight of the coffee-based dry matter, or
- the term "**roasted with sugar**" in case of liquid coffee extract and liquid chicory extract if the extract is obtained from the raw material roasted with sugar, or
- the terms "**with sugar**", "**preserved with sugar**", or "**with added sugar**" in the case of liquid coffee extract and liquid chicory extract if the sugar has been added to the raw material after roasting, or
- where sugars of types other than sucrose are used, this must be stated instead of the term "**sugar**", or
- the minimum coffee-based dry matter content expressed as a percentage of weight of the finished product in the case of liquid coffee extracts and coffee extract paste, or
- the minimum chicory-based dry matter content expressed as a percentage by weight of the finished product in the case of liquid chicory extracts and chicory extract paste**.**

Coffee and chicory extracts NOT intended to be supplied to the ultimate consumer shall only include the following:

(a) generic name as defined in Article 1 and the Annex to Directive 77/436/EEC;
(b) the net quantity, except in the case of products put up for sale in bulk;
(c) lot marking;
(d) the name or business name and address of the manufacturer, packer of EU seller.

These last four particulars can appear on a label or an accompanying document.

MS- Member States may require additional labelling particulars.

Council Directive 77/436/EEC of 27 June 1977 and subsequent amendments
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments
Council Directive 89/396/EEC of 14 June 1989 and subsequent amendments

9.10.2a GENERIC NAME

With reference to section 1.4.3, the name under which the products defined in Article 1 and in the Annex to Directive 77/436/EEC shall be the names reserved for them.

The following particulars may supplement the generic name:

- "**paste**" or "**in paste form**" or "**liquid**" or "**in liquid form**" as appropriate.

- the term "**concentrated**" for liquid coffee extract, provided that the coffee-based dry matter is more than 25 % by weight or for liquid chicory extract, provided that the chicory-based dry matter is more than 45 % by weight.

MS- Member States may require that the generic name be accompanied by an indication of a specific ingredient which characterizes the product.

Council Directive 77/436/EEC of 27 June 1977 and subsequent amendments
Council Directive 79/112/EEC of 18 December 1978 and subsequent amendments

9.10.3 PACKAGING

With reference to the packaging requirements outlined in section 3 and section 6, liquid and non-liquid coffee and chicory extracts should be prepackaged according to section 3.1.3 and section 3.1.4.

Ground and unground roasted coffee, chicory and coffee substitutes (other than those mentioned below) should be sold only in the following packaging sizes in grams:

125	250	500	1 000	2 000	3 000	4 000	5 000	10 000

Coffee extracts and chicory extract sold in solid or paste form in individuals packages between 25 g and 10 kg must be sold in the following nominal weights in grams or kilograms:

50 g	100 g	200 g	500 g	750 g	1 kg	1.5 kg	2 kg	2.5 kg	3 kg

- 250 g is for mixtures of coffee and chicory extracts only and for coffee extracts intended exclusively for use in automatic vending machines
- 300 g is for coffee extracts only

Council Directive 71/316/EEC of 26 July 1971 and subsequent amendments
Council Directive 75/106/EEC of 19 December 1974 and subsequent amendments
Council Directive 77/436/EEC of 27 June 1977 and subsequent amendments
Council Directive 76/211/EEC of 20 January 1976 and subsequent amendments
Council Directive 80/232/EEC of 15 January 1980 and subsequent amendments

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1. The Agricultural Situation in the European Union 1998 Report. European Commission.
2. Quarterly Agri-Food Trade Highlights, Second Quarter 1999. Agriculture and Agri-Food Canada.
3. Wine as defined in Council Regulation (EEC) 822/87 of 16 March 1987 and subsequent amendments on the common organization of the market in wine
4. only for processed cheeses and products based on processed cheeses

5. modified starches must always be complemented by the indication of its specific vegetable origin, when that ingredient may contain gluten
6. as authorized by Directive 94/35/EC
7. as authorized by Directive 94/35/EC
8. if during a scientific assessment it can be demonstrated that the characteristics of the food or food ingredient are different in comparison with a conventional food or food ingredient then the labelling must indicate the characteristics or properties modified together with the method by which that characteristic or property was obtained
9. ibid
10. ibid

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