European Product Labelling Guide
INTRODUCTION

Within my role in the Enterprise Europe Network, one of the issues I’m regularly asked about is product labelling, i.e: “What regulations apply to my product?” or “What information has to be displayed on my product?”.

European legislation can be complex and consequently sourcing the answers to these questions isn’t necessarily the simplest task, therefore the purpose of this guide is to pull together all the information on European Union product labelling rules so that it is accessible from one source but broken up into a consistent and readable format. The hope is that it will give companies a clearer understanding as to what rules may be applicable to them, so that they can better prepare themselves for trading in the European market.

I think you will find this guide useful, but if you require more information please contact your local Enterprise Europe team.

Thank you.

Ross Thomson

European Information Executive
Enterprise Europe Network
DISCLAIMER

All information was sourced from http://europa.eu/, unless stated otherwise.

Whilst every effort has been made to ensure that the information and content within this document is accurate, up-to-date and reliable, the Enterprise Europe Network and its partners cannot be held responsible for inaccuracies or errors. Any images used are to be taken as purely hypothetical examples; their accuracy has not been verified and they are not intended to promote any product or labelling style.

Use of this guide, or actions taken from the information provided, are solely at the user's own risk. The information held within the guide should never be used as formal legal advice, users should always seek professional advice regarding labelling rules before placing any products on the market.

If you require more information please don’t hesitate in contacting your local Enterprise Europe team.
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CHAPTER 1

GENERAL LABELLING PROVISIONS
1. The Food Labelling Rules

1.1. Labelling, Presentation and Advertising of Foodstuffs

The Legislation

Directive 2000/13/EC applies to pre-packaged foodstuffs to be delivered to the final consumer or to restaurants, hospitals, canteens and other similar mass caterers. It does not apply to products intended for export outside the European Union (EU). It is also the most significant and influential piece of legislation in the field of food labelling, as will become apparent in Chapter 2 where it becomes clear that all other food labelling legislation is built around the general principles laid out in this Directive.

The main principle in the Directive is that the labelling, presentation and advertising of foodstuffs must not:

- mislead the consumer as to the foodstuff’s characteristics or effects;
- attribute to a foodstuff (except for natural mineral waters and foodstuffs intended for special diets, which are covered by specific Community provisions) properties for the prevention, treatment or cure of a human illness.

For more information click here.

The Labelling

The labelling of foodstuffs must include compulsory information and the particulars indicated on products must be easy to understand, visible, legible and indelible. In addition some of them must also appear in the same field of vision and must not be positioned on different parts of the label.
The compulsory particulars include:

<table>
<thead>
<tr>
<th>1. Name under which the product is sold</th>
<th>Name of product.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2. List of ingredients</strong></td>
<td>Listed in descending order of weight and designated by their specific name, (subject to the derogations provided in Annexes I, II, III and III a). Ingredients which belong to more than one category are indicated according to their principal function.</td>
</tr>
<tr>
<td>Under certain conditions, the listing of ingredients is not required for:</td>
<td></td>
</tr>
<tr>
<td>1. fresh fruit and vegetables,</td>
<td></td>
</tr>
<tr>
<td>2. carbonated water,</td>
<td></td>
</tr>
<tr>
<td>3. fermentation vinegars,</td>
<td></td>
</tr>
<tr>
<td>4. cheese, butter, fermented milk and cream,</td>
<td></td>
</tr>
<tr>
<td>5. products comprising a single ingredient, where the trade name is identical with the ingredient name, or the trade name enables the nature of the ingredient to be clearly identified.</td>
<td></td>
</tr>
<tr>
<td><strong>3. Quantity of ingredients or categories of ingredients expressed as a percentage</strong></td>
<td>This requirement applies when an ingredient or a category of ingredients:</td>
</tr>
<tr>
<td>1. appears in the name under which the foodstuff is sold or is usually associated with that name by the consumer,</td>
<td></td>
</tr>
<tr>
<td>2. is emphasised on the labelling in words, pictures or graphics, or</td>
<td></td>
</tr>
<tr>
<td>3. is essential to characterise an indicated foodstuff (but certain exceptions may be provided);</td>
<td></td>
</tr>
<tr>
<td><strong>4. Net quantity</strong></td>
<td>Expressed in volume for liquids and units of mass for other products. However, there are specific provisions for foodstuffs sold by number and solid foodstuffs presented in a liquid medium;</td>
</tr>
<tr>
<td><strong>5. Date of minimum durability</strong></td>
<td>This date consists of the day, month and year, except</td>
</tr>
</tbody>
</table>
in the case of foodstuffs that will not keep for more than three months (the day and month are sufficient), foodstuffs which will not keep for more than 18 months (the month and year are sufficient), and foodstuffs which will keep for more than 18 months (year is sufficient). The date shall be preceded by the words: ‘Best before …’ when the date includes an indication of the day or ‘Best before end …’ in other cases. The date of durability is not required for the following products:

1. untreated fresh fruits and vegetables,
2. wines and beverages containing 10 % or more by volume of alcohol,
3. non-alcoholic soft drinks,
4. fruit juices and alcoholic beverages in individual containers of more than five litres, intended for supply to mass caterers,
5. bakers' or pastry cooks' wares which are normally consumed within 24 hours of their manufacture,
6. vinegar,
7. cooking salt,
8. solid sugar,
9. confectionery products consisting almost solely of flavoured and/or coloured sugars,
10. chewing gums and similar chewing products,
11. individual portions of ice-cream.

In the case of foodstuffs which are highly perishable, the date of minimum durability shall be replaced by the ‘use by’ date;

<table>
<thead>
<tr>
<th>6. Any special storage conditions or conditions of use</th>
<th>Instructions for the safe storage and use of the product.</th>
</tr>
</thead>
</table>

| 7. The name or business name and address of the manufacturer or packager, or of a seller established within the Community | Member States shall be authorised, in respect of butter produced in their territory, to require only an indication of the manufacturer, packager or seller; |
### CHAPTER 1

<table>
<thead>
<tr>
<th>8. The place of origin or provenance</th>
<th>Where failure to give such particulars might mislead the consumer</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. Instructions for use</td>
<td>Should be included to enable appropriate use of the foodstuff</td>
</tr>
<tr>
<td>10. Indication of the acquired alcoholic strength of beverages</td>
<td>Required when beverages contain more than 1.2% by volume of alcohol.</td>
</tr>
</tbody>
</table>

**Examples**

Below you will see examples of the labelling for some of the topics mentioned above:

<table>
<thead>
<tr>
<th>List of ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Garlic sauce with parsley and chives</td>
</tr>
<tr>
<td>Ingredients Water, Vegetable Oil, Sugar, Modified Maize Starch, Spirit Vinegar, Garlic Purée (1%), Salt, Roasted Garlic Purée (0.5%), Whey Powder, Onion, Chives, Mustard Flour, Parsley, Stabilisers (Xanthan Gum, Guar Gum), Garlic Powder, Citric Acid, White Pepper.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quantity of ingredients or categories of ingredients expressed as a percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net weight: Βάρος καθορισμένο: Nettopaino: Nettovikt: Nettovægt: Peso netto: 200g</td>
</tr>
<tr>
<td>Date of minimum durability</td>
</tr>
<tr>
<td>---------------------------</td>
</tr>
<tr>
<td>Instructions for use</td>
</tr>
<tr>
<td>Any special storage</td>
</tr>
<tr>
<td>conditions or conditions</td>
</tr>
<tr>
<td>of use</td>
</tr>
</tbody>
</table>
Other Provisions

The European provisions applicable to specific foodstuffs may authorise making particulars such as the list of ingredients and date of minimum durability optional. These provisions may provide for other compulsory particulars, provided this does not result in the purchaser being inadequately informed.

Special provisions apply to:

- reusable glass bottles and small packaging items or containers;
- pre-packaged foodstuffs. Where pre-packaged foodstuffs are marketed at a stage prior to sale to the final consumer or are supplied to mass caterers for processing, the particulars need appear only on the commercial documents, provided that the name under which the product is sold, the date of minimum durability and the details of the manufacturer or packager appear on the outer packaging of the foodstuff;
- foodstuffs offered for sale without pre-packaging and foodstuffs packaged on the sales premises at the consumer’s request.

Safeguard Clause

The marketing of foodstuffs which comply with the Directive may be prohibited only in the case of non-harmonised national provisions that are justified on particular grounds, such as the protection of public health, prevention of fraud or the protection of industrial or commercial property.
2. PREPACKED PRODUCTS

2.1. PREPACKED PRODUCTS

The Legislation

Under Council Directive 76/211/EEC the labelling of pre-packages and prepacked products must contain various information relevant to the consumer, such as how the producer or the packager indicates the weight or the volume contained (taking into account the maximum permitted measurement errors).

Prepacked products are sold individually at a constant weight or volume chosen in advance by the filler. The weight or volume must be at least 5 grams or 5 millilitres for the smallest packages and no more than 10 kilograms or 10 litres for the largest packages.

Scope

The Directive applies to all types of prepacked consumer products.

<table>
<thead>
<tr>
<th>KEY TERMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Prepackage”: a prepackage is the combination of a product and the individual package in which it is prepacked.</td>
</tr>
<tr>
<td>“Prepacked product”: a product is prepacked when it is placed in a package of whatever nature without the purchaser being present and the quantity of product contained in the package has a predetermined value and cannot be altered without the package either being opened or undergoing a perceptible modification.</td>
</tr>
</tbody>
</table>
For more information click here

The Labelling

Use of the EC sign

Prepacked products may bear the EC sign if they comply with the requirements set out in the Directive with regard to quality and metrological control (Annex I, section 5 and Annex II).

Indication of weight or volume

For the prepackage to be able to bear the EC sign, the labelling must indicate the volume in the case of liquid products and the weight in the case of other products.

The label of the prepacked product must also bear the weight and volume indications used in trade practice or comply with the national regulations of the destination country if such indications vary in the Member States

Examples

A label bearing the ‘EC’ sign:
2.2. IDENTIFICATION OF PREPACKED FOODSTUFF BY LOT

The Legislation

Directive 89/396/EEC applies to all prepacked foodstuff and the term "lot" means a batch of sales units of a foodstuff produced, manufactured or packaged under identical conditions. For example:

- agricultural products sold at temporary storage, preparation or packaging stations, producers' organisations, preparation or processing systems;
- products which are not prepacked;
- products in packagings or containers, the largest side of which has an area of less than 10 cm²;
- individual portions of ice cream.

For more information click here

The Labelling

The lot indicated on the packaging or container is determined by the producer, manufacturer or packager of the foodstuff in question, or the first seller within the Community. The indication is preceded by the letter "L", except where it can be distinguished clearly from other labelling indications. In all cases, it must be clearly visible, clearly legible and indelible. It is not necessary to indicate the lot if the date of minimum durability or "use by" date (indicating the day, month and year) appears on the label.
3. Deregulation of Pack Sizes

3.1. Deregulation

The Legislation

**Directive 2007/45/EC** sets out that principle that Regulations prescribing mandatory nominal quantities for prepackaged products are banned. However, countries in which mandatory nominal quantities are prescribed for milk, butter, dried pasta and coffee may maintain their restrictive rules until 11 October 2012. The rules relating to white sugar may be maintained until 11 October 2013.

For wines and spirits, the Directive contains the range of nominal quantities of contents of prepackages. These also apply to individual prepackages making up multiple prepackages.

In the case of aerosol dispensers, the Directive states that they must indicate the nominal total capacity of the container in a manner which does not create confusion with the nominal volume of the contents.

The Directive repeals:


The repealing of these Directives will be effective from 11 April 2009, six months after the deadline for transposition of the present Directive into the legislation of the Member States.
For more information click here.

**Background**

This Directive takes the opposite approach to that followed since 1970, following developments in Court of Justice case law and the creation of consumer protection instruments such as labelling and consumer information. At that time, consumer protection was not so advanced; for example, there was no obligation to indicate the unit pricing of all products for sale, and no ban on misleading advertising.

The liberalisation of pack sizes encourages free movement in the internal market by removing potential barriers to competitiveness and stimulating innovation and access to markets. Also, maintaining certain fixed sizes allows SMEs in particular to adapt, and thus also reduce the costs to the consumer. Under this new legislation, consumers will be given the freedom to choose between different pack sizes. The industry will be better able to adapt to consumer demand. Some sections of the population, such as people with diabetes, will be able to find food in pack sizes which meet their needs.
4. Price

4.1. Prices of Products Offered to Consumers

The Legislation

Under Directive 98/6/EC the selling price and the unit price must be indicated in an unambiguous, easily identifiable and clearly legible manner for all products offered by traders to consumers ("unambiguous" meaning the final price including VAT and all other taxes).

The unit price need not be indicated if it is identical to the selling price. However, Member States may decide not to apply this rule:

- to products supplied in the course of the provision of a service;
- to sales by auction and sales of works of art and antiques.

For more information click here.

The Labelling

For products sold in bulk, only the unit price must be indicated. However any advertising which mentions the selling price must also indicate the unit price. Each Member States does retain some autonomy over aspects of pricing, such as:

- waive the obligation to indicate the unit price of products for which such indication would not be useful or would be liable to create confusion;
in the case of non-food products, draw up a list of the products to which the obligation to indicate the unit price will remain applicable.

However Member States also have obligations under the Directive and must:

- take appropriate measures to inform all persons concerned about the transposition of this legislation;
- lay down, and provide information on, the system of penalties for infringements of the national provisions adopted in application of this Directive.
CHAPTER 2

FOOD AND DRINK LABELLING
1. NUTRITIONAL INFORMATION

1.1. NUTRITION AND ALLERGENS

1.1.1. Nutritional Labelling

The Legislation

Council Directive 90/496/EEC concerns nutrition labelling of foodstuffs for the final consumer and for mass caterers (restaurants, hospitals, canteens, etc.). Generally speaking nutrition labelling is optional, but if a nutrition claim is made on the label, in a presentation or in advertising then the rules become mandatory.

The Directive does not apply to natural mineral waters or other waters intended for human consumption, or food supplements. These areas have their own specific rules which are covered in more detail below (see 1.1.3 for supplements and 3.5.1 for mineral water).

For more information click here

The Labelling

Only nutrition claims are allowed which relate to the energy value, the nutrients referred to in the Annex to the Directive (proteins, carbohydrates, fat, dietary fibres, sodium, vitamins and minerals) or to substances which belong to one of the categories of these nutrients or which are components of them.

The information in nutrition labelling comes under group 1 or group 2, as indicated below:
CHAPTER 2

Group 1:

1. the energy value, and
2. the amount of protein, carbohydrate and fat,

Group 2:

3. the energy value
4. the amount of protein, carbohydrate, sugar, fat, saturated fatty acids, dietary fibre and sodium.

Generally group 1 information is only normally required, however where the nutrition claim refers to sugars, saturated fatty acids, dietary fibres or sodium, group 2 information must be provided instead.

The declared energy value and amount of nutrients must be given in figures using specific units of measurement. The information must be expressed per 100g or per 100ml. They can also be expressed per package or per portion. Information on vitamins and minerals must, in addition, be expressed as a percentage of the recommended daily allowance (RDA), which may also be given in graphic form.

Nutrition labelling may also include the quantities of amidone, polyols, monounsaturated fatty acids, polyunsaturated fatty acids, cholesterol and the mineral salts and vitamins specified in the Annex.

All of the above information must be grouped together in a clearly visible place and must be in legible, indelible characters and in a language easily understood by the purchaser. Member States may not introduce nutrition labelling specifications that are more detailed than those contained in this Directive.

Examples

As mentioned above the information in nutrition labelling comes under two groups. Here are examples of the two different labels:
CHAPTER 2

Group 1 label (in 6 different languages):

Group 2 label:
CHAPTER 2

Other Provisions

With regard to foodstuffs which are not pre-packaged when sold to the final consumer and mass caterers and foodstuffs which are packaged at the places of immediate sale, the scope of the information in food labelling and the manner in which it is provided may be laid down in national provisions until Community measures are possibly adopted in accordance with the procedure provided for in this Directive.

Committee

The Commission is assisted by the Standing Committee on the Food Chain and Animal Health.
1.1.2. Nutrition and Health Claims

**The Legislation**

Regulation (EC) No 1924/2006 applies to all nutrition and health claims including:

- commercial communications (labelling, presentation and promotional campaigns);
- trade marks and other brand names which may be construed as nutrition or health claims.

It applies to claims relating to all types of food intended for final consumers, including foods intended for supply to hospitals, canteens etc. However it does not apply to claims relating to the adverse effects of a product.

<table>
<thead>
<tr>
<th><strong>Key terms used in the act</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>“Claim”</strong> any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics;</td>
</tr>
<tr>
<td><strong>“Nutrition claim”</strong> any claim which states, suggests or implies that a food has particular beneficial nutritional properties;</td>
</tr>
<tr>
<td><strong>“Health claim”</strong> any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;</td>
</tr>
<tr>
<td><strong>“Nutrients”</strong> proteins, carbohydrates, fats, fibres, sodium, vitamins and minerals listed in the Annex to Directive 90/496/EEC, and substances which belong to or are components of one of those categories.</td>
</tr>
</tbody>
</table>

**Consumer protection**

The legislation on nutrition and health claims protects consumers by prohibiting any information which:

- is false, difficult to understand or misleading (e.g. which attributes medicinal properties to food wrongly or without scientific evidence);
- casts doubt on the safety or nutritional adequacy of other foods;
- encourages or condones excessive consumption of a food;
• encourages consumption of a food by stating or suggesting directly or indirectly that a balanced diet does not provide all the nutrients * that are needed;
• attempts to scare consumers by mentioning changes in bodily functions.

This Regulation supplements Directive 2000/13/EC relating to food labelling and Directive 2006/114/EC on misleading and comparative advertising which could mislead the consumer.

General conditions of use

Nutritional and health claims must meet the following conditions:

• the presence, absence or reduced content of a nutrient or other substance in respect of which the claim is made must have a beneficial nutritional or physiological effect, and be scientifically proven;
• the nutrient or substance in respect of which the claim is made is present in significant quantities in order to produce the nutritional or physiological effect claimed. Its absence or presence in a reduced quantity should also produce the expected nutritional or physiological effect;
• the nutrient or substance in respect of which the claim is made is in an immediately consumable form;
• the specific conditions of use must be complied with, for example, the active substance (e.g. vitamins, fibres, etc.) must be present in sufficient quantity in the food to have beneficial effects. Furthermore, if it is claimed that a food is energy-reduced, the energy value must be reduced by at least 30% of the total energy content of the food (25% in the case of salt).
• nutritional and health claims relating to beverages containing more than 1.2% of alcohol by volume are prohibited, with the exception of those which refer to a reduction in the alcohol or energy content of an alcoholic beverage.

Specific conditions of use

Only the nutritional claims listed in the Annex to this Regulation are authorised. Comparative nutritional claims are possible for foods in the same category whose composition does not allow a claim. They must relate to an identical quantity of food and indicate the difference in the nutrient content and/or energy value.

The Regulation prohibits health claims which refer to the rate or amount of weight loss or suggest it is detrimental to health not to consume a certain type of food, references to an individual doctor or health professional or to associations other than national medical associations and health-related charities, and claims which suggest that health could be affected by not consuming the food.

However, by way of derogation from Directive 2000/13/EC on labelling (which prohibits any reference to properties for the prevention, treatment or cure of a human disease), the
Regulation authorises claims concerning the reduction of the risk of a disease, provided that an application for authorisation has been approved.

For more information click [here](#).

**The Labelling**

The labelling, presentation and publicity related to health claims must provide certain obligatory information:

- a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;
- the quantity of the food and pattern of consumption which will ensure the claimed beneficial effect;
- a statement addressed to persons who should avoid the substance concerned;
- a warning of the health risks caused by excessive consumption.

**Examples**

Here is an example of a label on a ‘diet’ drink:

![Label Example](image)

**Other Provisions**

**Application for authorisation**

To obtain authorisation for a new claim or amend the existing list, the manufacturer must submit an application to the Member State concerned, which will forward it to the European Food Safety Authority (EFSA). The Commission then makes a decision on the use of the claim on the basis of the EFSA’s opinion.
1.1.3. Food Supplements

The Legislation

Directive 2002/46/EC concerns food supplements, defined as concentrated sources of nutrients (vitamins and mineral salts) or other substances with a nutritional or physiological effect, alone or in combination, which are marketed in dose form (e.g. capsules, tablets, sachets, etc.) in order to supplement a normal diet.

Composition of food supplements

With regard to vitamins and minerals, food supplements may only contain the vitamins and mineral salts laid down in Annex I of the Directive, and the vitamin and mineral formulations listed in Annex II, singly or in combination.

The Commission is responsible for establishing the purity criteria for substances contained in food supplements, and the maximum and minimum quantities authorised, with the assistance of the Standing Committee on the Food Chain and Animal Health.

For more information click here

The Labelling

The products covered by the Directive are sold under the name “food supplements”. Furthermore, without prejudice to the provisions of Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs, the labelling of food supplements must contain:

- the names of the categories of the nutrients or substances that characterize the product or an indication of the nature of those nutrients or substances;
- the portion of the product recommended for daily consumption and a warning of the risks to health if this is exceeded;
- a declaration to the effect that the supplement is not a substitute for a varied diet;
- the reference "This is not a medicinal product", where the presentation of the product is similar to that of a medicinal product;
a warning to the effect that the product should be stored out of the reach of young children.

The labelling of food supplements must not contain:

- any statement attributing to the product properties of preventing, treating or curing a human disease;
- any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

**Examples**

Below you can examples of labels from a food supplement product:

<table>
<thead>
<tr>
<th>Nutritional labelling and warnings</th>
<th>The ingredients and instructions for use</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Nutritional label" /></td>
<td><img src="image2" alt="Ingredients label" /></td>
</tr>
</tbody>
</table>
**Other Provisions**

**Monitoring system**

To facilitate efficient monitoring of food supplements, the Directive provides that Member States may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of that placing on the market by forwarding it a model of the label used.

**Safeguard clause**

The Member States may not prohibit or restrict trade in food supplements which comply with this Directive, except where they find that the products pose a public health risk. Where such a risk occurs, a Member State may temporarily suspend or restrict application of the provisions of the Directive. It shall immediately inform the other Member States and the European Commission thereof and give reasons for its decision. The Commission shall examine the grounds adduced by the Member State for temporarily suspending or restricting the trade in food supplements and shall consult the Standing Committee on the Food Chain and Animal Health before delivering its opinion and taking appropriate measures.

**Committees**

The Commission will be assisted in implementing the Directive by the Standing Committee on the Food Chain and Animal Health (e.g. determining the purity criteria for nutrients, establishing maximum levels, amending annexes, etc.).

In addition, the Commission shall consult the European Food Safety Authority (EFSA) before adopting provisions which may influence public health.
1.1.4. Gluten-Free Foodstuffs

The Legislation

Commission Regulation (EC) No 41/2009 applies to all foodstuffs with the exception of infant formulae and follow-on formulae. The Regulation lays down two thresholds suited to the degree of intolerance to gluten in consumers affected by coeliac disease. These thresholds comply with the standards adopted by the Commission from the Codex Alimentarius in July 2008.

This legislation will take effect from 1 January 2012.

For more information click here

The Labelling

<table>
<thead>
<tr>
<th>‘Gluten-free’ foodstuffs</th>
<th>Gluten-free foodstuffs must contain less than 20 mg/kg of gluten in the finished product.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very low gluten</td>
<td>Very low gluten foodstuffs must contain less than 100 mg/kg of gluten in the finished product</td>
</tr>
</tbody>
</table>
1.1.5. Addition of Vitamins, Minerals and Other Substances

Regulation (EC) No 1925/2006 covers the vitamins, minerals and other substances which are added to foods. It applies without prejudice to the provisions relating to:

- foods for particular nutritional uses;
- novel foods and novel food ingredients;
- genetically modified foods;
- food additives and flavourings;
- oenological practices and processes.

In addition provisions of this Regulation relating to vitamins and to minerals do not apply to food supplements covered by Directive 2002/46/EC.

List of vitamins and mineral substances which may be added to foods

Only vitamins and/or minerals listed in Annex I, in the form detailed in Annex II, may be added to foods, subject to the rules laid down in this Regulation. These include:

<table>
<thead>
<tr>
<th>Vitamins</th>
<th>Minerals</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Vitamins A, C, D, E, K, B1, B2, B6, B12</td>
<td>- Calcium</td>
</tr>
<tr>
<td>- Niacin</td>
<td>- Magnesium</td>
</tr>
<tr>
<td>- Pantothenic acid</td>
<td>- Iron</td>
</tr>
<tr>
<td>- Folic acid</td>
<td>- Manganese</td>
</tr>
<tr>
<td>- Biotin</td>
<td>- Sodium</td>
</tr>
<tr>
<td></td>
<td>- Iodine</td>
</tr>
<tr>
<td></td>
<td>- Zinc</td>
</tr>
<tr>
<td></td>
<td>- Manganese</td>
</tr>
<tr>
<td></td>
<td>- Potassium</td>
</tr>
<tr>
<td></td>
<td>- Selenium</td>
</tr>
<tr>
<td></td>
<td>- Chromium</td>
</tr>
<tr>
<td></td>
<td>- Molybdenum</td>
</tr>
<tr>
<td></td>
<td>- Fluoride</td>
</tr>
<tr>
<td></td>
<td>- Chloride</td>
</tr>
<tr>
<td></td>
<td>- Phosphorus</td>
</tr>
</tbody>
</table>

The modifications to the lists are adopted taking account of the opinion of the European Food Safety Authority (EFSA). However, until 19 January 2014 Member States may allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided the following conditions are met:
CHAPTER 2

- the substance in question is added to foods marketed in the European Union by 19 January 2007 at the latest;
- the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food, on the basis of a dossier supporting use of the substance in question to be submitted to the Commission by the Member State not later than 19 January 2010.

**Maximum and minimum levels**

Foods to which vitamins and minerals have been added voluntarily can make a contribution to achieving adequate intakes of these substances, consequently reducing the risk of deficiencies. However, the Regulation specifies that excessive intakes of vitamins and minerals may result in adverse health effects. For this reason, the Regulation provides for the setting of maximum quantities of vitamins and minerals added to foods. The maximum amounts take account of the upper safe levels for vitamins and minerals following a scientific risk assessment, the potential intake of vitamins and minerals from other foods and the reference intakes of vitamins and minerals recommended for the population. Furthermore, if necessary, it also takes account of the contribution of individual products to the overall diet of the population and of the nutrient profile established in accordance with Regulation (EC) 1924/2006.

**Prohibitions and restrictions**

Vitamins and minerals may not be added to:

- unprocessed foodstuffs, including fruit, vegetables, meat, poultry and fish; and
- without exception, beverages containing more than 1.2 % by volume of alcohol - and provided that no nutrition or health claim is made.

The Regulation provides for a procedure to prohibit or restrict the use of substances other than vitamins or minerals which have a nutritional or physiological effect. For some substances, these procedures are accompanied by other specific European control measures.

For more information on the Regulation click [here](#).

*The Labelling*

The nutrition labelling of products which vitamins and minerals have been added to and which are covered by the Regulation is compulsory. It must contain the following information:

- the total amounts of vitamins and minerals where they are added to a food;
- the amount of protein, carbohydrate, sugars, fat, saturates, fibre and sodium (in accordance with Directive 90/496/EEC on nutritional labelling of foods);
• the energy value of the product (in accordance with the same Directive on nutritional labelling).

The labelling, presentation and advertising of foods to which vitamins and minerals have been added shall not mislead or deceive the consumer as to their nutritional merit.

Similarly, the labelling, presentation and advertising of foods to which vitamins and minerals have been added shall not include any mention stating or implying that a balanced and varied diet is not an adequate source of nutritional substances.

**Examples**

Below you will find examples of labelling for a drink which has been enriched with vitamins:

<table>
<thead>
<tr>
<th>Ingredients and instructions</th>
<th>Nutritional information</th>
</tr>
</thead>
</table>
| *CONTAINS NATURALLY OCCURRING SUGARS*  
Fruit content: 100%. Ingredients: apple juice from concentrate, orange juice from concentrate, nectarine purée, passion fruit juice from concentrate, banana purée, guava purée, lemon juice from concentrate, Brazil plum purée, mango purée, apricot purée, vitamin C, niacin, vitamin E, pantothenic acid, beta carotene (provitamin A), vitamin B6, riboflavin, thiamin, folic acid, biotin, vitamin B12.  
Shake well before opening. Store in a cool and dry place. Once opened, store upright in the refrigerator and consume within 3-4 days. Best before: see top of pack. |  
| GB/IE | FI  
Nutrition Information |  
Ravintoaarro | g/100 ml | RDA  
--- | --- | --- | ---  
Energy | Energiarvoa | 220 kJ/52 kcal |  
Protein | Proteiinia | 0.4 g |  
Carbohydrate | Hiilihydraatteja | 12.0 g |  
of which sugars | joista sokerelta | 11.0 g |  
Fat | Rasva | 0.2 g |  
of which saturates | joista työdyttynetä rasvahappoja | 0.03 g |  
Fibre | Ravintokultua | 0.3 g |  
Sodium | Natriumia | <0.01 g |  
Salt equivalent | --- | 0.01 g |  
Vitamin C | C-vitamiinia | 30 mg | 50%  
Niacin | Niasinia | 9.0 mg | 50%  
Vitamin E | E-vitamiinia | 5.0 mg | 50%  
Vitamin A ** | A-vitamiinia ** | 300 µg | 38%  
Pantothenic acid | Pantoteenihappoa | 3.0 mg | 50%  
Vitamin B6 | B6-vitamiinia | 1.0 mg | 50%  
Riboflavin | B2-vitamiinia | 0.8 mg | 50%  
Thiamin | B1-vitamiinia | 0.7 mg | 50%  
Folic acid | Foolihappoja | 100 µg | 50%  
Biotin | Biotiinia | 0.075 mg | 50%  
Vitamin B12 | B12-vitamiinia | 0.5 µg | 50%  
RDA = Recommended daily allowance/ RDA = EU daily reference amount  
** = equivalent to provitamin A/ ** = laskettu betakaroteenista |
1.1.6. Caffeine and Quinine

The Legislation

Commission Directive 2002/67/EC on the labelling of foods and beverages containing caffeine or quinine or with a high level of caffeine. The Directive takes into account the general rules on labelling as set out in Directive 2000/13/EC.

This Directive is part of the move to simplify certain vertical Directives on foodstuffs and to harmonise the essential requirements which must be met by the products concerned by these Directives if they are to be able to move freely within the internal market.

For more information click here

The Labelling

This Directive provides for consumers to be given more accurate and complete information on the labelling of foodstuffs and beverages by making it compulsory to state the presence of quinine and caffeine, even if they are only used as a flavouring. For caffeine, once a certain threshold is exceeded (more than 150 mg per litre), the label must, in the same field of vision as the product name, state "high caffeine content" and specify the quantity.

This measure protects the health of consumers, who may be affected by the absorption of caffeine or quinine, for example when consuming beverages other than those based on coffee or tea, whose caffeine content is often unknown.

The legislation currently in force does not provide for compulsory and specific mention of flavourings in the list of ingredients. Quinine and caffeine, used as a flavouring, are therefore not systematically listed in the ingredients.
Examples

An example of a label of an energy drink which has exceeded the caffeine threshold:
1.2. SPECIAL DIETS

1.2.1. Foodstuff for Particular Nutritional Use

The Legislation

Directive 2009/39/EC applies to foodstuffs for particular nutritional uses. These foodstuffs are clearly distinguishable from foodstuffs for normal consumption owing to their composition or manufacturing process. Moreover, they must meet the particular nutritional requirements of the following categories of person:

- those whose digestive processes or metabolism are disturbed;
- those suffering from a particular physiological condition; and
- infants or young children in good health.

Only foodstuffs which meet the nutritional requirements of the two first categories of person mentioned above may bear the words “dietetic” or “dietary”.

Specific provisions

Specific provisions apply to the following groups of foodstuffs for particular nutritional uses:

- infant formulae and follow-on formulae;
- processed cereal-based foods and baby foods for infants and young children;
- foods intended for weight reduction;
- dietary foods for special medical purposes;
- foodstuffs for persons who are gluten-intolerant.

Detailed provisions shall be laid down in specific directives or regulations which may include provisions mainly relating to the nature or composition of products and to labelling.

Specific nutritional substances
It is possible to enrich foodstuffs by adding nutritional substances in order to meet particular nutritional needs and/or particular legal requirements. These enriched foods must be safe for consumption and be prepared on the basis of scientific data.

Their composition must comply with the purity criteria laid down by European legislation and national law, or those recommended by international bodies.

For more information click here

The Labelling

Foodstuffs intended for particular nutritional uses which have not been regulated by a specific directive shall comply with the rules on labelling, presentation and advertising of foodstuffs for general consumption. Nonetheless, the designation under which a dietetic product is sold must be accompanied by an indication of its particular nutritional characteristics and include additional information concerning:

- the composition or manufacturing process which gives the product its particular nutritional characteristics;
- the energy value in kilojoules (kJ) and kilocalories (kcal);
- the carbohydrate, protein and fat content per 100 grams or 100 millilitres of product.

Foodstuffs intended for particular nutritional uses shall only be allowed on the market in pre-packaged form, and the packaging shall completely cover the products, except for the retail trade or if a specific directive provides otherwise.

Other Provisions

Placing on the market

When a foodstuff that does not belong to the groups of foodstuffs for which specific provisions apply is placed on the market, the manufacturer or importer of the said product shall notify the competent authority of the Member State where the product is marketed for the first time and forward a label of the label used. Where the product is subsequently placed on the market in another Member State, the manufacturer or importer shall send the competent authority of that Member State the model of the label together with an indication of the recipient of the first notification.
The competent authority may require the manufacturer or importer to produce the scientific work and data establishing the foodstuff’s compliance with a particular nutritional objective for one of the three categories of consumer identified above.

Suspension and withdrawal from sale

A Member State may suspend or restrict trade in a foodstuff intended for particular nutritional uses if the latter endangers human health or if it does not comply with this Directive or the specific directives adopted in implementation of this Directive.

The Commission shall examine the reasons given by the Member State and consult the Standing Committee on the Food Chain and Animal Health before taking the appropriate measures.
1.2.2. Energy-Restricted Diet Food

The Legislation

Commission Directive 96/8/EC is a specific Directive within the meaning of Article 4 of Directive 89/398/EEC and lays down compositional and labelling requirements for foods for particular nutritional uses which are intended for use in energy-restricted diets for weight reduction and are presented as such.

Foods for use in energy-restricted diets for weight reduction are specially formulated foods which, when used as instructed by the manufacturer, replace the whole or part of the total daily diet. They are divided in two categories:

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

Member States shall ensure that the products listed below may be marketed within the Community only if they conform to the rules laid down in this Directive. In addition foods covered by this Directive shall comply with the compositional criteria specified in Annex 1.

The name under which the product is sold shall be:

- for products presented as a replacement for the whole of the daily diet: 'Total diet replacement for weight control';
- for products presented as a replacement for one or more meals of the daily diet: 'Meal replacement for weight control'.

For more information click here

The Labelling
In addition to the rules set out in the rules on labelling, presentation and advertising of foodstuffs, the following provisions are mandatory for diet replacement food:

- 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;
- the average quantity of each mineral and each vitamin for which mandatory requirements are stipulated in paragraph 5 of Annex 1, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption. In addition, for products presented as a replacement for one or more meals of the daily diet, information on vitamins and minerals listed in the Table of point 5 of Annex I shall also be expressed as a percentage of the values as defined in the Annex to Council Directive 90/496/EEC;
- instructions for appropriate preparation, where necessary, and a statement as to the importance of following those instructions;
- if a product, when used as instructed by the manufacturer, provides a daily intake of polyols in excess of 20 g per day, there shall be a statement to the effect that the food may have a laxative effect;
- a statement on the importance of maintaining an adequate daily fluid intake;
- for products presented as a replacement for the whole of the daily diet:
  - a statement that the product provides adequate amounts of all essential nutrients for the day;
  - a statement that the product should not be used for more than three weeks without medical advice;
- for products presented as a replacement for one or more meals of the daily diet: a statement to the effect that the products are 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.

The labelling, advertising and presentation of the products concerned shall not make any reference to the rate or amount of weight loss which may result from their use.
1.2.3. Dietary Foods for Special Medical Purposes

The Legislation

Commission Directive 1999/21/EC is another specific directive within the meaning of Article 4 of Directive 89/398/EEC. It lays down compositional and labelling requirements for dietary foods which are intended for special medical purposes and are presented as such.

Classification

<table>
<thead>
<tr>
<th>Dietary foods for special medical purposes are classified in the following three categories:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Nutritionally complete foods with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;</td>
</tr>
<tr>
<td>2. Nutritionally complete foods with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended. These foods may also be used as a partial replacement or as a supplement to the patient's diet;</td>
</tr>
<tr>
<td>3. 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. These foods may also be used as a partial replacement or as a supplement to the patient's diet.</td>
</tr>
</tbody>
</table>

General obligation

Member States shall ensure that dietary foods for special medical purposes may be marketed within the Community only if they comply with the rules laid down in this Directive.

Composition

The formulation of dietary foods for special medical purposes shall be based on sound medical and nutritional principles. Their use, in accordance with the manufacturer's instructions, shall be safe and beneficial and effective in meeting the particular nutritional requirements of the persons for whom they are intended, as demonstrated by generally accepted scientific data. They must comply with the compositional criteria specified in the Annex.
Trade name

This Directive specifies the name under which dietary foods for special medical purposes are sold in the 22 official languages of the European Union.

For more information click here

The Labelling

In addition to the particulars provided for in the general rules on labelling, presentation and advertising of foodstuffs, labelling shall also bear the following mandatory particulars:

- the available energy value expressed in kJ and kcal, and the content of protein, carbohydrate and fat, expressed in numerical form, per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;
- the average quantity of each mineral substance and each vitamin mentioned in the Annex present in the product, expressed in numerical form per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;
- 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, expressed in numerical form, per 100 g or per 100 ml of the product as sold and where appropriate per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions. This information may in addition be provided per serving as quantified on the label or per portion, provided that the number of portions contained in the package is stated;
- 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.

The labelling shall in addition bear the following mandatory particulars, preceded by the words "important notice" or their equivalent:

- a statement that the product must be used under medical supervision;
- a statement as to whether the product is suitable for use as the sole source of nourishment;
- where appropriate, a statement that the product is intended for a specific age group;
• 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.

The labelling shall also include:

• the statement "For the dietary management of…", where the blank shall be filled in with the diseases, disorders or medical conditions for which the product is intended;
• where appropriate, a statement concerning adequate precautions and contraindications;
• a description of the properties and/or characteristics that make the product useful in particular, as the case may be, 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, as appropriate.

Other Provisions

Foods for infants

This Directive also sets maximum and minimum values for vitamins, minerals and trace elements in nutritionally complete foods intended for use by infants.

Directive 2006/141/EC adapts one of its values, the minimum level of manganese in foods intended for infants, to take account of the latest scientific advice. The new requirements for infant formulae manufactured from cows' milk proteins or based on protein hydrolysates shall apply mandatorily to infant dietary foods for special medical purposes as of 1 January 2012.

Official monitoring

To facilitate efficient official monitoring of dietary foods for special medical purposes, when a product is placed on the market, the manufacturer or, where a product is manufactured in a third country, the importer shall notify the competent authority of the Member States where the product is being marketed by forwarding to it a model of the label used for the product. Member States may, if they can demonstrate that notification is not necessary in order to monitor those products efficiently in their territory, not impose that obligation.

The competent authorities within the meaning of this Article are those referred to in Article 9(4) of Directive 89/398/EEC.
2.1. GENETICALLY MODIFIED ORGANISMS

2.1.1. Traceability and labelling of GMOs

The Legislation

Regulation (EC) No 1830/2003 concerning the traceability and labelling of GMOs and products produced from GMOs stipulates that traceability will be required throughout the food chain. This measure has two main objectives:

- to inform consumers through the compulsory labelling of this type of products,
- to create a "safety net" based on the traceability of these products at all stages of production and placing on the market.

This "safety net" will facilitate the monitoring and checking of the nutritional claims made on labels, the surveillance of the potential effects on human health or the environment and the withdrawal of products if an unforeseen risk to human health or the environment is identified.

The Regulation concerns the traceability of GMOs as products or product components, including seeds, and of food or feed products produced from GMOs. It does not preclude the application of existing stricter legislation concerning the traceability and labelling of products.

The traceability rules apply to all GMOs; consequently, applications for GMOs for use in food or feed (Regulation (EC) No 1829/2003) must comply with them, as must applications for GMOs for crops (Directive 2001/18/EC, part C).
Food products produced from GMOs

When placing a product on the market, the industrial operator must transmit the following information in writing to the operator receiving the product:

- an indication of each food ingredient produced from GMOs;
- an indication of each raw material or additive for feedingstuffs produced from GMOs;
- if there is no list of ingredients, the product must nevertheless bear an indication that it is produced from GMOs.

GMO adventitious presence threshold

For food or feed products, including those intended directly for processing, traces of GMOs will continue to be exempt from the labelling obligation if they do not exceed the threshold of 0.9% and if their presence is adventitious and technically unavoidable.

The adventitious presence of GMOs is an important point of the Regulation.

The Member States carry out measures for the inspection and monitoring of products, including sampling and quantitative and qualitative analyses of food and feed. These measures entail the Member States being able to detain a product that does not meet the conditions laid down in this Regulation.

For more information click here.

The Labelling

The Regulation covers all foodstuffs produced from GMOs. It also covers all genetically modified feedingstuffs, with the same protection as for foodstuffs. All products approved in accordance with this Regulation are subject to compulsory labelling; consumers will therefore be better informed about GM products, whether for human or animal consumption. The consumer’s safety is guaranteed as a result of the traceability of products consisting of or containing GMOs.

Food or feed produced from or containing GMOs must also meet the specific labelling requirements of Regulation (EC) No 1829/2003. In addition, genetically modified foods and feedingstuffs are subject to the general legislation on this subject, Directive 2000/13/EC on labelling and Directive 96/25/EC on the circulation of feed materials.

Products consisting of or containing GMOs
In order to facilitate the traceability of GMOs and also to protect the environment, the Regulation requires operators to transmit the following information in writing:

- an indication that the products consist of or contain GMOs;
- the unique alphanumerical identifiers assigned to the GMOs contained in the products.

Through this system of unique identifiers of GMOs, it is possible to know these products' features and characteristics for the purposes of surveillance of traceability. In the case of products which are or contain mixtures of GMOs, the industrial operator may submit a declaration of use of these products, together with a list of the unique identifiers assigned to all the GMOs used to constitute the mixture.

Moreover, the Regulation stipulates that operators who place on the market a pre-packaged product consisting of or containing GMOs must, at all stages of the production and distribution chain, ensure that the words "This product contains genetically modified organisms" or "Product produced from GM (name of organism)" appear on a label affixed to the product. In the case of products, including in large quantities, which are not packaged and if the use of a label is impossible, the operator must ensure that this information is transmitted with the product. It may take the form of accompanying documents, for example.

**Other Provisions**


It also harmonises the disparate legislation on the labelling of GMOs by amending Regulation (EC) No 258/97 concerning novel foods and novel food ingredients. Lastly, it repeals Regulation (EC) No 1139/98 (concerning the compulsory indication on the labelling of certain foodstuffs produced from genetically modified maize and soya) and Regulation (EC) No 50/2000 on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified.
2.1.2. Food and Feed (GMO)

The Legislation

Regulation (EC) No 1829/2003 is stricter than the previous legislation and supplements Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms (GMOs).

The Regulation applies to three types of product:

- genetically modified organisms for food and feed use;
- food and feed containing GMOs;
- food and feed produced from or containing ingredients produced from GMOs.

Authorisation procedure

The Regulation provides for a single authorisation procedure for food products containing GMOs. The industrial operator can submit his application in accordance with this Regulation for all food products containing GMOs in compliance with the provisions provided for by Directive 2001/18/EC on the deliberate release of GMOs into the environment.

The industrial operator submits a single application for food and feed uses and for cultivation. This means that a GMO which has obtained authorisation can be used not only in food and animal feed but also for cultivation or deliberate release into the environment.

GMO adventitious presence threshold

The presence of GMOs in traditional crops is difficult to avoid. Minute traces in food products are tolerated if their presence is accidental or the result of technically unavoidable contamination during growing, harvesting, transport or processing. It is the responsibility of the farmer to demonstrate to the authorities the adventitious or technically unavoidable presence of a GMO in a food product.

For more information click here

The Labelling

Food and feed products containing GMOs must be labelled as such. The words ‘genetically
modified’ or ‘produced from genetically modified (name of the organism)’ must be clearly visible on the labelling of these products.

Food and feed products which contain a proportion of GMOs of less than 0.9 % of each ingredient are not labelled as GMO on the condition that the presence of the genetically modified organism is adventitious or technically unavoidable.

All genetically modified organisms and products thereof for food use must respect the labelling conditions provided for in this Regulation and also those laid down in Regulation (EC) No 1830/2003 concerning the traceability and labelling of GMOs.

Other Provisions

Assessment (EFSA) and risk management (Commission)

Once the application has been made by an industrial operator, the national authority concerned acknowledges receipt in writing within 14 days and informs the European Food Safety Authority (EFSA), which is responsible for risk assessment in the food sector. The latter has 6 months in which to conduct this assessment.

The Commission is responsible for risk management. On the basis of the risk assessment carried out by the EFSA, the Commission draws up a draft decision accepting or rejecting the application within 3 months. It then submits this draft to the Standing Committee on the Food Chain and Animal Health. If this committee accepts the proposal, it is finally adopted by the Commission; if it does not, the proposal is assessed by the Council of Ministers. If the latter does not reach a position within three months or if it is unable to reach a qualified majority for or against, the Commission adopts its proposal.

The marketing authorisation is renewable for ten-year periods.
2.1.3. Unique Identifiers for GMOs

The Legislation

Commission Regulation (EC) No 65/2004 applies to all genetically modified organisms that will be imported into the Community for cultivation and for human food and animal feed, except medicinal products for human and veterinary use.

Authorisation to place on the market

Since the beginning of the 1990s, the placing on the market of genetically modified organisms has been regulated by Directive 90/220/EEC. Since 1997, the regulations on GMOs, limited to Directive 90/220/EEC (covering the import, processing and cultivation of GMOs and their use in animal feed) have been strengthened by a Regulation concerning novel foods and novel food ingredients intended for human food (Regulation 97/258/EC).

The regulatory framework for GMOs was amended and updated by the adoption of Directive 2001/18/EC repealing the above-mentioned Directive 90/220/EEC, and by the adoption of two Regulations, one relating to GMOs in human food and animal feed (Regulation 1829/2003/EC) and the other to the labelling and traceability of GMOs (Regulation 1830/2003/EC).

All GMOs must be assessed before they can be sown or placed on the market. This risk assessment is carried out on a case-by-case basis and examines the expected or unexpected possible effects that the GMO is likely to have on health and on the environment. Therefore, effects linked to a GMO’s potential toxicity/allergenicity or its effects on non-target organisms for example are evaluated by national and Community scientific bodies (including the European Food Safety Authority).

For more information click here.

The Labelling
Once GMO products have been authorised to be placed on the market (Directive 2001/18/EC or Regulation 1829/2003), the appropriate identifier unique to each GMO must be included on the labelling. The identifier is made up of 9 characters, including letters and numbers, combined in a uniform way (see the Regulation's annex). This format was approved within the framework of the Organisation for Economic Cooperation and Development (OECD). The identifier for each specific GMO is therefore listed in the OECD's BioTrack database.

The Commission or the authority that approved the product's marketing must inform the Biosafety Clearing-House (set up under the Cartagena Biosafety Protocol) in writing of this unique identifier.

*Example*

As laid out in the Annex of the Directive, the format of the unique identifier comprises of nine alphanumeric digits in total. The first component represents the applicant/consent holder and comprises two or three alphanumeric digits. The second component comprises five or six alphanumeric digits and represents the transformation event. The third component provides for verification and is represented by a final numerical digit.

The following provides an example of an unique identifier developed using this format:

> PIC FILE= "L_2004010EN.000802.TIF" >
Other Provisions

The unique identifier is a GMO identification measure that is also linked to labelling and which facilitates the traceability of these products throughout the food chain, in application of Regulation 1830/2003.
2.2. ADDITIVES, FLAVOURING AND ENZYMES

2.2.1. Food Additives

The Legislation

Regulation (EC) No 1333/2008 brings together in a single legislative act all types of food additives, including colours and sweeteners. The Regulation lays down rules on food additives used in foods with a view to ensuring the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and fair practices in the food trade.

A food additive may only be approved if it does not pose a safety concern to the health of consumers, if there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means and if its use does not mislead the consumer.

This Regulation shall not apply to the following substances unless they are also used as food additives:

- processing aids,
- substances used for the protection of plants and plant products,
- nutrients added to food, substances used for the treatment of water,
- flavourings
- enzymes.

Community lists of food additives
CHAPTER 2

Annex I defines the different functional classes of food additives: sweeteners, colours, preservatives, antioxidants, carriers, acids, acidity regulators, anti-caking agents, anti-foaming agents, bulking agents, etc.

Additives are included in a list of additives which are authorised at Community level giving details of their conditions of use (Annex II).

Moreover, this Regulation creates a list of food additives for use in other additives and in food enzymes, as well as their conditions of use (Annex III).

Before incorporating all food additives in the lists in Annexes II and III of this Regulation, the Commission must examine all existing authorisations with regard to criteria such as quantities absorbed, technological need and the potential to mislead the consumer. Whilst these lists are being drawn up, the Annexes of Directives 94/35/EC, 94/36/EC and 95/2/EC will be regularly updated and remain in force.

If the production methods or raw materials used in a food additive already included in a Community list are altered considerably, the additive produced in this way shall be considered as a different additive. Before being placed on the market, this new additive shall be submitted to the European Food Safety Authority (EFSA) for an assessment of health risks.

For more information click here

*The Labelling*

Labelling of food additives must comply with the general labelling conditions defined in Directive 2000/13/EC. It must include, in particular, the information necessary for their identification (name, batch, manufacturer, etc.).
Below you can see a list of ingredients for a product that contains many different colours, sweeteners, and stabilisers:


Other Provisions

Common authorisation procedure and risk assessment

11. Risk assessment and the authorisation of food additives are integrated into a common authorisation procedure for food additives, enzymes and flavourings, established by Regulation (EC) No 1331/2008.

Reassessment

The Commission will re-examine all additives that have already been authorised with the assistance of the Standing Committee on the Food Chain and Animal Health. At the same time, all food additives which were permitted before 20 January 2009 shall be subject to a new assessment carried out by the EFSA. After consulting the Authority, the Commission will prepare an assessment programme by 20 January 2010 with a view to defining the needs and order of priorities for risk assessment.
2.2.2. Food Flavouring

The Legislation

Regulation (EC) No 1334/2008 aims at facilitating the free circulation of foodstuffs and guaranteeing the health and well-being of consumers. Generally speaking it applies to flavourings used to impart odour and/or taste to food, however the Regulation does not apply to:

- substances which have exclusively a sweet, sour or salty taste;
- raw foods;
- smoke flavourings;
- mixtures of spices and/or fresh, dried or frozen herbs, mixtures of teas and mixtures for infusion, as long as they have not been used as food ingredients.

Conditions of use

The marketing or use of flavourings which do not satisfy purity criteria and maximum levels for dangerous or undesirable elements or substances is prohibited. Some flavourings or food ingredients with flavouring proprieties may be used in or on food without being subject to an assessment and an authorisation as long as they present no risk for human health and their use does not mislead the consumer.

Community list of flavourings and source materials

Only the flavourings and source materials on the Community list may be placed on the market and used in or on food under the conditions of use specified therein. The list has been amended according to the common authorisation procedure for food additives, food enzymes and food flavourings as defined in Regulation (EC) No 1331/2008. Flavourings or source materials which have obtained an authorisation in line with Regulation (EC) No 1829/2003 may be included in the Community list.

For more information click here

The Labelling

Labelling of food flavourings must comply with the general labelling conditions defined in Directive 2000/13/EC. Labels must also include:
The term “natural” may only be used for substances or preparations derived directly from an animal or vegetable material. The statement “identical to natural flavourings” has been removed.

**Examples**

Looking at the same example as above, you can see the mention of flavourings:

```
```
2.2.3. Food Enzymes

The Legislation

Food enzymes other than those used as food additives are not currently regulated or are regulated as processing aids under the legislation of the Member States. Differences between national laws concerning the assessment and authorisation of food enzymes may hinder their free movement within the internal market by distorting the rules of competition.

**Regulation (EC) No 1332/2008** lays down the rules on food enzymes used in foods, including such enzymes used as processing aids. It does not cover food enzymes used in the production of food additives falling within the scope of **Regulation (EC) No 1333/2008**, or those used in the production of processing aids.

**Community list of food enzymes**

The creation of a list of authorised enzymes will make it possible to harmonise at European level all enzymes used as food additives. This list shall include all enzymes which perform a technological function in foods such as invertase (E 1103), lysozyme (E 1105), urease and betaglucanase.

The establishment of the positive list of food enzymes will benefit the consumer because the list will lay down common rules for the assessment and authorisation of these products. The list shall be established on the basis of the applications for authorisation submitted to the Commission. A period of 24 months shall be allowed for the submission of applications with effect from the entry into force of the implementing measures for **Regulation (EC) No 1331/2008** establishing a common authorisation procedure for food additives, food enzymes and food flavourings. These applications shall be forwarded to the **European Food Safety Authority** (EFSA).

Only the enzymes mentioned in the Community list may be placed on the market and added to food. The list of enzymes should include:

- the name of the enzyme;
- its specifications (including its origin, purity criteria, etc.);
- the foods to which it may be added;
- the conditions under which it may be used;
- restrictions on its sale;
CHAPTER 2

• specific labelling requirements.

Conditions for the inclusion of food enzymes in the Community list

An enzyme may be included in the Community list if and only if:

• it does not pose a concern to the health of the consumer, in the concentration used and on the basis of the existing scientific information;
• its use is justified by a technological need;
• its use does not mislead the consumer.

For more information click here

The Labelling

The labelling of food enzymes intended for sale to the final consumer should comply with the general conditions for labelling laid down in Directive 2000/13/EC. It should also include:

• the name of the food enzyme or the accepted name laid down in the nomenclature of the International Union of Biochemistry and Molecular Biology (IUBMB);
• the statement ‘for food’ or the statement ‘restricted use in food’ or a more specific reference to its intended food use.

The information should be easily visible, clearly legible, indelible and written in a language easily understood by the consumer.
2.2.4. Authorisation Procedure

The Legislation

Regulation (EC) No 1331/2008 lays down a common procedure for the assessment and common authorisation of food additives, enzymes and food flavourings. This procedure facilitates the free movement of food while guaranteeing the health and welfare of consumers.

The common procedure lays down the arrangements for drawing up and updating the Community lists for each category of substances. Only substances included in these lists are authorised on the Community market. The common procedure for updating the Community list may be started either on the initiative of the Commission or following an application by a Member State or an interested party. Applications shall be sent to the Commission.

The Commission shall forward the applications to the European Food Safety Authority (EFSA) for risk assessment. The EFSA shall give its opinion within nine months of receipt of the application. That period may be extended if the Authority requests additional information from the applicant.

The common procedure shall end with the adoption by the Commission of a Regulation updating the list of substances within nine months of receipt of the EFSA’s opinion. That period may be extended if the Commission requests additional information concerning aspects of risk management. The new period shall be determined together with the applicant. The Commission may also end the common procedure at any time, irrespective of the stage it has reached. In this case, it shall inform the applicant and the Member States if necessary, stating the reasons for its decision.

Implementing measures

The Commission shall adopt the implementing measures for this Regulation within two years from the adoption of the sectoral food law (the Regulations on additives, on enzymes and on flavourings). Six months after the entry into force of each sectoral food law, the EFSA shall present a proposal to the Commission concerning the data required for risk assessment of the substances concerned with a view to the adoption of the implementing measures of this Regulation.

Transparency
The EFSA shall ensure the transparency of its activities by making public its opinions and any extensions of periods for the provision of additional information.

Confidentiality

The manufacturer shall indicate which information is confidential when the application is submitted. The Commission shall then determine which information in the application for authorisation is confidential and shall notify the applicant accordingly. After being made aware of the Commission’s opinion on the confidential aspects, the applicant may withdraw its application so as to preserve that confidentiality if it does not agree with that opinion.

The following information shall not, in any circumstances, be regarded as confidential:

- the name and address of the applicant;
- the name and description of the substance;
- the justification for the use of the substance;
- the information concerning the safety of the substances;
- where applicable, the analysis method.

Emergencies

If an emergency is connected with one of the substances on the authorised lists, the Commission shall initiate the procedures relating to food safety.

Comitology

The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health for the updating of the list of additives, enzymes and flavourings.

List of competent authorities

Six months after the entry into force of each sectoral food law, Member States shall forward to the Commission the name and address of the national competent authority and a contact point.

For more information click [here](#).
2.2.5. Extraction Solvents

The Legislation


Extraction solvents

This Directive applies to extraction solvents used in the production of foodstuffs or food ingredients. It also applies to extraction solvents imported into the European Union (EU). However it shall not apply to extraction solvents used in the production of food additives, vitamins and other nutritional additives (unless such food additives, vitamins or nutritional additives are listed in Annex I).

Use and marketing

Member States shall authorise the use on their territory of extraction solvents used in the production of foodstuffs or food ingredients. However, this is subject to compliance with conditions of use and permitted residues. Only extraction solvents listed in Annex I may be used. Member States shall not prohibit, restrict or limit the marketing of a foodstuff or ingredient produced using an extraction solvent which meets the requirements of this Directive.

Water to which substances regulating acidity or alkalinity may have been added and other food substances which possess solvent properties are authorised as extraction solvents in the manufacture of foodstuffs or food ingredients.

Purity criteria

This Directive may, if necessary, establish specific purity criteria for the extraction solvents listed in Annex I, and in particular maximum permitted limits of mercury and cadmium.

The suspension or withdrawal of authorisation

A Member State may temporarily suspend or restrict an authorisation granted for an extraction solvent. To do this, the Member State must have grounds justifying that the solvent in question represents a risk for human health. It shall inform the Commission and the other Member States of its decision without delay.
The Commission shall examine the grounds cited as soon as possible and express an opinion. If appropriate, the Commission shall approve the measures taken by the Member State or supplement them with appropriate measures.

For more information click [here](#).

**The Labelling**

This Directive lays down labelling requirements including:

- the commercial name as indicated in Annex I;
- a clear indication that the extraction solvent is of a quality suitable for use for the extraction of food or food ingredients;
- the number of the batch or lot;
- the commercial name of the manufacturer or packer;
- the net quantity;
- if necessary, the special storage conditions or conditions of use.

There may be exemptions from these labelling rules. Only the first two particulars (the commercial name and use) may appear on the label if the extraction solvents are accompanied by commercial documents for the batch or lot which include the remaining information.

The particulars must be easily visible, clearly legible and indelible. They must be expressed in a language which can be easily understood by the purchaser.

**Specifications**

From Annex I

**Part 1**

Extraction solvents to be used in compliance with good manufacturing practice for all uses (as a residue or derivative):

- Propane
- Butane
- Ethyl acetate
- Ethanol
- Carbon dioxide
Part 2

Extraction solvents for which conditions of use are specified:

<table>
<thead>
<tr>
<th>Name</th>
<th>Conditions of use</th>
<th>Maximum residue limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hexane</td>
<td>Production or fractionation of fats and oils and production of cocoa butter</td>
<td>1 mg/kg in the fat or oil or cocoa butter</td>
</tr>
<tr>
<td></td>
<td>Preparation of defatted protein products and defatted flours</td>
<td>10 mg/kg in the food containing the defatted protein products and the defatted flours</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30 mg/kg in the defatted soya products as sold</td>
</tr>
<tr>
<td></td>
<td>Preparation of defatted cereal germs</td>
<td>5 mg/kg in the defatted cereal germs</td>
</tr>
<tr>
<td>Methyl acetate</td>
<td>Decaffeination of, or removal of irritants and bitterings from coffee and tea</td>
<td>20 mg/kg in the coffee or tea</td>
</tr>
<tr>
<td></td>
<td>Production of sugar from molasses</td>
<td>1 mg/kg in the sugar</td>
</tr>
<tr>
<td>Ethylmethylketone</td>
<td>Fractionation of fats and oils</td>
<td>5 mg/kg in the fat or oil</td>
</tr>
<tr>
<td></td>
<td>Decaffeination of, or removal of irritants and bitterings from coffee and tea</td>
<td>20 mg/kg in the coffee or tea</td>
</tr>
<tr>
<td>Dichloromethane</td>
<td>Decaffeination of, or removal of irritants and bitterings from coffee and tea</td>
<td>2 mg/kg in the roasted coffee and 5 mg/kg in the tea</td>
</tr>
<tr>
<td>Methanol</td>
<td>For all uses</td>
<td>10 mg/kg</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>For all uses</td>
<td>10 mg/kg</td>
</tr>
</tbody>
</table>

Part 3

Extraction solvents for which conditions of use are specified:
<table>
<thead>
<tr>
<th>Name</th>
<th>Maximum residue limits in the foodstuff due to the use of extraction solvents in the preparation of flavourings from natural flavouring materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diethyl ether</td>
<td>2 mg/kg</td>
</tr>
<tr>
<td>Hexane</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Cyclohexane</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Methyl acetate</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Butan-1-ol</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Butan-2-ol</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Ethylmethylketone</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Dichloromethane</td>
<td>0,02 mg/kg</td>
</tr>
<tr>
<td>Propan-1-ol</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>1,1,1,2-tetrafluoroethane</td>
<td>0,02 mg/kg</td>
</tr>
</tbody>
</table>
2.3. PRODUCTION METHODS

2.3.1. Agriculture and Foodstuff as Traditional Specialities Guaranteed

The Legislation

Under Council Regulation (EC) No 509/2006 agricultural products intended for human consumption or foodstuff with a traditional composition, or produced according to a traditional production method may become a traditional speciality guaranteed (TSG). This possibility encourages the diversification of agricultural production and has positive consequences in several areas. The introduction of the designation TSG boosts farmers' revenues and maintains the population in less favoured or remote areas by promoting the rural economy. It also increases the market value of the products of economic operators, by guaranteeing that they are distinguishable from other similar products or foodstuffs. In addition, thanks to the introduction of this designation, consumers will able be to make more informed choices on the basis of clear information on the specific characteristics of the products they buy.

The register of products

TSGs recognised at Community level are entered into a register, which is kept by the Commission. They are divided into two lists according to whether or not the use of the name is reserved to those producers who comply with the product specification. A product may only be registered if:

- it is produced using traditional raw materials;
- it is characterised by a traditional composition or by a method of production/processing that corresponds to a traditional production/processing method.

In order to be registered, the name must:
• be specific in itself;
• indicate the specific character of the agricultural product or foodstuff.

Names that refer only to claims of a general nature used for a set of products or provided for by a particular piece of Community legislation, and names that are misleading for consumers cannot be registered. In addition, these rules apply without prejudice to Community rules governing intellectual property or concerning geographical indications and trademarks.

**Product specification**

In order to be recognised as a TSG, an agricultural product or foodstuff must comply with the product specification, and must include the following elements:

• the name, given in one or more languages, and an indication whether the application for registration is being made with or without reservation of the name;
• the description of the product, with an indication of its main physical, chemical, microbiological and organoleptic properties;
• the description of the production method to be applied by the producers, including where relevant the nature and characteristics of the raw materials or ingredients used and the manufacturing method;
• the key elements that define the product’s specific character;
• the key elements that demonstrate the product’s traditional character;
• the minimum requirements and procedures for checking its specific character.

**Application for registration**

The application for registration may be made only by a group of producers or processors. A joint application may be submitted by several groups originating from different Member States or third countries.

The application for registration must include:

• the name and address of the applicant group;
• the product specification;
• the name and address of the authorities or bodies verifying compliance with the provisions of the product specification and their specific tasks;
• the documents that demonstrate the specific nature and traditional character of the product.

Applications are to be lodged with the Member State where a group is established. The Member State examines it and initiates a national objection procedure, ensuring adequate publication of the application and providing for a reasonable period in which any natural or legal person having a legitimate interest and established or resident on its territory may lodge an objection. Then it forwards the completed application to the Commission, including a declaration that all the conditions have been met.
Where an application for an agricultural product or foodstuff comes from a group in a third country, it has to be sent to the Commission either directly or through the authorities of that country.

Examination by the Commission

The Commission shall check, within a maximum of twelve months, that the application is justified and that it meets all the necessary conditions. Each month, it makes public the list of the names for which registration applications have been submitted. If the conditions are met, it publishes in the Official Journal of the European Union the name and address of the applicant group, the product specification and the name and address of the authorities or bodies verifying compliance with the provisions of the product specification. If the conditions are not met, the Commission will reject the application for registration.

Objections

Within six months from the date of publication in the OJ, any Member State, third country, natural or legal person having a legitimate interest may object to the registration proposed by lodging a duly substantiated statement. They must show that either the conditions have not been meet, or that the name is already in lawful use, is renowned and is economically significant for similar agricultural products or foodstuffs. Where the Commission receives no admissible objection, it will register the name.

Where the Commission judges the objection to be admissible, it invites the interested parties to engage in the appropriate consultations. If they reach an agreement within six months, they notify the Commission of all the factors that enabled that agreement to be reached, including the opinions of the applicant and the objector. If no agreement is reached, the Commission takes a decision, bearing in mind traditional fair practice and the actual likelihood of confusion. If the Commission takes the view that compliance with the conditions of the product specification of an agricultural product or foodstuff registered as a TSG is no longer ensured, it must initiate the procedure for cancelling the registration.

Amending the product specification

A group established on the territory of a Member State or in a third country may submit a request to the Commission for the amendment of a product specification either directly or through the authorities of the country in question.

You can find more information here.

The Labelling
Only producers complying with the product specification may refer to a TSG on the labelling, advertising or other documents relating to an agricultural product or foodstuff. Where reference is made to a traditional speciality guaranteed on the labelling of an agricultural product or foodstuff produced within the Community, the registered name is to be accompanied either by the Community symbol or the indication "traditional speciality guaranteed". From the date of publication, all names entered in the register must be used in accordance with the rules stated above.

Registered names may be used in labelling, even if they do not correspond to the product specification. In such cases, it is not permitted to indicate "traditional speciality guaranteed", the abbreviation "TSG", or the associated Community symbol on the labelling. In addition, at the group's request, a TSG may be registered with reservation of the name, unless the same name is already in lawful use, is renowned and is economically significant for similar agricultural products or foodstuffs.

Examples

Here is the TSG logo:
Official controls

The control of the obligations established by this Regulation may be carried out by authorities designated by the Member States or by a control body operating as a product certification body. The costs of such verification are to be borne by the operators subject to those controls. In respect of agricultural products and foodstuffs originating from a third country, verification of compliance with the product specification must be ensured by one or more public authorities designated by the third country or by one or more product certification bodies.

A producer intending to produce a traditional speciality guaranteed for the first time must notify this fact to the authorities of the Member State. A third country producer intending to produce a traditional speciality guaranteed for the first time must notify this fact to the designated authorities or bodies.

Protection

The Member States must take the necessary measures to ensure legal protection against any misuse or misleading use of the term "traditional speciality guaranteed", the abbreviation TSG and the associated Community symbol and against any imitation of names registered and reserved. Registered names must be protected against any practice liable to mislead the consumer, including practices suggesting that a product is a traditional speciality guaranteed recognised by the Community.

Committee procedure

The Community is assisted by the Standing Committee on Traditional Specialities Guaranteed.

Fees

The Member States may charge a fee to cover their costs, including those incurred in examining applications for registration, statements of objection, applications for amendments and requests for cancellations under this Regulation.
2.3.2. Geographical Indications and Designation of Origin

The Legislation

Council Regulation (EC) No 834/2007 sets out provisions on agricultural products and foodstuffs (excluding all wine-sector products, except wine vinegar) from a defined geographical area. If there is a link between the characteristics of certain products and their geographical origin, they may qualify for either a protected geographical indication (PGI) or a protected designation of origin (PDO). The use of corresponding EU symbols on the labels of such products provides consumers with clear and concise information on their origin. The introduction of these two terms also benefits the rural economy, since it boosts farmers' income and maintains the population in less favoured or remote areas.

Designation of origin and geographical indication

The two types of geographical description are different. A PDO (Protected Designation of Origin) covers the term used to describe foodstuffs which are produced, processed and prepared in a given geographical area using recognised know-how (such as Mozzarella di Bufala Campana). A PGI indicates a link with the area in at least one of the stages of production, processing or preparation (such as Turrón de Alicante). The link with the area is therefore stronger for PDOs.

Names that have become generic, i.e. those that, although linked to the place or region where the product was initially produced or sold, denote the common name of a product in the EU (such as Dijon mustard) may not be registered. Names that conflict with the name of a plant variety or an animal breed and as a result are likely to mislead the consumer as to the true origin of the product may not be registered. A name wholly or partially homonymous with that of a name already registered under this Regulation must only be registered with due regard for local and traditional usage and the actual risk of confusion.

A PDO or PGI may not be registered where the reputation and the length of time it has been used are liable to mislead the consumer as to the true identity of the product.
### Key terms used in the act

<table>
<thead>
<tr>
<th>Geographical Indication</th>
<th>Designation of origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>is linked to the name of a region, a specific place or, in exceptional cases, a country, used to describe an agricultural product or a foodstuff:</td>
<td>is linked to the name of a region, a specific place or, in exceptional cases, a country, used to describe an agricultural product or a foodstuff:</td>
</tr>
<tr>
<td>- originating in that region, specific place or country</td>
<td>- originating in that region, specific place or country, and</td>
</tr>
<tr>
<td>- which possesses a specific quality, reputation or other characteristics attributable to that geographical origin,</td>
<td>- the quality or characteristics of which are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors, and</td>
</tr>
<tr>
<td>- the production and/or processing and/or preparation of which take place in the defined geographical area.</td>
<td>- the production, processing and preparation of which take place in the defined geographical area.</td>
</tr>
</tbody>
</table>

### Product specification

In order to obtain a PDO or PGI, agricultural products or foodstuffs must comply with the product specification, which must include the following aspects:

- the name of the PDO or PGI;
- the description of the product, with an indication of its main physical, chemical, microbiological and organoleptic properties;
- definition of the geographical area;
- information proving that the product originates from that area;
- information justifying the link between the product and the geographical area;
- description of the production method and, if appropriate, the authentic and unvarying local methods as well as information concerning packaging that takes place in the defined geographical area in order to safeguard quality, ensure the origin or ensure control;
- the name and address of authorities or bodies that verify compliance with the provisions contained in the product specification;
- any specific labelling rule for the product in question;
- any requirements laid down by Community or national provisions.
Protection

Registered names are protected against:

- 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" or similar;
- any other false or misleading indication as to the provenance, origin, nature or essential qualities of the product, on the inner or outer packaging, advertising material or documents relating to the product concerned, and the packing of the product in a container liable to convey a false impression as to its origin;
- any other practice liable to mislead the consumer as to the true origin of the product;
- commercial use of a registered name in respect of products not covered by the registration if they are comparable to the products registered under that name or if this use exploits the reputation of the protected name.

Relations between trade marks, designations of origin and geographical indications

Where a PDO or a PGI is registered, applications to register trade marks corresponding to one of the above situations and relating to the same class of product are refused if they are submitted after the date of submission of the registration application to the Commission. In certain cases specified in the Regulation, a trade mark may co-exist with a geographical indication or a designation of origin.

For more information click here.

The Labelling

A registered name may be used by any operator marketing products conforming to the corresponding specification. The terms "protected designation of origin" and "protected geographical indication" or the associated EU symbols must be included on the labelling of products originating in the EU and may be included on those originating in third countries and sold under these designations.
Application for registration

Applications for registration may only be made by a group of producers or processors or, in exceptional cases, natural or legal persons. If the application concerns a cross-border area, it may be made jointly by several groups.

The application for registration must include:

- the name and address of the applicant group;
- the product specification;
- a single document setting out the main aspects of the product specification and a description of the link between the product and its geographical area of origin.

Applications are made to the Member State on whose territory the geographical area is situated. The Member State examines it and initiates a national objection procedure, ensuring that the application is sufficiently publicised and allowing a reasonable period within which any natural or legal person having a legitimate interest and established or resident on its territory may lodge an objection. Where the Member State deems the application to be acceptable, it forwards the single document to the Commission together with a declaration stating that all the necessary conditions have been met.
Where an application for registration concerns a geographical area in a third country, it has to be sent to the Commission either directly or through the authorities of that country.

Examination by the Commission

The Commission checks that the application is justified and that it meets all the necessary conditions. This check must be carried out within twelve months. Each month, the Commission publishes the list of the names for which registration applications have been submitted. If the conditions are met, it publishes in the Official Journal of the European Union (OJ) the single document and the publication reference of the product specification. If the conditions are not met, the Commission will reject the application for registration.

Objections

Within six months from the date of publication in the OJ, any Member State, third country, natural or legal person having a legitimate interest may object to the registration proposed by lodging a duly substantiated statement. Proof must be given that either the product specification fails to meet the required conditions, or that the name conflicts with a trade mark or agricultural product or that it has become a generic name. Where the Commission receives no admissible objection, it will register the name.

Where the Commission judges that an objection is admissible, it invites the interested parties to engage in the appropriate consultations. If they reach an agreement within six months, they notify the Commission of all the factors that enabled that agreement to be reached, including the opinions of the applicant and the objector. If no agreement is reached, the Commission takes a decision, bearing in mind traditional fair practice and the actual likelihood of confusion.

Amending the product specification

A group may request the product specification to be amended to take into account technical or scientific developments or to revise the definition of the geographical area. Applications for amendments are made in accordance with procedures similar to those for registering a designation.

Official controls

Controls on the requirements set out in this Regulation are carried out under Regulation (EC) No 882/2004. Verification of compliance of a product with its product specification may be ensured by one or more public authorities set up for this purpose or by one or more product certification bodies. For EU designations, the costs of such verification are to be borne by the operators subject to those controls.

Cancellation
If the Commission deems that compliance with the conditions laid down in the product specification for a protected designation is no longer ensured or if any natural or legal person with a legitimate interest requests cancellation of the registration, the Commission may initiate the procedure to cancel a registration.

Committee procedure

The Commission is assisted by the Standing Committee on Protected Geographical Indications and Protected Designations of Origin.

Fees

Member States may charge a fee to cover their costs, including those incurred in scrutinising applications for registration, statements of objection, applications for amendments and requests for cancellations under this Regulation.
2.3.3. Organic Products

The Legislation

Council Regulation (EC) No 834/2007 lays down a new legal framework for organic products. It sets out the objectives and principles applicable to this type of production and illustrates the rules on production, labelling, controls and trade with third countries. This Regulation enters into application on 1 January 2009.

Scope

The framework established by this Regulation governs:

- agricultural products (including aquaculture products), either processed or unprocessed and intended for human consumption;
- animal feed;
- vegetative propagating material and seed used for crops;
- yeasts used as food or feed.

This Regulation contains the basic objectives and general principles for organic farming. The objectives focus on sustainable agriculture and production quality, which must meet consumers’ needs. The general principles concern, inter alia, specific production methods, the use of natural resources and stringent restrictions on synthetic chemical inputs. Furthermore, the Regulation lays down specific principles concerning farming, the processing of organic food and organic animal feed.

Production rules

According to the general rules for organic production, genetically modified organisms (GMOs) are prohibited in all their forms. Rules concerning the labelling of food allow operators to ensure compliance with this prohibition. Treatment by ionising radiation is also prohibited. Those wishing to operate both types of agricultural production (organic and non-organic) must ensure that animals and land for these two activities are separated.

Organic plant production must comply with certain rules concerning:

- ground treatment, which must preserve life and the natural fertility of the ground;
• the prevention of damage, which must be based on natural methods but which can make use of a limited number of plant protection products authorised by the Commission;
• seed and plant propagation material, which must be produced using organic methods;
• cleaning products, for which authorisation must be requested from the Commission.

Wild plants collected in some areas are also classified as organic products if they comply with certain conditions relating to their harvest and provenance. Seaweed may also be considered as an organic product as long as its area of production and harvest comply with certain conditions.

Organic livestock production must comply with certain rules concerning:

• the animals' origin - they must have been born and reared in organic holdings;
• livestock husbandry practices, which, *inter alia*, relate to certain features of animal housing;
• animal breeding methods, generally natural;
• animal feed, which must be organic;
• the prevention of disease;
• cleaning and disinfection, involving the exclusive use of products authorised by the Commission.

Similar specific rules apply to aquaculture animals.

The Commission authorises the use of a limited number of products and substances in organic farming. These products may be for plant care, animal feed and the cleaning of buildings used for livestock and plant production. The Commission may also set certain limits and conditions for the application of these products. Holdings which are entering into a new organic farming activity must comply with a conversion period. The rules laid down in this Regulation also govern this conversion period.

Organic processed feed must contain organic raw materials and may not be processed using chemical solvents. Processed food must contain mainly ingredients of agricultural origin. Other ingredients are permitted if authorisation has been requested from the Commission. Organic yeast must be produced from organic substrates and other authorised ingredients.

The Commission may make exceptions to provisions concerning objectives, production rules and labelling. These exceptions will be limited in time and apply to certain particular cases.

*Controls*

Compliance with the provisions contained in this Regulation will be guaranteed by a system of controls based on Regulation (EC) No 882/2004 and precautionary and control measures established by the Commission. This system guarantees the traceability of food pursuant to Regulation (EC) No 178/2002.
An assessment of the risk of infringement will determine the type and frequency of controls. These will be organised by authorities appointed by Member States. Under certain conditions, these authorities may delegate control duties to accredited bodies, but they shall remain responsible for the supervision of the controls carried out and the granting of exemptions. Member States must notify the Commission regularly of the list of authorities and control bodies (list of bodies or authorities responsible for control published in 2007).

The authorities must also control the activities of each operator involved in the marketing of an organic product before it is placed on the market. Following this control, the operator receives documentary evidence which certifies that it complies with the provisions of this Regulation. If irregularities are noted, the authority shall ensure that the labelling of the products at issue do not contain any reference to organic production.

**Context**

This Regulation has been produced as part of a series of initiatives to foster organic farming. In the same framework, the Commission adopted an Action Plan for Organic Food and Farming in 2004.

The first legal framework for organic farming was laid down in 1991 with Regulation (EC) No. 2092/91. Since its adoption, several amendments have been introduced into this Regulation, because organic farming has become more and more important in all Member States (annual growth for this sector is estimated at almost 25 % between 1993 and 1998 and around 30% since 1998). A report on organic farming will be published by the end of 2011.

For more information click here.

**The Labelling**

Labelling, advertising or commercial documents may use terms such as “eco” and “bio” to describe an organic product, its ingredients, or raw materials. Also the labelling of an organic product must be clearly visible on the packaging and contain a reference to the control body that certifies the product concerned.

From 1 July 2010, the use of the European Union logo on organic food products will be mandatory, as will an indication of the provenance of raw materials used in the product. This indication must be shown in the same field of vision as the Community logo.

**Examples**
**Other Provisions**

*Trade with third countries*

Products from third countries may also be placed on the Community market as organic products as long as they comply with the provisions of this Regulation and if they have been subject to control. This control may be carried out either by a body recognised by the European Community, or by an accredited control body.

*Marketing and statistical surveillance*

The marketing of an organic product may not be hindered in any way by any authority of a Member State other than the authority which has inspected the product. The Commission carries out statistical surveillance activities based on the data provided by Member States. The [Standing Committee on Organic Farming](https://www.organic-farming.org) assists the Commission in defining policies for organic farming.
2.4. PREPERATION

2.4.1. Foodstuff Treated with Ionising Radiation

The Legislation

Directive 1999/2/EC applies to the manufacture, marketing and importation of foods and food ingredients treated with ionising radiation. It does not apply to foodstuffs exposed to ionising radiation generated by measuring or inspection devices within certain specified limits nor to foodstuffs which are prepared for patients requiring sterile diets under medical supervision.

Ionising radiation is used to reduce the number of pathogenic micro-organisms in food ingredients in order to increase the storage life of the end product.

Conditions for application

Irradiated foodstuffs may be placed on the market only if they comply with the Directive. To this end, Annexes I, II and III lay down provisions on:

- the conditions for authorising food irradiation (technological need, benefit to the consumer, etc.) and permissible purposes (to reduce the incidence of disease, rid foodstuffs of harmful organisms) in addition to the general requirement that foodstuffs must be in a wholesome state and the obligation not to replace hygiene measures. Irradiation may be combined with other chemical treatment, only if the chemical treatment is for different purposes;
- sources of ionising radiation (gamma rays, X rays and electrons of certain characteristics);
- dosimetry (determination of the overall average absorbed dose and procedures for measuring it). The Directive also specifies that the maximum radiation dose for foodstuffs may be given in partial doses.

Requirements will evolve to adapt with scientific and technical progress.
Products covered

Both treatment and placing on the market must comply with the Directive and the dose limits recommended by the Standing Committee on the Food Chain and Animal Health and therefore the list of Member States' authorisations and the list of approved facilities for the treatment of foods and food ingredients with ionising radiation.

Submission of information

The Member States are required to forward the following information to the Commission:

- the names of the competent national regulatory authorities (responsible for prior approval of irradiation facilities and allocation of a reference number to them) and for inspection of irradiation of foodstuffs;
- the references of the irradiation facilities approved;
- the results of checks carried out in the ionising irradiation facilities and at the product marketing stage.

Registration obligations

Irradiation facilities must keep a record for each source of ionising radiation showing the information specified (nature and quantity of foodstuffs irradiated, data for control of the irradiation process, etc.). These records must be kept for five years. Detailed rules on keeping of the register will be adopted by the Commission, assisted by the Standing Committee on the food chain and animal health.

You can find more information here.

The Labelling

The words "irradiated" or "treated with ionising radiation" must appear:

- on the label or packaging;
- on the documents which accompany irradiated foodstuffs or foodstuffs containing irradiated ingredients.

In the case of products intended for sale to the ultimate consumer, the information requirements laid down in Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs must be complied with. Products not intended for sale to the ultimate consumer must be marked to indicate that they have been irradiated and the name and address of the facility where this was carried out.
Import arrangements

Foodstuffs may be imported from a third country provided:

- they comply with the conditions laid down in the framework Directive;
- they are accompanied by documents showing the name, address and records of an irradiation facility approved by the Community.

The Commission may conclude technical arrangements with third countries on the approval and inspection of irradiation facilities in those countries.

Protection of health

A Member State may contact the Commission if it considers that the irradiation of a foodstuff may endanger human health, even though it meets the requirements of the Directive. The Commission shall then consult the Standing Committee on the Food Chain and Animal Health before adopting an appropriate measure.
2.4.2. Quick Frozen Food

**The Legislation**


**Freezing process**

Quick-frozen foodstuffs are those subjected to the "quick-freezing" process, in which the temperature zone of maximum crystallisation is spanned as rapidly as possible and the product is then held (after thermal stabilisation) at a temperature of -18°C or lower.

Quick freezing must be carried out promptly, using appropriate technical equipment, on raw materials of sound, genuine and merchantable quality. Only air, nitrogen and carbon dioxide meeting specific purity criteria may be employed as cryogenic media. The purity criteria are set by the Commission.

Deviations from the temperature of -18°C for quick-frozen foods are permitted during transport and local distribution and in retail display cabinets. The temperature in such instances must not exceed 3°C. However, it may be as much as 6°C in retail display cabinets if Member States so decide.

**Product packaging**

Quick-frozen foods must be packaged in pre-packaging which protects them against external contamination and drying.

**Official checks**

Member States must ensure that the equipment used for quick-frozen foods complies with the Directive and they must conduct random official checks on product temperature. The Commission must adopt the detailed rules for sampling and for monitoring temperature in the modes of transport, warehousing and storage.

You can find more information [here](#).
The labelling of quick-frozen foods must include the sales name, the indication "quick-frozen" and the batch identification. The other compulsory information varies according to whom the product is intended for:

- ultimate consumers, restaurants, hospitals, canteens: the date of minimum durability, the period during which the product may be stored by the purchaser, the storage temperature and the storage equipment required;
- others: the net quantity and the identity of the manufacturer, packer or seller.
3. SPECIFIC FOOD/DRINK RULES

3.1. MEAT

3.1.1. Identification and Labelling of Beef and Veal

The Legislation

Regulation (EC) No 1760/2000 establishes:

- a cattle identification and registration system (Title I);
- a compulsory labelling system (Title II, Section I) and a voluntary labelling system (Title II, Section II) for beef and veal).

CATTLE

Every Member State must set up a cattle identification and registration system. This system must comprise the following elements:

1. Double eartags for the individual identification of cattle:

   a) Cattle from the European Community

   All animals on a holding born after 31 December 1997 or intended for intra-Community trade after 1 January 1998 are identified by an eartag inserted in each ear within twenty days of birth
and, at any rate, before they leave the holding of birth. Both eartags bear the same unique code identifying the animal and the holding on which it was born. In the case of cattle intended for cultural and sporting events, the tags may be replaced by an identification system offering equivalent guarantees and authorised by the Commission.

b) Cattle from third countries

Any imported animal which has passed the veterinary checks laid down by Directive 91/496/EEC must be identified by an eartag applied within twenty days of the veterinary checks and, at any rate, before it leaves the holding. This requirement does not apply where the holding of destination is a slaughterhouse situated in the Member State where the checks are carried out and the animal is slaughtered within twenty days of undergoing the checks.

c) Provisions covering all cattle:

- any animal from another Member State retains its original eartag;
- no eartag may be removed or replaced without the permission of the competent national authority;
- the European Parliament and the Council are to decide by 31 December 2001 on the feasibility of using electronic identification arrangements.

2. Computerised databases:

In accordance with Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine, Member States have, since 31 December 1999, operated a computerised database which records cattle identities, the holdings on their territory and cattle movements.

3. Individual cattle passports:

a) issue of the passport:

Since 1 January 1998, the responsible national authority has issued passports for all cattle within fourteen days of the notification of their birth or, in the case of imported cattle, within fourteen days of the notification of their re-identification by the Member State concerned. The authority may also issue passports for animals from other Member States. In such cases, the passport accompanying the animal must be surrendered to the Member State which issued it.

b) holding and surrender of the passport:

The passport accompanies the animal throughout all movements. It is returned to the responsible authority:
• when the animal is slaughtered: the passport is surrendered by the animal's keeper or, where relevant, by the operator of the slaughterhouse, within seven days of slaughter;
• when the animal is exported to a third country: the passport is surrendered by the last keeper to the responsible authority at the place where the animal is exported.

c) exceptions:

Member States which have a computerised database may decide not to issue passports to cattle which are to remain in their country and may require an animal to be accompanied by a passport only if it is moved to another Member State.

4. Individual holding registers

With the exception of hauliers, any keeper of animals must maintain a computerised or manual register. He must therefore report to the responsible authority all births and losses of livestock and all movements to and from the holding and, where relevant, enter these details in the animal's passport. Information on the origin, identification and destination of animals is available upon request to the responsible authority for a period of at least three years. The Commission may lay down special rules applicable to cattle movements in mountain areas.

5. Committee procedures

By means of the management procedure, the European Commission, assisted by the Committee for the European Agricultural Guidance and Guarantee Fund, draws up the arrangements for implementing the system for the identification and registration of cattle (e.g. eartags, passport, register, checks, penalties, transitional provisions, etc.).

For more information click here

The Labelling

Operators or organisations marketing Community or imported beef are obliged to label the beef at all stages of the marketing process. When the product is not pre-wrapped, they must supply relevant information in written and visible form to the consumer at the point of sale.

The following information must be shown on the label:

• the reference number or code establishing the link between the meat and the animal, or group of animals, from which the meat was derived;
"Slaughtered in" (country where slaughter took place and licence number of the slaughterhouse);  
"Cutting/cut in" (country where cutting was performed and licence number of the cutting plant).

Moreover, since 1 January 2002, operators must also indicate:

- the country where the animals were born;
- the country where the animals were fattened/bred;
- and the country where the animals were slaughtered.

Where the beef is derived from an animal born, bred and slaughtered in a single country, this information may be grouped together under one heading, "Origin", followed by the name of the country in question. By way of derogation, imported meat for which not all compulsory information is available is labelled "Origin: non-EC", followed by the name of the third country in which it was slaughtered.

Labelling for minced beef must show:

- the reference number or code establishing the link between the meat and the animal, or group of animals, from which the meat was derived;
- the indication "Produced in" (followed by the name of the country of production) and the indication "Origin" where the country or countries concerned are not the same as the country of production;
- the country of slaughter;

Operators may supplement the above with information on the place (establishment) of slaughter, the place of cutting (establishment and country), the date of mincing, the country of birth and the country or countries of breeding.

**Voluntary labelling**

Operators or organisations marketing beef may include information complementary to what is required in their labelling.

**Approval procedure**

To this end, they must send a specification for approval to the responsible authority of the Member State in which the beef in question is produced or sold. The specification must include:

- the information to be displayed on the label;
- the measures to be taken to guarantee that the information is accurate;
- the checks applicable at all stages of production and sale, including those to be carried out by independent bodies recognised by the responsible authority; and
• the penalties to be applied, in the case of organisations, to members who fail to comply with the specifications.

Specifications which do not ensure a link between the identification of the product and the animal or which provide for labels containing misleading or insufficiently clear information will be refused. The European Commission, assisted by a Management Committee, will lay down the period after which a specification that has been neither approved nor rejected by the responsible authority will be considered to have been approved. It may also establish an accelerated approval procedure for certain types of meat.

In the case of voluntary labelling of imported beef, the specification must be approved in advance by the responsible authority in the third country where the meat is produced. This country subsequently notifies the Commission of the authority responsible for approval, the criteria and procedures followed in examining the specification, and the list of operators involved. However, approval will be valid within the Community only if the criteria applied by the third country are judged to be equivalent to those laid down in the Community Regulation.

Information

Member States notify the Commission of the voluntary labels they approve so that it may inform the other Member States through the Management Committee for Beef and Veal.

Penalties

Where an operator or organisation fails to comply with the specification, the Member State may withdraw the approval or impose supplementary conditions.

Provisions relating to both labelling systems

Committee procedures: by means of the management procedure, the European Commission, assisted by the Management Committee for Beef and Veal, draws up the implementing arrangements for beef labelling (e.g. definition of minced beef, definition of specific information which may be shown on labels, transitional measures, etc.).

Examples
Identification of where the animal was born, raised and slaughtered

The reference number for the slaughterhouse

Here we can see the reference number to identify where the meat was minced.

Other Provisions

Enforcement

Experts from the Commission, in conjunction with the responsible authorities, carry out on-the-spot inspections to ensure that the checks are conducted in compliance with the Regulation. The findings of the inspections are discussed with the responsible authority and set out in a report. On the basis of this report, the Commission may decide to review the situation within the Standing Veterinary Committee and to adopt the necessary decisions in accordance with the procedure laid down in the Regulation.
3.2. Edible Oils and Fats: Erucic Acid

The Legislation

The aim of Council Directive 76/621/EEC is to protect consumers from the possible negative effects of erucic acid in oils and fats. In order to achieve this, it fixes the maximum level of the substance which oils and fats intended for human consumption may contain.

Scope

This Directive covers:

- oils, fats and blends intended for human consumption;
- foodstuffs with a fat content of 5% or more.

Maximum level of erucic acid

The level of erucic acid contained in the products concerned must not exceed 5% of the total level of fatty acids in the fat component.

The preventive and protective character of these rules is reinforced by a safeguard clause. Under this clause, a Member State may suspend application of these provisions if new scientific findings conclude that the maximum level of erucic acid established in this Directive represents a danger to human health. In this case, the Member State must inform the Commission and the other Member States accordingly. The Commission will refer the matter to the Standing Committee on the Food Chain and Animal Health and, in accordance with the normal procedure, submit to it a proposal for measures to be taken to amend the Directive.
The sampling and analysis methods for determining the erucic acid level in fats and foodstuffs to which they have been added are also agreed in accordance with the procedure of the Standing Committee on the Food Chain and Animal Health.

For more information click here
3.2.2. Spreadable Fats

The Legislation

Council Regulation (EC) No 2991/94 protects consumers from the possibility of confusing butter, margarine and other spreadable fats (e.g. minarines), by differentiating them according to their percentage of fat content and their animal or vegetable origin.

Definition

Spreadable fats are products with a fat content of at least 10% but less than 90% by weight and which remain solid at a temperature of 20°C (complete definition in Article 1).

Scope

To avoid any possible confusion, the Regulation limits the use of the terms "butter" and "margarine" to products with a fat content of not less than 80%.

Sales and import descriptions

The various sales descriptions which are permitted, such as "minarine", "butter" and "cream" or the terms "vegetable" or "traditional" are defined in Articles 3 and 4. Spreadable fats which are imported from non-Community countries are subject to the same requirements as those manufactured in the European Union (EU).

For more information click here

The Labelling

"Reduced fat" claims

Under the terms of the Regulation, the fact that the product has a reduced fat content must be mentioned clearly in the product designation. The Regulation therefore permits the use of nutritional claims which underline that the product has a reduced fat content. (Such claims consist of labelling, presentation and advertising information informing consumers about the characteristics of a food or of one of its ingredients.)
Ingredients label for a ‘light’ vegetable fat spread:
3.3. MILK DERIVATIVES

3.3.1. Dehydrated Preserved Milk

The Legislation


- partly dehydrated milk (sweetened or not);
- wholly dehydrated milk (containing different percentages of fats).

For these products, the Directive also contains a list of particular designations used in certain countries.

Background

This Directive takes into account the general rules on labelling in the Community, in particular:

- the Directive on authorised additives;
- the Directive on nutrition labelling for foodstuffs;
- the Directive on infant formulae;
- the Directive on the labelling and advertising of foodstuffs;
- the Regulation on the addition of vitamins, minerals and certain other substances to foods.

For more information click here
The Labelling

Marketing of the products governed by this Directive must comply with the Directive on the labelling and presentation of foodstuffs. Furthermore, the labelling must state near the trade name the percentage of fat and the percentage of fat-free dried milk extract.

The labelling of wholly dehydrated milk must specify the method of dilution or product reconstitution and explain clearly that the product is not intended as a food for infants under twelve months.

The Annex as amended by Directive 2007/61/EC, lays out the following definitions:

1. Partly dehydrated milk

This means the liquid product, whether or not sweetened, obtained by the partial removal of water from milk, from wholly or partly skimmed milk or from a mixture of these products, which may have an admixture of cream or of wholly dehydrated milk or both, the addition of wholly dehydrated milk not to exceed, in the finished products, 25 % of total milk solids.

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<th>Types of unsweetened condensed milk</th>
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<tr>
<td>(a) Condensed high-fat milk</td>
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<td>(b) Condensed milk</td>
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<td>(c) Condensed, partly skimmed milk</td>
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<td>(d) Condensed skimmed milk</td>
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<th>Types of sweetened condensed milk</th>
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<td>(e) Sweetened condensed milk</td>
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2. Totally dehydrated milk

This means the solid product, where the water content does not exceed 5 % by weight of the finished product, obtained by the removal of water from milk, from wholly or partly skimmed milk, from cream or from a mixture of these products.

| (a) Dried high-fat milk or high-fat milk powder | Dehydrated milk containing, by weight, not less than 42 % fat. |
| (b) Dried whole milk or whole milk powder | Dehydrated milk containing, by weight, not less than 26 % and less than 42 % fat. |
| (c) Dried partly skimmed milk or partly skimmed-milk powder | Dehydrated milk with a fat content of more than 1,5 % and less than 26 % by weight. |
| (d) Dried skimmed milk or skimmed-milk powder | Dehydrated milk containing, by weight, not more than 1,5 % fat. |
3.3.2. Edible Caseins and Caseinates

The Legislation

Directive 83/417/EEC defines the lactoproteins to which it applies and reserves the names corresponding to those definitions. These names must be used in trade to designate products conforming to the rules of the directive.

Background


Scope

The products defined by the directive may not be placed on the market unless they conform to the definitions and rules laid down in the directive. Products which are not covered by the directive must be named and labelled in such a way that the buyer is not misled as to their nature, quality or use.

The composition characteristics and processing specifications of caseins and caseinates are laid down and included in the definition of the products concerned. In addition, caseins and caseinates are subjected to heat treatment for health and hygiene reasons.

Purity criteria

Purity criteria for edible caseins and caseinates and sampling procedures are adopted by the Council, acting on a proposal from the Commission.

Free circulation and safeguard clause

The directive ensures the free movement of edible caseins and caseinates in the EU, except in cases relating to the protection of human health, the prevention of fraud (cf. the case of...
misleading or comparative advertising) and the protection of industrial and commercial property.

For more information click here

**The Labelling**

Without prejudice to Community provisions on the labelling of foodstuffs, labelling of caseins and caseinates must include:

- for caseinates: the cation or cations;
- for mixtures: the words "mixture of..." the products which make up the mixture, the cation or cations for caseinates, and the protein content in the case of mixtures containing caseinates.
- the net quantity expressed in kilograms or grams;
- the name or company name and address of the manufacturer or packager, or seller established within the Community;
- the name of the country of origin for products imported from third countries;
- the manufacturing date or an indication identifying the batch or lot.

The directive also requires that the indications on the label should also be easily understood by consumers. (For further information concerning the use of the languages for consumer information).

**Other Provisions**

*Committee procedure*

The Commission is assisted by the Standing Committee on the Food Chain and Animal Health (established by Regulation (EC) No 807/2003).
3.4. **SUGAR PRODUCTS**

3.4.1. **Sugars**

*The Legislation*

**Council Directive 2001/111/EC** improves the labelling of certain edible sugars in order to better inform consumers and to prevent them from being misled by the products they buy. It applies without prejudice to the general provisions relating to the labelling of foodstuffs.

**Sugars**

Directive 2001/111/EC defines eleven sugar varieties:

- semi-white sugar;
- sugar (white sugar);
- extra-white sugar;
- sugar solution;
- invert sugar solution;
- invert sugar syrup;
- glucose syrup;
- dried glucose syrup;
- dextrose monohydrate;
- dextrose or dextrose anhydrous;
- fructose.

Each variety has corresponding compositional characteristics and rules relating to packaging and labelling.

For more information click [here](#)
Directive 2001/111/EC lays down certain specific provisions for pre-packaged products weighing less than 20 g, for sugar solutions, for invert sugar syrup containing crystals as well as for certain products containing more than 5% fructose. The net weight of pre-packaged products weighing less than 20 g need not be indicated on the labelling. However, the labelling of invert sugar solutions and invert sugar syrup must indicate the levels of dry matter and invert sugar content. Furthermore, the labelling of invert sugar syrup containing crystals must include the qualifying term ‘crystallised’. Finally, glucose syrups (including dried glucose syrups) which contain more than 5% of fructose (dry matter) must be labelled as ‘glucose-fructose syrup’ or ‘fructose-glucose syrup’ and ‘dried glucose-fructose syrup’ or ‘dried fructose-glucose syrup’, to reflect whether the glucose component or the fructose component is in greater proportion.

For the products defined in the Annex, Member States shall not adopt national provisions not provided for by this Directive.

**Examples**

Here is an ingredients list for a syrup product:

```
Ingredients: sugar, glucose-fructose syrup, water, concentrated multivitamin juice, 65%-concentrated raspberry juice (0.3%), colours: anthocyanins, caramel, acidity regulator, citric acid, enriching substance: vitamin C, flavour.
```

**Other Provisions**

**Context**

This Directive forms part of the programme to simplify certain vertical Directives relating to foodstuffs in order to take account only of the essential requirements to be met by the products they cover so that those products may move freely within the internal market.
3.4.2. Fruit Jams and Chestnut Puree

The Legislation


Background

This Directive forms part of the programme to simplify certain vertical Directives relating to foodstuffs. It takes account of the Directive on labelling and the advertising of foodstuffs.

Scope

Products intended for the manufacture of fine bakery wares, pastries or biscuits are not covered by this Directive. Annex II to the Directive establishes a list of authorised additives such as honey, sugar, fruit juice and certain spirits.

For more information click here

The Labelling

The products concerned are defined on the basis of their composition so as to ensure that the product names are used correctly in trade, and not in a manner which may mislead. The product name should be supplemented by an indication of the fruit or fruits used, in descending order of weight. However, for products manufactured from three or more fruits, the indication of the fruits used may be replaced by the words "mixed fruit" or a similar wording, or by the number of fruits used.

In addition, the labelling of jams, jellies, marmalades and sweetened chestnut puree must include the following:

- fruit content per 100 grams of product;
- total sugar content if no nutrition claim is made for sugars on the labelling pursuant to Directive 90/496/EEC;
• residual content of sulphur dioxide, where it is more than 10 mg/kg.

The Member States may not obstruct the marketing of products that comply with the provisions of this Directive.

**Examples**

Here is an ingredients list for a jam product:

```
Prepared with 50g of fruit per 100g. Total sugar content 63g per 100g.
Ingredients: raspberries, sugar, glucose-fructose syrup, gelling agent: pectin; citric acid. Suitable for vegetarians. Best before:
```
3.4.3. Cocoa and Chocolate

The Legislation

**Directive 2000/36/EC** lays down the rules on composition and labelling of cocoa and chocolate products intended for human consumption as specified in Annex I, namely:

- cocoa butter;
- cocoa and powdered chocolate, including reduced-fat or non-fat;
- chocolate, milk chocolate - including family chocolate-, white chocolate, filled chocolate, "chocolate a la taza " and chocolates or pralines.


**Composition**

The Directive defines the characteristics of each product referred to above, and more particularly of:

- cocoa butter: free fatty acid content and unsaponifiable matter;
- chocolates: minimum percentages of cocoa butter, cocoa powder, dry non-fat cocoa, dry milk solids, milk fat, as well as hazelnuts and flour or starch, as appropriate.

The minimum contents of the products are calculated either after deduction of flavourings, additional edible matter and/or filling, or according to the total weight of the finished product, as appropriate.

In addition, the Directive specifies that chocolate, milk chocolates - including plain chocolate-, white chocolate, as well as "chocolate a la taza ", may contain:

- up to 5% vegetable fat other than cocoa butter, as mentioned in Annex II, namely, illepe, palm oil, sal, shea, kokum gurgi, mango kernels and copra oil, but only if Member States permit this in chocolate intended for use in the manufacture of ice cream and similar products. These vegetable fats, alone or in a mixture, are cocoa butter equivalents. They are thus non-lauric, miscible in any proportion with cocoa butter and compatible with its physical properties, and have to be obtained by processes of refinement and/or fractionation.

In view of the possible impact of this provision on those countries producing cocoa and vegetable fats other than cocoa butter, the Commission will present a study of this
impact by 3 February 2006, and, if necessary, a proposal for amending the list of authorised vegetable fats other than cocoa butter. Any modifications will have to be approved by the Parliament and the Council under the codecision procedure.

- other edible substances up to 40% of the total weight of the finished product. However, this excludes animal fats and preparations not exclusively derived from milk, as well as flour or starch (except "chocolate a la taza").
- flavourings that do not imitate the natural flavour of chocolate or of milk fat. This provision also applies to cocoas and powdered chocolates.

For more information click [here](#)

**The Labelling**

Directive 2000/13/EC on the labelling, presentation and advertising of foodstuffs applies to cocoa and chocolate products in accordance with certain specifications:

a) sale names

Only products manufactured according to the compositional rules laid down by the Directive may be marketed with the following sale names:

- Cocoa powder, cocoa;
- Fat-reduced cocoa powder, fat-reduced cocoa;
- Powdered chocolate;
- Powdered drinking chocolate, sweetened cocoa, sweetened cocoa powder (possibly supplemented by the terms "fat-reduced");
- Chocolate (possibly supplemented by the terms "vermicelli" or "flakes", "couverture", and "gianduja");
- Milk, cream or skimmed milk chocolate (possibly supplemented by the terms "vermicelli" or "flakes", "couverture" and "gianduja");
- Family milk chocolate;
- White chocolate;
- Filled chocolate;
- Chocolate a la taza;
- Chocolate familiar a la taza;
- Chocolates or pralines.

In exceptional cases, these sale names may be used for other products that cannot be confused with those defined in this Directive in the country of sale. The sale names for chocolate, white and filled milk chocolates, and chocolates or pralines may be replaced by the sale name "assorted chocolates" or "assorted filled chocolates" when sold as assortments. The sale names "chocolate", "milk chocolate" and "couverture" may, in certain cases, be supplemented by descriptions relating to quality criteria (higher cocoa and milk content).
b) additional information

- Labelling of chocolate products containing vegetable fats other than cocoa butter must bear the conspicuous and clearly legible statement “contains vegetable fat in addition to cocoa butter”. This statement shall be in the same field of vision as the list of ingredients, clearly separated from that list, in letters at least as large and in bold with the sales name nearby;
- the labelling of powdered chocolate, of sweetened cocoas, as well as of chocolate, milk chocolate, family milk chocolate, *chocolate a la taza* and *chocolate familiar a la taza* must indicate the total dry cocoa solids content. In addition, the labelling of non-fat and reduced-fat cocoas and powdered chocolate must indicate the cocoa butter content.

**Examples**

Here is an ingredients list for a chocolate product:

```
Ingredients: sugar, cocoa butter, whole milk powder (17%), cream powder (5%), whey product, lactose, strawberry crisp (3.5%) (maltodextrin, strawberries, sugar, modified starch, thickener: sodium alginate; flavouring, citric acid), emulsifier: soya lecithin; flavouring. White chocolate contains: cocoa solids 28% minimum. Contains milk and soya. May contain traces of nuts, wheat and gluten. Suitable for vegetarians. No artificial preservatives or colours. Store in a cool and dry place. Best before: see below.
```
The implementation of the Directive is guaranteed by the Commission with the assistance of:

- the Standing Committee on Foodstuffs;
- a regulatory committee to oversee the alignment of this Directive with general Community legislation on foodstuffs, as well as the adaptation of these provisions on authorised flavourings, on minimum contents and on sugars used in the manufacture of chocolates to technological progress.
3.4.4. Honey

**The Legislation**

Council Directive 2001/110/EC establishes common rules concerning the composition and definition of honey. Furthermore, it specifies the different types of products which can be placed on the market under appropriate names, as well as the rules concerning labelling, presentation and information on origin.

**Definition**

Honey is the natural sweet substance produced by *Apis mellifera* bees from the nectar of plants or from secretions of living parts of plants or excretions of plant-sucking insects on the living parts of plants, which the bees collect, transform by combining with specific substances of their own, deposit, dehydrate, store and leave in honeycombs to ripen and mature. When placed on the market as honey or used in a product intended for human consumption, honey must meet the composition criteria set out in Annex II to this Directive.

**Context**

Directive 2001/110/EC is the last in a series of five vertical directives in the field of foodstuffs submitted by the Commission in June 1996 as part of a simplification exercise. The other Directives concern preserved milk, certain sugars, fruit juices and jams.


For more information click [here](#).

**The Labelling**

This Directive supplements the general rules relating to the labelling of foodstuffs as provided for in Directive 2000/13/EC by requiring that essential consumer information is included on the labelling. In particular, the labelling must include the country of origin of the honey (with a degree of flexibility for a blend of honeys from different origins), and the product names as set out in Annex I. However, these names may be replaced in certain cases by the simple product name ‘honey’ (except in the case of ‘filtered honey’, ‘comb honey’, ‘chunk honey or cut comb in honey’ or ‘baker’s honey’).
Information on regional, territorial or topographical origin, or on floral or vegetable origin, or on specific quality criteria may supplement this labelling (except for ‘filtered honey’ and ‘baker’s honey’).

**Examples**

Here is some information supplied on a honey product:
3.5. 

3.5.1. Natural Mineral Waters

The Legislation

The harmonisation performed by Directive 2009/54/EC promotes the marketing of natural mineral waters in the internal market.

Natural mineral waters are characterised by their original purity, their specific nature (particularly a high mineral or trace element content) and in some cases by their effects. Their characteristics must be recognised by the competent national authorities, whether the water has been extracted from the ground of a Member State or has been imported into the Community. Member States must communicate the list of recognised mineral waters to the Commission and this list is then published in the Official Journal of the European Union.

This Directive does not apply to waters which are medicinal products within the meaning of Directive 2001/83/EC and to natural mineral waters which are used at source for curative purposes (in the case of thermal or hydromineral establishments).

Treatment and potability of water

Only three treatments are authorised, insofar as they do not alter the composition of the water as regards its essential constituents. These are:

- the separation of unstable elements;
- the separation of iron, manganese, sulphur and arsenic compounds by treatment with ozone and under the conditions laid down by the Commission following consultation of the European Food Safety Agency (EFSA);
- the separation of other undesirable constituents in compliance with the conditions for use laid down by the Commission following consultation of the EFSA.
The revivable total colony count and the number of parasites and pathogenic micro-organisms is checked at source and when the water is bottled. When marketed, a higher bacterial count may only be due to a normal increase. Water must not have any defects from the point of view of touch, taste and smell. It must be packaged in a container which avoids the possibility of adulteration or contamination.

**Context**

Directive 80/777/EEC is repealed so as to recast its successive amendments. Member States must however continue to transpose its amending directives, since these provisions are considered as amending Directive 2009/54/EC. A correlation table is available in Annex IV of this Directive.

For more information click [here](#).

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**The Labelling**

The general rules for labelling, presentation and advertising are set out in Directive 2000/13/EC. The sales description of natural mineral water is strictly controlled according to its characteristics and any treatments.

Labelling includes mandatory information:

- the statement of analytical composition;
- the name of the spring and the place of exploitation;
- information on any treatments.

Indications attributing properties relating to the prevention, treatment or cure of a human illness are prohibited. The properties of the water may be mentioned, in compliance with this Directive or according to the criteria established at national level by recognised scientific methods.
Here is the statement of analytical composition for a mineral water product:

<table>
<thead>
<tr>
<th>Constituent</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium/Sódio</td>
<td>13.8 mg/l</td>
</tr>
<tr>
<td>Magnesium/Magnésio</td>
<td>2.9 mg/l</td>
</tr>
<tr>
<td>Calcium/Cálculo</td>
<td>28.0 mg/l</td>
</tr>
<tr>
<td>Chloride/Clorete</td>
<td>33.0 mg/l</td>
</tr>
<tr>
<td>Sulphate/Sulfato</td>
<td>40.8 mg/l</td>
</tr>
<tr>
<td>Nitrate/Nitrato</td>
<td>&lt; 0.5 mg/l</td>
</tr>
</tbody>
</table>

**Other Provisions**

**Powers of the Commission**

The Commission is assisted by the Standing Committee on the Food Chain and Animal Health. It may take measures concerning:

- limits for the concentrations of constituents of waters;
- the indication on the labelling of high levels of certain constituents;
- the use of ozone-enriched air;
- information on treatments;
- checks on microbiological characteristics.

It takes all necessary decisions in the event of a threat to public health, following consultation of the EFSA.
Marketing

A Member State may temporarily restrict or suspend trade in a product circulating freely within its territory. It must first inform the Commission and the other Member States, and justify its decision.
3.5.2. Fruit Juices

The products covered by Council Directive 2001/112/EC are:

- fruit juice,
- concentrated fruit juice,
- dehydrated fruit juice, and
- fruit nectar.

These products are defined on the basis of their composition and preparation processes so as to ensure that the terms are used correctly in trade, and not in a manner which may mislead. The Directive also defines particular designations used in certain countries and languages.

Background

This Directive forms part of the programme to simplify certain vertical Directives relating to foodstuffs. It applies without prejudice to the general provisions relating to the labelling of foodstuffs.

For more information click here

The Labelling

Fruit juices are labelled in accordance with the general rules laid down in Directive 2000/13/EC. However, specific provisions are adopted in this Directive in order to improve consumer information. These provisions require the addition of wording indicating:

- if a product is a mixture of different fruits;
- if a product has been sweetened;
- if a product has been obtained entirely or partly from a concentrate.

In the case of concentrated fruit juice, if the product is not intended for delivery to the final consumer, the labelling must indicate any addition of sugars, lemon juice or acidifying agents.
The Directive lists the raw materials which may be used to manufacture juice and nectar, and also the additives which may be authorised, subject to the Directive on nutrition labelling for foodstuffs. The minimum content of fruit juice and/or fruit purée in fruit nectar must conform to the levels indicated in the Directive and must be stated in the product labelling.

**Examples**

Here is the ingredients list for a fruit juice product:

```
Fruit content: 100%.
Ingredients: apple juice from concentrate, orange juice from concentrate, nectarine purée, pineapple juice from concentrate, banana purée, guava purée, lemon juice from concentrate, Brazil plum purée, mango purée, apricot purée, vitamin C, niacin, vitamin E, pantothenic acid, beta carotene (provitamin A), vitamin B6, riboflavin, thiamin, folic acid, biotin, vitamin B12.
```
3.5.3. Aromatized Drinks

The Legislation

Council Regulation (EEC) No 1601/91 distinguishes between three categories of aromatized drinks according to their wine content, their alcoholic strength, and whether or not they contain added alcohol (See also amending act(s)).

Aromatized drinks

This Regulation covers aromatized drinks, specifically:

- aromatized wines (vermouth, bitter aromatized wine, egg-based aromatized wine, vākevā viiniglōgiStarkvinsglōgg, etc.);
- aromatized wine-based drinks (sangria, bitter soda, Glühwein, etc.);
- aromatized wine-product cocktails.

The use of water in the preparation of these drinks is authorized provided that the quality of the water complies with the provisions of the Directive on natural mineral waters. The list of authorised additives and their use are laid down in accordance with the Regulation on food additives.

The oenological practices and processes applicable to wines and grape must, which are involved in the composition of aromatized drinks, are laid down in Regulation (EC) No 491/2009. Any ethyl alcohol used to dilute or dissolve authorized additives must be of agricultural origin and its use limited to a strict minimum.

Designations

The designations of aromatized drinks laid down in this Regulation are mandatory and reserved exclusively for these drinks. Since the reputation of certain drinks is closely linked with their traditional place of origin, it is compulsory to indicate the place of origin in cases where the drink does not originate in the region where it is traditionally produced.

Aromatized drinks which do not comply with the Regulations may not be marketed using terms such as ‘style’, ‘type’, ‘flavour’ or similar indications associating them with one of the designations laid down in the Regulation.
The Member States are responsible under certain conditions for preventing the incorrect use within the EU of a geographical indication protected by a third country which is a member of the World Trade Organization (WTO).

For more information click here

The Labelling

Aromatized drinks are subject to the general rules established by Directive 2000/13/EC on foodstuffs. However, taking into account the nature of these drinks, complementary provisions have been laid down in this Regulation. The sale and placing into circulation of all aromatized drinks in bottles whose closing device is covered with a lead-based capsule or foil was banned from 1 January 1993 onwards.

Aromatized drinks exported to third countries must comply with this Regulation. Member States must ensure the provisions applicable to aromatized drinks are complied with by appointing one or more monitoring agencies.
3.5.4. Coffee and Chicory Extracts

The Legislation


Scope

The Directive covers the following products:

- coffee extract and soluble coffee extract;
- soluble or instant coffee (with the exception of café torrefacto soluble);
- chicory extract;
- soluble chicory;
- instant chicory.

These products must comply with certain minimum composition requirements, in particular as regards the dry matter content.

For more information click here

The Labelling

Coffee and chicory extracts must be labelled in accordance with the provisions of Directive 2000/13/EC, which relates to the labelling, presentation and advertising of foodstuffs. However, only the above-mentioned descriptions may be used in trade in these products, possibly accompanied by information concerning the form ("paste", "liquid", "concentrated", etc.), any added substances, and the caffeine content. An indication of the minimum coffee- or chicory-based dry matter content as a percentage by weight of the finished product is also obligatory.
Examples

Here is the ingredients list for a coffee product:


Other Provisions

Trade in coffee or chicory extracts conforming to the provisions of this Directive may not be impeded by conflicting national provisions. The Commission is to be assisted by the standing committee on the food chain and animal health in applying this Directive.
3.5.5. Alcoholic Beverages

The Legislation

Generally speaking alcoholic beverages fall under the general rules on the labelling and presentation of foodstuffs. However the rules do vary slightly according to the type of beverage and the country in which the beverage is being sold.

Alcoholic strength by ‘% volume’

Commission Directive 87/250/EEC lays down specific provisions for the labelling of alcoholic beverages for sale to the ultimate consumer. These specific provisions supplement the general rules on the labelling and presentation of foodstuffs.

The labelling of alcoholic beverages containing more than 1.2 % by volume of alcohol must indicate the alcoholic strength by volume, i.e. the figure corresponding to the alcoholic strength followed by the symbol ‘% vol.’. The figure shall be given to not more than one decimal place. In certain cases, the figure shall be preceded by the word ‘alcohol’ or the abbreviation ‘alc.’. In addition the Directive clarifies that alcoholic strength is determined at a temperature of 20 °C.

This Directive shall apply to beverages with an alcoholic strength by volume exceeding 1.2 %, other than grape must in fermentation of with fermentation arrested otherwise than by the addition of alcohol (classified under heading 22.04 of the Common Customs Tariff), and wine of fresh grapes and grape must with fermentation arrested by the addition of alcohol (classified under heading 22.05 of the Common Customs Tariff).

The tolerances allowed in respect of the indication of the alcoholic strength by volume are:

- 0.3 % for beverages not mentioned below;
- 0.5 % vol. for beers having an alcoholic strength not exceeding 5.5 % vol. and beverages made from grapes classified under subheading 22.07 B II of the Common Customs Tariff;
- 1 % vol. for beers having an alcoholic strength exceeding 5.5 % vol. and beverages made from grapes classified under subheading 22.07 B I of the Common Customs Tariff, ciders, perries and other similar fermented beverages produced from fruits other than grapes, and beverages based on fermented honey;
- 1.5 % vol. for beverages containing macerated fruit or parts of plants.

For more information click here
Spirits

**Regulation (EC) No 110/2008** sets the rules regarding the definition, description, presentation and labelling of spirit drinks, and also the protection of geographical indications. It applies to all spirit drinks, whether produced in the European Union (EU) or in a third country.

Spirit drinks are alcoholic drinks intended for human consumption. By definition, spirit drinks possess particular organoleptic qualities and have a minimum alcoholic strength of 15 % vol. Spirit drinks are produced either directly by distillation, by maceration or by the addition of flavourings, or by mixing a spirit drink with another drink, ethyl alcohol of agricultural origin or certain distillates.

Annex II to the Regulation contains a list of the spirit drinks classified by category (rum, whisky, vodka, etc.).

**Sales denomination**

Spirit drinks which meet the specifications applicable to the products defined in one of the 46 categories of spirit drinks in Annex II shall be marketed under one of the denominations listed in the Annex. Spirit drinks which do not meet the specifications required for their inclusion in one of the 46 categories in Annex II shall be marketed under the denomination ‘spirit drink’.

Spirit drinks which meet the specifications of several of the categories in Annex II may be sold under one or more of the denominations listed for these categories. Sales denominations may be supplemented or replaced by a geographical indication so long as this does not mislead the consumer.

For more information click [here](#)

**The Labelling**

**General Provisions**

<table>
<thead>
<tr>
<th>Alcohol must include the following information:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Name under which the product is sold</td>
</tr>
<tr>
<td>- No trademark or brand name may substitute for the generic name, but may be used in addition</td>
</tr>
<tr>
<td>- Net quantity of pre-packaged beverage in metric units (e.g., liter, centiliter, milliliter)</td>
</tr>
<tr>
<td>- Indication of the acquired alcoholic strength:</td>
</tr>
<tr>
<td>- The labeling of beverages containing more than 1.2% by volume of alcohol must</td>
</tr>
</tbody>
</table>

---

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**CHAPTER 2**

indicate the actual alcoholic strength by volume, i.e. showing the word "alcohol" or the abbreviation "alc." followed by the symbol "% vol."

- Date of minimum durability:
- This must consist of day, month, and year—in that order—and be preceded by the words "best before," "best before end," or "use by" for highly perishable goods.
- Any special conditions for keeping or use
- Name or business name and address of the manufacturer, packager, or importer established in the EU
- Place of origin or provenance
- Instructions of use, where appropriate
- Lot marking on pre-packaged beverages, with the marking preceded by the letter "L"

***This information was sourced from International Center for Alcoholic Policies***

**Wine-specific labelling**

The following must appear on a label in a single field of vision:

(i.e., can be viewed without having to turn the bottle, except for the Importer’s details, the Lot number, and allergenic ingredients)

- Wine of "(country name)"
- Actual alcoholic strength
- Nominal volume
- Lot number
- Importer details
- Must include name of importer, local administrative area, and member state, preceded by the word(s) "Importer" or "Imported by"

- Allergenic ingredients (i.e., if wine contains sulfites):
- Wine variety and vintage may not be shown on labels of wine with non-geographical origin; only wine with a proper geographical indication may display such information

***This information was sourced from International Center for Alcoholic Policies***

**Spirits**

Although the general rules concerning the presentation and labelling of foodstuffs apply to spirit drinks, however specific labelling and presentation rules are provided for by Regulation (EC) No 110/2008. Where the labelling of a spirit drink indicates the raw material used to produce the ethyl alcohol of agricultural origin, each agricultural alcohol used shall be mentioned in descending order of the quantity used.
The term ‘blend’, ‘blending’ or ‘blended’ may be used only if the spirit drink is a blend of two or more spirit drinks belonging to the same category. These drinks are distinguished only by minor differences in composition due to the method of preparation, the stills employed, the period of maturation or ageing or the geographical area of production. The maturation period or age may be specified only where it refers to the youngest alcoholic component and provided it was subject to revenue supervision or equivalent. However lead-based capsules or foil cannot be used as closing devices for the containers of spirit drinks.

The particulars provided for in this Regulation shall be given in one or more official languages of the European Union so as to better inform the consumer, except:

- the terms in italics in Annex II;
- the geographical indications registered in Annex III.

**Geographical indications**

The geographical indication identifies a spirit drink as originating in the territory of a country, or a region or locality in that territory, where a given quality, reputation or other characteristic of that spirit drink is essentially attributable to its geographical origin.

**Registration of a geographical indication**

An application for registration is submitted to the European Commission by the Member State or third country concerned. The application shall include a technical file comprising the following information:

- the name and category of the spirit drink including the geographical indication;
- a description of the spirit drink;
- the definition of the geographical area;
- a description of the method for obtaining the spirit drink;
- details bearing out the link with the geographical environment or the geographical origin;
- any requirements laid down by European, national and/or regional provisions;
- the name and contact address of the applicant;
- any supplement to the geographical indication and/or any specific labelling rule.

The Commission shall verify, within 12 months of the date of submission of the application, whether that application complies with this Regulation before publishing the technical file in the *Official Journal of the European Union*.

Within six months of the date of publication of the technical file, any natural or legal person may object to the registration of the geographical indication.

**Cancellation of a geographical indication**
The Commission may cancel the registration of a geographical indication if the spirit drink no longer possesses the characteristics detailed in the technical file which accompanied the application for registration.

**Examples**

Here is an example of part of a label from an alcoholic beverage:

![Alcoholic beverage label](image)

**Other Provisions**

**Additional Considerations**

Alcohol is a drug and therefore different European countries have different levels of tolerance towards how alcohol is marketed. Therefore despite European legislation on the topic there are still a few national consideration which you must watch out for:

* Austria
  - Wine labels must show the origin of the wine and the amount of sugar and alcohol indicated as dry, semi-dry, sweet, or semi-sweet
  - Beer labels must show the amount of flavourings in weight percentage, amount of alcohol in volume percentage, and conditions for storage
France

- Use of foreign names and vintage is forbidden when an equivalent French word exists (spirit names such as vodka and whiskey are acceptable)

Germany

- Wine, sparkling wine, flavored wines, flavored wine beverages and cocktails, and spirits imported from non-EU countries are subject to special labeling regulations

Sweden

- Must state the true alcoholic strength in percent by volume, as well as the minimum fluid content in milliliters
- Labels on beer should state the alcoholic strength by weight, as well as the Roman numeral "III"
- There is a general ban on the import of flavored spirits with an alcoholic strength of more than 60% by volume
- If the beer contains antioxidants, dye stuffs, preservatives, or sorbitol, this must be shown on the label

***This information was sourced from International Center for Alcoholic Policies***
3.6. **NOVEL FOODS**

### 3.6.1. Novel Foods and Ingredients

**The Legislation**

The novel foods and food ingredients concerned by Regulation (EC) No 258/97 are those which are not yet currently used for human consumption.

*Novel foods and food ingredients*

This Regulation applies to foods and food ingredients in the following categories:

- foods and food ingredients which present a new or modified primary molecular structure;
- foods and food ingredients which consist of micro-organisms, fungi or algae;
- foods and food ingredients which consist of or are isolated from plants and ingredients isolated from animals;
- foods and food ingredients whose nutritional value, metabolism or level of undesirable substances has been significantly changed by the production process.

*Not covered*

The Regulation is not applicable to food additives, flavourings, extraction solvents, nor to food enzymes (which are the subject of Regulation (EC) No 1332/2008). Genetically Modified Organisms (GMOs) are no longer covered by this Regulation, but by Regulation (EC) No 1823/2003 instead.

Furthermore, foods and food ingredients covered by this Regulation must not:

- present a danger for the consumer;
- mislead him/her;
- be nutritionally disadvantageous for him/her.
Evaluation procedure

The foods and foods ingredients referred to in the Regulation must undergo Community assessment before being placed on the market.

Under the assessment procedure, the competent body of the Member State which receives an application must make an initial assessment and determine whether or not an additional assessment is required. If neither the Commission nor the Member States raise an objection, and if no additional assessment is required, the Member State informs the applicant that he may place the product on the market. In other cases an authorisation decision is required. This decision is adopted in accordance with the measures proposed by the Commission within the Committee on Food Safety and Animal Health.

The decision defines the scope of the authorisation and specifies, as appropriate, the conditions of use, the designation of the food or food ingredient, its specification and the specific labelling requirements. Any decision or provision concerning a novel food or food ingredient which is likely to have an effect on public health must be referred to the Scientific Committee for Food.

Suspension procedure

Member States are authorised to suspend or restrict provisionally the marketing and use in their territory of any novel food or food ingredient if they believe that its use constitutes a health hazard or a risk to the environment. They inform the Commission, which takes steps in accordance with the procedure regarding authorisations for placing products on the market.

For more information click here.

The Labelling

The Regulation lays down specific requirements concerning the labelling of novel food and food ingredients which have been added to the European general requirements on food labelling. Without prejudice to the general requirements of European legislation concerning the labelling of foodstuffs, the labelling of novel food and food ingredients must mention:

- any characteristics such as composition, nutritional value or the intended use of the foodstuff;
- the presence of materials which may have implications for the health of some individuals;
- the presence of materials which give rise to ethical concerns.
3.7. FOODS FOR INFANTS AND YOUNG CHILDREN

3.7.1. Instant Formulae

The Legislation


Scope

This Directive lays down the compositional and labelling requirements for infant formulae and follow-on formulae intended for use by Community infants in good health.

Composition

Infant formulae and follow-on formulae shall be manufactured from cows’ milk proteins or soya proteins and other food substances (minerals, vitamins, amino acids, etc.) set out in the Annex to the Directive. Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children.

Placing on the market

When infant formulae or follow-on formulae are placed on the market, the manufacturer or importer of the said formulae shall forward a model of the label used to the competent authority of the Member State where the product is to be marketed. This measure will facilitate official monitoring of the formulae being marketed.

Pesticide residues
The maximum pesticide residue level in infant formulae and follow-on formulae is set at 0.01 mg/kg of the product proposed ready for consumption. The use of the pesticides listed in Annex VIII is prohibited in agricultural products intended for the production of infant formulae and follow-on formulae.

You can find more information here.

The Labelling

The name under which infant formulae and follow-on formulae are sold, shall be respectively: “infant formulae” and “follow-on formulae”, unless they are entirely manufactured from cows' milk proteins. In this case their name shall be, respectively: "infant milk" and "follow-on milk".

Mandatory particulars are added to the general rules for the labelling, presentation and advertising of foodstuffs. These particulars state:

- **in the case of infant formulae:**
  - that the product is suitable for particular nutritional use by infants from birth when they are not breast fed;
  - the superiority of breast feeding;
  - that the product is only to be used on the advice of independent persons qualified in this field.

- **in the case of follow-on formulae:**
  - that the product is suitable for particular nutritional use by infants aged over six months,
  - that it should form only part of a diversified diet,
  - that it is not to be used as a substitute for breast milk during the first six months of life,
  - that the decision to begin complementary feeding should be made only on the advice of professionals responsible for maternal and child care;

- **in the case of infant formulae and follow-on formulae:**
  - the energy value and protein, carbohydrate and fat content,
  - the average quantity of each mineral substance and vitamin (see Annexes I and II),
  - instructions concerning the preparation, storage and disposal of the product.
The labelling of infant formulae shall not include pictures of infants, nor shall it include other pictures or text which may idealise the use of the product.

**Other Provisions**

**Advertising**

Advertising of infant formulae shall be restricted to publications specialising in baby care and scientific publications. Member States shall ensure that advertising does not favour bottle-feeding over breast feeding. In any case, Member States may further restrict or prohibit the advertising of infant formulae.
3.7.2. Processed Cereal-Based Foods and Baby Foods

The Legislation

Commission Directive 2006/125/EC is a specific directive within the meaning of Article 4 of Directive 89/398/EEC.

Scope

This Directive covers foodstuffs for particular nutritional use that fulfil the nutritional requirements of infants and young children in good health and are 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. They comprise:

- 'processed cereal-based foods', which are divided into the following four categories:
  - simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids;
  - cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid;
  - pastas which are to be used after cooking in boiling water or other appropriate liquids;
  - rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids;
- "baby foods" other than processed cereal-based foods.

This Directive does not apply to milks intended for young children.

General obligation

Member States must ensure that only products which comply with this Directive are marketed in the European Union (EU).

Composition

Only ingredients suitable for particular nutritional use for infants and young children (supported by scientific data) may be used in the manufacture of the foods concerned.
Processed cereal-based foods must comply with the compositional criteria specified in Annex I. Baby foods which are described in Annex II must comply with the compositional criteria specified therein.

Only the nutritional substances listed in Annex IV may be added in the manufacture of processed cereal-based foods and baby foods within the maximum limits laid down by the directive. The purity criteria for those substances must be laid down at a later stage. Processed cereal-based foods and baby foods may not contain any substance in such quantity as to endanger the health of infants and young children (see Regulation (EC) No 1881/2006 under 'Related acts' below).

**Maximum pesticide levels**

This Directive sets the maximum permissible level of pesticide residues in processed cereal-based foods and baby foods at 0.01 mg/kg, except for certain substances whose limit is laid down in Annex VI. Standardised analytical methods must be used for determining the presence of pesticide residues.

**Prohibited pesticides**

This Directive prohibits the use of certain pesticides in agricultural products intended for baby foods (list in Annex VII). For pesticides or pesticide metabolites in this list, the maximum level of 0.01 mg/kg may be excessive for infants and young children. This is the case for pesticides or metabolites of pesticides with an acceptable daily intake lower than 0.0005 mg/kg body weight.

The limit of quantification of the analytical methods is 0.003 mg/kg. At this level pesticides are considered not to have been used. This limit may be altered in the light of technical progress or data on environmental contamination.

For more information click [here](#).

**The Labelling**

In addition to the mandatory particulars stipulated by Directive 2000/13/EC, labelling must bear the following information:

- the age from which the product may be used, which must not be less than four months. Products recommended for use from the age of four months may indicate that they are suitable from that age unless persons having qualifications in medicine, nutrition etc. advise otherwise;
• the presence or absence of gluten if the indicated age from which the product may be used is below six months;
• the available energy value (in kJ and kcal) and the protein, carbohydrate and lipid content (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;
• the average quantity of each mineral substance and of each vitamin governed by a specific level in Annex I and Annex II 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;
• instructions for appropriate preparation, when necessary, and a statement as to the importance of following those instructions.

The labelling may include non-mandatory particulars:

• the average quantity of the nutrients set out in Annex IV (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;
• information on vitamins and minerals shown in Annex V (as a percentage of the reference values given therein) per 100 g or 100 ml of the product as sold, and where appropriate, per specified quantity of the product as proposed for consumption, provided that the quantities present are at least equal to 15% of the reference values.
CHAPTER 3

PACKAGING AND CONTAINERS FOR FOODSTUFFS
1. **ACTIVE AND INTELLIGENCE PACKAGING**

1.1. **“ACTIVE” AND “INTELLIGENT” PACKAGING**

1.1.1. **General**

*The Legislation*

**Regulation (EC) No 1935/2004** aims at guaranteeing a high level of protection of human health and the interests of consumers with regard to the placing on the Community market of materials and articles intended to come into contact with food either directly or indirectly.

**Scope**

This Regulation covers all materials and articles that are intended to come into contact with food: all types of packaging, bottles (plastic and glass), cutlery, and even adhesives and inks for printing labels. It also introduces specific provisions concerning “active” and “intelligent” packaging which extends the shelf-life of food or which reacts when food has gone off (packaging which changes colour, for example).

The Regulation does not cover:

- materials and articles which are supplied as antiques;
- covering or coating materials, such as materials which cover cheese rinds, prepared meat products or fruit;
- fixed water supply equipment.
Requirements for materials and articles

Materials and articles which come into contact with food shall be produced in line with good manufacturing practice. They must under no circumstances transfer substances to the food with which they are in contact in quantities likely to:

- endanger human health;
- bring about an unacceptable change in the composition of the food; or
- bring about a deterioration in the organoleptic characteristics thereof.

If “active” materials and articles change the composition or organoleptic characteristics of food, they must comply with Directive 89/107/EEC on additives and/or any national rules. The labelling, advertising and presentation of a material or article shall not mislead consumers under any circumstances.

Specific measures for groups of materials and articles

Annex I of this Regulation identifies 17 groups of materials and articles for which specific measures may be adopted:

- intelligent materials and articles;
- adhesives;
- ceramics;
- cork;
- rubbers;
- glass;
- ion-exchange resins;
- metals and alloys;
- paper and cardboard;
- plastic materials;
- printing inks;
- regenerated cellulose;
- silicones;
- textiles;
- varnishing and coatings;
- waxes;
- wood.

These specific measures may include:

- the list of substances authorised for use in the manufacture of materials and articles that are intended to come into contact with food;
- criteria of purity;
- specific conditions of use;
- limits on the migration of certain constituents into or on to food;
provisions aimed at protecting human health or ensuring compliance with requirements for materials and articles that are intended to come into contact with food;
• basic rules for checking compliance with the provisions above;
• rules concerning the collection of samples;
• provisions for ensuring traceability;
• additional provisions of labelling for active and intelligent materials and articles;
• provisions concerning the establishment of a Community Register of authorised substances, processes, materials or articles;
• specific procedural rules for the authorisation of a substance, process, material or article.

In the absence of specific measures, Member States may maintain or adopt national provisions.

For more information click here

The Labelling

The nature of materials and articles intended to come into contact with food is to be described on their labelling. Materials and articles which are not clearly intended to contain or to package food must bear the words “For food contact” or the symbol given in Annex II (the symbol represents a glass and a fork).

Examples

Here is the ‘For food contact’ symbol illustrated in Annex II:
Authorisation of substances

Applications for authorisation of a new substance for the manufacture of materials or articles intended to come into contact with food shall be made to the competent authority of the Member State where the substance is to be placed on the market. Applications shall then be sent to the European Food Safety Authority which is responsible for evaluating the toxicity of substances in order to avoid any risk to consumers.

Traceability

This Regulation also establishes the requirements to be met regarding the traceability of food contact materials from production to sale. The labelling or documentation accompanying materials and articles placed on the market in the Community should guarantee the traceability of the said materials and articles. This facilitates control, the recall of defective products, consumer information and the attribution of responsibility.
1.1.2. Specific Requirements

The Legislation

Commission Regulation (EC) No 450/2009 establishes specific requirements for the marketing of active and intelligent materials and articles intended to come into contact with food. It supplements the general principles defined in Regulation (EC) No 1935/2004 and describes the procedure for the authorisation of substances at Community level.

Scope

This Regulation shall apply to active or intelligent materials and articles which are placed on the Community market.

Requirements for active and intelligent materials and articles

Active and intelligent materials and articles:

- must be suitable and effective for the intended purpose of use;
- must not release to food any components in sufficient quantity as to endanger human health or to bring about an unacceptable change in the composition or organoleptic characteristics of food;
- must not mislead consumers through their labelling, presentation or advertising material.

These specific requirements are without prejudice to Community or national provisions applicable to materials and articles to which active or intelligent components are added or into which they are incorporated.

Composition

Only substances which are included in the Community list of authorised substances may be used in components of active and intelligent materials and articles. However, the following substances may be used in components of active and intelligent materials and articles without being included in the Community list:
• released active substances, added or incorporated by techniques such as grafting or immobilisation which are used in full compliance with the relevant Community and national provisions (for example, legislation on food additives and food enzymes);
• substances used in the components which are not in direct contact with food or the environment surrounding the food; and if they are not "mutagenic", "carcinogenic", or "toxic to reproduction" or substances produced deliberately in a particle size that exhibits chemical and physical properties that significantly differ from those at a larger scale.

Applications for authorisation of substances constituting the components of active and intelligent materials and articles

Applications for authorisation of substances constituting the components of active and intelligent materials and articles are to be made to the competent authorities of a Member State accompanied by a technical dossier containing the information described in the guide to safety assessment prepared by the European Food Safety Authority. The Member State sends the application to the Authority which is responsible for assessing whether the substance meets the above conditions.

For more information click here

The Labelling

Active and intelligent materials and articles:

• in contact with food are to be labelled appropriately to allow the consumer to identify the non-edible parts. In this case the words “DO NOT EAT” must be added to the label as well as (if possible) the symbol reproduced in Annex I;
• labelled so that it is clear that they are active and/or intelligent.

Released active substances are considered as ingredients and are to be labelled pursuant to the general rules for the labelling of foodstuffs.
Examples

Here is the ‘do not eat’ symbol highlighted in Annex I:

Community list of authorised substances

In order to be included in the Community list, substances constituting the components of active and intelligent materials and articles must meet the requirements that apply to the said products (see above).

The Commission shall adopt the Community list after the Authority has delivered its opinion on all substances for which a valid application for market authorisation has been submitted.

The Community list shall specify:

- the identity of the substance(s);
- the function of the substance(s);
- the reference number;
- if necessary, the conditions of use of the substance(s) or component.

Manufacturers must establish a quality assurance system and a quality control system (see below) following the detailed manufacturing regulations, for example the processes involving printing inks. Materials in contact with food include objects such as containers and packaging, but also all materials in contact with foodstuffs, such as paper and cardboard or those which could possibly transfer their constituents to food, for example inks and adhesives.

Annex 1 to Regulation (EC) No 1935/2004 includes a list of the materials covered by this Regulation: active and intelligent objects, adhesives, ceramics, cork, rubbers, glass, ion-exchange resins, metals and alloys, paper and cardboard, plastics, printing inks, regenerated cellulose, silicones, textiles, varnishes and coatings, waxes and wood.

Quality assurance system and quality control system

This Regulation includes an obligation for manufacturers to implement a quality assurance system (taking account of the personnel required to put the system in place and the size of the business), as well as a quality control system. The latter provides for measures to be taken should a business fail to comply with good manufacturing practice. In addition, manufacturers shall create and maintain documentation regarding the specifications, manufacturing formulae and product processing which are important for the compliance and safety of the finished article, as well as those related to the various manufacturing operations. They are required to make the documentation available to the competent authorities at their request.
3. **PLASTICS**

3.1. **RECYCLED**

**The Legislation**


**Scope**

This Regulation covers recycled plastic materials and articles which may come partially or totally into contact with food. It does not apply to recycled plastic materials and articles:

- made with monomers and substances derived from chemical depolymerization of plastic materials and articles;
- made from unused production offcuts or process scraps;
- in which the recycled plastic is used behind a plastic functional barrier *.

The materials and articles covered by this Regulation are subject to Directive 2002/72/EC on plastic materials intended for food packaging.

**Requirements for recycled plastic materials and articles**

The recycled plastic used for the manufacture of materials and articles covered by this Regulation must be obtained from an authorised recycling process. The said process is to be managed using a quality assurance system which complies with the rules laid down in the
An Annex of Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

**Conditions for the authorisation of recycling processes**

Authorisation may be granted if recycling processes comply with the following conditions:

- the quality of plastic input must be characterised and controlled;
- the plastic input must originate from plastic materials and articles that have been manufactured in accordance with Community legislation on plastic food contact materials and articles;
- the recycling process must be able to guarantee that there can be no contamination or that it is reduced to a concentration that does not pose a risk to human health;
- the conditions of use of recycled plastic must guarantee that the final materials and articles do not release into food components in a quantity likely to endanger human health or to bring about an unacceptable change in the composition of the food, or to bring about a deterioration in the organoleptic characteristics thereof.

**Applications for authorisation of recycling processes**

Applications for authorisation for a recycling process are to be made to the competent authority of a Member State accompanied by a technical dossier containing the information described in the guidelines for the safety assessment of a recycling process prepared by the [European Food Safety Authority](https://www.efsa.europa.eu/en).

The Member State sends the application to the Authority which is responsible for assessing whether the said process meets the above conditions. Following a transitory phase, the Authority will have a period of six months from receipt of the application to give its opinion. The Commission shall take into account the opinion of the Authority and adopt a Decision that it will send to the applicant. In this Decision, it will grant or refuse authorisation of the recycling process.

**Community register**

The Commission shall maintain a register of authorised recycling processes. The register shall be made available to the public.

**Official control**

Recycling plants and converters shall be subject to official controls. These controls aim at verifying that the recycling processes correspond to the processes for which authorisation was granted and that the quality assurance system is in place.

The authorisation holder shall notify the competent authority in the Member State about the recycling or manufacturing site in which the authorised recycling process is being applied.
Member States shall send this information to the Commission who will keep updated a register of recycling sites in the Community and third countries.

Declaration of compliance and record keeping

In addition to the conditions laid down by Directive 2002/72/EC, the declaration of compliance of recycled plastic materials and articles shall certify that the recycled plastic used comes from an authorised recycling process and shall bear the EC register number corresponding to the recycling process.

In addition to the conditions laid down by Directive 2002/72/EC, the declaration of compliance for recycled plastic materials shall certify that:

- the recycling process has been authorised. A precise indication of the EC register number for the process;
- the plastic input, the recycling process and the recycled plastic meet the specifications for which the authorisation has been granted;
- a quality assurance system is in place.

For more information click here

The Labelling

Voluntary self-declaration of the recycled content in recycled plastic materials and articles shall follow the rules laid down in ISO 14021:1999 or equivalent.
3.2. Testing

The Legislation


The basic rules necessary for testing migration are included in the Annex to Directive 97/48/EC. The Annex also explains that migration tests may be carried out using simulants.

Verification of compliance of migration into foodstuffs shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use. For food simulants verification shall be carried out using conventional migration tests, the basic rules for which are described in Directive 93/8/EEC. The Directives lay down the procedure to be followed in cases where, for a given plastic material or article, the basic rules for migration tests are inappropriate.

Migration limit, lists of approved substances and simulants

The limit on overall migration and the list of substances approved within the scope of this Directive are stipulated in Directive 2002/72/EC (see "Related acts" below). The list of simulants for testing migration is found in Directive 85/572 (see "Related acts" below).

Background

Directive 2002/72/EC protects consumers' health by banning materials and articles in contact with foodstuffs which may transfer their constituents to foodstuffs in quantities which could endanger human health and by prohibiting substantial changes to foodstuffs, including their organoleptic characteristics. (Changes to organoleptic characteristics are permitted only in active materials if the substance is an additive that is authorised in foodstuffs).
The latest scientific progress has led to innovations concerning articles in contact with foodstuffs. Regulation (EC) No 1935/2004 authorises two types of packaging: "intelligent" (indicating if the product has expired or deteriorated) and "active" (making chemical changes to foodstuffs to increase their durability).

For further information on materials in contact with foodstuffs, please consult:

- materials containing vinyl chloride monomer.

For more information click here.
3.3. **Restriction of Epoxy Derivatives in Food Packaging**

*The Legislation*

**Commission Regulation (EC) No 1895/2005** covers epoxy derivatives in materials and articles intended to come into contact with food.

**Authorisation of BADGE**

Following the opinion issued by the [European Food Safety Authority](https://efsaneuropa.eu) (EFSA), the European Commission permits the use of the substance known as BADGE in materials and articles used in packaging or other articles intended to come into contact with food, including *active and intelligent packaging*. The specific migration limit for this substance is:

- 9 mg/kg in food or food simulants;
- 9 mg/6dm² for containers with a capacity of less than 500 ml or more than 10 litres, but also for sheet and film.

(See also "Provisional arrangements" below.)

In addition, materials and articles containing BADGE must be accompanied by a written declaration stating that they comply with the rules. This compulsory declaration will be required as of 1 January 2007.

**Prohibition of BFDGE and NOGE**

Two other substances used in manufacturing packaging or other items in contact with food have been prohibited: BFDGE and NOGE.
NOGE and BFDGE had been prohibited since 31 December 2004, in accordance with Directive 2002/16/EC, now repealed. The current Regulation maintains this ban, applicable as of 1 January 2005. However, the Regulation permits the exhaustion of existing stocks of these products (see "Provisional arrangements" below).

Exceptions for large containers

Large containers (capacity greater than 10 000 litres) may continue to use BADGE, NOGE and BFDGE in their special surface coatings without having to comply with limits for migration (or transfer of significant levels of these substances to the products in contact). The level of migration for this type of container is negligible, according to the Regulation.

Provisional arrangements

BADGE, NOGE and BFDGE placed on the market before 1 March 2003 may continue to be marketed, provided the date of filling appears on them.

Background

Materials and articles containing BADGE, BFDGE and NOGE may transfer significant levels of these substances to foodstuffs (migration), particularly when used as additives, which may pose a risk to human health.

The use and/or presence of BADGE had been prohibited as of 31 December 2005 by Directive 2002/16/EC, but Regulation (EC) No 1895/2005, which repeals it, once again permits the use of this group of substances. After analysing the toxicological data transmitted for this group of substances, the European Food Safety Authority (EFSA) concluded that they do not raise concerns about carcinogenicity and genotoxicity in vivo.

For more information click here
3.4. Vinyl Chloride Monomer

The Legislation

Council Directive 78/142/EEC covers materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs. Materials and articles which are intended to come into contact with foodstuffs may not transfer certain constituents to these materials and articles in quantities liable to endanger human health.

In order to guarantee that these foodstuffs contain no trace of vinyl chloride monomer detectable by a method by a general Community method of analysis, materials and articles intended to come into contact with foodstuffs must comply with this Directive. Thus materials and articles:

- must not contain vinyl chloride monomer in quantities above one milligram per kilogram in the final product; and
- must not transfer vinyl chloride monomer to foodstuffs in quantities above 0.01 mg/kg in the final product.

For more information click here.
Commission Directive 93/11/EEC is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. Elastomer or rubber teats and soothers are capable of releasing N-nitrosamines and N-nitrosatable substances (substances likely to be transformed into N-nitrosamines) which, by virtue of their toxicity, pose a threat to human health.

Accordingly, the migration of substances must not exceed the following limits:

- 0.01 mg of the total quantity of N-nitrosamines released per kg (parts of elastomer or rubber teats and soothers)
- 0.1 mg of the total quantity of N-nitrosatable substances (parts of elastomer or rubber teats and soothers).

These limits must be checked by means of a test, subject to the conditions set out in the annex to this Directive. The analytical method to be employed is also laid down in this annex.

Teats and soothers which do not comply with this Directive are prohibited from 1 April 1995.
4. Ceramics

4.1. Ceramic Objects In Contact With Foodstuffs

The Legislation

**Council Directive 84/500/EEC** covers ceramic articles intended to come into contact with foodstuffs. Ceramic objects used to contain foodstuffs may transfer lead and cadmium to these foodstuffs. These two metals are toxic and can constitute a risk to human health. The Directive lays down maximum limits for the cadmium and lead transferred by ceramic objects to the foodstuffs with which they enter into contact.

**Declaration of conformity**

To be sold, these ceramics must be accompanied by a written declaration provided by the manufacturer or importer, guaranteeing that they do not exceed the maximum limits for lead and cadmium. The information required is described in Annex II (introduced by **Directive 2005/31/EC**). The declaration was introduced to meet the requirements of **Regulation 1935/2004** on materials and articles intended to come into contact with food (**Directive 84/500/EEC** is a measure specific to the groups of materials and objects listed in **Regulation 1935/2004**).

The maximum limits for lead and cadmium must be checked by means of a test and a method of analysis (Annex III, introduced by **Directive 2005/31/EC**). These methods take into account the very latest scientific progress in methods of analysis for official tests of lead and cadmium in foodstuffs, in accordance with **Directive 2001/22/EC**.

For more information click [here](#)

Scope

It applies to regenerated cellulose film which constitutes a finished product in itself, or forms part of a finished product containing other materials and which are intended to come into contact or are placed in contact with foodstuffs.

It does not apply to synthetic casings of regenerated cellulose.

Description

Regenerated cellulose film is defined as a thin sheet obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface. Regenerated cellulose film may be coated on one or both sides.

The regenerated cellulose films covered by this Directive belong to one of the following categories:

- uncoated regenerated cellulose film;
• coated regenerated cellulose film with coating derived from cellulose; or
• coated regenerated cellulose film with coating consisting of plastics.

Authorised substances and restrictions

The Directive lays down a positive list of substances authorised in the manufacture of regenerated cellulose film with restrictions of use (see Annex II).

Regenerated cellulose films which are uncoated or coated with plastics may be manufactured with substances other than those specified in Annex II if they are employed as colouring matter or as adhesives, provided that there is no trace of migration of the substances into or onto foodstuffs. Regenerated cellulose films which are coated with plastics shall comply with the provisions laid down by Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs. In addition it is stated that printed surfaces of regenerated cellulose film should not come into contact with the foodstuffs.

For more information click here

The Labelling

At the marketing stages other than the retail stages, materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs shall be accompanied by a written declaration in accordance with Regulation (EC) No 1935/2004. However, materials and articles which, by their nature, are clearly intended to come into contact with foodstuffs are not subject to this obligation.

Where special conditions of use are indicated, the material or article made of regenerated cellulose film shall be labelled accordingly.
CHAPTER 4

NON-FOODSTUFF LABELLING
1. ENVIRONMENTAL LABELLING

1.1. ECOLABEL


The EU Ecolabel may be awarded to products and services which have a lower environmental impact than other products in the same group. The label criteria were devised using scientific data on the whole of a product’s life cycle, from product development to disposal. The label may be awarded to all goods or services distributed, consumed or used on the Community market whether in return for payment or free of charge. It does not apply to medicinal products for human or veterinary use, or to medical devices.

Award criteria

The label shall be awarded in consideration of European environmental and ethical objectives. In particular:

- the impact of goods and services on climate change, nature and biodiversity, energy and resource consumption, generation of waste, pollution, emissions and the release of hazardous substances into the environment;
- the substitution of hazardous substances by safer substances;
- durability and reusability of products;
- ultimate impact on the environment, including on consumer health and safety;
- compliance with social and ethical standards, such as international labour standards;
- taking into account criteria established by other labels at national and regional levels;
- reducing animal testing.
The label cannot be awarded to products containing substances classified by Regulation (EC) No 1272/2008 as toxic, hazardous to the environment, carcinogenic or mutagenic, or substances subject to the regulatory framework for the management of chemicals.

Competent bodies

Member States shall designate one or more bodies responsible for the labelling process at national level. Their operations shall be transparent and their activities shall be open to the involvement of all interested parties. They are specifically responsible for regularly checking that products comply with the label criteria. Their remit also includes receiving complaints, informing the public, monitoring false advertising and prohibiting products.

The procedure for award and use of the label

In order to be awarded the label, economic operators shall submit an application to:

- one or more Member State(s), which will send it to the competent national body;
- a third State, which will send it to the Member State where the product is marketed.

For more information click here

The Labelling

If the product complies with the label criteria, the competent body shall conclude a contract with the operator, establishing the terms of use and withdrawal of the label. The operator may then place the label on the product. The use of the label is subject to payment of a fee when the application is made, and an annual fee.

The Commission has created a catalogue of products which have been awarded the label.
Examples

Here is the EU Ecolabel logo:

Other Provisions

*The European Union Ecolabelling Board (EUEB)*

The Commission shall establish a committee representing the national competent bodies. The Commission shall consult the EUEB when developing or revising the award criteria and requirements of the label.
2. Energy Labelling

2.1. General Products

The Legislation

Directive 2010/30/EU establishes a framework for labelling and consumer information regarding energy consumption for energy-related products.

Which products are concerned?

The Directive shall apply to products which are likely to have a direct or indirect impact on the consumption of energy and on other potential resources during use. It does not apply to:

- second-hand products;
- any means of transport for persons or goods;
- product rating plates.

What sort of information must be provided?

Suppliers shall place on the market products that have a label containing information on the product’s consumption of electric energy or other forms of energy. Suppliers must also make available technical documentation including:

- a general description of the product;
- the results of design calculations carried out;
- test reports;
- the references allowing identification of similar models.

The technical documentation must be available for a period of five years, suppliers shall provide dealers with labels and product information free of charge. In addition dealers must affix labels in such a way that they are visible and legible.
What are the conditions for distance selling?

In some situations, the final consumer does not see the product – in particular when purchasing by mail order, by catalogue or through the Internet. However, the consumer must have access to product information through delegated acts which specify the way in which the label or the fiche is displayed or provided to the end-user.

Transitional provisions


For more information click here

The Labelling

The labelling conditions differ depending on the product. Over the coming months and years the Commission shall create further legislation covering specific products (called a 'delegated act'), but all issued in accordance to the general rules set out in this Directive. The rules shall indicate in particular:

- a description of the product;
- measurement standards and methods;
- details of the technical documentation;
- the design and content of the label. The classification of the product on the label shall be indicated using the letters A to G. The most efficient class shall be represented by A++. A scale with a maximum of seven colours shall also be used, and dark green shall always represent the maximum level of efficiency;
- the location where the label shall be fixed to the product;
- the duration of label classification.

If a product is covered by a delegated act, contracting authorities which conclude public works, supply or service contracts as referred to in Directive 2004/18/EC shall procure products which comply with high performance levels, expressed as ‘energy classes’. These criteria are as follows:

- products which allow significant energy savings to be made;
- equivalent products on the market shall have a wide disparity in performance levels;
- the Commission shall take into account relevant EU legislation and self-regulation.

A delegated act shall take into account environmental parameters, so the European Commission has the power to adopt delegated acts for a period of five years from 19 June
2010. The period shall be renewed automatically unless the European Parliament or the Council revoke this right. These two institutions also have the power to object to a delegated act.

Examples

Here is the layout for the new energy efficiency label:
2.2. OFFICE EQUIPMENT

The Legislation

The European Union (EU) and the United States of America (US) signed a new Energy Star agreement on 28 December 2006, the aim of which is for manufacturers to voluntarily apply agreed specifications to measure the energy performance of office equipment. The agreement was signed for a period of five years and details can be found within Council Decision 2006/1005/EC.

The "Energy Star"® label can be used for office equipment meeting these specifications, so that consumers can easily identify low-energy appliances. They are: computers, computer monitors, photocopiers, printers, digital duplicators, faxes, franking machines, multifunction devices and scanners.

The previous Energy Star agreement remains applicable only to computers until 31 December 2007 at the latest. The new technical specifications for computers contain provisions on the active mode, unlike the previous agreement, which only took account of the standby mode.

Voluntary participation of manufacturers

Manufacturers, retailers and dealers of office equipment may join the Energy Star programme and use the "Energy Star®" label. Equipment labelled as such must meet the agreed specifications (Annex C) and may be tested by the manufacturer or by independent test laboratories.

Programme management and monitoring

The US and the EU each have a managing body for the programme: the US has the Environmental Protection Agency (EPA) and the EU has the European Community Energy Star Board (ECESB), set up in 2003 (see below under "Related Acts").

The agreement sets out guidelines for the correct use of the Energy Star name and label.
The Commission - via the managing body - is responsible within the EU for testing office equipment carrying this label or checking that it meets the requirements.

If the product fails to meet the requirements, the ECESB:

- notifies the manufacturer in writing that it fails to comply with the requirements;
- drafts a plan to ensure compliance with the conditions in the programme;
- if the conditions are not then met, cancels the manufacturer's participation in the programme.

*Amending and ending the agreement*

Either the EU or the US may amend the programme of the managing bodies by common agreement. This includes amending technical specifications or including a new type of product if it becomes more energy efficient. The agreement may also be ended by giving three months' notice in writing to the other party. If the agreement is ended, the EU may no longer use the label "Energy Star®".

*Community decision-making*

The Community decision-making process is used to establish the internal procedures needed to ensure the agreement operates smoothly. This decision authorises the Commission to regularly adapt and reassess the technical specifications. The Commission is supported by a Community advisory committee made up of national representatives and all stakeholders.

*Background*

The first Energy Star agreement was signed with the US in 2001 for a 5-year period. This agreement renews the former agreement, with some changes made:

- the technical specifications applicable to computer monitors, computers and imaging equipment were revised;
- three obligations for the EU were removed: promotion of the Energy Star logo by the Commission and Member States, production by the ECESB of a report on market penetration of products meeting the criteria and information on the activities of the ECESB for the Commission to draw up and send to the European Parliament and the Council.

For more information click [here](#)
Examples

The Energy Star logo:
Directive 2009/125/EC establishes ecodesign requirements for energy-related products in the European Union. However this Directive shall not apply to means of transport for persons or goods.

Ecodesign parameters for products

Ecodesign parameters relate to different phases in the product life cycle:

- raw material selection and use;
- manufacturing;
- packaging, transport, and distribution;
- installation and maintenance;
- use;
- end-of-life.

For each phase, the following aspects of the product must be assessed:

- predicted consumption of materials, of energy and of other resources;
- anticipated emissions to air, water or soil;
- anticipated pollution (noise, vibration, radiation, electromagnetic fields);
- expected generation of waste material;
- possibilities for reuse, recycling and recovery of materials or of energy, taking into account the Directive on waste electrical and electronic equipment.

Placing on the market and CE marking

All products covered by implementing measures must bear CE marking before being placed on the market. Market surveillance is to be carried out by competent authorities designated by Member States that have the task of:
verifying product conformity;
• requiring the parties concerned to provide the necessary information;
• taking samples of products and subjecting them to compliance checks.

Free movement

Member States may not hinder the placing on the market of a product which complies with ecodesign requirements. If the product does not fulfil ecodesign requirements, Member States must take suitable measures which may go as far as the prohibition of the placing on the market of the product. In this case, the Member State in question shall inform the European Commission of its intentions if non-compliance is due to:

• failure to satisfy the requirements of the applicable implementing measure;
• the incorrect application of harmonised standards;
• shortcomings in harmonised standards.

Conformity assessment

Before being placed on the market, all products must undergo conformity assessment concerning all of the ecodesign requirements. Once the product has been placed on the market, the manufacturer or its authorised representative shall keep all documents relating to the conformity assessment issued in order to facilitate inspections by Member States that are likely to take place in the ten years following the product’s manufacture.

Presumption of conformity

Products bearing the Community eco-label are presumed to comply with the ecodesign requirements stated in the applicable implementing measures. The Commission also has the power to decide whether other eco-labels are equivalent to the Community eco-label.

Harmonised standards

If harmonised standards do not entirely satisfy the provisions of this Directive, the Member State concerned or the Commission shall inform the Standing Committee set up under the Directive on information procedures in the field of technical standards and regulations. The Committee will then give an opinion, which the Commission shall take into account.

Small and medium-sized enterprises

The Commission can assist small and medium-sized enterprises and very small firms in integrating environmental aspects, in particular energy efficiency, when designing their products.

Consumer information
Manufacturers must be able to provide consumers with information on the role that they can play in the sustainable use of the product concerned, as well as the ecological profile of the product and the advantages of ecodesign.

This Directive repeals Directive 2005/32/EC.

Context

There are still too many disparities between Member States in terms of the ecodesign of energy-related products and this hinders the proper functioning of the internal market. This Directive therefore endeavours to improve the harmonisation of national legislation in this field whilst extending its scope to all energy-using products.

For more information click here
Council Directive 92/75/EEC applies to the following types of household appliances, even where these are sold for non-household uses:

- refrigerators, freezers and their combinations;
- washing machines, dryers and their combinations;
- dishwashers;
- ovens;
- water heaters and hot-water storage appliances;
- lighting sources;
- air-conditioning appliances.

Household appliances offered for sale, hire or hire-purchase must be accompanied by a fiche and a label providing information relating to their consumption of energy (electrical or other) or of other essential resources. The supplier must establish technical documentation sufficient to enable the accuracy of the information contained in the label and the fiche to be assessed. This documentation must include:

- a general description of the product;
- the results of design calculations, where necessary;
- test reports;
- where values are derived from those obtained for similar models, the same information for these models.

The supplier shall make this documentation available for inspection purposes for a period ending five years after the last product has been manufactured.

Suppliers must provide:

- a free label, to be attached to the appliance by the dealer in the appropriate position and in the appropriate language version;
• a product fiche, contained in all the brochures relating to the product or, where these are not provided, in all other literature provided with the appliance.

Suppliers are responsible for the accuracy of the information contained in the labels and fiches that they supply and are deemed to have given their consent to the publication of the information. Where appliances are offered for sale, hire or hire-purchase by catalogue or by other means whereby the potential customer is unable to see the appliance displayed, the essential information contained in the label or fiche must be provided to the potential customer before purchase. Information on airborne noise, integrated into Directive 2005/32/EC, and other public information relating to the appliance in question and provided pursuant to other Community legislation, must be included on the label or fiche.

Member States must take the necessary measures to:

• ensure that all suppliers and dealers established in their territory fulfil their obligations under this Directive;
• prohibit the display of labels, marks, symbols or inscriptions relating to energy consumption which do not comply with the requirements of this Directive and which are likely to cause confusion, with the exception of Community or national environmental labels;
• launch educational and promotional information campaigns aimed at encouraging more responsible use of energy by private consumers.

Where Member States have grounds for suspecting that the information contained in labels or fiches is incorrect, they may require suppliers to provide evidence.

The Directives adopted in implementation of the present Directive must specify:

• the exact definition of the type of appliances to be included;
• the measurement standards and methods to be used in obtaining the information relating to energy consumption;
• details of the technical documentation required;
• the design and content of the label;
• the location where the label shall be fixed to the appliance;
• the content and where appropriate the format of the fiche, on which must be included the information appearing on the label;
• the information details to be provided in the case of mail-order offers for sale.

For more information click here.
At the December 1997 Kyoto Conference on climate change, the Community undertook to reduce its emissions of a basket of greenhouse gases by 8% during the period 2008 to 2012 relative to 1990 levels. Directive 1999/94/EC is part of an overall Community strategy aimed at meeting this commitment to reduce CO2 emissions, in particular those caused by passenger cars.

The purpose of the Directive is to ensure that information relating to the fuel economy and CO2 emissions of new passenger cars offered for sale or lease in the Community is made available to consumers. This consumer information system is to be set up using the following four methods:

- attaching a fuel consumption and CO2 emissions label to the vehicle;
- producing a fuel consumption and CO2 emissions guide;
- displaying posters in car showrooms;
- including fuel consumption and CO2 emissions data in promotional material.

The Directive stipulates that a fuel economy label must be attached to the windscreen of all new passenger cars at the point of sale. This label must be clearly visible and meet certain requirements set out in Annex I. In particular, it must contain an estimate of fuel consumption, expressed in litres per 100 kilometres or in kilometres per litre (or in miles per gallon), and of CO2 emissions.

A fuel economy guide must be produced at national level at least once a year. It must set out all the information specified in Annex II, including a list of the 10 most fuel-efficient new car versions in terms of their CO2 emissions by fuel type. This guide must be compact, portable and free of charge. Consumers must be able to obtain it both at the point of sale of the dealer and from a designated body within each Member State. In addition, the Commission will make available an electronic version of the guide, accessible on the Internet.

For each make on sale, the dealer must display on posters or in any other form (including electronic displays) a list of the fuel consumption data of all the models. These data should be...
broken down by type of fuel and ranked in order of fuel efficiency as indicated by CO2 emission levels.

The Directive also provides that promotional material (advertisements in newspapers, posters, brochures) used in marketing new cars must contain fuel consumption and CO2 emissions data. It requires the prohibition of any marking relating to fuel consumption which does not comply with the above provisions and which might cause confusion. Member States must notify the Commission of the competent body or bodies responsible for the implementation and functioning of the consumer information scheme. The Commission is assisted by the committee set up under the Directive on the indication of the energy consumption of household appliances.

Background

Consumer information, achieved by means of labels showing a vehicle's CO2 emissions, is one of the three pillars of the strategy the EU adopted in 1995 to reduce CO2 emissions. The other two pillars are a voluntary commitment by automobile manufacturers to reduce CO2 emissions and the promotion of fuel-efficient cars via fiscal measures.

For more information click here
3. CLOTHING

3.1. TEXTILE PRODUCTS

The Legislation

Directive 2008/121/EC defines the legal framework applicable to textile names. It applies to:

- textile products which are made exclusively of textile fibres;
- textile fibres;
- products treated as textile products.

Only textile products that comply with the provisions of the Directive may be marketed. The following textile products are excluded from the application of the Directive:

- those intended for export to third countries;
- those entering Member States, under customs control, for transit purposes;
- those imported from third countries for inward processing;
- those which are contracted out to persons working in their own homes or to independent firms.

Authorised textile product names

The names set out in Annex I of the Directive must not be used for other fibres. Thus the term “silk” may not be used to indicate the shape or particular presentation in continuous yarn of textile fibres. Only textile products exclusively composed of the same fibre may be labelled as “100%”, “pure” or “all”. Wool may be described as “pure wool” or “fleece wool” as long as it is composed of one fibre.

The composition of textile products
If a textile product is composed of two or more fibres, one of which accounts for at least 85% of the total weight, it is designated by:

- the name of that fibre followed by its percentage by weight;
- the name of that fibre followed by the words "85% minimum";
- the full percentage composition of the product.

If all fibres in the product separately account for less than 10% of its composition, the term “other fibres” may be used, followed by the total percentage or their name, as long as the percentage composition of the product is stipulated. The presence of other fibres must be given in descending order of composition.

Products having a pure cotton warp or a pure flax weft, in which the percentage of flax accounts for not less than 40% may be given the name “cotton linen union” followed by “pure cotton warp - pure flax weft”. For textile fibres intended for end consumers, a quantity of extraneous fibres of up to 2% of the total weight of the textile product is tolerated. This tolerance is increased to 5% for products which have undergone a carding process. A manufacturing tolerance of 3% in relation to the total weight of fibres is permitted between the percentage stated on the label and the percentage obtained from analysis.

For more information click here

**The Labelling**

Textile products must be marked and labelled when marketed. If products are not intended for end consumers, labelling and marking may be replaced by accompanying commercial documents. If products are intended for end consumers, names, descriptions and textile fibre content must be clearly and legibly indicated on labels, marks, packaging or promotional documents. Member States may require information to be provided in their national language or languages.

Any textile product containing several components with different compositions must bear a label stating the fibre content of each component. Two textile products with the same composition and forming a single unit may bear only one label. In addition, the Directive gives precise indications as to the labelling of certain products such as corsetry articles.
Here is a clothing label indicating the textile fibre content and washing conditions:
3.2. **FOOTWEAR**

**The Legislation**

*Directive 94/11/EC* covers labelling for the materials used in footwear, including parts sold separately, and rules regarding labelling.

For more information click [here](#).

**The Labelling**

For each pair, at least one of the footwear items (defined and illustrated in the Directive) must bear information relating to the upper, the lining and insole sock, and the outer-sole of the footwear article. The information may be conveyed by means of approved pictograms or textual information, as defined and illustrated in the Annex to the Directive, and must relate to the material which constitutes at least 80% of the surface area of the upper, the lining and insole sock of the footwear article, and at least 80% of the volume of the outer-sole. However, if no single material accounts for at least 80%, information must be given concerning the two main materials in the composition of the article.

Given that the aim of the above measures is to provide information, the label must be legible, durable and accessible, and the manufacturer or his authorised agent established in the Community is responsible for supplying the label and for the accuracy of the information contained on it. Only the information provided for in the Directive has to be supplied, but there is nothing to prevent additional information being given on the label.
Examples

Here are some of the symbols as defined by the Directive:

<table>
<thead>
<tr>
<th><strong>Upper</strong></th>
<th>![Image of Upper]</th>
</tr>
</thead>
<tbody>
<tr>
<td>This is the outer face of the structural element which is attached to the outersole.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Lining and sock</strong></th>
<th>![Image of Lining and sock]</th>
</tr>
</thead>
<tbody>
<tr>
<td>These are the lining of the upper and the insole, constituting the inside of the footwear article.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Outer sole</strong></th>
<th>![Image of Outer sole]</th>
</tr>
</thead>
<tbody>
<tr>
<td>This is the bottom part of the footwear article, which is subjected to abrasive wear and attached to the upper.</td>
<td></td>
</tr>
</tbody>
</table>

<p>| <strong>Leather</strong> | ![Image of Leather] |</p>
<table>
<thead>
<tr>
<th>Coated Leather</th>
<th><img src="image1.png" alt="Image" /></th>
</tr>
</thead>
<tbody>
<tr>
<td>Natural textile materials and synthetic or nonwoven textile materials</td>
<td><img src="image2.png" alt="Image" /></td>
</tr>
<tr>
<td>All other materials</td>
<td><img src="image3.png" alt="Image" /></td>
</tr>
</tbody>
</table>
A cosmetic product is any substance or preparation intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, and/or correcting body odours, and/or protecting them or keeping them in good condition. Such products, listed in Annex 1 (illustrative list), must not be harmful to human health when they are applied under normal or foreseeable conditions of use.

Member States take all necessary measures to ensure that only cosmetic products which conform to the provisions of Council Directive 76/768/EEC are placed on the market. The marketing of such products may not be refused, prohibited or restricted. However, if a Member State notes that a product, although complying with the requirements of the Directive, represents a hazard to health, it may provisionally prohibit the marketing of that product in its territory or subject it to special conditions. It must then immediately inform the other Member States and the Commission thereof, giving the reasons for its decision. The Commission must consult the Member States concerned, deliver its opinion without delay and take the appropriate steps.

This Directive shall be replaced by Regulation (EC) No 1223/2009 from 2013 onwards. Some of the provisions of the Regulation shall be applicable from 1 December 2010. They relate to substances classified as carcinogenic, mutagenic or toxic to reproduction (CMR category 2, 1A and 1B), banned (Annex II) or restricted substances, certain dyes, preservatives and ultra-violet filters.

**Ingredients/composition**
The Directive sets out a list of substances which cannot be included in the composition of cosmetic products (Annex II) and a list of substances which cosmetic products may contain only under the restrictions and conditions laid down (Annex III).

The Directive also contains lists of colourings (Annex IV), preservatives (Annex VI) and UV filters (Annex VII) permitted in cosmetic products.

*Market surveillance*

The manufacturer or his agent, or the person to whose order a cosmetic product is manufactured, or the person responsible for placing an imported cosmetic product on the Community market, must keep certain product and safety information at the disposal of the competent monitoring authorities.

Member States must check the safety of the product and take all necessary measures to ensure that neither manufacturers nor importers established in the Community place on the market products which do not comply with the Directive. Member States must also ensure that cosmetic products are not attributed characteristics which they do not possess.

*Notification to the competent authority*

The manufacturer or his agent, or the person to whose order a cosmetic product is manufactured, or the person responsible for placing an imported cosmetic product on the Community market, must notify the competent authority of the Member State of the place of manufacture of the cosmetic product or of the place where it was first imported into the Community before being placed on the Community market.

*Animal testing*

The Directive puts an end to animal testing by imposing bans on:

- testing finished cosmetic products and ingredients on animals (testing ban);
- marketing finished cosmetic products which have been tested on animals or which contain ingredients that have been tested on animals (marketing ban).

The testing ban on finished cosmetic products has applied since 11 September 2004, whereas the testing ban on ingredients or combinations of ingredients is applied progressively as alternative methods are validated and adopted. The deadline is 11 March 2009 (six years after entry into force of the Directive).

The marketing ban is applied progressively as alternative methods are validated and adopted through European Union (EU) legislation, with due regard to the development of validation within the Organisation for Economic Cooperation and Development (OECD). The deadline is 11 March 2009 (six years after entry into force of the Directive) for products tested for all human health effects with the exception of repeated-dose toxicity, reproductive toxicity and...
toxicokinetics. For these specific health effects, the deadline is 11 March 2013 (10 years after entry into force of the Directive). The deadlines for both the testing ban and the marketing ban will apply irrespective of the availability of alternative non-animal tests. In managing the provisions on cosmetic products, the Commission is assisted by the Standing Committee on Cosmetic Products.

For more information click [here](#).

### The Labelling

Containers and/or packaging must bear, in indelible, easily legible and visible characters:

- the name or trade name and address or registered office of the manufacturer or of the person responsible for marketing the cosmetic product within the Community;
- the nominal contents at the time of packaging, by weight or by volume;
- for products with a minimum durability of less than 30 months: the date of minimum durability indicated by “Best used before the end of...”;
- for products with a minimum durability of more than 30 months: the period of time after opening for which the product can be used without any harm to the consumer (this information is indicated by a special symbol representing an open cream jar);
- for products with a minimum durability of less than 30 months: the date of minimum durability;
- particular precautions for use;
- the batch number or product reference to permit identification;
- the product function.

This information must be in the national or official language or languages of the respective Member State. Moreover, the label must contain a list of ingredients, in descending order, preceded by the word "Ingredients". Perfume and aromatic compositions must be referred to only by the word "perfume" or "aroma", except where these have been identified as a significant cause of allergic reactions in sensitive consumers. With regard to the list of ingredients, Member States may require these to be labelled with the common ingredients nomenclature.
Regulation (EC) No 1223/2009 recasts the old Directive 76/768/EEC due to the many amendments made to it and the new amendments that were required. The new Regulation shall apply in 2013. However, some of its provisions will apply from 1 December 2010: they concern substances which are carcinogenic, mutagenic or toxic for reproduction (classified as CMR).

Market surveillance

A responsible person established in the Community shall be designated for each product placed on the market. This person shall ensure compliance of the products with the rules set out in the Regulation. In particular, they shall ensure compliance with requirements relating to human health, safety and consumer information. They shall maintain a product information file accessible to the public authorities.

In order to ensure product traceability, responsible persons shall identify the distributors to whom they supply the cosmetic product: for a period of three years following the date on which the batch of the cosmetic product was made available to the distributor. The same applies to all other persons involved in the supply chain.

In case of product non-compliance, the responsible person shall take measures to render it compliant, withdraw it from the market or recall it to the manufacturing company in all Member States where the product is available. Where the responsible person does not take all appropriate measures, the competent national authorities may take the necessary corrective measures.

If a product which complies with the requirements of the Regulation presents or could present a serious risk to human health, the competent national authority shall take all necessary provisional measures to withdraw, recall or restrict the availability of the product on the market.
Limitations for certain substances

The Annexes of this Regulation give a list of prohibited substances (Annex II) or restricted substances (Annex III) with respect to use in cosmetic products. Certain colorants (other than those in Annex IV), preservatives (other than those in Annex V) and UV-filters (other than those in Annex VI) are also prohibited.

The Regulation prohibits the use of substances recognised as carcinogenic, mutagenic or toxic for reproduction (classified as CMR), apart from in exceptional cases. It provides for a high level of protection of human health where nanomaterials are used in cosmetic products.

Animal testing

Animal testing must be replaced by alternative methods. The Regulation prohibits the performance of animal testing in the European Union for:

- finished products,
- ingredients or combinations of ingredients.

For more information click [here](#).

The Labelling

Product labelling contributes to consumer protection. Containers or packaging must bear written information in indelible, easily legible and visible lettering. This information concerns:

- the name or registered name and the address of the responsible person;
- the country of origin for imported products;
- the weight or volume of the content at the time of packaging;
- a use-by date for products kept in appropriate conditions;
- precautions for use, including for cosmetics for professional use;
- the batch number of manufacture or the reference for identifying the cosmetic product;
- the list of ingredients, i.e. any substance or mixture intentionally used in the product during the process of manufacturing.

The language of the information shall be determined by the Member State where the product is made available to the end user.
The Regulation also prohibits the placing on the European Union market of:

- products where the final formulation has been the subject of animal testing;
- products containing ingredients or combinations of ingredients which have been the subject of animal testing.

A derogation from the ban relating to placing products on the market shall be granted until 11 March 2013 in order to test repeated-dose toxicity, the effects of certain substances on reproduction and to study toxicokinetics. In exceptional circumstances, Member States may request the Commission to grant a derogation, after consulting the Scientific Committee for Consumer Safety (SCCS), if an ingredient in wide use which cannot be replaced gives rise to serious concerns.

Committee procedure

The Commission shall be assisted by the Standing Committee on Cosmetic Products.
5. **Detergents**

5.1. **Detergents**

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**The Legislation**

Regulation (EC) No 648/2004 permits improved protection of the aquatic environment against the surfactants in detergents and other cleaning products. These surfactants – also called tensides – are included in detergents and other cleaning products in order to reduce the surface tension of liquids so that they can wet surfaces and clean them more effectively. The legislation has been made more restrictive by including all types of surfactants and imposing stricter testing methods for detergents to determine the ultimate rather than the initial biodegradability.

**Protection of consumers**

Consumers will be better protected against fragrance substances and preservation agents that are present in detergents and can cause allergies. Specific labelling has been introduced to inform consumers about the presence in detergents of this type of substance. The Regulation makes the provisions of Commission Recommendation 89/542 on the labelling of these allergenic substances compulsory, by incorporating them into the new legislation.

For healthcare professionals it is possible to obtain from manufacturers full listings of the ingredients in detergents so that they can determine whether there is a causal link between a patient's allergy and a product which is present in a detergent.

**Context**

This Regulation expands the scope of the existing legislation. It repeals five directives on biodegradable surfactant detergents (Directives 73/404/EEC, 73/405/EEC, 82/242/EEC,
82/243/EEC and 86/94/EEC) and Commission Recommendation 89/542 on the labelling of detergents. It also aims to harmonise the regulations in Member States in a uniform and simultaneous manner and to simplify future changes.

For more information click here

The Labelling

Manufacturers must list on the labelling all components in decreasing order of concentration as well as the address of a website where consumers can obtain the complete list of ingredients, in addition all allergens must be indicated on the label. This Regulation also adds an additional testing method for surfactants with limited solubility in water (amendment to Annex III). This method complies with the standard ISO 10708: 1997 "Water quality - Evaluation in an aqueous medium of the ultimate aerobic biodegradability of organic compounds". The legislation on detergents henceforth applies to all types of surfactant detergents, including fabric softeners and washing machine products.
6. **DANGEROUS MATERIALS**

6.1. **CHEMICALS**

**The Legislation**

**Regulation (EC) No 1272/2008** harmonises requirements concerning the classification, labelling and packaging of chemical substances and mixtures in line with the international system approved by the United Nations. This harmonisation enhances protection of health and the environment, and improves the free circulation of chemical substances and mixtures.

Enterprises must classify, label and pack their substances and mixtures in line with the provisions of this Regulation before putting them on the market.

**Scope**

The Regulation covers chemical substances and mixtures which are composed of two chemical substances or more.

The Regulation does not apply to:

- radioactive substances and mixtures covered by Directive 96/29/Euratom;
- substances subject to customs supervision which are in temporary storage, in a free zone or free warehouse with a view to re-exportation or still in transit;
- non-isolated intermediates (substances which are manufactured in order to be chemically transformed into another substance);
- substances and mixtures for scientific research and development which are not placed on the market;
- waste;
- medicinal products;
• cosmetic products;
• some medical devices;
• food;
• the transport of dangerous goods.

Classification

The classification of chemical substances and mixtures is based on categories which take into account the degree of hazard and the specific nature of the hazardous properties. These include inflammable substances or mixtures, those which are highly toxic, those which are dangerous for the aquatic environment, etc. Annex I establishes the criteria for the classification and labelling of hazardous substances and mixtures.

The Annexes of the Regulation also include the list of hazard statements, the list of precautionary statements, pictograms for each hazard class and the lists of classifications and labelling harmonised at Community level.

Packaging

Packaging containing hazardous substances or mixtures shall comply with the following requirements:

• packaging must prevent any of the contents escaping;
• packaging must be made of materials which are resistant if they come into contact with the contents;
• packaging must be strong and solid;
• packaging must have sealable fastenings.

In some cases, child-resistant fastenings and tactile warnings are required.

Harmonisation procedure

In order to trigger the harmonisation procedure for the classification and labelling of substances, Member States, or even manufacturers, importers or downstream users, can submit a proposal for the harmonised classification and labelling of substances, containing the information set out in Annex VI, Part 1 of this Regulation to the European Chemicals Agency. Generally, only substances satisfying the classification criteria for Category 1 respiratory sensitisation, mutagenicity, carcinogenicity or reproductive toxicity, or active ingredients in pesticides or biocides will be subject to such harmonisation, but other substances may be subject thereto if a necessity for harmonisation is demonstrated.

Within eighteen months from receipt of the proposal, the risk assessment committee of the Agency shall give an opinion on the proposal.
The Agency shall send this opinion to the Commission which, if it considers that harmonisation is appropriate, will include the substance and its classification and labelling elements in Annex VI, Part 3 of this Regulation.

**Context**

This Regulation supplements the [REACH system](#) for registration, assessment, authorisation and restrictions concerning chemical substances.


For more information click [here](#)

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**The Labelling**

### Labelling must mention:

- the name of the substance or mixture and/or an identification number
- the name, address and telephone number of the supplier
- the nominal quantity of the substance or mixture

### Also, if applicable, must include:

- hazard pictograms (see Annex V of the Regulation);
- the signal words “Danger” or “Warning”;
- hazard statements such as “Fire or projection hazard”, “Fatal if swallowed”, etc. (see Annex III of the Regulation);
- precautionary statements such as “Keep only in original container”, “Protect from moisture”, “Keep out of reach of children”, etc. (see Annex IV of the Regulation);
- supplemental information, for example on physical properties or health hazards (see Annex II of the Regulation).

Hazard pictograms shall be in the shape of a square set at a point. They shall have a black symbol on a white background with a red frame sufficiently wide to be clearly visible. Each hazard pictogram shall cover at least one fifteenth of the surface area of the harmonised label and the minimum area shall not be less than 1 cm².
The dimensions of the label shall be as follows:

<table>
<thead>
<tr>
<th>Capacity of the package</th>
<th>Dimensions (in millimetres)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not exceeding 3 litres</td>
<td>If possible, at least 52 × 74</td>
</tr>
<tr>
<td>Greater than 3 litres but not exceeding 50 litres</td>
<td>At least 74 × 105</td>
</tr>
<tr>
<td>Greater than 50 litres but not exceeding 500 litres</td>
<td>At least 105 × 148</td>
</tr>
<tr>
<td>Greater than 500 litres</td>
<td>At least 148 × 210</td>
</tr>
</tbody>
</table>

The label for the hazardous substance or mixture shall be written in the official language(s) of the Member State where it is placed on the market, unless the Member State concerned provides otherwise.

Hazard pictograms, signal words, hazard statements and precautionary statements shall be located together on the label in an order established by the supplier, provided that the statements are grouped by language.
Here are the European hazard symbols as defined by Directive 67/548/EEC:

<table>
<thead>
<tr>
<th>Hazard Type</th>
<th>Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explosive</td>
<td>![Explosive Symbol]</td>
</tr>
<tr>
<td>Oxidizing</td>
<td>![Oxidizing Symbol]</td>
</tr>
<tr>
<td>Highly Flammable</td>
<td>![Highly Flammable Symbol]</td>
</tr>
<tr>
<td>Extremely Flammable</td>
<td>![Extremely Flammable Symbol]</td>
</tr>
<tr>
<td>Toxic</td>
<td>![Toxic Symbol]</td>
</tr>
<tr>
<td>Very Toxic</td>
<td>![Very Toxic Symbol]</td>
</tr>
<tr>
<td>Harmful</td>
<td>![Harmful Symbol]</td>
</tr>
<tr>
<td>Irritant</td>
<td>![Irritant Symbol]</td>
</tr>
<tr>
<td>Corrosive</td>
<td>![Corrosive Symbol]</td>
</tr>
<tr>
<td>Dangerous to the Environment</td>
<td>![Dangerous to the Environment Symbol]</td>
</tr>
</tbody>
</table>
CHAPTER 4

Other Provisions

The classification and labelling inventory

At the latest one month after having placed a substance on the market, the manufacturer or importer shall notify the Agency of information concerning its identity, the identity of the substance, hazard classes, concentration limits, etc. All this information shall be included in an inventory of classification and labelling that the Agency shall update on a regular basis.
6.2. Substances

The Legislation

Council Directive 67/548/EEC is the first harmonising Directive in the field of chemical products. Given the extent of that field, the Commission limited the scope of this first Directive to the harmonisation of the classification, packaging and labelling of dangerous substances.

The Directive does not affect provisions relating to:

- medicinal products;
- cosmetic products;
- mixtures of substances in the form of waste;
- food;
- animal feed;
- pesticides;
- radioactive substances;
- other substances or preparations for which notification or approval procedures exist;
- the carriage of dangerous substances;
- unrefined substances which are in transit and are subject to customs inspection.

Definitions

For the purposes of the Directive, "substances" means chemical elements and their compounds as they occur in the natural state or as produced by industry. "Preparations" means mixtures or solutions composed of two or more substances.

Classification

The classification of dangerous substances is based on categories clearly defined in the Directive according to the greatest degree of hazard and the specific nature of the risks. These categories include explosive substances, inflammable substances, toxic substances, harmful substances, etc.
The Annexes to the Directive contain, among other things, a list of dangerous substances (Annex I), their classification and the provisions for their labelling, the symbols relating to each substance, the standard phrases relating to the nature of the special risks of each substance as well as, if the case arises, any phrases giving advice on safety precautions for the substance.

Packaging

The packaging of substances must comply with the following provisions:

- the packaging must prevent any loss of the contents, except where special safety devices are prescribed;
- the materials constituting the packaging and fastenings must not be liable to attack by the contents or liable to form harmful or dangerous compounds with the contents;
- packaging and fastenings must be resistant and solid.

For more information click [here](#)

**The Labelling**

<table>
<thead>
<tr>
<th>The labelling must indicate:</th>
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</thead>
<tbody>
<tr>
<td>• the name of the substance</td>
</tr>
<tr>
<td>• the origin of the substance (name and address of the manufacturer, distributor or importer);</td>
</tr>
<tr>
<td>• danger symbols and indication of danger involved in the use of the substance;</td>
</tr>
<tr>
<td>• a reference to the special risks arising from such dangers.</td>
</tr>
</tbody>
</table>

This information must be presented in accordance with the Annexes to the Directive (symbols, standard phrases, etc.), the same applies to any advice on safety precautions. In addition, it must comply with provisions on the size of the labelling. In particular, the dimensions of the label must not be less than those of a standard A8 sheet (52 x 74 mm), and each symbol must cover at least one tenth of the surface area of the label. Where the packaging is too small, the labelling may be affixed in some other manner.

Member States may require their national language or languages to be used in the labelling of dangerous substances.

Member States may allow dangerous substances which are not toxic or explosive to derogate from the general rules on labelling established in Articles 23 and 24 of this Directive. The
labelling of these substances may therefore be optional or differ from the established rules if they are present in such small quantities that there is no danger to users,

In the context of the international and/or national transport of dangerous substances, the labelling must comply with the international and/or national rules. Member States may not hamper the free movement within the European Community of dangerous substances which comply with the Directive, unless they establish that the substance constitutes a hazard to health and/or the environment. In such a case, the Member State must inform the Commission, which must launch a consultation procedure to assess the hazards and take any other necessary action

Member States must inform the Commission of measures taken pursuant to the Directive.

**Other Provisions**

Annex I is deleted by Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, and replaced by Table 3.1 of Annex VI to that Regulation with effect from 20 January 2009.

Annex II will be repealed on 1 June 2015.

Annex III will be repealed on 1 June 2015.

Annex IV will be repealed on 1 June 2015.


Annex VI will be repealed on 1 June 2015. However, the provisions on the labelling and packaging of substances in Annex VI will no longer apply with effect from 1 December 2010.


Annex IX will be repealed with effect from 1 June 2015.

This Directive will be repealed in its entirety on 1 June 2015.
Directive 1999/45/EC applies to dangerous preparations which contain at least one dangerous substance within the meaning of Article 2 or which are considered dangerous within the meaning of Articles 5, 6 or 7. The term “preparation” covers mixtures or solutions composed of two or more substances.

This Directive provides specific provisions for preparations which are not considered dangerous (within the meaning of Articles 5, 6 or 7), but which may nevertheless present a specific hazard.

This Directive shall not apply to the following preparations in the finished state, intended for the final user:

- medicinal products for human or veterinary use;
- cosmetic products;
- mixtures of substances in the form of waste covered by Directive 2006/12/EC on waste disposal;
- foodstuffs;
- animal feedingstuffs;
- preparations containing radioactive substances;
- medical devices which are invasive or used in direct physical contact with the human body;
- the carriage of dangerous preparations by rail, road, inland waterway, sea or air;
- preparations in transit which are under customs supervision, provided they do not undergo any treatment or processing.

Classification

The classification of dangerous preparations shall be based on the definitions of categories of danger laid down in Article 2 of the Directive. These categories take into account the degree
and specific nature of the hazards involved. They include preparations considered dangerous due to:

- physico-chemical properties (for example, explosive, oxidising, or flammable); and/or
- the health hazards it presents (for example, toxic, carcinogenic or harmful); and/or
- the environmental hazards it presents.

The general principles of classification and labelling of dangerous substances applies to the methods specified in Regulation (EC) No 440/2008 and the criteria laid down in Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances, save where alternative criteria in the Directive are applied.

**Packaging**

The main requirements relating to packaging are as follows:

- it shall be so designed and constructed that its contents cannot escape;
- the materials constituting the packaging and fastenings must not be susceptible to adverse attack by the contents, or liable to form dangerous compounds with the contents;
- packaging and fastenings must be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;
- the shape and/or graphic decoration of packaging shall not arouse the curiosity of children nor mislead consumers;
- it shall be designed so that it cannot be confused with foodstuffs, animal feedingstuffs, medicinal products or cosmetics;
- containers for preparations must be fitted with child-resistant fastenings and/or carrying a tactile warning of danger.

**Obligations and duties of the Member States**

The Member States appoint a national authority who shall inform the Commission on the application of this Directive. Those responsible for placing dangerous preparations on the market must hold at the disposal of that authority all information relating to the classification of the preparation (safety data, etc.).

Member States are required to designate the bodies responsible for receiving information on the health effects of preparations. This information can be used only in response to requests of a medical nature.

**Confidentiality**

The person responsible for placing a dangerous preparation on the market may make a request for confidentiality. This request is addressed to the competent authority of the Member States in which the preparation is to be first placed on the market. This procedure prevents the
disclosure of the chemical identity of a certain substance on the label and does not risk the confidential nature of intellectual property. When the authority has made its decision, it shall inform the person responsible for placing the preparation on the market.

**Free movement clause**

Member States may not prohibit, restrict or impede the placing on the market of dangerous preparations which satisfy the requirements of this Directive.

**Safeguard clause**

A Member State may provisionally prohibit the placing on the market of a dangerous preparation or subject it to special conditions in its territory, even if it complies with the provisions of this Directive.

The Member States shall inform the Commission and the other Member States immediately of the adoption of such a measure and the reasons for its decision. The Commission shall consult Member States as soon as possible before making its decision.

For more information click [here](#).

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### The Labelling

Any package must be clearly and indelibly marked with certain specific information such as:

- the trade name of the preparation;
- the name and contact details of the person responsible for placing it on the market;
- in general the chemical name of the substance or substances present in the preparation which have given rise to the classification of the preparation with regard to health hazards;
- the danger symbols and indications of danger, the risk phrases and the safety advice. Specific provisions concerning the presentation, format and wording of this information are laid down in Annexes II and VI to the [Directive 67/548/EEC](#).

Member States may require the labelling of a preparation to be produced in their official language(s).

Under certain very restricted conditions specified in Article 12 of the Directive, some dangerous preparations may be exempt from the general requirements on packaging and labelling. Henceforth, the labelling of these preparations may be optional or may differ from the
requirements laid down if the quantities present are so low that they do not present any hazard to users.

**Other Provisions**

*Procedure for adaptation to technical progress*

The amendments required to adapt the nine annexes to technical progress are adopted by the Commission with the assistance of a regulatory committee made up of representatives of the Member States and chaired by a representative of the Commission.

*Implementation*

This Directive shall be repealed with effect on 1 June 2015 by Regulation (EC) No 1272/2008 on the classification, labelling and packaging of chemicals and their mixtures.
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European Union, 2011

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Created by Ross Thomson, Highland Opportunity Ltd, Inverness, UK.

Special Thanks to
- Michelle Hardie
- Ilona Warburton
- Michelle Wemyss
- Highland Employer Coalition