ENGLISH

INTERNAL MARKET

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# A NEW COMMUNITY STANDARDS POLICY

**The new approach in harmonization**

**Motor vehicles**

**Tractors and agricultural machinery**

**Foodstuffs**

**Pharmaceutical products**

**Chemical products**

**Construction**

**Other areas**

**COMMISSION OF THE EUROPEAN COMMUNITIES**

Volume 4

JANUARY 1993

In June 1985, the Commission of the European Communities issued a White Paper on 'Completing the internal market', setting out a target for establishing a single European market in goods, services, people and capital by 1992.

The White Paper included a detailed legislative timetable containing over 300 measures and proposals.

In September 1992, the Commission issued its 'Seventh report on the implementation of the White Paper on completing the internal market'. This updated and modified the original legislative timetable contained in the White Paper.

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# A NEW COMMUNITY STANDARDS POLICY

## How to use this booklet

**This series of booklets sets out:**

(i) to inform the interested European public about the steps which are being taken to bring about the single market;

(ii) to summarize the approach which is being taken in individual business sectors;

(iii) to provide an initial guide to the content and current status of each proposal which the Commission has drafted with a view to completing the internal market.

**This booklet contains:**

(i) a brief description of how the Community makes laws;

(ii) a general introduction to the issues and problems arising in connection with the new Community standards policy;

(iii) specific introductions to the approach being taken towards Community standards;

(iv) a brief summary of each measure which has been adopted or proposed in the standardization field with a view to establishing a genuine internal market. Where a measure has been proposed but not yet adopted, the summary also gives details of the European Parliament's opinion and of the current status of the proposal. Where the measure has been adopted, the summary gives the deadline for implementing the legislation in the Member States, together with details of any follow-up work and of the implementing measures taken by the Commission.

**The reader should:**

(i) ensure he is familiar with how the Community makes laws and recommendations; if this is not the case, he should turn to page iii;

(ii) read the general introduction to services for an overview of the issues (page 1);

(iii) select from the contents (page vii) the section(s) which cover the sector(s) of interest.

The summaries provide references to the appropriate copies of the *Official Journal of the European Communities* for those readers wishing to examine measures in more detail. Copies of the Official Journal can be obtained from the sales offices listed inside the back cover.

**Note to the reader**

This publication provides a snapshot, as at 1 January 1993, of a situation which is evolving all the time. It was designed as a documentary tool and does not bind the Commission in any way.

# HOW THE EUROPEAN COMMUNITY MAKES LAWS
# AN OUTLINE

It is necessary to be familiar with the procedures by which the Community passes laws in order to understand the detail contained in the summaries. Each summary relates to a specific measure intended to facilitate the creation of the single market. In broad terms:

(i) the Commission (which has both executive and administrative roles) initiates and drafts a proposal which it submits to the Council;

(ii) the European Parliament (which is elected by the citizens of the Community) and the Economic and Social Committee (which consists of representatives from employer organizations, trade unions and other interest groups) consider and comment on the proposal;

(iii) the Council (whose members represent the governments of the Member States, normally at ministerial level) adopts the proposal which then becomes law. In some cases, this power can be exercised by the Commission.

This booklet contains summaries of different types of measures; their consideration and adoption can follow different procedures. These are discussed below.

## 1. LAWS AND OTHER MEASURES

### Regulations

A regulation is a law which is binding and directly applicable in all Member States without any implementing national legislation. Both the Council and the Commission can adopt regulations.

### Directives

A directive is an EEC law binding on the Member States as to the result to be achieved, but the choice of method is their own. In practice, national implementing legislation in the form deemed appropriate in each Member State is necessary in most cases. This is an important point as businesses affected by a directive have to take account of the national implementing legislation as well as the directive.

### Decisions

A decision is binding entirely on those to whom it is addressed. No national implementing legislation is required. The decisions summarized in this booklet are Council decisions although in certain cases the Commission has the power to adopt Commission decisions.

### Recommendations

A recommendation has no binding effect (it is not a law). Recommendations can be adopted by both the Council and the Commission.

The majority of the measures included in this booklet are Council directives.

## EEC legislation from start to finish (directives and regulations)

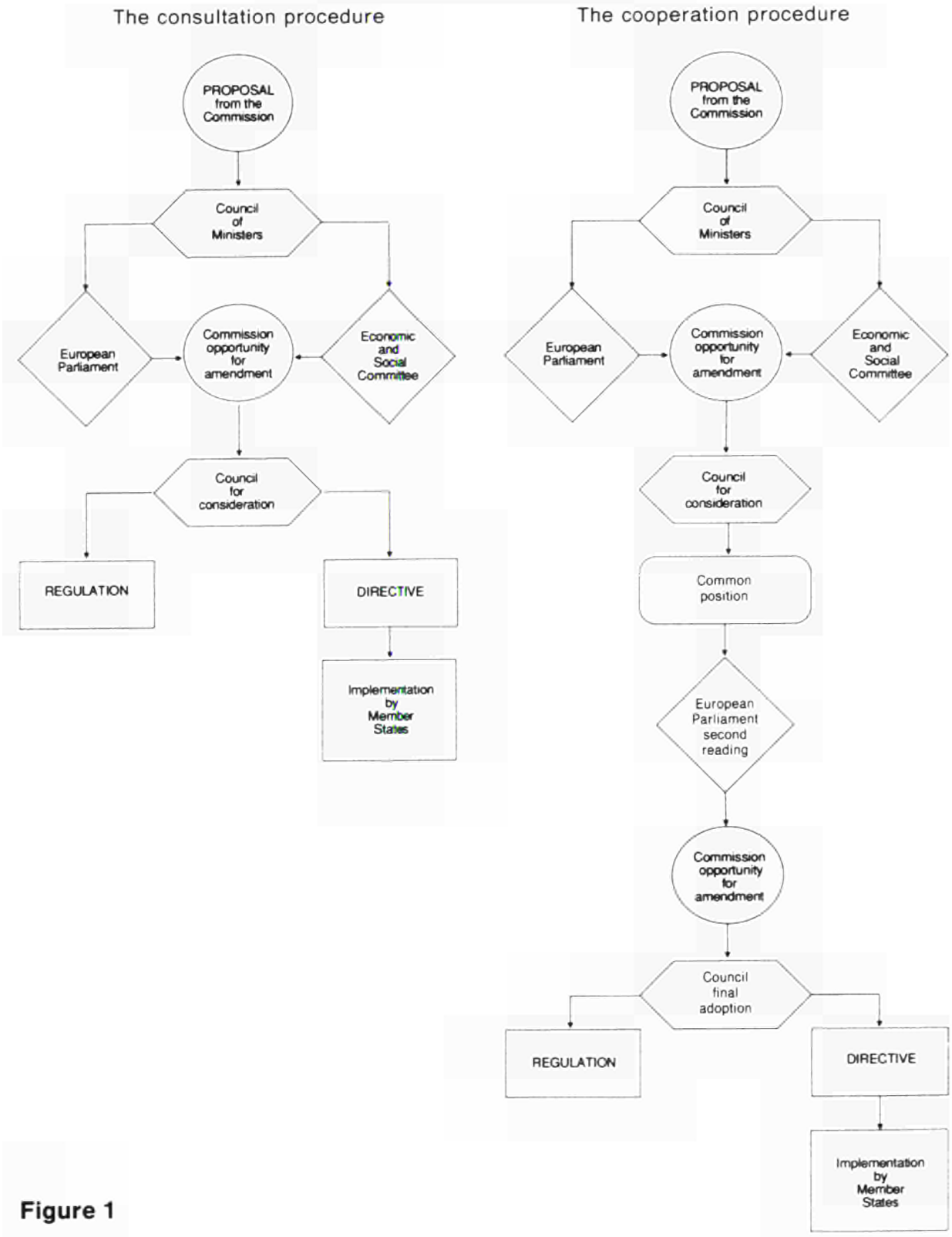


**Figure 1**

## 2. PROCEDURES FOR MAKING LAWS

The Community's decision-making procedures are best illustrated by tracing the progress of a directive. The following text should be read in conjunction with the flow chart in Figure 1.

Since the entry into force of the Single European Act on 1 July 1987 there are two distinct procedures for the adoption of a directive: the consultation procedure and the cooperation procedure. The EEC Treaty article upon which a proposal is based dictates which procedure is followed.

In both cases a directive begins with a proposal from the Commission to the Council.

Under the consultation procedure, the Council requests an opinion from the European Parliament and, in most cases, from the Economic and Social Committee. Once these have been given, the Commission then has the opportunity to amend the proposal if it so wishes. The proposal is then examined by the Council which may adopt it as proposed, adopt it in an amended form, or fail to reach agreement in which case the proposal remains 'on the table'.

Under the cooperation procedure, the Council requests opinions from the Parliament and the Economic and Social Committee in the same way. Once these opinions have been received the Council has to adopt what is called a common position, although it seems that the proposal will again remain on the table failing any common position being reached. On a common position being reached, this is transmitted to the Parliament which has three months to accept, reject, or propose amendments to it, on its second reading.

At this stage the Commission may again amend the proposal if it wishes. The proposal is then returned to the Council which has three months to take a final decision. In the absence of a decision, the proposal lapses.

Whether the Council can adopt a proposal by a qualified majority or has to reach a unanimous decision depends in the first instance upon the article of the Treaty which is the basis for the measure. However, there are certain situations where unanimity must be reached by the Council:

(i) to introduce amendments of its own initiative to a proposal;

(ii) to adopt amendments proposed by the Parliament but not taken up by the Commission;

(iii) to adopt a measure when the Parliament has rejected the Council common position under the cooperation procedure.

The question of whether a directive or a regulation is subject to the cooperation procedure, the consultation procedure or neither of these depends on its legal basis.

There are a limited number of decisions summarized in this booklet. The European Parliament and the Economic and Social Committee are consulted on some of these.

There are also a limited number of recommendations in this booklet. Some Council recommendations are submitted to the European Parliament and the Economic and Social Committee for their opinion before adoption.

## 3. PUBLICATION OF TEXTS

At certain stages in the Community decision-making procedure, texts are published in the *Official Journal of the European Communities*. There is an 'L' series which contains legislation and a 'C' series which contains other information, such as communications issued by the Commission.

This booklet contains summaries of both adopted legislation and proposals for legislation. In the case of adopted legislation, the summary gives the reference to the Official Journal 'L' series in which the text has been published. Readers interested in the legislative history of a measure will find in the text the Official Journal 'C' series references for the corresponding Commission proposal(s) and the opinions of the European Parliament and the Economic and Social Committee.

In the case of proposals for legislation, the summary gives the Offical Journal 'C' series references for the Commission proposal(s) and the opinions of the European Parliament and the Economic and Social Committee, if published by 31 December 1992.

# A NEW COMMUNITY STANDARDS POLICY

## INTRODUCTION



## 1. THE NEW APPROACH IN HARMONIZATION



## 2. MOTOR VEHICLES

## 5. PHARMACEUTICAL PRODUCTS



## 6. CHEMICAL PRODUCTS

## 7. CONSTRUCTION



## 8. OTHER AREAS

# INTRODUCTION

WHY HARMONIZATION OF TECHNICAL STANDARDS AND REGULATIONS?

## 1957 — Treaty of Rome

This was intended to create a single market across the European Community, based on the principle of the free movement of goods, persons, services and capital. In the particular case of goods, Article 30 of the Treaty prohibited not only quantitative restrictions on imports but also all measures having an equivalent effect.

Although a customs union was established very quickly and significant progress made with regard to the free movement of goods and persons, a number of administrative, physical and technical barriers continued to exist which prevented the creation of a genuine single market. In fact, Article 36 of the Treaty permits prohibitions or restrictions on the movement of goods if justified on certain grounds such as health protection, on condition that these grounds are not used as a means of arbitrary discrimination or disguised restrictions on trade. Whatever the justification for those barriers they nevertheless raised barriers to free movement which impeded the incorporation of the national markets into a single market.

## 1985 — White Paper

The continued maintenance of internal barriers perpetuated the costs and disadvantages of separate national markets. The need for substantial further action was realized. To this end, the Commission published a White Paper 'Completing the internal market' which listed some 282 legislative proposals and a timetable for their adoption; it was endorsed by the Heads of State or Government.

## 1987 — Single European Act

This Act, which amends the EEC Treaty, was ratified by the governments and parliaments of all Community countries, and confirmed the aim of achieving a single European market by 1992 and the timetable of the 1985 White Paper. It adapted the Community's decision-making procedures, and increased the scope for voting by a qualified majority (as opposed to unanimously) within the Council. The Single European Act has facilitated the adoption of the measures set out in the White Paper.

## 1993 — Current status

The entire legislative programme set out in the White Paper is being completed — and more. Only the proposal for a Directive laying down health standards for foodstuffs treated by ionizing radiation still needs to be adopted. From 1 January 1993 products may be thus moved within the Community either as a result of the mutual recognition of national rules or on the basis of certificates of conformity, marks of conformity, labels or marketing authorizations issued under harmonizations Directives.

## Technical standards and regulations

The rules, under the EEC Treaty, intended to remove barriers to the free movement of goods (customs duties, taxes having an equivalent effect, quantitative restrictions and measures having an equivalent effect, national monopolies, State aid and tax discrimination) do not in themselves enable the free movement of goods to be achieved within the Community.

Likewise, the principle of mutual recognition, according to which all products lawfully manufactured in a Member State must be accepted by the others is subject to the exception in Article 36 of the EEC Treaty (public morality, public policy or public security; the protection of health and life of humans, animals, etc.). Even where justified these disparities have an impact on the proper functioning of the internal market: they must thus be eliminated by means of harmonization.

Up to 1985 the Community removed those technical barriers by harmonizing technical product specifications. This led to the introduction of highly specific instruments, the content of which was highly technical in order to be able to meet the individual requirements of each product category. This approach had become more and more difficult to extend since it froze technical specifications without taking account of the diversity of production methods and because it made its own management increasingly complex as a result of technological innovation. In a communication dated 31 January 1985 the Commission therefore put a new approach concerning technical harmonization and standardization to the Council, which approved this in its resolution of 7 May 1985.

This new approach to harmonization is based on the following principle: directives, which are the main vehicles of harmonization in that they only lay down the aims to be achieved while leaving the Member States free to chose the most appropriate forms and methods needed for their useful implementation, are restricted to defining the essential requirements to be met while making the European standardization bodies responsible for devising the technical solutions enabling those aims to be achieved. The Council, acting on a qualified majority under Article 100a of the EEC Treaty, as introduced into the Treaty of Rome by the Single European Act, thus legislates via the 'reference back to standards' method.

The new approach thus offers advantages in terms of flexibility and transparency and enables a better balance to be struck between Community harmonization and national and mutual recognition, between the role of the lawmaker and that of the standardization bodies, between environmental and consumer protection and consumers' freedom of choice.

There are exceptions to this approach: firstly, areas closely associated with public-health protection such as that of pharmaceuticals, chemical products and foodstuffs. Exceptions are also formed by the areas in which equipment compatibility is an essential factor in free movement: this applies particularly to means of transport and telecommunications.

# 1. THE NEW APPROACH IN HARMONIZATION

## 1992 target: current position and outlook

The problems caused by the existence of different technical regulations and national standards within the Community have been recognized for many years, and much progress has been made in the removal of such barriers to trade.

However, to pave the way for completion of the internal market a series of measures have been taken to speed up the harmonization process.

1. Directive 83/189/EEC laying down a procedure for the provision of information

On 28 March 1983 the Council adopted Directive 83/189/EEC (Official Journal L 109, 26.4.1983) laying down a procedure for the provision of information in the field of technical standards and regulations.

In the case of technical regulations, the Member States are required to inform the Commission of all new draft technical regulations.

The Commission has been given the power to freeze introduction of these new regulations for up to one year if it decides that a Community measure is needed in the field in question.

On 1 November 1990 a procedure for exchanging information on draft technical regulations was introduced between the EEC and the countries in EFTA (the European Free Trade Association).

As regards standards, the information procedure requires the national standardization bodies to notify the Commission of their programmes and of all new draft national standards. The Directive provides for the involvement of other standardization bodies or, on request, for transfer of the drafts to European level. From the outset this information procedure has applied to all 18 members of the European committees for standards (CEN, Cenelec and ETSI).

Originally these two information procedures covered only industrial products. Now, however, they have been extended to all agricultural, food, cosmetics and medicinal products (summary 1.1).

2. New approach in technical harmonization.

On 7 May 1985 the Council adopted a resolution (Official Journal C 136, 4.6.1985) setting out a new approach to technical harmonization and to standardization. This resolution lays down the principles governing the approach then to be devised by the Community in order to achieve the '1992 internal market' programme for the removal of technical barriers, as set out in the White Paper (COM(85) 310 final).

The four fundamental principles on which the new approach is based are:

— the harmonization of laws is limited to the adoption of essential safety requirements (or other requirements in the general interest) which products put on the market must meet and which must therefore, as a matter of course, enjoy free movement throughout the Community;

— the task of drawing up the technical specifications needed for the production and placing on the market of products conforming to the essential requirements established by the Directives, while taking into account the current stage of technology, is entrusted to the competent standardization bodies;

— the technical specifications are not mandatory and maintain their status as voluntary standards;

— nevertheless, at the same time the national authorities are obliged to recognize that products manufactured in conformity with the harmonized standards (or, provisionally, with national standards) are presumed to conform to the 'essential requirements' established in the Directive. This leaves the producer the choice of not manufacturing in conformity with the standards, in which case, however, he has an obligation to prove that his products conform to the essential requirements of the Directive.

## 3. Harmonization measures adopted by the Community

The new approach has been applied to the following fields:

— pressure vessels (summary 1.2);
— toy safety (summary 1.3);
— machine safety (summaries 1.4 to 1.6);
— electromagnetic compatibility (summary 1.7); the relevant Directive was amended by another Directive in April 1992;
— non-automatic weighing instruments (summary 1.8);
— active implantable medical devices (summary 1.9); a more general Directive on medical devices was put forward in 1991 but has still not been adopted (summary 1.10);
— gas appliances (summary 1.11);
— personal protective equipment (summary 1.12);
— tests and certificates: conformity assessment procedures (summary 1.13);
— lifts powered hydraulically or oil-electrically (summary 1.14); a more general Directive on lifts was put forward during 1992 and is in the process of adoption (summary 1.15);
— electrical equipment for use in potentially explosive atmospheres (summary 1.16); this Directive has been supplemented by a proosal on protective devices and systems that is currently before the Council for adoption (summary 1.17).

Measures have been proposed on:

— pleasure craft (summary 1.19);
— an EC mark of conformity: the Commission has proposed that the Council adopt a regulation aimed at laying down a single system for the affixing of the EC mark to industrial products in order to facilitate the free movement of those products (summary 1.18).

## 4. European standardization bodies

CEN (European Standardization Committee)
Rue de Stassart 36
B-1050 Brussels
Tel.: (32) 2 519 68 11
Fax: (32) 2 519 68 19

Cenelec (European Committee for Electrotechnical Standardization)
Rue de Stassart 35
B-1050 Brussels
Tel.: (32) 2 519 68 71
Fax: (32) 2 519 69 19

ETSI (European Telecommunications Standards Institute)
Boîte postale 152
F-Cedex 06561 Valbonne
Tel.: (33) 92 94 42 00
Fax: (33) 93 65 47 16

5. National standardization bodies

Aenor (Spain)
Asociación española de normalización y certificación
Fernández de la Hoz 52
E-28010 Madrid

Afnor (France)
Association française de normalisation
Tour Europe — Cédex 7
F-92049 Paris La Défense

UTE (France)
Union technique de l'électricité
Cédex 64
F-92052 Paris La Défense

BSI (United Kingdom)
British Standards Institution
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BEC (United Kingdom)
British Electrotechnical Committee
British Standards Institution
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DS (Denmark)
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ITM (Luxembourg)
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SEE (Luxembourg)
Service de l'énergie de l'Etat
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ETCI (Ireland)
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CEI (Italy)
Comitato Elettrotecnico Italiano
Viale Monza 259
I-20126 Milano

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.1. Extension of information procedures on standards and technical rules

*(1) Objective*

To strengthen the principles underlying the information provision procedure, i.e. to improve the transparency of new technical specifications at national level and to provide discipline for joint action.

*(2) Community measures*

Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations.

Council Directive 88/182/EEC of 22 March 1988 amending Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations.

*(3) Contents*

1. This measure defines terms such as 'technical specification', 'standard', 'standardization programme', 'draft standard', 'technical regulation' and 'draft technical regulation'. The procedure for the provision of information on technical standards and regulations applies to any industrially manufactured product and to agricultural products, foodstuffs, medicinal products and cosmetics.
2. Where standards are concerned, the Directives create the conditions for transparency and cooperation between national standards institutions and constitute the legal framework for cooperation between European standards institutions and the Community. Thus they require national standards institutions to inform one another of their work programmes; they lay down certain fundamental rights and obligations (such as the right to participate in the work of the other institutions, the right to request the drafting of a European rather than a national standard, etc.); they allow the Commission to instruct institutions to draw up European standards and they provide the instrument whereby European standards institutions are recognized.
3. The Directives are intended to prevent the creation of new barriers to trade by imposing on all Member States an obligation to take the necessary steps (to communicate information, to publish draft standards, to prevent national standards institutions from taking any action which might prejudice the desired harmonization).
4. Where technical regulations are concerned, the Directives give the Commission and the Member States the power to delay the introduction of these new regulations for six months if they consider that barriers to trade may be created, and up to one year if the Commission decides that they should be replaced by a Community initiative. A proposal for a Community measure has been presented to the Council.
5. However, a Member State may derogate from the obligations imposed upon it by these Directives should an emergency arise from a serious and unforeseeable situation relating to the protection of public health or safety, or the protection of animals or plants, such that technical regulations must be prepared in a very short space of time in order to enact and introduce them immediately, without any consultations being possible.

6. Every two years the Commission is to send Parliament and the Economic and Social Committee a report on the implementation of this Directive and must regularly publish in the *Official Journal of the European Communities* a list of the titles of the draft technical regulations of which it has been notified.

*(4) Deadline for implementation of the legislation in the Member States*

— Directive 83/189/EEC: 31.3.1984
— Directive 88/182/EEC: 1.1.1989

*(5) Date of entry into force (if different from the above)*

*(6) References*

Official Journal L 109, 26.4.1983
Official Journal L 81, 26.3.1988

*(7) Follow-up work*

On 27 November 1992 the Commission presented a proposal for a Council Directive amending for the second time Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations (COM(92) 491 final, Official Journal C 340, 23.12.1992).

The Commission proposes a basic instrument to ensure the correct functioning of the internal market while increasing transparency by extending and making more explicit the scope of Directive 83/189/EEC, by clarifying some concepts and rules of procedure and by providing fuller information for economic operators.

*(8) Commission implementing measures*

Commission Decision of 3 May 1990 amending the lists of standards institutions contained in the annex to Directive 83/189/EEC.

On 5 April 1991 the Commission presented a report on the implementation of Directive 83/189/EEC in 1988 and 1989 (COM(91) 102 final).

On 11 December 1992 the Commission adopted a report on the implementation of Directive 83/189/EEC in 1990 and 1991 (COM(92) 565 final).

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.2. Simple pressure vessels

*(1) Objective*

To ensure an appropriate level of safety throughout the Community for simple pressure vessels.

*(2) Community measures*

Council Directive 87/404/EEC of 25 June 1987 on the harmonization of the laws of the Member States relating to simple pressure vessels.

Council Directive 90/488/EEC of 17 September 1990 amending Directive 87/404/EEC on the harmonization of the laws of the Member States relating to simple pressure vessels (measures relating to the transitional period).

*(3) Contents*

1. This Directive applies to simple pressure vessels manufactured in series, i.e. any simple welded vessel of non-alloy quality steel, non-alloy aluminium or non-age hardening aluminium alloys subjected to an internal gauge pressure greater than 0.5 bar which is intended to contain air or nitrogen and which is not intended to be fired. Vessels specifically designed for nuclear use, or for installation in or the propulsion of ships and aircraft, and fire extinguishers are excluded from the scope of the Directive.
2. Vessels must conform with certain safety requirements to qualify for marketing authorization, e.g. the pressurized parts must be capable of being welded; when designing a vessel the manufacturer must define its use and select maximum and minimum working temperatures and maximum working pressure; parts must be of a minimum thickness, etc.
3. If a vessel bears the EC mark Member States have to presume compliance with the essential safety requirements (see summary 1.18 regarding the EC mark of conformity).
4. Prior to production of the vessels the manufacturer can:
— either, if he has chosen a design in line with the harmonized standards, request certification of the design and manufacturing schedule;
— or submit a prototype vessel for EC type-examination.
If the prototype satisfies the criteria for the EC type-examination, which must be carried out by an approved inspection body, an EC type-examination certificate is issued.
5. EC verification that series-manufactured vessels conform with the standards or with the approved prototype is carried out on batches of vessels submitted by the manufacturer. The aim of the tests is to ensure compliance and to check that the EC mark is affixed to complying vessels. When the product of pressure and capacity is less than or equal to 3 000 bar/litre the manufacturer may choose the 'EC declaration of conformity' procedure instead of EC verification. In this case it shall be subject to 'EC surveillance' by the approved body when the product of pressure and capacity is over 200 bar/litre.
6. If an EC mark is wrongly affixed then the body responsible for EC surveillance must report to the Member State concerned and, where appropriate, withdraw the EC type-examination certificate.
7. The EC mark must be visible, easily legible and indelible. Any other mark or inscription which is likely to be confused with it is prohibited.

8. The Directive establishes a transitional period ending on 1 July 1992, during which time Member States must permit the placing on the market and/or placing in service of vessels conforming to the rules in force in their territories before 1 July 1990.

*(4) Deadline for implementation of the legislation in the Member States*

— 1.1.1990
— 1.7.1991 for measures relating to the transitional period.

*(5) Date of entry into force (if different from the above)*

1.7.1990

*(6) References*

Official Journal L 220, 8.8.1987
Official Journal L 270, 2.10.1990

*(7) Follow-up work*

*(8) Commission implementing measures*

Communication — Official Journal C 104, 24.4.1992
Commission communication publishing the titles and references of harmonized standards under Council Directive 87/404/EEC relating to simple pressure vessels as amended by Council Directive 90/448/EEC.

Communication — Official Journal C 328, 12.12.1992
Commission communication in the framework of the implementation of Council Directive 87/404/EEC on simple pressure vessels, as amended by Directive 90/448/EEC. Publication of titles and references of harmonized standards under the Directive.

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.3. Toy safety

*(1) Objective*

To harmonize the safety regulations on toys throughout the Community in order to protect child health and facilitate trade.

*(2) Community measures*

Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys.

*(3) Contents*

Toys are one of the few product categories for which essential requirements have been adopted.

1. For the purpose of the Directive a toy is defined as any product or material designed or clearly intended for use in play by children of less than 14 years of age. Several products are, however, not regarded as toys for the purposes of the Directive, including Christmas decorations, fireworks, playground equipment, and sports equipment.
2. Toys may be placed on the market only if they do not jeopardize the health and/or safety of users or third parties. The essential safety requirements are defined in an annex.
3. The Member States may not impede the placing on the market in their territory of toys which satisfy the provisions of the Directive. All toys bearing the EC mark (see summary 1.18 regarding the mark of conformity) are presumed to comply with the essential requirements set out in Annex II to the Directive.
4. If a Member State ascertains that a toy bearing the EC mark is likely to jeopardize the safety or health of consumers and/or third parties, it must take all appropriate measures to withdraw it from the market and must inform the Commission immediately.
5. Before being marketed, toys manufactured in accordance with the harmonized standards or conforming with the approved model must have an EC mark attached to them by the manufacturer or his authorized representative established within the Community.
6. The manufacturer, his representative in the Community or, if neither is established in the Community, the person who places the toy on the Community market shall keep information on the product available for inspection, e.g. product design and manufacture details, EC type-certificates, etc. The authorities shall ensure the confidentiality of this information.
7. Provision for the establishment of approved bodies to carry out the EC type-examination.
8. Procedure for EC-type examination and certification of a product.
9. Member States are required to take the necessary measures to ensure that random checks are performed to make sure that toys comply with the Directive.
10. The EC mark and the name and address of the manufacturer, his representative or the importer into the Community must be visible, easily legible and indelible. Any inscription likely to be confused with the EC mark is prohibited. The EC mark shall consist of the symbol 'EC'.
11. Where the Commission or a Member State considers that the harmonized standards do not meet the essential requirements of the Directive, it must refer the matter to the Standing Committee.

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| | 12. The annexes contain detailed essential health and safety requirements for toys. For example, parts of toys for use by children under 36 months should not be of a size so that they can be easily swallowed; toys intended for use in water should be designed to reduce any risks of the toy sinking; toys should be made only of materials that are not readily flammable; they should not contain dangerous substances which are used to operate the toy (except chemical toys); they must not be explosive, etc.<br>13. The annexes also contain conditions to be fulfilled by the approved bodies (e.g. technically qualified personnel must carry out the relevant tests), and precautions to be taken when using toys (e.g. toys must be accompanied by appropriate clearly legible warnings to reduce inherent risks in their use). | |
| *(4) Deadline for implementation of the legislation in the Member States* | 30.6.1989 | |
| *(5) Date of entry into force (if different from the above)* | 1.1.1990 | |
| *(6) References* | Amending opinion | Official Journal L 187, 16.7.1988<br>Official Journal L 37, 9.2.1991 |
| *(7) Follow-up work* | | |
| *(8) Commission implementing measures* | List of approved bodies published in the *Official Journal of the European Communities* to date:<br>— Official Journal C 154, 23.6.1990<br>— Official Journal C 162, 3.7.1990<br>— Official Journal C 278, 6.11.1990<br>— Official Journal C 34, 9.2.1991<br>— Official Journal C 68, 16.3.1991<br>— Official Journal C 264, 10.10.1991<br>— Official Journal C 272, 17.10.1991<br>— Official Journal C 279, 26.10.1991<br>— Official Journal C 282, 29.10.1991<br>— Official Journal C 25, 1.2.1992<br>— Official Journal C 264, 13.10.1992 | |

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.4. Machine safety

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| *(1) Objective* | To harmonize the design and manufacture of machinery so as to ensure the safety of workers and other people using machinery. |
| *(2) Community measures* | Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery. |
| *(3) Contents* | 1. The Directive applies to machinery and lays down essential health and safety requirements. Machinery means a powered assembly with mechanically linked parts of which at least one is movable. Certain types of machinery are excluded from the scope of this measure.<br>2. Member States must take all appropriate measures to ensure that machinery is marketed and used only if it complies with the Directive, that is if it does not endanger the health or safety of persons, domestic animals or property.<br>3. Member States may not prohibit, restrict or hinder the marketing and use on their territory of machines which comply with the Directive. Machines bearing the EC mark (see summary 1.18 regarding the EC mark of conformity) and accompanied by the EC declaration of conformity must be considered to be compatible with the essential health and safety requirements.<br>4. Where a Member State or the Commission considers that the harmonized standards do not fully satisfy the essential health and safety requirements specified in Annex I, the Commission or the Member State will refer the matter to the Standing Committee which must deliver an opinion without delay. The Commission will then notify Member States whether or not it is necessary to withdraw the standards concerned from the relevant publications.<br>5. Where a Member State ascertains that a machine bearing the EC mark is liable to endanger the safety of persons, domestic animals or property, it must take all the measures necessary to withdraw it from the market. The Member State will then inform the Commission of its action and the reason for its decision.<br>6. In order to certify machinery in accordance with the essential requirements laid down in the annexes to the Directive, the manufacturer must draw up documentation including a technical construction file composed of overall drawings and detailed drawings, etc. When the machinery conforms to the requirements the manufacturer will issue an EC declaration of conformity.<br>7. The EC mark will consist of the symbol 'EC'.<br>8. A more stringent certification procedure is applied to categories of machinery regarded as potentially more hazardous and dangerous.<br>9. Annexes containing the essential health and safety requirements, an EC declaration of conformity form and a model EC mark. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.1.1992 |

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| *(5) Date of entry into force (if different from the above)* | 1.1.1993 |
| *(6) References* | Official Journal L 183, 29.6.1989 |
| *(7) Follow-up work* | See summaries 1.5 and 1.6.<br>The Commission will also be submitting a proposal for a Directive on second-hand machinery. |
| *(8) Commission implementing measures* | The Commission has published a communication pursuant to Council Directive 89/392/EEC on machinery, as amended by Directive 91/368/EEC (Official Journal C 271, 20.10.1992).<br>This communication contains a list of bodies notified by France to carry out type-examinations under the Directive. |

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.5. Machine safety: mobile machinery and lifting appliances

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| *(1) Objective* | To ensure protection at the workplace against risks associated with mobile machinery and lifting appliances. |
| *(2) Community measures* | Council Directive 91/368/EEC of 20 June 1991 amending Council Directive 89/392/EEC on the approximation of the laws of the Member States on machinery. |
| *(3) Contents* | 1. This Directive concerns the following machinery: machinery creating a hazard as a result of its mobility (i.e. stand-alone mobile machinery and more complex systems such as machinery that is self-propelled, drawn, pushed or carried by other mobile machinery or a tractor), and machinery capable of raising loads comprising not only the independent lifting apparatus but also more complex systems.<br>2. Cancellation, with effect from 31 December 1994, of Directives 73/361/EEC (in part), 76/434/EEC, and with effect from 31 December 1995, Directives 86/295/EEC, 86/296/EEC, 86/663/EEC and 89/240/EEC.<br>3. Annex 1 to this Directive first lays down essential health and safety requirements to reduce the specific hazards arising from the mobility of the machinery. Safety requirements are then laid down for the workplace, the controls and indicators, and measures to protect against mechanical and other hazards are defined.<br>4. Annex 1 of the present Directive also lays down essential health and safety requirements to reduce the specific hazards inherent in lifting operations. These requirements refer first to general protection measures and then to appliances driven by a source of energy other than human power and to marking and the instruction manual. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.1.1992 |
| *(5) Date of entry into force (if different from the above)* | 1.1.1993 |
| *(6) References* | Official Journal L 198, 22.7.1991<br>Amended opinion — Official Journal L 305, 6.11.1991 |
| *(7) Follow-up work* | See summary 1.6. |
| *(8) Commission implementing measures* | The Commission has published a communication pursuant to Council Directive 89/392/EEC on machinery, as amended by Directive 91/368/EEC (Official Journal C 271, 20.10.1992).<br>This communication contains a list of bodies notified by France to carry out type-examinations under the Directive. |

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.6. Machine safety: appliances for lifting persons

*(1) Objective*

To ensure protection at the workplace against risks associated with machinery for lifting persons.

*(2) Proposal*

Proposal for a Council Directive amending Directive 89/392/EEC on the approximation of the laws of the Member States relating to machinery.

*(3) Contents*

1. This Directive concerns machinery specifically designed for lifting persons (elevating platforms used for the maintenance of facades of buildings, elevating platforms fitted on lorries, etc.) as well as machinery which, while not designed primarily for lifting persons, nevertheless causes the operator to be lifted in the course of the machine operations.
2. Machinery which entails the risk of falling from a height of more than 3 metres as well as machines for the manufacture of pyrotechnics and certain safety components (ROPs, FOPs, electronically sensitive devices to detect persons, etc.) are required to undergo an EC type-examination. The EC declaration of conformity procedure whereby the manufacturer states that the machinery placed on the market complies with all essential health and safety requirements applies to machinery which is not already mentioned above.
3. This Directive supplements Directive 89/392/EEC on machine safety (summary 1.4) as amended by Directive 91/368/EEC on the safety of mobile machinery and lifting appliances (summary 1.5).

*(4) Opinion of the European Parliament*

First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted all of the amended proposals.

*(5) Current status*

The Council adopted a common position on 17 December 1992. Under the cooperation procedure this is now before Parliament for a second reading.

*(6) References*

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| Commission proposal<br>COM(91) 547 final | Official Journal C 25, 1.2.1992 |
| Amended proposal<br>COM(92) 363 final | Official Journal C 252, 29.9.1992 |
| European Parliament opinion<br>First reading | Official Journal C 241, 21.9.1992 |
| Economic and Social<br>Committee opinion | Official Journal C 223, 31.8.1992 |

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.7. Electromagnetic compatibility

*(1) Objective*

To harmonize national provisions on electromagnetic disturbance levels by establishing protection requirements and referring the task of defining the characteristics of the products to European or national standards.

*(2) Community measures*

Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility.

Council Directive 92/31/EEC of 28 April 1992 amending Directive 89/336/EEC on the harmonization of the laws of the Member States relating to electromagnetic compatibility.

*(3) Contents*

*Directive 89/336/EEC*

1. The Directive applies to a wide sweep of equipment including in the widest sense all electrical apparatus, equipment and installations, including vehicles, electricity, transport and telecommunications distribution and transport networks, likely to cause or be affected by electromagnetic disturbance. The annex to the Directive includes a list of the equipment covered by the Directive and equipment not covered.
2. Definitions of the terms 'apparatus', 'electromagnetic disturbance', 'commissioning', 'immunity', 'electromagnetic compatibility', etc.
3. The apparatus shall be so constructed that:
— the electromagnetic disturbance it generates does not exceed a level allowing radio and telecommunications equipment and other apparatus to operate as intended;
— the apparatus has an adequate level of intrinsic immunity to electromagnetic disturbance.
4. The protection requirements as described above are drawn up in objective terms, whereas the limit values and the methods of measurement must be given in harmonized standards.
5. The Directive provides for three assessment procedures for the conformity of apparatus:
— a procedure for apparatus for which the manufacturer has applied harmonized standards (Article 10(1));
— a procedure for apparatus for which the manufacturer has not applied, or has applied only in part, the harmonized standards, or where standards do not exist (Article 10(2));
— a procedure for apparatus designed for the transmission of radio communications (Article 10(5)).
6. The Directive refers to three bodies with different functions:
— competent authorities, represented by the national administrations, which are responsible for the application of the relevant obligations;
— competent bodies, which meet the criteria listed in the Directive and which are responsible for issuing the technical reports or certificates in accordance with the second procedure described in point 5;
— notified bodies which meet the criteria listed in the Directive and which are responsible for issuing the EC type-examination certification in accordance with the third procedure described in point 5.

7. Recognized competent bodies are recommended to have themselves notified to the Commission which will publish a list of names and addresses. In the case of notified bodies, the list must be communicated by the Member States to the Commission.
8. All apparatus covered by the Directive and accompanied by one of the attestations provided for must bear the EC conformity mark (see summary 1.18 regarding the EC mark of conformity). Arrangements for the marking of products; for example, the mark is affixed by the manufacturer (or his authorized representative) on the apparatus or else to the packaging, the instructions for use or the guarantee certificate.
9. The Directive contains a safeguard clause: any measure taken by a State to withdraw from the market or restrict the free movement of an apparatus accompanied by one of the means of attestation provided for in the Directive and bearing the EC mark must immediately be notified to the Commission. This notification shall be followed by a consultation procedure between the Commission and the parties concerned. The Commission shall inform the Member States of the results forthwith.

*Directive 92/31/EEC*
This Directive introduces a transitory period up to 31 December 1995 during which the placing on the market of apparatus manufactured under Directive 89/336/EEC in accordance with national regulations in force on 30 June 1992 is authorized.

*(4) Deadline for implementation of the legislation in the Member States*

— Directive 89/336/EEC: 1.7.1991
— Directive 92/31/EEC: 1.8.1992

*(5) Date of entry into force (if different from the above)*

1.1.1992

*(6) References*

Official Journal L 139, 23.5.1989
Official Journal L 126, 12.5.1992

*(7) Follow-up work*

A Commission communication in the framework of the implementation of the 'new approach' Directives was published on 19 February 1992 (Official Journal C 44, 19.2.1992).
It concerned the publication of titles and references of European harmonized standards presumed to comply with one or more of the protection requirements laid down in Directive 89/336/EEC.
This communication has been supplemented by a Commission communication in the framework of the implementation of Council Directive 89/336/EEC (Official Journal C 90, 10.4.1992), which publishes the titles and references of harmonized standards under Directive 89/336/EEC.

A Commission communication forming part of the implementation of Directive 89/336/EEC was published on 24 November 1992 (Official Journal C 306, 24.11.1992).

The communication publishes, for information purposes, a list of the bodies in Denmark, Germany, Italy and the United Kingdom identified in pursuance of Directive 89/336/EEC.

*(8) Commission implementing measures*

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.8. Non-automatic weighing instruments

*(1) Objective*

To set the essential metrological and performance requirements necessary to guarantee effective protection for users and consumers and to lay down certification rules and procedures.

*(2) Community measures*

Council Directive 90/384/EEC, of 20 June 1990 on the harmonization of the laws of the Member States relating to non-automatic weighing instruments.

*(3) Contents*

1. Definitions of 'weighing instrument' and 'non-automatic weighing instrument'.
2. The Directive applies to all non-automatic weighing instruments. Instruments designed for the following uses:
— determination of weight for commercial transactions;
— determination of weight for a toll, tariff, tax, bonus, penalty, payment, indemnity or similar fee;
— determination of weight for the application of legislative or regulatory provisions: legal opinions by experts;
— determination of weight in the course of medical practice, i.e. weighing of patients for the purpose of health monitoring, diagnosis and medical treatment;
— determination of weight for the purpose of making up prescriptions in the pharmacy and determination of weight during analyses carried out in medical and pharmaceutical laboratories;
— determination of prices as a function of weight for direct sales to the public and in the making-up of prepackaged products,
must satisfy the essential requirements set out in Annex 1 to the Directive and must bear the EC conformity mark (see summary 1.18 regarding the EC mark of conformity).
3. Member States must ensure that only those instruments complying with the provisions of the Directive may be placed on the market.
4. Member States shall not impede the placing on the market and the putting into service of instruments meeting the provisions of the Directive. Member States shall presume that instruments complying with national standards implementing the harmonized standards that meet the essential requirements are in conformity with these requirements. Publication of standards. Procedures in the case of non-compliance with the Directive, examination by the Commission and consultation with a standing committee. Provision for withdrawal in cases where the EC mark has been affixed to instruments not conforming to the relevant essential requirements.
5. Instruments for which compliance with the essential requirements is mandatory must undergo an EC type-examination, followed by either an EC declaration of production conformity or EC verification. Instruments which do not employ electronic devices and in which the load-measuring device does not use a spring to balance the load do not need to undergo an EC type-examination. If manufacturers so wish, these procedures may also be applied to instruments for which compliance with the essential requirements is not mandatory. Instruments normally designed for specific applications and for which

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| | compliance with the essential requirements is mandatory must undergo EC unit verification.<br>6. Provision for control of instruments in service, reverification, etc.<br>7. Annexes to the Directive including essential metrological requirements, essential design and construction requirements, details of an EC type-examination, type conformity declaration, EC verification, EC unit verification, technical documentation relating to the project, minimum criteria to be applied in designating the bodies notifed, EC conformity mark and other inscriptions on instruments. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.7.1992 |
| *(5) Date of entry into force (if different from the above)* | 1.1.1993 |
| *(6) References* | Official Journal L 189, 20.7.1990 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.9. Active implantable medical equipment

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| *(1) Objective* | To harmonize and improve the standard of safety to be met by active implantable electromedical devices used in human medicine. |
| *(2) Community measures* | Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical equipment. |
| *(3) Contents* | 1. Definitions of 'medical device', 'active implantable medical device', 'made-to-measure device', 'device intended for clinical investigations', 'destination', 'placing in service'.<br>2. Member States shall not impede the placing on the market, the free movement and the implantation of devices which meet the essential safety requirements specified in the annex and which bear the EC mark (see summary 1.18 regarding the EC mark of conformity). Marketing and implantation of devices without the EC mark will be permitted where the device is intended for clinical evaluation or is a prototype intended for research purposes.<br>3. Obligation on Member States to publish national standards implementing the relevant harmonized standards. Member States shall presume that devices complying with the abovementioned harmonized standards comply with the Directive's essential safety requirements. Provisions for those devices and national standards considered not to meet the essential health and safety requirements; consultation with a standing committee and withdrawal of a product from the market or of a standard. Requirement that, as soon as he becomes aware of any such situation as a result of applying technical/monitoring procedures, the manufacturer shall inform the competent authorities of any incident leading to the death or a deterioration in the state of health of the patient.<br>4. Devices shall be subject to a conformity assessment procedure. Member States shall designate bodies responsible for such procedures.<br>5. Annexes containing essential safety requirements for devices, EC type-examination, EC verification, EC declaration of conformity to type, declaration on special-purpose devices, clinical assessment, minimum criteria governing the appointment of the bodies to be notified, copy of the EC conformity mark. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.7.1992 |
| *(5) Date of entry into force (if different from the above)* | 1.1.1993 |

*(6) References*

*(7) Follow-up work*

*(8) Commission implementing measures*

Official Journal L 189, 20.7.1990

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.10. Medical devices

*(1) Objective*

To harmonize the conditions for placing on the market and putting into service medical devices in order to create the same basis for the protection of the health and safety of patients and users throughout the Community.

*(2) Proposal*

Proposal for a Council Directive concerning medical devices.

*(3) Contents*

1. This proposal for a Directive applies to medical devices and accessories, excluding devices used for *in-vitro* diagnosis and the active implantable devices covered by Directive 90/385/EEC (summary 1.9).
2. It contains definitions of terms such as 'medical device', 'custom-made device', 'device intended for clinical investigation', 'implantable device', 'manufacturer', 'intended purpose', 'bioavailability', etc.
3. The Member States will take all necessary steps to ensure that devices may be placed on the market and put into service only if they in no way compromise the safety and health of patients, users and other persons when properly installed, maintained and used in accordance with their intended purpose.
4. Such devices must meet the essential design and construction requirements set out in Annex 1, particularly with regard to the choice of materials used and the incompatibility with biological tissues and cells, in order to minimize the contamination risk to persons involved in the transport, storage and use of the devices and to patients.
5. The Member States will presume that devices which conform with the national standards implementing the relevant existing harmonized standards comply with the essential requirements. The Member States must publish the references of the national standards implementing the abovementioned harmonized standards.
6. The Member States may create no obstacles to the placing on the market or the putting into service of devices bearing the EC mark (see summary 1.18 regarding the EC mark of conformity). Similarly, they may create no obstacles to devices which do not bear the EC mark but are intended for clinical investigation and use by authorized persons or to custom-made devices meeting the conditions laid down in this proposal.
7. All devices placed on the market, other than custom-made devices or devices intended for clinical investigations, must bear the EC mark of conformity.
8. Any Member State which ascertains that devices complying with the proposal could compromise the health and/or safety of patients, users or other persons must take all appropriate measures to withdraw such devices from the market and must inform the Commission of any such interim measures.
9. Exact reasons must be given for all decisions to refuse or restrict the placing on the market or the putting into service of a device or the carrying out of clinical investigations or to withdraw devices from the market. Such decisions must be notified to the party concerned who must be informed of the remedies available and of the time-limits for them.

10. The proposal provides for the establishment of a Committee on Standards and Technical Regulations and a Committee on Medical Devices to assist the Commission.

*(4) Opinion of the European Parliament*

First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments.

*(5) Current status*

On 17 December 1992 the Council reached political agreement on a common position. Formal adoption of this common position is scheduled for the next meeting.

*(6) References*

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| Commission proposal<br>COM(91) 287 final | Official Journal C 237, 12.9.1991 |
| Amended proposal<br>COM(92) 356 final | Official Journal C 251, 28.9.1992 |
| European Parliament opinion<br>First reading | Official Journal C 150, 15.6.1992 |
| Economic and Social Committee opinion | Official Journal C 79, 30.3.1992 |

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.11. Gas appliances

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| *(1) Objective* | To ensure a single Community market in appliances burning gaseous fuels by laying down the essential safety requirements and type-approval rules. |
| *(2) Community measures* | Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to gas appliances. |
| *(3) Contents* | 1. This Directive applies to:<br>— appliances burning gaseous fuels and used for cooking, heating, hot water production, refrigeration, lighting and washing, hereinafter referred to as 'appliances'; burners using air under pressure and heating units fitted with such burners are treated as appliances;<br>— safety and control devices and subassemblies other than burners using air under pressure and heating units fitted with such burners, hereinafter referred to as 'equipment'.<br>2. Appliances designed specifically for use in an industrial process are excluded from the scope of the Directive.<br>3. Definitions of 'gaseous fuel' and of 'appliance under normal conditions of use'.<br>4. Member States must ensure that the appliances specified are only placed on the market or brought into service on condition that they do not jeopardize the safety of persons, domestic animals or property.<br>5. The appliances and equipment must satisfy the essential requirements stipulated in Annex I.<br>6. Member States must not prohibit, restrict or impede the placing on the market or the putting into service of appliances which satisfy the essential requirements set out in point 5 above.<br>7. If a Member State finds that, under normal conditions of use, an appliance fitted with an EC mark (see summary 1.18 regarding the EC mark of conformity) poses a risk to the safety of persons, domestic animals or property, it shall take all the steps necessary to have the appliance withdrawn or to prohibit or restrict the placing on the market of such an appliance. The Member States shall forthwith notify the Commission of these measures.<br>8. Member States shall presume that all appliances and equipment conforming to the national standards implementing the relevant harmonized standards comply with the essential requirements.<br>9. Obligation on Member States to publish national standards implementing the relevant harmonized standards and to communicate these to the Commission.<br>10. Annexes containing details of essential requirements, procedures for attestation of conformity, use of the EC mark, etc. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.7.1991 |
| *(5) Date of entry into force (if different from the above)* | 1.1.1992 |

*(6) References*

*(7) Follow-up work*

*(8) Commission implementing measures*

Official Journal L 196, 26.7.1990

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.12. Personal protective equipment

*(1) Objective*

To remove barriers to trade between Member States in personal protective equipment (PPE) by harmonizing basic requirements for the design, manufacture, testing and certification of these goods, while maintaining the highest possible level of safety.

*(2) Community measures*

Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the design of personal protective equipment.

*(3) Contents*

1. PPE means any device or appliance designed to be worn or held by an individual for protection against one or more safety and health hazards. The Directive applies to all PPE intended for professional and private use (sport, leisure, domestic use) except PPE covered by another Directive with the same objectives and PPE specifically referred to in Annex I.
2. This Directive, which runs parallel to the Directive dealing with the choice and use of PPE at the workplace, does not contain detailed design and manufacturing provisions but defines the basic safety requirements which the PPE must meet.
3. It defines the general requirements applicable to all PPE, additional requirements specific to certain types of PPE (e.g. equipment to protect eyes must not restrict the field of vision) and also additional requirements specific to particular risks.
4. Basic safety requirements may be satisfied either by national standards which implement harmonized standards, or by other technical specifications assessed by an approved inspection body as giving equivalent protection.
5. The harmonized standards may be changed should a Member State consider that they do not meet the Directive's basic safety requirements.
6. EC type-approval of product models prior to manufacture will be required for most PPE, although a simple declaration of the manufacturer is sufficient for PPE providing protection against minimal risks. However, in the case of PPE providing protection against lethal risks, the basic procedure is supplemented by a surveillance of the production.
7. Member States may not hinder the marketing of PPE or PPE components bearing the EC mark (see summary 1.18 regarding the EC mark of conformity). Any such PPE will be presumed to satisfy basic safety requirements. However, Member States may order any PPE to be withdrawn from the market if it threatens safety, provided that they inform the Commission. Member States will be informed immediately of the outcome of such consultations.
8. Member States will ensure that both sides of industry may contribute to the process of standardization at national level.
9. The EC conformity mark consists of the letters 'CE' followed by the last two figures of the year in which the EC mark is affixed and the number of the approving body, if any.

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| *(4) Deadline for implementation of the legislation in the Member States* | 31.12.1991 |
| *(5) Date of entry into force (if different from the above)* | 1.7.1992 |
| *(6) References* | Official Journal L 399, 30.12.1989 |
| *(7) Follow-up work* | A Commission communication as part of the implementation of the 'new approach' Directives was published on 19 February 1992 (Official Journal C 44, 19.2.1992).<br>Its purpose is the publication of titles and references of European harmonized standards complying with one or more of the essential requirements of Directive 89/686/EEC. |
| *(8) Commission implementing measures* | |

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.13. Certification and testing: procedures for assessing conformity of products

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| *(1) Objective* | To offer consumers, users and public authorities the guarantee that products placed on the market satisfy the various requirements expected of them, as expressed in the provisions of the Directives. |
| *(2) Community measures* | Council Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization Directives. |
| *(3) Contents* | 1. Conformity assessment involves modules covering the inspection of the design phase of the products or the inspection of their production phase. In certain cases, these two functions are so interleaved that they must be considered together when constructing a module.<br>2. As a rule, the product should pass inspections during both phases before it can be placed on the market.<br>3. The Directives will have to lay down the range of possible choices which can be examined by the Council in order to offer the public authorities an acceptable level of safety which they seek for a given product or product area.<br>4. The Directives will have to lay down requirements governing the conditions under which the manufacturer chooses the modules most appropriate to his products.<br>5. Notified bodies should be encouraged to apply the modules without placing excessive burdens on economic agents wherever possible. Close cooperation will be organized between notified bodies by the European Organization for Certification and Testing or, failing this, by the Commission so as to ensure consistent interpretation and application of the modules.<br>6. The EC mark (accompanied where appropriate by the identification symbol of the third party involved in the inspection of the production phase) is affixed to certify that the production phase has been satisfactorily completed in accordance with the requirements of the Directives. |
| *(4) Deadline for implementation of the legislation in the Member States* | Not applicable. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 380, 31.12.1990 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.14. Hydraulically and oil-electrically operated lifts

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| *(1) Objective* | To harmonize the technical specifications relating to the design of oil and hydraulic lifts. |
| *(2) Community measures* | Council Directive 90/486/EEC of 17 September 1990 amending Directive 84/529/EEC on the approximation of the laws of the Member States relating to electrically operated lifts. |
| *(3) Contents* | 1. The harmonization of the rules relating to the installation, testing and inspection of such appliances and the EEC type-examination procedures which lay down the necessary technical requirements also apply to oil and hydraulic lifts.<br>2. The Member States are not entitled to refuse, to prohibit or to restrict the installation and putting into service of lifts meeting the requirements of the Directive.<br>3. Annexes containing the technical requirements and procedures for the EEC type-examination certification. |
| *(4) Deadline for implementation of the legislation in the Member States* | 24.3.1991 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 270, 2.10.1990 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.15. Lifts

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|---|---|
| *(1) Objective* | To apply uniform rules for all lifts. |
| *(2) Proposal* | Proposal for a Council Directive on the approximation of the laws of the Member States regarding lifts. |
| *(3) Contents* | 1. The Directive applies to lifts permanently installed in permanent buildings and to the safety components used in such lifts. It does not apply to lifts designed for military purposes, mine lifts or stage lifts.<br>2. Lifts and safety components must undergo a conformity assessment procedure leading to the issue of the EC type-examination certificate.<br>3. Lifts and their safety components must satisfy the essential health and safety requirements in respect of their design and construction. These essential requirements cover all the hazards to which lift users may be exposed. The risks incurred by maintenance personnel are covered by Council Directive 89/392/EEC (summary 1.4).<br>4. Lifts and safety components which satisfy the essential health and safety requirements receive the EC mark of conformity.<br>5. Lifts bearing the EC mark may be placed on the market in all Member States. However, lifts and their safety components which are liable to endanger the safety of persons may be prohibited from sale or withdrawn from the market.<br>6. Council Directives 84/528/EEC and 84/529/EEC (Official Journal L 300, 19.11.1984) are repealed with effect from 1 January 1998. |
| *(4) Opinion of the European Parliament* | First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments. |
| *(5) Current status* | An amended proposal including Parliament's amendments accepted by the Commission is awaited. |
| *(6) References* | Commission proposal<br>COM(92) 35 final — Official Journal C 62, 11.3.1992<br>European Parliament opinion<br>First reading — Not yet published<br>Economic and Social Committee opinion — Official Journal C 287, 4.11.1992 |

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.16. Electrical equipment for use in potentially explosive atmospheres

| | |
|---|---|
| *(1) Objective* | To add new means of protection available for specific equipment which has become available as a result of technical progress. |
| *(2) Community measures* | Council Directive 90/487/EEC of 17 September 1990 amending Directive 79/196/EEC on the approximation of the laws of the Member States concerning electrical equipment for use in potentially explosive atmospheres employing certain types of protection. |
| *(3) Contents* | 1. The means of protection provided for in Directive 79/196/EEC are extended to include encapsulation 'm' and electrical systems with intrinsic safety 'i'.<br>2. Six new European standards are added to the references to harmonized European standards in Annex I to Directive 79/196/EEC. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.7.1992 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 270, 2.10.1990 |
| *(7) Follow-up work* | The Directive will be cancelled on 1 July 1996 (see summary 1.17). |
| *(8) Commission implementing measures* | |

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.17. Equipment for use in potentially explosive atmospheres: protective devices and systems

*(1) Objective*

To lay down uniform protection rules within the Community.

*(2) Proposal*

Proposal for a Council Directive on the forthcoming legislation for Member States on protective devices and systems for use in potentially explosive atmospheres.

*(3) Contents*

1. The Directive applies to electrical and non-electrical protective devices and systems (surface and mining equipment) used in potentially explosive atmospheres and to items of equipment for use outside potentially explosive atmospheres but which impinge upon devices that are present in any such atmospheres.
2. The Directive does not apply to:
— medical equipment,
— protective devices and systems used on premises where potentially explosive or chemically unstable substances are stored,
— on seagoing ships and mobile offshore units,
— on certain means of transport.
3. Protective devices and systems must meet the essential safety and health requirements. These are divided up into three categories:
— common requirements concerning protective devices and systems,
— additional requirements applying to devices which can trigger an explosion,
— additional requirements for protective systems.
4. The procedures for obtaining the EEC conformity mark (summary 1.18) depend upon the device and level of safety provided. The Directive sets out in detail the procedures to be followed with regard to the various categories of protective devices and systems used in potentially explosive atmospheres. These devices are typified by a protection-level scale which determines the type of procedure to be followed.
5. Certain procedures for the assessment and checking of protective devices and systems are pursued by a notified body; a list of these is published in the Official Journal as are the activities for which they have been notified. Moreover, procedures ranging from complete quality assurance to in-house production checking by manufacturers is called upon for well-defined conformity categories.
6. The EC conformity mark and the specific explosion-prevention markings must be affixed in a visible manner to machines, together with the identification number of the notified body.
7. The protective devices and systems complying with the Directive and bearing the EC conformity mark are considered to be able to move freely throughout the Community's markets. However, they may be withdrawn from the market if they adversely affect human or animal health or property.
8. With effect from 1 July 1996 this Directive repeals Council Directives 76/177/EEC (Official Journal L 24, 31.1.1976), 79/196/EEC (Official Journal L 43, 20.2.1979), 82/130/EEC (Official Journal L 59, 2.3.1982), 90/487/EEC (summary 1.16) and 91/269/EEC (Official Journal L 134, 29.5.1991).

| | | |
|---|---|---|
| *(4) Opinion of the European Parliament* | First reading: Parliament approved the Commission's proposal without amendment. | |
| *(5) Current status* | The proposal is currently before the Council for a common position. | |
| *(6) References* | Commission proposal<br>COM(91) 516 final | Official Journal C 46, 20.2.1992 |
| | European Parliament opinion<br>First reading | Official Journal C 125, 18.5.1992 |
| | Economic and Social Committee opinion | Official Journal C 106, 27.4.1992 |

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.18. EC mark of conformity

*(1) Objective*

To lay down a single set of rules for affixing the EC mark on industrial products.

*(2) Proposal*

Proposal for a Council Regulation concerning the affixing and use of the EC mark of conformity on industrial products.

*(3) Contents*

The proposal for a Council Regulation has, following a second amendment, been replaced by a proposal for a Directive and a proposal for a Council Decision.

Proposal for a Council Directive amending Council Directives:
— 87/404/EEC (simple pressure vessels),
— 88/378/EEC (toy safety),
— 89/106/EEC (construction products),
— 89/336/EEC (electromagnetic compatibility),
— 89/392/EEC (machinery),
— 89/686/EEC (personal protective equipment),
— 90/384/EEC (non-automatic weighing instruments),
— 90/385/EEC (active implantable medical devices),
— 90/396/EEC (appliances burning gaseous fuels),
— 91/263/EEC (telecommunications terminal equipment),
— 92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels),
— 73/23/EEC (electrical equipment designed for use within certain voltage limits).

1. This proposal for a Directive amends the various existing technical harmonization Directives, introducing provisions on the rules for affixing and using the EC conformity marking.
2. The rules for affixing the EC conformity marking are intended to ensure consistency and improved controls in respect of the design, manufacture, placing on the market, putting into service and use of the industrial products covered by the technical harmonization Directives concerned.
3. The EC marking on these industrial products indicates that the products comply with the two binding Community provisions that apply to them.
4. The affixing of any other mark, sign or indication liable to lead to confusion with the EC marking is prohibited. However, any other mark may be affixed to these products provided that the visibility and legibility of the EC marking is not thereby reduced.

Proposal for a Council Decision amending Council Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures, supplementing it with provisions relating to the arrangements for affixing and using the EC conformity marking.
This Decision lays down the rules for affixing the EC conformity marking used in the Community rules on the design, manufacture, placing on the market, putting into service and use of industrial products.

| | | |
|---|---|---|
| *(4) Opinion of the European Parliament* | First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments. | |
| *(5) Current status* | The amended proposal is currently before the Council for a common position. | |
| *(6) References* | Commission proposal<br>COM(91) 145 final | Official Journal C 160, 20.6.1991 |
| | Amended proposal<br>COM(92) 293 final | Official Journal C 195, 1.8.1992 |
| | Amended proposal<br>COM(92) 499 final I and II | Not yet published |
| | European Parliament opinion<br>First reading | Official Journal C 125, 18.5.1992 |
| | Economic and Social Committee opinion | Official Journal C 14, 20.1.1992 |

# 1. THE NEW APPROACH IN HARMONIZATION

## 1.19. Recreational craft

*(1) Objective*

To harmonize the laws, regulations and administrative provisions in force in the Member States as regards the safety characteristics of recreational craft in order to abolish barriers to trade and disparities in competition in the internal market.

*(2) Proposal*

Proposal for a Council Directive on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft.

*(3) Contents*

1. The Directive applies to all craft intended to be used for recreational purposes with a hull length of between 2.5 and 24 m and to the items and equipment set out in the annex. The craft must meet the essential requirements set out in the annex.
2. The Member States must take all necessary action to ensure that recreational craft can only be placed on the market or put into service if they do not constitute a threat to the safety of persons and goods when set up and used for their intended purpose. They may not prohibit, restrict or impede the marketing or use in their territory of recreational craft which fulfill the provisions of the Directive.
3. The Member States assume that recreational craft fulfill the essential requirements of the Directive if they comply with the harmonized Community standards relating to them. Any Member State which believes that the harmonized standards do not fully satisfy the essential requirements of the Directive must refer the matter to the Standing Committee set up under Council Directive 83/189/EEC (Official Journal L 109, 26.4.1983), stating its reasons. The Commission has the same right.
4. Before recreational craft are produced and marketed, they must, depending on their hull length and production characteristics, undergo one of the procedures (given in the annex) for assessment of their conformity with the provisions of the Directive.
5. Affixing of the EC mark shown in the annex signifies conformity with the provisions of the Directive.

*(4) Opinion of the European Parliament*

First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments.

*(5) Current status*

An amended proposal including Parliament's amendments accepted by the Commission is awaited.

*(6) References*

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|---|---|
| Commission proposal<br>COM(92) 141 final | Official Journal C 123, 15.5.1992 |
| European Parliament opinion<br>First reading | Not yet published |
| Economic and Social<br>Committee opinion | Official Journal C 313, 30.11.1992 |

## 2. MOTOR VEHICLES

### 1992 target: current position and outlook

1. EC type-approval and road safety

Under its 1969 general programme for the abolition of technical barriers to trade, the Community has been striving to introduce a comprehensive EC type-approval procedure for passenger cars. This allows any type of vehicle approved in one Member State as conforming with a uniform set of technical requirements to be freely marketed throughout the Community without having to undergo further tests. Since 1970 the type-approval procedure has been covered by a Directive which has been regularly adapted to new technical standards (summaries 2.1 to 2.4).

A uniform type-approval procedure necessitated harmonization of vehicle characteristics, systems and components. Forty-four Directives were required, the last of which concerning tyres, safety glass, the masses and dimensions of vehicles and speed governors (summaries 2.5 to 2.9 and summaries 2.22 to 2.25) have just been adopted. Other measures concerning lateral protection and spray suppression systems on certain categories of vehicles came into force recently (summaries 2.12 to 2.21).

2. EC type-approval and the environment

The Community has adopted several appropriate measures to safeguard the environment from pollution caused by engine exhaust emissions and motorcycle noise (summaries 2.10 and 2.11). These must be applied uniformly throughout the Community, both to ensure full protection for citizens and the environment, and to prevent emission requirements becoming a barrier to trade, necessitating modifications to car engines or to the components and features of imported motorcycles.

These concern:

— gaseous emissions from petrol and diesel engines (summaries 2.13 and 2.14);
— gaseous emissions from cars below 1 400 cc (summary 2.16);
— air pollution by motor vehicle emissions (summary 2.17);
— gaseous emissions from buses, coaches, lorries, taxis, ambulances and commercial vehicles (summary 2.19);
— particulate emissions from diesel engines (summary 2.15);
— emissions from diesel engines in vehicles, except those in category $M_1$ (summary 2.18).

3. Full harmonization

Until now, many of the proposals and measures in this section were optional, which meant that Member States were free to maintain national standards in their domestic markets in parallel with the Community standards which they had to observe.

This provision, which gave a producer exporting to a given market a choice of standards, no longer applies for reasons of safety and environmental protection. The Directives are now paramount. Moreover, the proposal for a Directive amending the Directive on the type-approval procedure providing for a transition in due course from optional to full harmonization has been adopted. This means that EC type-approval rules and procedures are now compulsory and replace the national systems' requirements, which have co-existed until now as a parallel option.

# 2. MOTOR VEHICLES

## 2.1. EEC type-approval: motor vehicles and trailers

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|---|---|
| *(1) Objective* | To abolish the existing 12 national type-approvals for motor vehicles and trailers and replace them with one Community-wide type-approval. |
| *(2) Community measures* | Council Directive 87/358/EEC of 25 June 1987 amending Directive 70/156/EEC on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers. |
| *(3) Contents* | 1. For the purpose of this Directive a vehicle is defined as any motor vehicle intended for use on the road, with or without bodywork, having at least four wheels and a maximum design speed exceeding 25 km/h, and its trailers, with the exception of vehicles which run on rails and agricultural tractors and machinery. EEC type-approval is defined as the procedure where a Member State certifies that a vehicle type satisfies the technical requirements of the specific Directives and the checks listed in the EEC type-approval certificate.<br>2. The Directive contains several clauses clarifying the type-approval procedure. These include the following: Member States have to approve all vehicles which satisfy the requirements in the Directive; spot checks should be carried out to ensure that production models conform to the approved type; each Member State sends to the others, within a period of one month, a copy of the type-approval certificate drawn up for each type of vehicle for which approval has been granted or refused. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.10.1988 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 192, 11.7.1987 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 2. MOTOR VEHICLES

### 2.2. EEC type-approval: two- or three-wheel motor vehicles

*(1) Objective*

To complete Community legislation on EEC type-approval of two- or three-wheel motor vehicles.

*(2) Community measures*

Council Directive 92/61/EEC of 30 June 1992 on the type-approval of two- or three-wheel motor vehicles.

*(3) Contents*

1. The Directive applies to all two- or three-wheel motor vehicles, twinned or otherwise, intended to travel on the road, and to the components or technical entities of such vehicles.
2. The vehicles covered by the Directive are subdivided into:
— mopeds: two- or three-wheel vehicles fitted with an engine having a cylinder capacity not exceeding 50 $cm^3$ and a maximum design speed of not more than 45 km/h;
— motor cycles: two-wheel vehicles having a cylinder capacity of more than 50 $cm^3$ and a maximum design speed of more than 45 km/h;
— tricycles: three-wheel vehicles fitted with an engine having a cylinder capacity of more than 50 $cm^3$ and a maximum design speed of more than 45 km/h.
— quadricycles: vehicles having a maximum unladen mass of less than 350 kg, maximum design speed not exceeding 45 km/h and a cylinder capacity of not more than 50 $cm^3$ or a power output of not more than 4 kW.
3. Definitions of the terms 'type of vehicle', 'variant', 'version', 'technical entity', 'component', etc.
4. All applications for type-approval or component type-approval are lodged by the manufacturers or producers or their authorized representative in a Member State.
5. Member States are to type-approve all types of vehicle and component type-approve technical entities or components which satisfy the following conditions:
— the type of vehicle meets the technical requirements of the specific regulations and corresponds to the data supplied by the manufacturer in accordance with the exhaustive list set out in the annex;
— the technical entity or component meets the technical requirements of the relevant specific regulation and corresponds to the data supplied by the manufacturer in accordance with the exhaustive list set out in the annex.
6. A certificate of conformity is to be completed by the manufacturer or his authorized representative for each vehicle produced in conformity with the approved type and for each non-original technical entity or component manufactured in conformity with the type that has been component type-approved.
7. Any vehicle produced in conformity with the approved type must bear a type-approval mark consisting of:
— the type-approval number;
— the letter 'e' followed by the identifying number or initials of the Member State conducting the type-approval;
— the vehicle identification number.

In addition, any technical entity and any component produced in conformity with the approved type must include, if the relevant specific regulation so provides, a component type-approval mark which meets the requirements set out in the annex.
8. The manufacturer of a vehicle and the producer of a technical entity or component are to be responsible for the manufacture of each vehicle or the production of each technical entity or component in conformity with the type which has been type-approved or component type-approved.
9. If a Member State confirms that vehicles, technical entities or components constitute a road safety hazard even though they are of a type which has been type-approved or component type-approved, it may ban the sale, placing in service or use in its territory for a maximum period of six months. It must immediately inform the Commission and the other Member States thereof.
10. Member States may not prohibit the marketing, sale, bringing into service or use of new vehicles and new technical entities or new components conforming to the provisions of the Directive. Only vehicles, technical entities and components complying with the Directive may be marketed, sold and used in the Member States.
11. Member States may introduce or continue to apply in their national legislation a second category of mopeds having a maximum design speed of 25 km/h, to the extent that this does not involve modifications to the vehicles beyond what is necessary to ensure effective limitation of their maximum speed. However, three years after the date of entry into force of the Regulation, the Council is to decide, on a proposal from the Commission, whether this possibility should be maintained or removed.
12. Member States which have special provisions regarding the presence of pedals on mopeds may, however, continue to apply their national legislation for a maximum period of three years from the date of entry into force of the Directive.
13. A committee is set up for the adaptation to technical progress of the Regulations on two- or three-wheel vehicles. It is composed of representatives of the Member States and is chaired by a representative of the Commission. The committee is to draw up its own rules of procedure.
14. Annexes containing the list of the components and characteristics of the vehicles conforming to the Directive, a model of the information document, a model of the type-approval form, a model of the certificate of conformity accompanying each vehicle in the series of the type that has been approved, and accompanying each technical entity or component not fitted as original equipment to the series of the type that has been component type-approved, a model of the type-approval mark, and provisions relating to checking the conformity of production.

*(4) Deadline for implementation of the legislation in the Member States* 1.1.1994

*(5) Date of entry into force (if different from the above)*

*(6) References*

*(7) Follow-up work*

*(8) Commission implementing measures*

# 2. MOTOR VEHICLES

## 2.3. EEC type-approval: motor vehicles and their trailers

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|---|---|
| *(1) Objective* | To facilitate the interchangeability of motor vehicles and trailers within the territory of the Community and to harmonize the technical requirements for mechanical coupling devices. |
| *(2) Proposal* | Proposal for a Council Directive relating to the mechanical coupling devices of motor vehicles and their trailers and their attachment to these vehicles. |
| *(3) Contents* | 1. This Directive contributes towards implementation of the EEC type-approval procedure provided for by Council Directive 70/156/EEC on the approximation of the laws of Member States relating to the type-approval of motor vehicles and their trailers (Official Journal L 42, 23.2.1970), as last amended by Council Directive 87/403/EEC (Official Journal L 220, 8.8.1987).<br>2. The Directive defines 'vehicle' and 'mechanical coupling type'.<br>3. With effect from 1 October 1995 Member States may prohibit the first entry into service of vehicles of which the mechanical coupling devices fail to comply with the provisions of this Directive. Conversely, Member States may not refuse EEC type-approval or national type-approval for a vehicle or prohibit the sale, registration or use of a vehicle on grounds relating to its coupling device, if the device satisfies the requirements laid down in the Directive. The same applies to component type-approval and to the sale or use of a mechanical coupling device.<br>4. A procedure for adaptation to technical progress is also included. |
| *(4) Opinion of the European Parliament* | First reading: Parliament approved the Commission's proposal without amendments. |
| *(5) Current status* | The proposal is currently before the Council for a common position. |
| *(6) References* | Commission proposal<br>COM(92) 108 final — Official Journal C 134, 25.5.1992<br>European Parliament opinion<br>First reading — Not yet published |

## 2. MOTOR VEHICLES

### 2.4. EEC type-approval: motor vehicles and their trailers (complete review of the procedure)

*(1) Objective*

To replace the national type-approval procedures for motor vehicles and their trailers by an EEC type-approval system based on uniform technical requirements in order to simplify and speed up the administrative action which manufacturers must take in order to be able to market their products.

*(2) Community measures*

Council Directive 92/53/EEC of 18 June 1992 amending Directive 70/156/EEC on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers.

*(3) Contents*

1. The Directive defines the terms 'type-approval', 'vehicle', 'component', 'manufacturer', 'testing body', etc.
2. The application for the type-approval of a vehicle is submitted by its manufacturer to the competent authorities in each Member State. It is accompanied by a 'manufacturer' file containing the characteristics of the vehicle and the type-approval documents for each separate Directive applying (sound level, emissions, lights, etc.). The Member State concerned grants an approval per type of vehicle on the basis of that information.
3. This procedure and the information that is to appear in the manufacturer file and the type approval documents is described in the annex. Where this information is altered the Member State having conducted the original type-approval will examine whether this needs to be extended or amended. Where this proves to be so the competent authorities will publish the amended pages of the type-approval file and will issue an amended type-approval certificate; if a type-approval of a type of vehicle becomes invalid the Member State concerned will send the other Member States the identification number of the last vehicle produced.
4. The vehicles manufactured in accordance with the type-approved model are accompanied by a certificate of conformity corresponding to the model set out in the annex. The components used in the manufacture of the model selected will bear the manufacturer's mark, a statement of its type and/or, if so provided for by a separate Directive, the type-approval number or mark.
5. Member States will only register new vehicles if they are accompanied by a valid certificate of conformity. That registration may be refused for at the most six months if the vehicle seriously impairs road safety. The Member State issuing any such refusal will inform the other Member States and the Commission thereof. There will be exceptions for military or civil protection vehicles, vehicles produced in small batches, etc.
6. The type-approval procedures in force in non-member countries may be recognized as being equivalent by the Council as part of multilateral or bilateral agreements.
7. Any Member State type-approving a vehicle will check the compatibility of the vehicles produced therewith. A vehicle may not be considered not to conform to the type which has been approved if the tolerances provided for in the separate Directives are met.

| | |
|---|---|
| | 8. Any decision on the refusal or withdrawal of type-approval, registration or sale shall be justified and forwarded to the interested party.<br>9. The Member States shall notify the Commission and the other Member States of the details of the competent authorities and testing bodies that they have approved. |
| *(4) Deadline for implementation of the legislation in the Member States* | 31.12.1992 |
| *(5) Date of entry into force (if different from the above)* | 1.1.1993 |
| *(6) References* | Official Journal L 225, 10.8.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 2. MOTOR VEHICLES

### 2.5. Weights and dimensions

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|---|---|
| *(1) Objective* | To harmonize the national laws concerning the weights and dimensions of cars. |
| *(2) Community measures* | Council Directive 92/21/EEC of 31 March 1992 on the weights and dimensions of category $M_1$ motor vehicles. |
| *(3) Contents* | 1. The Directive lays down the maximum permissible dimensions of the vehicles concerned with regard to length, width and height.<br>2. It furthermore contains requirements relating to the determination of the maximum technically permissible laden weight and the distribution of this weight between the vehicle axles.<br>3. The Directive also contains requirements for the maximum towed weight authorized for motor vehicles. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.7.1992 |
| *(5) Date of entry into force (if different from the above)* | 1.10.1992 |
| *(6) References* | Official Journal L 129, 14.5.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 2. MOTOR VEHICLES

## 2.6. Weights and dimensions: motor vehicles and their trailers

*(1) Objective*

To fix the maximum masses and dimensions of motor vehicles and their trailers for the purposes of issuing EEC type-approval certificates for lorries, trailers, buses and coaches.

*(2) Proposal*

Proposal for a Council Directive relating to the masses and dimensions of certain categories of motor vehicles and their trailers.

*(3) Contents*

1. The Directive applies to the masses, dimensions and technical requirements for all vehicles, except those in category $M_1$, which are intended to be type-approved, according to their design characteristics.
2. Applications for EEC type-approval of motor vehicles and their trailers must be submitted by the manufacturer or his agent.
3. An EEC type-approval certificate is issued on presentation of three documents relating, in particular, to the description of the vehicle and after checks and tests have been carried out by the testing body.
4. Member States may not refuse EEC type-approval or national type-approval of a vehicle type, or refuse or prohibit the sale, registration, entry into service or use of a vehicle on grounds relating to its masses and dimensions if these satisfy the requirements of this Directive.
5. From 1 October 1993 Member States may no longer issue the document provided for in Council Directive 70/156/EEC (Official Journal L 42, 23.2.1970) in respect of a type of vehicle of which the masses and dimensions do not meet the requirements of the Directive. Similarly, they may refuse to grant national type-approval in respect of a type of vehicle of which the masses and dimensions do not meet the requirements of the Directive.

*(4) Opinion of the European Parliament*

First reading: Parliament approved the Commission proposal subject to certain amendments. The Commission accepted some of these amendments.

*(5) Current status*

An amended proposal including Parliament's amendments withheld by the Commission is awaited.

*(6) References*

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| Commission proposal<br>COM(91) 239 final | Official Journal C 230, 4.9.1991 |
| European Parliament opinion<br>First reading | Not yet published |
| Economic and Social<br>Committee opinion | Official Journal C 49, 24.2.1992. |

## 2. MOTOR VEHICLES

### 2.7. Tyres

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|---|---|
| *(1) Objective* | To harmonize the national type-approval for tyres and their fitting to motor vehicles and their trailers. |
| *(2) Community measures* | Council Directive 92/23/EEC of 31 March 1992 on tyres for motor vehicles and their trailers. |
| *(3) Contents* | 1. The Directive applies to original and replacement tyres fitted to motor vehicles in category $M_1$ and trailers in Council Directive 70/156/EEC (published in Official Journal L 42, 23.2.1970).<br>2. It concerns the technical requirements for the construction and testing of tyres for passenger cars and trailers and requirements relating to the fitting of the tyres to the vehicle. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.7.1992 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 129, 14.5.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 2. MOTOR VEHICLES

## 2.8. Tyres: tyre pressure gauges for motor vehicles

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|---|---|
| *(1) Objective* | To bring national provisions relating to tyre pressure gauges, including technical specifications, closer together so as to facilitate intra-Community trade in these products. |
| *(2) Community measures* | Council Directive 86/217/EEC of 26 May 1986 on the approximation of the laws of the Member States relating to tyre pressure gauges for motor vehicles. |
| *(3) Contents* | 1. This Directive applies to pressure gauges intended to measure the inflation pressure of motor vehicle tyres.<br>2. To obtain an EC mark, pressure gauges are subject to EC pattern-approval and verification. Requirements that they must satisfy include:<br>— the metrological characteristics specified in paragraph 2 of the annex;<br>— robust and careful construction to maintain their metrological characteristics;<br>— guaranteed direct and accurate reading of pressure measured;<br>— the dial must specify the symbol for the quantity measured and the symbol for the unit of measurement. More detail can be found in the technical annex.<br>3. Member States may not refuse, prohibit or restrict the marketing and use of tyre pressure gauges for reasons connected with their metrological characteristics if they bear the EC pattern-approval and verification marks. |
| *(4) Deadline for implementation of the legislation in the Member States* | 30.11.1987 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 152, 6.6.1986 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 2. MOTOR VEHICLES

### 2.9. Safety glass and glazing materials

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|---|---|
| *(1) Objective* | To bring into line the national provisions relating to safety glass and glazing materials used in motor vehicles and their trailers. |
| *(2) Community measures* | Council Directive 92/22/EEC of 31 March 1992 concerning safety glass and glazing materials for motor vehicles and their trailers. |
| *(3) Contents* | 1. The proposal for a Council Directive aims at laying down requirements for the type-approval of the different types of glass and requirements for EEC type-approval of particular vehicles with regard to the installation of the various glazing materials.<br>2. The proposal also lays down the materials permitted for use in windscreens and for glass other than windscreens. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.7.1992 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 129, 14.5.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 2. MOTOR VEHICLES

## 2.10. Motorcycle exhaust system noise

| | |
|---|---|
| *(1) Objective* | To lay down common limits for the permissible sound level of motorcycles and requirements for their exhaust systems. |
| *(2) Community measures* | Council Directive 89/235/EEC of 13 March 1989 amending Directive 78/1015/EEC on the approximation of the laws of the Member States on the permissible sound levels and exhaust systems of motorcycles. |
| *(3) Contents* | 1. Details of the different existing national type-approvals in different Member States:<br>— Belgium: agréation par type;<br>— Denmark: standardtypegodkendelse.<br>2. The national model certificate shall be replaced by the model EEC type-approval certificate in Annex IV of the Directive.<br>3. From 1 October 1988, Member States in which motorcycles are subject to national type-approval shall apply harmonized technical requirements in the place of the national requirements.<br>4. From 1 October 1989 Member States may not refuse for reasons connected with permissible sound levels and original or replacement exhaust systems to grant EEC or national type-approval to a motorcycle complying with the Directive.<br>5. From 1 October 1990, Member States may prohibit the sale, registration, entry into service or use of motorcycles the sound and exhaust levels of which do not comply with the Directive.<br>6. Annex containing new conformity testing methods, application for type-approval and markings. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.10.1989 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 98, 11.4.1989 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 2. MOTOR VEHICLES

### 2.11. Motor vehicle exhaust system noise

| | |
|---|---|
| *(1) Objective* | To reduce the permissible sound level for motor vehicles in the Community. |
| *(2) Community measures* | Council Directive 92/97/EEC of 10 November 1992 amending Directive 70/157/EEC on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles. |
| *(3) Contents* | 1. The Commission considers that a significant reduction in sound limit values (from 2 to 3 dB (CA) depending on the category of vehicle) could be proposed for 1995.<br>2. Vehicles' compliance with the statutory limit values on sound levels is to be checked when type-approval tests are carried out and when vehicles are first put into service.<br>3. From 1 July 1993 Member States may no longer refuse, in respect of a type of motor vehicle, to grant EEC type-approval, to issue the document referred to in the last indent of Article 10(1) of Directive 70/156/EEC (Official Journal L 42, 23.2.1970) or to grant national type-approval if the sound level and the exhaust system comply with the provisions of this Directive. Nor may they prohibit the entry into service of vehicles.<br>4. From 1 October 1995 Member States may no longer grant EEC type-approval or issue the document referred to in Directive 70/156/EEC in respect of a type of motor vehicle of which the sound level and the exhaust system do not comply with the requirements of the Directive. They must also refrain from the national type-approval of a type of motor vehicle.<br>5. From 1 October 1996 Member States must prohibit the initial entry into service of vehicles of which the sound level and the exhaust system fail to comply with the requirements of the Directive. Unlike previous Directives on this subject, this Directive is binding on the Member States.<br>6. A Member State may make provision for tax incentives in respect of all nationally manufactured motor vehicles and all imported vehicles offered for sale on its domestic market.<br>7. Subsequent measures, *inter alia*, to limit the noise arising from contact between tyres and the road surface will be decided upon before 1 October 1995, on the basis of a Commission proposal which will take account of the studies and research to be carried out on this source of noise.<br>8. The Member States shall ensure that the type-approval sound level values for each type of vehicle are widely publicized before 1 October 1994. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.7.1993 |

| | |
|---|---|
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 371, 19.12.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 2. MOTOR VEHICLES

### 2.12. Lateral protection for goods vehicles

| | |
|---|---|
| *(1) Objective* | To harmonize the requirements to be met by vehicles as regards the side-guards of motor vehicles and their trailers. |
| *(2) Community measures* | Council Directive 89/297/EEC of 13 April 1989 on the approximation of the laws of the Member States relating to the lateral protection (side-guards) of certain motor vehicles and their trailers. |
| *(3) Contents* | 1. The Directive applies to big and heavy goods vehicles and their trailers (categories $N_2$, $N_3$, $O_3$ and $O_4$ as defined in Council Directive 70/156/EEC (Official Journal L 42, 23.2.1970) on type-approval of motor vehicles and their trailers) intended for road use with or without bodywork and having a maximum design speed above 25 km/h. It does not apply to buses as their normal bodywork fulfils the requirements.<br>2. No Member State may refuse for reasons connected with lateral protection to grant type-approval to vehicles which meet the requirements set out in the annex or prevent their sale, registration and use. Any modifications to parts or characteristics referred to in the annex shall be transmitted to the Member State which carried out the EEC type-approval. The Member State may then decide whether to hold fresh tests on the modified type.<br>3. Annexes containing technical requirements for lateral protection and application form for EEC type-approval. Appendix containing model of annex to type-approval certificate with information on lateral protection.<br>4. Consultation of a standing committee by the Commission before adapting the annex to technical progress. |
| *(4) Deadline for implementation of the legislation in the Member States* | 30.10.1989 |
| *(5) Date of entry into force (if different from the above)* | — 1.6.1990 and 1.5.1991 |
| *(6) References* | Official Journal L 124, 5.5.1989 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 2. MOTOR VEHICLES

## 2.13. Air pollution: exhaust gases

| | |
|---|---|
| *(1) Objective* | To reduce pollution caused by cars. |
| *(2) Community measures* | Council Directive 88/76/EEC of 3 December 1987 amending Directive 70/220/EEC on the approximation of the laws of the Member States relating to measures to be taken against air pollution by gases from the engines of motor vehicles. |
| *(3) Contents* | 1. Amendments to the technical annexes to Council Directive 70/220/EEC (Official Journal L 76, 6.4.1970) to move towards standards which will have an effect on the European environment equivalent to that produced by US standards, bearing in mind particular differences between Europe and the USA. These include reduced limits for pollutants and adapted testing procedures.<br>2. No Member State may, on grounds relating to air pollution by gases from an engine or to engine fuel requirements, refuse to grant type-approval or prohibit the entry into service of any vehicle with emissions of gaseous pollutants and engine fuel requirements which conform with the requirements of this Directive.<br>3. National or EEC type-approvals for vehicles with engines which do not comply with the Directive may be refused. Member States may prohibit the entry into service of such vehicles at a later stage.<br>4. By 31 December 1987 the Council will decide on a further reduction in the limit values to be applied to emissions of pollutants in 1992 and 1993 at the latest. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.7.1988 |
| *(5) Date of entry into force (if different from the above)* | — 1.10.1988 for refusing type-approval for vehicles with an engine capacity greater than 2 litres which do not comply with the Directive.<br>— 1.10.1989 for refusing type-approval for other vehicles whose engines do not comply with the Directive.<br>— 1.10.1990 for prohibiting the entry into service of vehicles whose engines do not comply with the Directive. |
| *(6) References* | Official Journal L 36, 9.2.1988 |
| *(7) Follow-up work* | See summary 2.16. |
| *(8) Commission implementing measures* | |

## 2. MOTOR VEHICLES

### 2.14. Air pollution: emission of gaseous pollutants from diesel engines

| | |
|---|---|
| *(1) Objective* | To approximate the technical requirements for diesel engines within the Community to combat air pollution. |
| *(2) Community measures* | Council Directive 88/77/EEC of 3 December 1987 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous pollutants from diesel engines for use in vehicles. |
| *(3) Contents* | 1. For the purpose of this Directive a vehicle is any vehicle propelled by a diesel engine intended for use on the road, with or without bodywork, having at least four wheels and a maximum design speed exceeding 25 km/h, with the exception of vehicles which run on rails, agricultural tractors and machines, and public works vehicles.<br>2. From 1 July 1988 no Member State may, on grounds relating to the gaseous pollutants emitted from an engine, refuse to grant EEC or national type-approval or prohibit the entry into service, use, sale or registration of vehicles equipped with engines which satisfy the requirements of the Directive. From 1 October 1990 Member States may prohibit the entry into service, use, registration and sale of new vehicles equipped with engines which fail to satisfy the requirements of the Directive.<br>3. If an engine which has received type-approval is modified, the Member State which granted type-approval must decide whether fresh tests need to be performed and take appropriate action. If the tests reveal failure to comply with the Directive, the modifications will not be approved.<br>4. The amendments necessary to adapt the requirements of the annexes to technical progress will be adopted in accordance with the procedure laid down in Directive 70/156/EEC (Official Journal L 42, 23.2.1970).<br>5. The technical annexes include detailed information on the type-approval and testing procedures (with specifications of the limits for emissions of gaseous pollutants). |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.7.1988 |
| *(5) Date of entry into force (if different from the above)* | 30.9.1990 for the particular types of vehicle and diesel engines specified in the annex. |
| *(6) References* | Official Journal L 36, 9.2.1988 |
| *(7) Follow-up work* | See summary 2.18. |
| *(8) Commission implementing measures* | |

# 2. MOTOR VEHICLES

## 2.15. Air pollution: emissions of gaseous pollutants from diesel engines

| | |
|---|---|
| *(1) Objective* | To set limits for permissible emissions of gaseous pollutants from diesel engines. |
| *(2) Community measures* | Council Directive 88/436/EEC of 16 June 1988 amending Directive 70/220/EEC on the approximation of the laws of the Member States relating to measures to be taken against air pollution by gases from engines of motor vehicles (restriction of particulate pollutant emissions from diesel engines). |
| *(3) Contents* | 1. Amendment of the title and the annexes of the original Directive so as to extend its scope to cover pollution from vehicles equipped with compression-ignition (diesel) engines. In addition, particulate emissions are included. Other amendments to the annexes include new testing procedures to take account of particulates.<br>2. From 1 October 1988 no Member State may, on grounds relating to air pollution, refuse to grant EEC or national type-approval or prohibit the entry into service of vehicles fitted with engines which comply with the Directive.<br>3. From 1 October 1989, according to the type of vehicle, Member States may refuse national type-approval for vehicles whose particulate pollutant emissions do not comply with the requirements of the Directive. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.10.1988 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 214, 6.8.1988 |
| *(7) Follow-up work* | See summary 2.17. |
| *(8) Commission implementing measures* | |

## 2. MOTOR VEHICLES

### 2.16. Air pollution: exhaust gas emissions from cars below 1.4 litres

*(1) Objective*

To introduce more stringent limit values for exhaust gas emissions from small cars.

*(2) Community measures*

Council Directive 89/458/EEC of 18 July 1989 amending, with regard to European emission standards for cars below 1.4 litres, Directive 70/220/EEC on the approximation of the laws of the Member States relating to measures to be taken against air pollution by emissions from motor vehicles.

*(3) Contents*

1. The limits for exhaust gas emissions from cars with an engine capacity below 1.4 litres will be:
— for type-approval:
19 g/test for CO, 5 g/test for HC + $NO_x$;
— for control of conformity of production:
22 g/test for CO, 5.8 g/test for HC + $NO_x$.
2. Dates of entry into force of these standards:
— 1 July 1992 for all new models;
— 31 December 1992 for all new vehicles brought into service.
3. The Member States will be able to offer tax incentives for this vehicle category provided the incentives:
— are available to all cars produced in the country concerned and to all vehicles imported for sale on the market of a Member State and fitted with devices allowing them to satisfy the European standards which will apply in 1992 before that date;
— end as soon as the mandatory emission limit values set for new vehicles enter into force;
— are, for each type of vehicle, substantially lower than the actual cost of purchasing and fitting the devices added in order to observe the values laid down;
— are compatible with the provisions of the EEC Treaty and are notified to the Commission.
4. The Council will decide measures to reduce $CO_2$ emissions from motor vehicles on a proposal from the Commission (which will take account of the results of the work in progress on the greenhouse effect).

*(4) Deadline for implementation of the legislation in the Member States*

1.1.1990

*(5) Date of entry into force (if different from the above)*

*(6) References*

Official Journal L 226, 3.8.1989

*(7) Follow-up work*

See summary 2.17.

*(8) Commission implementing measures*

# 2. MOTOR VEHICLES

## 2.17. Air pollution: new standards

*(1) Objective*

To consolidate Community Regulations on emissions of air pollutants from private cars.

*(2) Community measures*

Council Directive 91/441/EEC of 26 June 1991 amending Directive 70/220/EEC on the approximation of the laws of the Member States relating to measures to be taken against air pollution by emissions from motor vehicles.

*(3) Contents*

1. From 1 January 1991, no Member State may:
— refuse to grant EEC type-approval or national approval for a type of motor vehicle, or
— prohibit the initial entry into service of motor vehicles, where emissions from this type of vehicle meet the provisions of Council Directive 70/220/EEC (Official Journal L 76, 6.4.1970), as amended by the Directive concerned.
2. From 1 July 1992, Member States:
— must refuse to grant EEC type-approval or to issue the document provided for in Article 10 of Council Directive 70/156/EEC (Official Journal L 42, 23.2.1970) for a type of motor vehicle;
— must refuse national type-approval for a type of motor vehicle, the emissions of which do not meet the requirements of the annexes to amended Directive 70/220/EEC.
3. From 31 December 1992, Member States must prohibit the initial entry into service of vehicles the emissions from which do not meet the requirement of the annexes to Directive 70/220/EEC as amended.
4. The limit values proposed, referring to the new testing procedure for the approval of new types of vehicles, are:
— CO: 2.72 g/km; $HC + NO_x$: 0.97 g/km; particulates: 0.14, g/km; and for any new car:
— CO: 3.16 g/km; $HC + NO_x$: 1.13 g/km; particulates: 0.18 g/km.
5. Member States may make provision for tax incentives for the vehicles covered by the Directive. Such incentives must satisfy the following conditions:
— they must apply to all domestic car production and to vehicles imported for marketing in a Member State and fitted with equipment allowing the European standards which have to be met in 1992 to be satisfied ahead of time;
— they must cease as soon as the emission values laid down for new vehicles become compulsory;
— they must be of a value, for each type of vehicle, substantially lower than the actual cost of the equipment fitted to meet the values set and of its fitting to the vehicle.
6. The Commission will present a new proposal taking account of technical progress by 31 December 1992; the Council will decide on the proposal by 31 December 1993.

*(4) Deadline for implementation of the legislation in the Member States*

1.1.1992

| | |
|---|---|
| *(5) Date of entry into force (if different from the above)* | 1.1.1993 |
| *(6) References* | Official Journal L 242, 30.8.1991 |
| *(7) Follow-up work* | The Commission presented to the Council a proposal for a Directive amending Directive 70/220/EEC on the approximation of the laws of the Member States relating to measures to be taken against air pollution by emissions from motor vehicles (COM(92) 64 final, Official Journal C 100, 22.4.1992).<br>The aim of the proposal is to extend to other vehicle categories (light commercial vehicles up to 3.5 tonnes, passenger cars designed to carry no more than six passengers, vehicles not exceeding 2 tonnes and off road vehicles) the application of standards equivalent to those applicable to passenger cars.<br>The standards will apply from 1 January 1993 and will be mandatory for all vehicles concerned from 1 October 1994.<br>On 15 December 1992 the Council adopted a common position. |
| *(8) Commission implementing measures* | |

## 2. MOTOR VEHICLES

### 2.18. Air pollution: emissions from diesel engines in commercial vehicles, except for those in category $M_1$

*(1) Objective*

To make a further reduction in limit values for emissions of three gaseous pollutants (carbon monoxide, hydrocarbons and nitrogen oxides) from commercial vehicles.

*(2) Community measures*

Council Directive 91/542/EEC of 1 October 1991, amending Directive 88/77/EEC on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous pollutants from diesel engines for use in vehicles.

*(3) Contents*

1. After 1 January 1992 Member States may not:
— refuse to grant EEC type-approval, or to issue the document provided for by Article 10 of Council Directive 70/156/EEC (Official Journal L 42, 23.2.1970) or to grant national type-approval for a type of vehicle with a diesel engine, or
— prohibit the registration, sale, entry into service or use of new vehicles of that type, or
— refuse to grant EEC type-approval or national type-approval for a type of diesel engine, or
— prohibit the sale or use of new diesel engines,
if they satisfy the requirements contained in Council Directive 88/77/EEC (Official Journal L 36, 9.2.1988).
2. After 1 July 1992 Member States:
— may no longer grant EEC type-approval or issue the document provided for by Article 10 of Directive 70/156/EEC, and
— must refuse to grant national type-approval for types of diesel engine and types of vehicle with a diesel engine,
where emissions do not comply with limits laid down in line A of the table in Annex I of Directive 88/77/EEC.
3. After 1 October 1995 Member States:
— may no longer grant EEC type-approval or issue the document provided for by Article 10 of Directive 70/156/EEC, and
— must refuse to grant national type-approval for types of diesel engine and types of vehicle with a diesel engine,
where emissions do not comply with limits laid down in line B of the table in Annex I of Directive 88/77/EEC.
4. Until 30 September 1993 points 2 and 3 shall not apply to types of vehicle with a diesel engine if that engine is accompanied by a type-approval certificate issued before 1 July 1992 in accordance with the provisions of Directive 88/77/EEC and of Annex VIII of this Directive.
5. After 1 October 1993 Member States shall prohibit the registration, sale, entry into service and use of new vehicles with a diesel engine and shall prohibit the sale and use of new diesel engines where emissions do not comply with limits laid down in line A of the table of Annex I of Directive 88/77/EEC.
6. After 1 October 1996 Member States shall prohibit the registration, sale, entry into service and use of new vehicles with a diesel engine and shall prohibit the sale and use of new diesel engines where emissions do not comply with limits laid down in line B of the table of Annex I of Directive 88/77/EEC.

7. By the end of 1991 the Commission will be presenting a new proposal for making an improved diesel fuel available in the Member States with a maximium authorized sulphur content of 0.05%.
8. Member States may make provision for tax incentives for the vehicles covered by this Directive. Such incentives must:
— apply to all domestic car production and to imported vehicles which are marketed in a Member State and are fitted with equipment allowing the European standards to be met in 1996 to be satisfied;
— cease on the date set for the compulsory entry into force of the emission values for new vehicles;
— be of a value, for each type of vehicle, lower than the actual cost of the equipment fitted to meet the values set and of its fitting to the vehicle.
9. Before the end of 1993 the Commission will be reporting on the progress made regarding:
— the availability of techniques for controlling air-polluting emissions from diesel engines, particularly those of less than 85 kW;
— a new statistical method for the monitoring of production conformity to be adopted in accordance with the provisions of Directive 88/77/EEC.
If necessary, it will submit a proposal for revising upwards the limit values for particulate emissions. The Council shall take a decision on the basis of that proposal not later than 30 September 1994.
10. Before the end of 1996, in the light of the technical progress achieved, the Commission shall submit a revision of the limit values for polluting emissions combined with a revision of the test procedure. The new limit values shall not be applicable before 1 October 1999 as regards new type-approvals.
11. Annexes containing amendments to the annexes of Directive 88/77/EEC concerning scope, definitions and abbreviations, application for EEC type-approval, requirements and tests and production conformity; information document; test procedure; technical characteristics of reference fuel prescribed for approval tests and to verify conformity of production; analytical and sampling systems; EEC type-approval certificate.

*(4) Deadline for implementation of the legislation in the Member States*

1.1.1992

*(5) Date of entry into force (if different from the above)*

*(6) References*

Official Journal L 295, 25.10.1991

*(7) Follow-up work*

*(8) Commission implementing measures*

# 2. MOTOR VEHICLES

## 2.19. Air pollution: exhaust emissions by buses, coaches, heavy goods vehicles, taxis, ambulances and commercial vehicles

| | |
|---|---|
| *(1) Objective* | To lay down limit values for gaseous emissions from motor vehicles with spark ignition (petrol) engines and the opacity of the smoke emitted by motor vehicles with compression ignition (diesel) engines. |
| *(2) Community measures* | Council Directive 92/55/EEC of 22 June 1992 amending Directive 77/143/EEC on the approximation of the laws of the Member States relating to roadworthiness tests for motor vehicles and their trailers (exhaust emissions). |
| *(3) Contents* | 1. In the case of motor vehicles with petrol engines, the Directive provides for the visual inspection of the exhaust system (for vehicles whether or not fitted with an advanced emission control system such as a three-way catalytic convertor with lambda probe) and for the visual inspection of the emission control system (for vehicles fitted with an advanced control system and, where appropriate, for vehicles not so equipped).<br>2. As concerns vehicles with petrol engines not fitted with an advanced regulation system, the Directive lays down a maximum carbon monoxide content of 4.5 vol. % for cars manufactured prior to October 1986 and of 3.5 vol. % for cars manufactured thereafter. These measurements have to be made at engine idle speed.<br>3. For vehicles with petrol engines fitted with an advanced control system, the maximum carbon monoxide content may not exceed 0.5 vol. % (the measurement being made at engine idle speed) and 0.3 vol. % (the measurement being made at increased idling speed without engine load with the engine speed equivalent to at least 2 000 r.p.m.).<br>4. For vehicles with diesel engines the Directive provides that, in the case of naturally aspirated diesel engines, the opacity of the exhaust gas may not exceed $2.5m^{-1}$, or $3.0m^{-1}$ in the case of turbo-charged engines. |
| *(4) Deadline for implementation of the legislation in the Member States* | 22.6.1993 |
| *(5) Date of entry into force (if different from the above)* | — 1.1.1994: vehicles covered under point 8.2.1 (a) of Annex II<br>— 1.1.1996: vehicles covered under point 8.2.2 of Annex II<br>— 1.1.1997: vehicles covered under point 8.2.1 (b) of Annex II |
| *(6) References* | Official Journal L 225, 10.8.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 2. MOTOR VEHICLES

### 2.20. Air pollution: sulphur content of certain liquid fuels (gasoils and kerosenes)

*(1) Objective*

To limit the sulphur content of certain liquid fuels.

*(2) Proposal*

Proposal for a Council Directive relating to the sulphur content of gasoil.

*(3) Contents*

1. The Directive shall not apply to gasoils intended for processing or to those contained in the fuel tanks of motor vehicles crossing a frontier between a third country and a Member State.
2. During the first stage, a single limit value of 0.2% by weight shall be fixed for the sulphur content of all gasoils as from 1 October 1994; this will be lowered to 0.05% by weight as from 1 October 1996. This provision shall apply to all gasoils falling under CN Code 2710 00 69, and to any petroleum product which, by reason of its distillation limits, falls into the category of middle distillates (including kerosenes). For diesel fuels, a limit value of 0.05% by weight shall apply as from 1 October 1996. Member States shall take all necessary steps to ensure the gradual availability of this product.
3. In the event of difficulties in the supply of crude oil or petroleum products, the Member State concerned is required to inform the Commission thereof. The Commission may authorize a higher limit for sulphur content for a period not exceeding six months.
4. Member States may not under any circumstances prohibit the marketing of gasoils once they comply with the above requirements.
5. By way of derogation, the Greek Government will be allowed to authorize the marketing of bunker gasoils with a sulphur content of more than 0.2% by weight until 30 September 1999.

*(4) Opinion of the European Parliament*

First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments.
Second reading: Parliament approved the common position subject to certain amendments. The Commission accepted some of these amendments.

*(5) Current status*

A re-examined proposal incorporating the Commission's amendments is awaited.

*(6) References*

| | |
|---|---|
| Commission proposal<br>COM(91) 154 final | Official Journal C 174, 5.7.1991 |
| Amended proposal<br>COM(92) 119 final | Official Journal C 120, 12.5.1992 |
| Opinion of the European Parliament<br>First reading | Official Journal C 94, 13.4.1992 |
| Opinion of the Economic and Social Committee | Official Journal C 14, 20.1.1992 |

# 2. MOTOR VEHICLES

## 2.21. Spray-suppression devices

| | |
|---|---|
| *(1) Objective* | To harmonize the national type-approval procedures for the spray-suppression devices of certain categories of motor vehicles and their trailers. |
| *(2) Community measures* | Council Directive 91/226/EEC of 27 March 1991 on the approximation of the laws of the Member States relating to the spray-suppression devices of certain categories of motor vehicles and their trailers. |
| *(3) Contents* | 1. This Directive applies to devices intended to reduce the projection of spray or the throwing-up of mud and pebbles coming from tyres of moving vehicles.<br>2. The Member States will issue an EEC component type-approval mark for any type of spray-suppression device which complies with the requirements set out in the annexes to the Directive.<br>3. The Member States do not have the right to prohibit or restrict the marketing of spray-suppression devices bearing the EEC component type-approval mark.<br>4. The Member States will inform the other Member States when they issue an EEC component type-approval mark for a type of spray-suppression device.<br>5. A Member State may temporarily withdraw an approved device from the market if it considers that it does not conform to the approved type. It will immediately inform the Commission thereof; the Commission will examine the reasons for the decision and take appropriate action.<br>6. Annexes containing the definitions, the requirements relating to the EEC component type-approval of spray-suppression devices and the EEC type-approval of vehicles with regard to the fitting of spray-suppression devices, the conformity of production, the cessation of production, and diagrams of the devices. |
| *(4) Deadline for implementation of the legislation in the Member States* | 10.4.1992 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 103, 23.4.1991 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 2. MOTOR VEHICLES

### 2.22. Weights, dimensions and characteristics of road vehicles: tyres and air suspension

| | |
|---|---|
| *(1) Objective* | To reduce wear and tear to road surfaces by imposing the appropriate measures on heavy vehicles. |
| *(2) Community measures* | Council Directive 92/7/EEC of 10 February 1992 amending Directive 85/3/EEC on the weights, dimensions and certain other technical characteristics of certain road vehicles. |
| *(3) Contents* | 1. The present Directive amends Council Directive 85/3/EEC (Official Journal L 2, 3.1.1985) on the weights, dimensions and certain technical characteristics of certain road vehicles.<br>2. It defines the principles of equivalence between mechanical and pneumatic suspensions whilst at the same time taking into consideration the effects of drive axle weight on road surfaces.<br>3. Annex I to Directive 85/3/EEC has therefore been amended and a further Annex III has also been added. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.1.1993 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 57, 2.3.1992 |
| *(7) Follow-up work* | The Council is still examining the rest of the proposal which the Commission has not withdrawn and which concerns suspensions that are less destructive of road surfaces in conjunction with the maximum authorized weight per drive axle covered by the Directive. |
| *(8) Commission implementing measures* | |

# 2. MOTOR VEHICLES

## 2.23. Weights, dimensions and characteristics of road vehicles: maximum dimensions for road trains

| | |
|---|---|
| *(1) Objective* | To fix the maximum length of road trains, with a view to improving the driver's safety and comfort. |
| *(2) Community measures* | Council Directive 91/60/EEC of 4 February 1991, amending Directive 85/3/EEC, with a view to fixing certain maximum authorized dimensions for road trains. |
| *(3) Contents* | 1. The present Directive amends Council Directive 85/3/EEC (Official Journal L 2, 3.1.1985).<br>2. Road trains, the motor vehicle of which was put into circulation before 31 December 1991, which do not comply with the new requirements set out in the annex shall until 31 December 1998 be deemed to conform to such requirements provided that they do not exceed the total length of 18 metres.<br>3. Amendments to Annex 1 fixing the maximum length of road trains and the maximum distance between the loading area behind the cabin and the rearmost point of the trailer of the combination. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.10.1991 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 37, 9.2.1991 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 2. MOTOR VEHICLES

### 2.24. Speed limitation devices for heavy vehicles and coaches

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|---|---|
| *(1) Objective* | To limit the maximum speed of heavy vehicles used to carry goods or passengers on the Community's roads. |
| *(2) Community measures* | Council Directive 92/24/EEC of 31 March 1992 relating to speed limitation devices of certain categories of motor vehicles. |
| *(3) Contents* | 1. This Directive applies to EEC type-approved speed limitation devices and their installation in motor vehicles.<br>2. An application for EEC type-approval of a speed limitation device must be submitted by the manufacturer of the vehicle or the manufacturer of the device.<br>3. The speed limitation device must be so designed, constructed and assembled as to resist the corrosion and ageing phenomena to which it may be exposed.<br>4. It must be impossible to raise or override the limitation threshold whilst a vehicle is in use.<br>5. The holder of an approval must ensure conformity of production. In particular, he must guarantee the existence of procedures allowing effective quality control of the speed limitation device.<br>6. EEC type-approval may be withdrawn where production does not comply with the requirements.<br>7. Member States may not refuse type-approval or national type-approval for a vehicle, or refuse or prohibit the sale, registration, entry into service or use of a vehicle on grounds relating to its equipment with a speed limitation device, if the latter conforms to the requirements of this Directive. Similarly, Member States may not refuse EEC or national type-approval for a speed limiting device, or prohibit the sale or use of a speed limiting device.<br>8. From 1 January 1994 Member States may no longer issue the document provided for in the third indent of Article 10(1) of Directive 70/156/EEC (Official Journal L 42, 23.2.1970) in respect of a type of vehicle of which the speed limitation devices do not meet the requirements of the Directive. Similarly, from 1 October 1994 they can refuse to grant national type-approval in respect of a type of vehicle of which the speed limitation devices do not comply with the provisions of this Directive. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.1.1993 |
| *(5) Date of entry into force (if different from the above)* | |

*(6) References*

*(7) Follow-up work*

*(8) Commission implementing measures*

Official Journal L 129, 14.5.1992

## 2. MOTOR VEHICLES

### 2.25. Installation and use of speed limitation devices in certain categories of motor vehicle

| | |
|---|---|
| *(1) Objective* | To limit the maximum speed of commercial vehicles operating on Community roads. |
| *(2) Community measures* | Council Directive 92/6/EEC of 10 February 1992 relating to the installation and use of speed limitation devices in certain categories of motor vehicles in the Community. |
| *(3) Contents* | 1. The Directive applies to category $M_3$ vehicles of over 10 tonnes and category $N_3$ vehicles.<br>2. As in Council Directive 70/156/EEC (Official Journal L 42, 23.2.1970), the following definitions apply:<br>— Category $M_3$: vehicles used for the carriage of passengers, comprising of more than eight seats in addition to the driver's seat and having a maximum weight exceeding 5 tonnes;<br>— Category $N_3$: vehicles used for the carriage of goods and having a maximum weight exceeding 12 tonnes.<br>3. Category $M_3$ and category $N_3$ motor vehicles referred to in point 1 and registered in any Member State after 1 January 1988 may use the public highway as long as they are fitted with a device which limits vehicle speed to a maximum of 100 km/h and 85 km/h respectively.<br>4. The Directive does not apply to motor vehicles:<br>— of the armed forces, civil protection forces, the fire brigades or the forces responsible for maintaining public order;<br>— which, because of their design, cannot exceed 80 km/h if they are category $N_3$ vehicles, or 100 km/h if they are category $M_3$ vehicles and weigh over 10 tonnes;<br>— used solely in urban areas to provide public services. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.10.1993 |
| *(5) Date of entry into force (if different from the above)* | — 1.1.1994: for new vehicles;<br>— 1.1.1995: for vehicles registered after 1 January 1988. |
| *(6) References* | Official Journal L 57, 2.3.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 2. MOTOR VEHICLES

## 2.26. External projections on cabs of utility vehicles

| | |
|---|---|
| *(1) Objective* | To improve road safety in the Community, a separate Directive for the issue of the EEC type-approval certificate. |
| *(2) Community measures* | Council Directive 92/114/EEC of 17 December 1992 relating to external projections forward of the cab's rear panel of motor vehicles of category N. |
| *(3) Contents* | 1. This Directive applies to external projections forward of the cab's rear panel of motor vehicles of category N. It relates only to the external surfaces and does not apply to external rear-view mirrors or accessories such as radio aerials or luggage racks.<br>2. EEC vehicle type-approval is applied for by the vehicle manufacturer or his representative.<br>3. The manufacturer or his representative must provide various documents, notably a description of the type of vehicle.<br>4. EEC type-approval is granted if the vehicle satisfies the requirements for ornaments and headlamp visors and rims.<br>5. Any alteration to the type of vehicle or its external projections must be notified to the administrative department which issued the vehicle's type-approval.<br>6. Member States may not refuse EEC type-approval or national type-approval of a vehicle type, or refuse or prohibit the sale, registration, entry into service or use of a vehicle on grounds relating to the external projections forward of the rear panel of the vehicle's cab, if these vehicles satisfy the requirements of the Directive.<br>7. Member States must apply the Directive with effect from 1 October 1993. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.6.1993 |
| *(5) Date of entry into force (if different from the above)* | 1.10.1993 |
| *(6) References* | Official Journal L 409, 31.12.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 3. TRACTORS AND AGRICULTURAL MACHINERY

## 1992 target: current position and outlook

The existence of differing national technical regulations and standards is a major problem in the manufacture of agricultural machinery. Production lines cannot be rationalized, thus preventing manufacturers from taking advantage of economies of scale.

A further problem is the absence of Community-wide type-approval procedures. Individual Member States thus require national testing and certification of components and the tractor itself, a costly and wasteful process.

Summaries 3.1 and 3.2 cover the Directives which govern the operation and recognition of national type-approval procedures by laying down the sequence to be followed by those procedures, the exchanges of information between inspection authorities and the granting of the Community conformity mark. Summary 3.3 gives an example of a separate Directive lay down technical specifications for front-mounted roll-over protective structures for tractors. A certain number of Directives lay down similar technical specifications for each tractor component contributing to the overall safety of the vehicle.

Work on the White Paper was completed in December 1988 and since 31 December 1989 manufacturers have been able to obtain EEC type-approval from the inspection authorities and on this basis issue certificates of conformity for each of the tractors produced. The type-approval and certificates are recognized throughout the Community. However, since the system is optional manufacturers may continue to apply for national type-approval. They do so where they feel that the Community requirements, above all in respect of safety, are too stringent.

As in the motor-vehicle field the Commission will thus propose that EEC type-approval become mandatory for manufacturers. While taking account of technological developments it will also extend the scope of that type-approval to vehicles exceeding the current speed limit of 30 km/h.

# 3. TRACTORS AND AGRICULTURAL MACHINERY

## 3.1. EEC type-approval: components and characteristics

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|---|---|
| *(1) Objective* | To harmonize the technical requirements of tractors in all Member States. |
| *(2) Community measures* | Council Directive 89/173/EEC of 21 December 1988 concerning the approximation of the laws of Member States relating to certain components and characteristics of wheeled agricultural or forestry tractors. |
| *(3) Contents* | 1. The Directive applies only to tractors which are fitted with pneumatic tyres and have a maximum speed of between 6 and 30 km/h.<br>2. No Member State may refuse type-approval or national type-approval of a tractor, or refuse its registration or prohibit the sale, entry into service or use of a tractor if it complies with the provisions of the Directive.<br>3. Any amendments necessary to adapt the annexes to technical progress are to be adopted in conformity with the procedure laid down in Directive 74/150/EEC.<br>4. The annexes contain detailed technical requirements including minimum safety margins, weights and dimensions, requirements for the main components and characteristics of tractors (brakes, engine stopping device, windscreen, etc.). |
| *(4) Deadline for implementation of the legislation in the Member States* | 31.12.1989 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 67, 10.3.1989 |
| *(7) Follow-up work* | On 20 June 1991 the Commission presented a proposal for a Council Directive concerning the approximation of the laws of the Member States relating to wheeled agricultural or forestry tractors (SEC(91) 466 final).<br>This is a legislative consolidation of existing Directives relating to wheeled agricultural or forestry tractors. The Directive shall replace previous instruments, including Directive 89/173/EEC, and is limited to regrouping them and incorporating the formal amendments required by the consolidation procedure. |
| *(8) Commission implementing measures* | |

## 3. TRACTORS AND AGRICULTURAL MACHINERY

### 3.2. EEC type-approval

| | |
|---|---|
| *(1) Objective* | To replace Community rules by verification of the particulars supplied by the manufacturers. |
| *(2) Community measures* | Council Directive 88/297/EEC of 3 May 1988 amending Directive 74/150/EEC on the approximation of laws of the Member States relating to the type-approval of wheeled agricultural or forestry tractors. |
| *(3) Contents* | The parts or characteristics of the tractor must be checked to ensure conformity with the particulars in the information document 'CONF' rather than with the harmonized requirements 'SD'. |
| *(4) Deadline for implementation of the legislation in the Member States* | 31.12.1988 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 126, 20.5.1988 |
| *(7) Follow-up work* | On 20 June 1991 the Commission presented a proposal for a Council Directive concerning the approximation of the laws of the Member States relating to wheeled agricultural and forestry tractors.<br>This is a legislative consolidation of existing Directives relating to wheeled agricultural or forestry tractors. The Directive shall replace previous instruments, including Directive 88/297/EEC, and is limited to regrouping them and incorporating the formal amendments required by the consolidation procedure. |
| *(8) Commission implementing measures* | |

# 3. TRACTORS AND AGRICULTURAL MACHINERY

## 3.3. Front-mounted protection structures

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|---|---|
| *(1) Objective* | To harmonize the technical requirements for front-mounted roll-over protection structures on narrow-track tractors. |
| *(2) Community measures* | Council Directive 87/402/EEC of 25 June 1987 on roll-over protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors. |
| *(3) Contents* | 1. The Directive applies to narrow-track tractors, i.e. tractors with a minimum track width of less than 1 150 mm, and an unladen weight of between 600 and 3 000 kg.<br>2. No Member State may prohibit the placing on the market of a tractor, or refuse to grant EEC type-approval or national type-approval for a tractor, if it satisfies the requirements of the Directive.<br>3. All tractors covered by the Directive must be fitted with a roll-over protection structure.<br>4. The Directive will be adapted to technical progress.<br>5. The annexes set out testing procedures and the conditions for granting EEC component type-approval and type-approval. |
| *(4) Deadline for implementation of the legislation in the Member States* | 26.6.1989 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 220, 8.8.1987 |
| *(7) Follow-up work* | In 1988 the Commission presented a proposal amending Directive 87/402/EEC (COM(88) 629 final, published in Official Journal C 305, 30.11.1988) which the Council adopted on 21 December 1989 (Directive 89/681/EEC, published in Official Journal L 398, 30.12.1989).<br>In addition, on 20 June 1991 the Commission presented a proposal for a Council Directive concerning the approximation of the legislation of the Member States relating to wheeled agricultural or forestry tractors. This is a legislative consolidation of existing Directives relating to wheeled agricultural or forestry tractors. The Directive shall replace previous instruments, including Directive 87/402/EEC, and is limited to regrouping them and incorporating the formal amendments required by the consolidation procedure. |
| *(8) Commission implementing measures* | |

# 4. FOODSTUFFS

## 1992 target: current position and outlook

The creation of a single market for foodstuffs has been a gradual process based on the adoption of harmonizing rules which began in the early 1960s. The principle of mutual recognition was established by the judgment in the *Cassis de Dijon case*, which made it clear that the Treaty prohibits any national legislation seeking to prevent the admission of a product that has been lawfully produced and marketed in another Member State. This case was particularly relevant to the foodstuffs sector.

However, the principle deduced by the Court of Justice did not remove all the practical problems encountered by exporters, since it does not prohibit the adoption of restrictive national measures which can be justified on the grounds of protecting public health and the interests of consumers. Community procedures for notifying draft regulations were therefore put in place to deal with this problem. All Member States are obliged to forward all new draft regulations and standards, before they become national law, to the Commission and the other Member States for their comments.

The Commission subsequently framed a strategy which combined the adoption of harmonized rules at Community level applicable to foodstuffs in the Community with the principle of mutual recognition of national regulations and standards which did not need to be harmonized.

The main lines of the harmonization method were set out in the White Paper (COM(85) 310 final) and the communication entitled 'Completion of the internal market: Community legislation on foodstuffs'. What the Commission proposed was to strike a new balance between the legislative powers retained by the Council and the matters which could be dealt with by the Commission. This entailed delegating to the Commission, assisted by the Standing Committee on Foodstuffs, the task of establishing and administering the more detailed and technical provisions by means of specific Directives, leaving it to the Council to adopt general framework Directives laying down the essential requirements (protection of public health, consumer protection, fair trading and protection of the environment). This approach was further accentuated in a second explanatory communication of 24 October 1989 from the Commission (Official Journal C 271, 21.10.1989) and in a third explanatory communication two years later (Official Journal C 270, 15.10.1991).

A distinction can now be drawn between 'vertical' and 'horizontal' harmonization measures. The vertical measures, concerning the labelling of spirituous beverages (summary 4.12), coffee extracts and chicory extracts (summary 4.19), fruit juices and similar products (summary 4.20) and fruit jams, jellies, marmalades and chestnut puree (summary 4.21) are the legacy of the pre-1985 approach to harmonization, which sought to harmonize individual categories of products. The Commission has announced that it will be revising those Directives.

The horizontal measures which stem from the new approach in harmonization cover:

— additives (summaries 4.1 to 4.7),
— materials coming into contact with foodstuffs (summaries 4.8 and 4.9),
— labelling (summaries 4.10 to 4.13),
— foodstuffs intended for particular nutritional uses (summary 4.14),
— deep-frozen foodstuffs (summary 4.18),
— food hygiene (summary 4.27),
— novel foodstuffs and food ingredients (summary 4.29).

The proposals in the White Paper programme have now been adopted for the most part. The proposals not yet adopted concern additives — two proposals for Directives concerning sweeteners (summary 4.2) and colours (summary 4.3) to supplement the general Directive on authorized food additives are at present before the Council.

In the course of 1992 two Regulations were adopted concerning product quality — one lays down the rules for obtaining a Community certificate of specific character for agricultural products and foodstuffs (summary 4.24) and the other lays down rules regarding the protection of designations of origin and geographical indications of certain foodstuffs (summary 4.25).

The most recent proposals concerning foodstuffs are as follows : a proposal for a Directive concerning additional measures relating to the control of foodstuffs which will facilitate cooperation between the Member States' authorities and the Commission to provide the latter with assistance needed concerning scientific examinations (summary 4.16), a proposal for a Regulation on contaminants (summary 4.28), a proposal for a Directive on food hygiene laying down essential health protection requirements for all foodstuffs (summary 4.27) and a proposal for a Directive on novel foodstuffs and ingredients, in order to promote innovation while protecting consumers (summary 4.29).

On the basis of the framework Directives adopted by the Council, the Commission has adopted implementing measures concerning flavourings, materials coming in contact with foodstuffs, foodstuffs for particular nutritional purposes and deep-frozen food. Other measures are in preparation. The Commission has submitted to the Council proposals for implementing measures concerning additives (except flavourings) and labelling.

# 4. FOODSTUFFS

## 4.1. Authorized food additives

*(1) Objective*

To establish a common list of additives for use in foodstuffs intended for human consumption.

*(2) Community measures*

Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives for use in foodstuffs intended for human consumption.

*(3) Contents*

1. The scope of the Directive covers food additives used as ingredients during the manufacture or preparation of food and which are part of the finished product and listed in one of the categories in Annex I (a 'food additive' being any substance not normally consumed as a food itself, the intentional addition of which results in its becoming an ingredient).
2. The only substances which may be used as food additives are those included in the approved lists and then only under the conditions of use mentioned in those lists (e.g. preservatives, emulsifiers, sweeteners, raising agents).
3. The Council will draw up:
— a list of substances the use of which is authorized to the exclusion of all others;
— a list of foodstuffs to which these substances may be added and the conditions under which they may be added, and restrictions which may be imposed in respect of technological purposes;
— rules concerning substances used as solvents including purity criteria where necessary.
4. A special procedure permitting the Commission to legislate after consulting the Standing Committee on Foodstuffs will apply to:
— the drawing up of purity criteria;
— where necessary, the methods of analysis needed to verify that the criteria of purity are satisfied;
— where necessary, the procedure for taking samples and the methods for the qualitative and quantitative analysis of food additives in and on foodstuffs;
— other rules necessary to ensure compliance with the rule that only listed additives may be used.
5. Provisions for action by Member States on listed additives even if the additives which are considered for specific reasons to carry a health risk comply with the Directive.
6. Conditions for provisional authorization by a Member State for the marketing and use of unlisted additives belonging to the categories listed in Annex 1 to the Directive in the light of scientific and technical progress, e.g. maximum limit of two years' circulation.
7. Information requirements on labelling and packaging of additives for sale to both the consumer and the manufacturer.

*(4) Deadline for implementation of the legislation in the Member States*

28.6.1990

| | |
|---|---|
| *(5) Date of entry into force (if different from the above)* | — 28.12.1990: permit trade in products which meet the requirements of the Directive;<br>— 28.12.1991: prohibit trade in products which do not meet the requirements of the Directive. |
| *(6) References* | Official Journal L 40, 11.2.1989 |
| *(7) Follow-up work* | See summaries 4.2 and 4.3.<br>On 18 June 1992 the Commission put forward a proposal for a Council Directive amending Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives intended for human consumption (COM(92) 255 final, published in Official Journal C 206, 13.8.1992).<br>Member States are authorized to prohibit the use of certain additives in foodstuffs produced using traditional methods on their territories, provided the prohibition existed at 1 January 1992 and that the free movement of goods is not affected.<br>However, Member States are required to permit on their territory the production of non-traditional products in conformity with the Directives on additives. |
| *(8) Commission implementing measures* | |

# 4. FOODSTUFFS

## 4.2. Authorized food additives: sweeteners and additives other than colours and sweeteners

*(1) Objective*

To lay down maximum levels for the use of sweeteners in foodstuffs and for food additives other than colours and sweeteners in order to protect the health of consumers.

*(2) Proposal*

Proposal for a Council Directive on sweeteners for use in foodstuffs.

Proposal for a Council Directive on food additives other than colours and sweeteners.

*(3) Contents*

The Directives are specific Directives forming part of the comprehensive Directive 89/107/EEC (summary 4.1).

*Proposal for a Directive on sweeteners for use in foodstuffs*

1. The Directive applies to food additives used to impart a sweet taste to foodstuffs or as table-top sweeteners. It does not apply to foodstuffs with sweetening properties such as honey.
2. The sweeteners which may be placed on the market for sale to consumers or for use in the production of foodstuffs and the maximum doses for the use of such additives in foodstuffs are specified in the annex. The doses specified refer to ready-to-eat foodstuffs only.
3. Member States are required to establish a system of regular surveys to monitor sweetener consumption. On the basis of this information, the conditions of use of sweeteners as laid down in the Directive may, if necessary, be amended.

*Proposal for a Directive on food additives other than colours and sweeteners*

1. The Directive lists in annexes the substances which may be used as food additives other than colours and sweeteners.
2. The presence of a food additive is permitted in a compound foodstuff to the extent that the food additive is permitted in the separate ingredients that make up the compound foodstuff. Its presence is also permitted in a foodstuff which is intended to be used solely in the preparation of another foodstuff provided the compound foodstuff conforms to the provisions of the Directive.
3. The maximum levels indicated in the annexes refer to foodstuffs as marketed.
4. Within five years of the adoption of the Directive, the Commission will review the conditions of use and propose modifications where necessary.

*(4) Opinion of the European Parliament*

First reading: Parliament has approved the Commission's proposal on sweeteners in foodstuffs without amendment.

*(5) Current status*

The proposal is currently before the Council for a common position.

| | | |
|---|---|---|
| *(6) References* | Commission proposal<br>COM(92) 255 final | Official Journal C 206, 13.8.1992 |
| | European Parliament opinion<br>First reading | Official Journal C 305, 23.11.1992 |
| | Economic and Social<br>Committee opinion | Official Journal C 332, 16.12.1992 |

# 4. FOODSTUFFS

## 4.3. Authorized food additives: colouring

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|---|---|
| *(1) Objective* | To lay down the list and maximum quantities of colours authorized for use in foodstuffs. |
| *(2) Proposal* | Proposal for a Council Directive on colours intended for use in foodstuffs. |
| *(3) Contents* | 1. The Directive applies to the colours used in authorized foodstuffs as listed in Annex I thereto, such as E 100 (curcumin) and E 102 (tartrazine).<br>2. The Directive does not apply to:<br>— foodstuffs, flavourings and their components, incorporated during the manufacturing of compound foodstuffs, such as paprika and saffron;<br>— colours used for the colouring of eggshells and for stamping meat and the inedible external parts of foodstuffs.<br>3. The Directive prohibits the use of colours in certain foodstuffs, including mineral water and whole milk.<br>4. Exceptions are allowed to the ban mentioned in paragraph 3 for certain foodstuffs, such as wholemeal bread, beer and smoked and cured fish, to which specific colours may be added. |
| *(4) Opinion of the European Parliament* | Not yet delivered. |
| *(5) Current status* | The proposal has been submitted to the European Parliament and the Economic and Social Committee for their opinion. |
| *(6) References* | Commission proposal COM(91) 444 final — Official Journal C 12, 18.1.1992<br>Economic and Social Committee opinion — Official Journal C 313, 30.11.1992 |

# 4. FOODSTUFFS

## 4.4. Additives: flavourings

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|---|---|
| *(1) Objective* | To harmonize the laws relating to flavourings so as to facilitate the free movement of food in the Community whilst protecting health. |
| *(2) Community measures* | Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production. |
| *(3) Contents* | 1. The Directive will apply to flavouring agents intended for use to impart odour or taste to food.<br>2. Requirement for Member States to ensure that any flavourings marketed or used satisfy the conditions laid down in the Directive such as purity criteria and percentage composition by weight of additive or dangerous or undesirable substances.<br>3. Provision for the adoption of specific Directives applicable to certain groups of flavourings, e.g. chemically synthesized flavouring substances.<br>4. The Commission, in collaboration with the Standing Committee on Foodstuffs, will adopt a list of authorized substances or matters and the methods of analysis required to monitor compliance with the approved composition and other applicable criteria.<br>5. By 1 July 1990 labelling rules for flavourings intended for sale to the final consumer will be adopted.<br>6. Procedures to be followed if a Member State believes an authorized flavouring to be dangerous to human health even if it complies with the Directive.<br>7. Labelling requirements for flavourings not for sale to the final consumer, e.g. the name and address of the manufacturer or producer, sales description, substances used.<br>8. Procedures for updating the Directives.<br>9. Technical annexes on maximum limits for certain substances found in flavourings. |
| *(4) Deadline for implementation of the legislation in the Member States* | 22.12.1989 |
| *(5) Date of entry into force (if different from the above)* | — 22.6.1990: authorization of flavourings complying with the Directive.<br>— 22.6.1991: prohibition of flavourings not complying with the Directive. |
| *(6) References* | Official Journal L 184, 15.7.1988 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | Directive 91/71/EEC — Official Journal L 42, 15.2.1991<br>Commission Directive of 16 January 1991 supplementing Council Directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production. |

This Directive lays down labelling requirements applicable to flavourings for sale to the final consumer. Labelling must include compulsory elements which are listed in the Directive and which must be clearly visible, clearly legible and indelible.
The Directive lays down the conditions for use of the term 'natural' in the labelling of flavourings.
Date of entry into force of the Directive:
— 30.6.1992: authorization of flavourings complying with the Directive;
— 1.1.1994: prohibition of flavourings not complying with the Directive.

# 4. FOODSTUFFS

## 4.5. Additives: extraction solvents

*(1) Objective*

To harmonize laws relating to extraction solvents so as to facilitate the free movement of food within the Community, whilst protecting health.

*(2) Community measures*

Council Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

Council Directive 92/115/EEC of 17 December 1992 amending Directive 88/344/EEC for the first time, on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

*(3) Contents*

*Directive 88/344/EEC*

1. The Directive applies to extraction solvents used in the production of foodstuffs or food ingredients including those imported into the Community. It does not apply to extraction solvents used for the production of additives, vitamins and other nutritional additives not listed in the annex to the Directive nor to extraction solvents exported from the Community. Member States must, however, ensure that the use of these additives does not result in dangerous levels of extraction solvent residue in foodstuffs.
2. Definitions of 'solvent' and 'extraction solvent'.
3. Member States shall authorize the use of extraction solvents listed in the annex to this Directive. They shall not authorize any others.
4. Member States may, on their territory, allow substances used for diluting or dissolving flavourings to be used as solvents for the extraction of flavourings from natural flavouring materials, until Community provisions on these substances are adopted.
5. Other extraction solvents including water to which substances regulating acidity or alkalinity may have been added, ethanol, and other food substances which possess solvent properties, are authorized as extraction solvents in the manufacture of foodstuffs and food ingredients.
6. Within two years of adoption of this Directive, the Commission will re-examine the provisions relating to Parts I and III of the annex (extraction solvents for which conditions of use are specified) and propose any necessary amendments (see Directive 92/115/EEC).
7. Purity criteria for extraction solvents, e.g. they shall not contain a toxicologically dangerous amount of any substance.
8. If a Member State believes an authorized solvent to be dangerous to human health the Member State may temporarily suspend authorization of the solvent. The Commission shall then examine the grounds given by the Member State.
9. Labelling requirements including the name of the substance, indication that the material is of suitably good quality, the business name of the manufacturer or packager, etc.
10. Annex containing list of authorized extraction solvents and conditions of use.

*Directive 92/115/EEC*
This Directive aims to regulate certain substances subject so far to national legislation on the basis of a recent opinion of the Scientific Committee for Food and also to revise the existing provisions.

*(4) Deadline for implementation of the legislation in the Member States*

— Directive 88/344/EEC: 13.6.1991
— Directive 92/115/EEC: to be admitted, no later than 1 July 1993, the sale of goods conforming to this Directive; to be prohibited, from 1 January 1993, the sale of goods not conforming to this Directive.

*(5) Date of entry into force (if different from the above)*

*(6) References*

Official Journal L 157, 24.6.1988
Official Journal L 409, 31.12.1982

*(7) Follow-up work*

*(8) Commission implementing measures*

# 4. FOODSTUFFS

## 4.6. Additives: preservatives (potassium bisulphite and thiabendazole)

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|---|---|
| *(1) Objective* | To include potassium acid sulphite (potassium bisulphite) which is used in wine production in the list of permitted preservatives. |
| *(2) Community measures* | Council Directive 85/585/EEC of 20 December 1985 amending Directive 64/54/EEC on the approximation of the laws of the Member States concerning the preservatives authorized for use in foodstuffs intended for human consumption. |
| *(3) Contents* | 1. Potassium acid sulphite (potassium bisulphite) is added to the list of permitted preservatives.<br>2. As from 1 January 1986 the use of thiabendazole (E 233) is not subject to temporary authorization. This will remove doubts about its suitability. However, this does not exclude further general EC rules on surface treatment of fruit. |
| *(4) Deadline for implementation of the legislation in the Member States* | 31.12.1986 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 372, 31.12.1985 |
| *(7) Follow-up work* | The Commission proposal also included the addition of natamycin to the list of permitted preservatives. This, however, was not adopted and is still undergoing consideration by the Council. This specific Directive must be seen as one element in the continuing process of keeping the list of permitted additives up to date. |
| *(8) Commission implementing measures* | |

# 4. FOODSTUFFS

## 4.7. Additives: emulsifiers, stabilizers, thickeners and gelling agents

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|---|---|
| *(1) Objective* | To extend the period of temporary authorization for certain emulsifiers, stabilizers, thickeners and gelling agents, and to prohibit the use of certain other substances. |
| *(2) Community measures* | Council Directive 86/102/EEC of 24 March 1986 amending for the fourth time Directive 74/329/EEC on the approximation of the laws of the Member States relating to emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs. |
| *(3) Contents* | This will allow for the re-evaluation of polysorbates in the light of any new information, the completion of an investigation of an authorized additive or the authorization of the sale of any products containing the additives which are already on the market. This specific Directive must be seen as one element in the continuing process of keeping the list of permitted additives up to date. It lays down:<br>1. New temporary authorization period for the substances listed in Annex II. Tragacanth and Karaya gum are pending a Commission enquiry.<br>2. Transitional period for certain other emulsifiers, stabilizers, thickeners and gelling agents as detailed above to allow for the sale of foodstuffs containing these substances which are already on the market, at the end of which the use of these substances will no longer be authorized. |
| *(4) Deadline for implementation of the legislation in the Member States* | 26.3.1987 |
| *(5) Date of entry into force (if different from the above)* | 26.3.1988 |
| *(6) References* | Official Journal L 88, 3.4.1986 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 4. FOODSTUFFS

## 4.8. Materials in contact with foodstuffs

*(1) Objective*

To lay down common rules for the composition of materials and articles intended to come into contact with foodstuffs.

*(2) Community measures*

Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs.

*(3) Contents*

1. The Directive applies to materials and articles intended to come into contact with foodstuffs. Covering or coating substances, such as the substances covering cheese rinds, prepared meat products or fruit, which may be consumed together with the food, do not belong to this category.
2. Materials and articles must be manufactured so that they do not transfer their constituents to food in quantities which could:
— endanger human health, or
— bring about an unacceptable change in the composition of the foodstuffs or a deterioration in their organoleptic properties.
3. Specific Directives will be adopted for plastics, regenerated cellulose film, elastomers and rubber, paper and board, ceramics, glass, metals and alloys, wood, including cork, textile products and paraffin wax or microcrystalline wax. The Directives may include a list of the authorized substances, special conditions of use, purity standards, etc.
4. The Commission will adopt these specific Directives in accordance with the procedure laid down, after consulting with the Standing Committee on Foodstuffs.
5. When a Member State establishes that the use of a material endangers human health although it complies with the relevant specific Directive, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. The Commission will examine as soon as possible the grounds of this decision and will take appropriate action.
6. Requirements for marketing materials and articles coming into contact with foodstuffs, e.g. they must bear an indication such as the words 'for food use'; they must bear the name and address of the manufacturer or a trade mark. This information must be easily visible, clearly legible and indelible.

*(4) Deadline for implementation of the legislation in the Member States*

10.7.1990

*(5) Date of entry into force (if different from the above)*

Member States shall, where appropriate, amend their laws, regulations and administrative provisions so as to:
— permit trade in and the use of materials and articles complying with this Directive by 10 July 1990 at the latest;
— prohibit trade in and the use of materials and articles which do not comply with this Directive from 10 January 1992 at the latest.

*(6) References*

Official Journal L 40, 11.2.1989

*(7) Follow-up work*

*(8) Commission implementing measures*

Directive 90/128/EEC (Official Journal L 75, 21.3.1990)
Commission Directive of 23 February 1990 relating to plastic materials and articles intended to come into contact with foodstuffs.
This Directive is the first measure implementing the framework Directive. It applies to plastic materials and articles which, in the finished product state, are intended to come into contact with foodstuffs and are intended for that purpose.

Directive 92/15/EEC (Official Journal L 102, 16.4.1992)
Commission Directive of 11 March 1992 amending Council Directive 83/229/EEC on the approximation of the laws of the Member States relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.
The aim of the Directive is to harmonize the use of certain phthalic esters by laying down thresholds below which human exposure to these substances does not involve any risk to human health, in accordance with the most recent opinions of the Scientific Committee on Food. The Directive furthermore authorizes the use of new additives such as tetraethyleneglycol.

# 4. FOODSTUFFS

## 4.9. Materials in contact with foodstuffs: testing

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| *(1) Objective* | To implement previous legislation on plastic packaging material to take account of technical progress in migration tests. |
| *(2) Community measures* | Council Directive 85/572/EEC of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs. |
| *(3) Contents* | 1. The simulants prescribed for use for testing migration of the constituents of plastic materials intended to come into contact with foodstuffs are restricted to those indicated in the annex.<br>2. Annex containing list of authorized simulants. |
| *(4) Deadline for implementation of the legislation in the Member States* | Same as for Council Directive 82/711/EEC (Official Journal L 297, 23.10.1982). |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 372, 31.12.1985 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 4. FOODSTUFFS

## 4.10. Labelling: labelling, presentation and advertising

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|---|---|
| *(1) Objective* | To ensure that consumers are properly informed of the treatment undergone by the foodstuffs they consume. |
| *(2) Community measures* | Council Directive 89/395/EEC of 14 June 1989 amending Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer. |
| *(3) Contents* | 1. The Directive applies to the labelling, presentation, and advertising of foodstuffs. The scope now includes foodstuffs intended for supply to restaurants, hospitals and other similar mass caterers, as well as foodstuffs intended for sale to the ultimate consumer and to mass caterers. It does not cover the authorization or prohibition of the ionizing radiation of foodstuffs (summary 4.22). However, any foodstuff or ingredient treated in this way must bear a suitable indication.<br>2. Clarification of requirements for labelling and listed ingredients.<br>3. An indication of the durability date is not required for fresh fruit and vegetables, wines, beverages containing 10% or more by volume of alcohol, solid sugar, etc.<br>4. Updating of the annex to the earlier Directive to include flavouring agents among products requiring the designation of flavouring ingredients.<br>5. The Commission will adopt specific Community provisions after consulting the Standing Committee on Foodstuffs, in accordance with the procedure laid down.<br>6. Indication on the labelling of the drained net weight of foodstuffs presented in a liquid medium (definition of 'liquid medium').<br>7. In their own territories the Member States may, until 31 December 1992, permit the minimum durability period to be expressed otherwise than in terms of the date of minimum durability.<br>8. Special conditions applicable to milk and milk products put up in glass bottles intended for re-use. |
| *(4) Deadline for implementation of the legislation in the Member States* | — 20.12.1990: permit trade in products conforming to the Directive;<br>— 20.6.1992: prohibit trade in products not conforming to the Directive. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 186, 30.6.1989 |
| *(7) Follow-up work* | A consolidated version of Directive 79/112/EEC was adopted by the Commission in December 1989. |

It is a legislative consolidation in that the new Directive will replace the various Directives involved in the consolidation operation. This Directive retains the substance of the consolidated texts and simply groups them together, making only the formal changes required by the consolidation operation itself.

On 9 April 1992 the Commission put forward a new proposal for a Council Directive amending Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (Official Journal C 122, 14.5.1992). The aim of the proposal is to fill a gap as regards the labelling of foodstuffs containing a single ingredient and to re-examine the labelling of alcoholic beverages. It also provides for compulsory indication of the quantity of certain ingredients (composition of foodstuffs) and supplements the provisions concerning the name under which a product is sold.

*(8) Commission implementing measures*

# 4. FOODSTUFFS

## 4.11. Labelling: alcoholic drinks

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|---|---|
| *(1) Objective* | To ensure that labels provide adequate information to consumers regarding the percentage of alcohol in alcoholic drinks. |
| *(2) Community measures* | Council Directive 86/197/EEC of 26 May 1986 amending Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer. |
| *(3) Contents* | Extension of labelling requirements to include compulsory indication of alcoholic strength for beverages containing more than 1.2% by volume of alcohol. |
| *(4) Deadline for implementation of the legislation in the Member States* | — 1.5.1988: permit trade in products conforming to this Directive;<br>— 1.5.1989: prohibit trade in products not conforming to this Directive. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 144, 29.5.1986 |
| *(7) Follow-up work* | The Commission has presented to the Council a proposal for a Directive amending Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (COM(91) 536 final).<br>The proposal determines the framework in which the labelling rules for the ingredients of alcoholic drinks will be adopted, namely in specific Regulations (wine, sparkling wine, spirits, etc.) or by means of the Standing Committee on Foodstuffs procedure (beer, etc.). |
| *(8) Commission implementing measures* | |

# 4. FOODSTUFFS

## 4.12. Labelling: spirit drinks

*(1) Objective*

To lay down common rules for describing alcoholic drinks. This will facilitate the free movement of these products within the Community.

*(2) Community measures*

Council Regulation (EEC) No 1576/89 of 30 May 1989 laying down general rules on the definition, description and presentation of spirit drinks.

Council Regulation (EEC) No 3280/92 of 9 November 1992 amending Regulation (EEC) No 1576/89 laying down general rules on the definition, description and presentation of spirit drinks.

*(3) Contents*

1. Definitions of generic terms including 'gin', 'rum', 'whisky' and of general terms including 'spirit drink', 'sweetening', 'mixing', 'blending', etc. Spirit drinks marketed for human consumption may not be described by associating words such as 'style', 'type' or 'flavour'.
2. Restrictions on the sale of spirit drinks, e.g. whisky sold in the Community must have a minimum alcoholic strength per volume of 40%.
3. Addition of substances to the products. Water may be added, provided it meets the quality requirements of water intended for human consumption. Except in a few cases, only natural aromatic substances and preparations may be used as flavourings.
4. Rules concerning the labelling and presentation of these products, with particular reference to origin and method of manufacture, e.g. the alcoholic strength must be expressed to the nearest half per cent, and the name under which the drinks are sold may be supplemented by the term 'blend' where the product has undergone this procedure.
5. From 1 January 1993 containers with a closing device covered by lead-based capsules or foil may not be used for these products.
6. Annexes setting out the characteristics of ethyl alcohol of agricultural origin and geographical designations for different categories of products.
7. Establishment of a list of geographical indications.

*(4) Deadline for implementation of the legislation in the Member States*

Not required.

*(5) Date of entry into force (if different from the above)*

— Regulation (EEC) No 1576/89: 15.12.1989 (15.6.1989) for Articles 13 to 16
— Regulation (EEC) No 3280/92: 16.11.1992

*(6) References*

Official Journal L 160, 12.6.1989
Official Journal L 327, 13.11.1992

*(7) Follow-up work*

*(8) Commission implementing measures*

Regulation (EEC) No 3773/89 (Official Journal L 365, 15.12.1989) Commission Regulation of 14 December 1989 laying down transitional measures relating to spirituous beverages.

Regulation (EEC) No 1014/90 (Official Journal L 105, 25.4.1990) Commission Regulation of 24 April 1990 laying down detailed implementing rules on the definition, description and presentation of spirit drinks.

Regulation (EEC) No 1759/90 (Official Journal L 162, 28.6.1990) Commission Regulation of 27 June 1990 amending Regulation (EEC) No 3773/89 laying down transitional measures relating to spirituous beverages.

Regulation (EEC) No 3207/90 (Official Journal L 307, 7.11.1990) Commission Regulation of 6 November 1990 amending Regulation (EEC) No 3773/89 laying down transitional measures relating to spirituous beverages.

Regulation (EEC) No 1180/91 (Official Journal L 115, 8.5.1991) Commission Regulation of 6 May 1991 amending Regulation (EEC) No 1014/90 laying down detailed implementing rules on the definition, description and presentation of spirit drinks.

Regulation (EEC) No 1781/91 (Official Journal L 160, 25.6.1991) Commission Regulation of 19 June 1991 amending Regulation (EEC) No 1014/90 laying down detailed implementing rules on the definition, description and presentation of spirit drinks.

Commission report to the Council on the alcoholic strength at which whisky is released on the market (presented under Article 3(4) of Regulation (EEC) No 1576/89) (SEC(92) 1832 final).
The report presents the findings of a market study carried out by the Commission with a view to the re-examination by the Council, before 31 December 1992, of the minimum alcoholic strength of whisky. In particular, the study assesses the impact of a prohibition of low-strength whiskies.

Regulation (EEC) No 3458/92 (Official Journal L 350, 1.12.1992) Commission Regulation of 30 November 1992 amending Regulation (EEC) No 1014/90 laying down detailed implementing rules on the definition, description and presentation of spirit drinks.

# 4. FOODSTUFFS

## 4.13. Labelling: nutrition labelling rules

*(1) Objective*

To lay down common rules on nutrition labelling to ensure free movement of foodstuffs throughout the Community while guaranteeing consumer protection.

*(2) Community measures*

Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling rules of foodstuffs.

*(3) Contents*

1. This Directive concerns nutrition labelling of foodstuffs for the ultimate consumer and for mass caterers (restaurants, hospitals, canteens, etc.).
2. The Directive does not apply to natural mineral waters or any other waters intended for human consumption or to diet integrators/food supplements.
3. Definitions of the terms 'nutrition labelling', 'nutrition claim' (any representation and any advertising which states or implies that a food has particular nutritional properties), 'nutrients' (proteins, carbohydrates, fat, dietary fibre, vitamins and minerals etc.)
4. Nutrition labelling is not compulsory unless a nutrition claim is made on the label or in advertising material.
5. Only nutrition claims are allowed which relate to the energy value and nutrients referred to above and to substances which belong to one of the categories of these nutrients or which are components of them.
6. Where nutrition labelling is provided, the information given shall be that contained in the following groups, depending on the labelling:
— either Group 1, which shall state:
  • the energy value, and
  • the amount of protein, carbohydrate and fat,
— or Group 2, which shall state:
  • the energy value, and
  • the amount of protein, carbohydrate, sugar, fat, saturated fatty acids, dietary fibre and sodium.

Until 1 October 1995 the voluntary inclusion in the nutrition labelling of one or more of the nutrients sugar, saturated fatty acids, dietary fibre or sodium does not bring into play the obligation referred to in Article 4(1) and (2) to mention all of these nutrients.
7. The declared energy value and amount of nutrients shall be given in figures using specific units of measurement. The information shall be expressed per 100g or per 100ml per package. 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.
8. All of the above information shall be grouped together in a clearly visible place and shall be in legible, indelible characters and in a language easily understood by the purchaser. Member States shall not introduce nutrition labelling specifications that are more detailed than those contained in this Directive.
9. With regard to foodstuffs which are not prepackaged when sold to the ultimate consumer and mass caterers and foodstuffs which are packaged at the places of immediate sale, the scope of the information

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| | referred to in point 6 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.<br>10. Any measure which may have an effect on public health shall be adopted after consulting the Scientific Committee for Food. |
| *(4) Deadline for implementation of the legislation in the Member States* | |
| *(5) Date of entry into force (if different from the above)* | — to be admitted no later than 1 April 1992, the sale of goods must conform to the present Directive.<br>— to be prohibited from 1 October 1993, the sale of goods not conforming to the present Directive. |
| *(6) References* | Official Journal L 276, 6.10.1990 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 4. FOODSTUFFS

## 4.14. Foodstuffs for particular nutritional uses

*(1) Objective*

To give a common definition and lay down common rules for the presentation of goods for particular nutritional uses.

*(2) Community measures*

Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of Member States relating to foodstuffs intended for particular nutritional uses.

*(3) Contents*

1. The Directive applies to foodstuffs intended for particular nutritional uses. They must be suitable for their claimed nutritional purposes, and marketed in such a way as to indicate their suitability. A particular nutritional use must fulfil the particular nutritional requirements of:
— certain categories of persons whose digestive system or metabolism is disturbed;
— certain categories of persons who are in a special physiological condition;
— infants or young children in good health.
2. The use of the adjectives 'dietetic' or 'dietary' is prohibited in the labelling, presentation and advertising of foodstuffs for normal consumption.
3. Specific provisions for groups of foods for particular nutritional uses will be laid down in specific Directives. These may include compositional requirements, hygiene requirements, list of additives, purity criteria, etc. Specific labelling requirements in addition to those required for foodstuffs in general, e.g. declaration of the energy value, carbohydrate, protein and fat content.
4. Procedures to be followed if a particular foodstuff, although complying with the relevant specific Directive, is believed to endanger human health.
5. Provisions for the adoption of future specific Directives.

*(4) Deadline for implementation of the legislation in the Member States*

— 16.5.1990: permit trade in products which meet the requirements of this Directive;
— 16.5.1991: prohibit trade in products which do not meet the requirements of this Directive.

*(5) Date of entry into force (if different from the above)*

*(6) References*

Official Journal L 186, 30.6.1989

*(7) Follow-up work*

On 18 June 1992, the Council adopted a Directive on infant formulas and follow-on formulas intended for export to third countries (Council Directive 92/52/EEC, published in Official Journal L 179, 1.7.1992).
The aim of the Directive is to make some of the provisions of Commission Directive 91/321/EEC applicable to the same products when exported to third countries.
The Council also adopted a resolution on the marketing of breast milk substitutes by Community manufacturers in developing countries.

*(8) Commission implementing measures*

Directive 91/321/EEC — Official Journal L 175, 4.7.1991
Commission Directive of 14 May 1991 on infant formulas and follow-on formulas. The Directive lays down compositional and labelling requirements and requirements for the advertising and marketing of these products.

— 1.12.1992: trade in products which meet the requirements of this Directive to be permitted;
— 1.6.1994: trade in products which do not meet the requirements of this Directive to be prohibited.

# 4. FOODSTUFFS

## 4.15. Official inspection of foodstuffs

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|---|---|
| *(1) Objective* | To provide for official inspections of food in order to protect the health and economic interests of consumers. |
| *(2) Community measures* | Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs. |
| *(3) Contents* | 1. The Directive lays down general principles governing the official inspection of foodstuffs, namely the inspection of foodstuffs, food additives, vitamins, mineral salts, trace elements and materials coming into contact with foodstuffs to ensure that they comply with provisions designed to prevent risks to public health, ensure fair trading and protect consumer interests.<br>2. Procedures concerning the carrying out of inspections both on a regular basis and in those instances when non-compliance is suspected.<br>3. Items subject to inspection include raw materials, semi-finished products, finished products, cleaning and maintenance products used in connection with the production of foodstuffs, etc.<br>4. Analysis of samples is entrusted to official laboratories.<br>5. Inspectors must have the right to carry out their inspections. They are bound by professional secrecy. Within one year of the adoption of the Directive by the Council, the Commission must present a report on:<br>— training provision for food inspectors;<br>— quality standards for laboratories involved in inspection and sampling;<br>— the possibility of establishing a Community inspection service, including opportunities for all institutions and persons involved in the inspections to exchange information.<br>6. Member States must draw up forward programmes laying down the nature and frequency of inspections and must inform the Commission annually of the implementation thereof. On the basis of this information the Commission must draw up a recommendation for a coordinated inspection programme. |
| *(4) Deadline for implementation of the legislation in the Member States* | 20.6.1990 |
| *(5) Date of entry into force (if different from the above)* | 20.6.1991 |
| *(6) References* | Official Journal L 186, 30.6.1989 |
| *(7) Follow-up work* | The Commission presented additional measures concerning the control of foodstuffs (summary 4.16). |
| *(8) Commission implementing measures* | On 13 September 1990 the Commission adopted a communication to the Council and to the European Parliament regarding the uniform application of Directive 89/397/EEC (COM(90) 392 final). |

The Commission notes that the professional function of a 'food inspector' in the various Member States is not clearly defined. It considers it essential to define areas in which personnel responsible for official food control must have received training to an appropriate professional level. It accepts the need for additional training. It considers that a system of quality standards should be introduced for all those laboratories which have been entrusted by the competent authorities with the control of foodstuffs. The Commission is proposing the recognition of equivalent analysis methods. Finally, the Commission believes that there are a number of arguments in favour of establishing a Community inspection service entrusted with the uniform application of Community law.

On 22 July 1991, the Commission adopted a second communication giving additional information on the basic training currently required by the Member States for 'food inspectors' (COM(91) 274 final).

On 9 November 1992 the Commission adopted a recommendation relating to a coordinated programme for the official inspection of foodstuffs for 1993.
To be certain that the requirements concerning health protection are complied with, to guarantee fair trading and to protect the interests of consumers, the Commission recommends to the Member States that they take samples of and check parameters in relation to the following products: adulteration of orange juice, nitrates, and nitrites in infant formulas containing vegetables, checking the weight of deep frozen seafood, microbiological analysis of ice-cream and of prepared dishes.

# 4. FOODSTUFFS

## 4.16. Additional measures concerning the control of foodstuffs

*(1) Objective*

To supplement the general principles for the inspection of foodstuffs and allow uniform application by the Member States of Council Directive 89/397/EEC on the official control of foodstuffs (summary 4.15).

*(2) Proposal*

Proposal of a Council Directive regarding additional measures concerning the control of foodstuffs.

*(3) Contents*

1. Officials must have adequate training in areas such as chemistry, (veterinary) medicine, microbiology, food hygiene, food processing and law.
2. To facilitate mutual recognition of the results obtained by the inspection authorities:
— the laboratories authorized to carry out the inspections must comply with the general criteria for the operation of testing laboratories laid down in European standard EN 45 001 and with certain OECD principles of good laboratory practice;
— the methods of analysis used by the laboratories must comply with the criteria laid down concerning specificity, detection limit, sensitivity, accuracy, etc.
3. Officials designated by the Commission will cooperate with the competent authorities of the Member States in the official control of foodstuffs.
4. The competent authorities are required to afford each other administrative assistance in all supervisory procedures in connection with legal provisions and quality standards applicable to foodstuffs and in all proceedings to end infringements.

*(4) Opinion of the European Parliament*

First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments.

*(5) Current status*

The proposal is currently before the Council in view of a common position.

*(6) References*

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| Commission proposal<br>COM(91) 526 final | Official Journal C 51, 26.2.1992 |
| Amended proposal<br>COM(92) 574 final | Not yet published |
| European Parliament opinion<br>First reading | Not yet published |
| Economic and Social Committee opinion | Official Journal C 332, 16.12.1992 |

# 4. FOODSTUFFS

## 4.17. Sampling and analysis of foodstuffs

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|---|---|
| *(1) Objective* | To allow the Commission to adopt Community methods for the sampling and analysis of foodstuffs where necessary. |
| *(2) Community measures* | Council Directive 85/591/EEC of 20 December 1985 on the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption. |
| *(3) Contents* | 1. Methods of sampling and analysis must be adopted by the Commission and, where appropriate, the Council when necessary. Account must be taken of:<br>— the need to ensure that Community law is uniformly applied;<br>— the existence of barriers to intra-Community trade.<br>2. Member States may use other tested and scientifically valid methods provided that this does not hinder the free movement of products recognized as complying with the rules by virtue of Community methods.<br>3. Use of measures adopted in accordance with the Directive and believed to be inappropriate may be temporarily suspended by a Member State in its territory pending appropriate action by the Commission. |
| *(4) Deadline for implementation of the legislation in the Member States* | 23.12.1987 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 372, 31.12.1985 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 4. FOODSTUFFS

## 4.18. Quick-frozen food

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|---|---|
| *(1) Objective* | To harmonize the Member States' laws on quick-frozen foods so as to facilitate their free movement within the Community. |
| *(2) Community measures* | Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption. |
| *(3) Contents* | 1. The Directive applies to quick-frozen foodstuffs. Quick freezing is a process whereby the temperature zone of maximum crystallization is spanned as rapidly as is necessary for the product temperature to be reduced to -18°C or lower (after thermal stabilization).<br>2. Quick freezing must be carried out with the aid of appropriate equipment immediately after the product has been processed.<br>3. A list of authorized cryogenic fluids is included.<br>4. Deviations from the mandatory temperature for quick-frozen foods are permitted during transport and local distribution and in retail display cabinets: the temperature must not exceed 3°C. However, it may be as much as 6°C in retail display cabinets if Member States so decide.<br>5. Member States must conduct random checks on quick-freezing equipment and on temperature levels.<br>6. Labelling requirements including the net quantity, batch identification (for sale to food producers), and the period during which the goods may be stored. The trade name must be supplemented by the term 'quick-frozen'.<br>7. Procedure for adopting methods of sampling, monitoring temperatures and storage.<br>8. Transitional period of eight years for retail display cabinets. |
| *(4) Deadline for implementation of the legislation in the Member States* | — 10.7.1990: permit trade in products which meet the requirements of the Directive;<br>— 10.1.1991: prohibit trade in products which do not meet the requirements of the Directive. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 40, 11.2.1989 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | Directive 92/1/EEC — Official Journal L 34, 11.2.1992<br>Commission Directive of 13 January 1992 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption.<br><br>Directive 92/2/EEC — Official Journal L 34, 11.2.1992<br>Commission Directive of 13 January 1992 laying down the sampling procedure and the Community method of analysis for the control of the temperatures of quick-frozen foods intended for human consumption. |

# 4. FOODSTUFFS

## 4.19. Coffee and chicory extracts

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| *(1) Objective* | To remove restrictions on the constituents of coffee and chicory products. This is to protect them from unfair competition from similar products manufactured outside the Community. |
| *(2) Community measures* | Council Directive 85/573/EEC of 19 December 1985 amending Directive 77/436/EEC on the approximation of the laws of the Member States relating to coffee and chicory extracts. |
| *(3) Contents* | 1. Removal of previous restrictions relating to the manufacture and sale of the abovementioned products.<br>2. New labelling requirements: e.g. the term 'decaffeinated' may be used provided that the anhydrous caffeine content does not exceed 0.3% by weight of the coffee-based dry material. The minimum coffee-based dry matter content expressed as a percentage by weight of the finished product must be stated.<br>3. Annex containing descriptions and definitions of coffee and chicory extracts to which the Directive applies. |
| *(4) Deadline for implementation of the legislation in the Member States* | — 1.1.1987: permit trade in products which meet the requirements of the Directive;<br>— 1.7.1988: prohibit trade in products which do not meet the requirements of the Directive. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 372, 31.12.1985 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 4. FOODSTUFFS

## 4.20. Fruit juices and similar products

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|---|---|
| *(1) Objective* | To update existing legislation on fruit juices in the light of changing eating habits and of technical developments in the production of some juices. |
| *(2) Community measures* | Council Directive 89/394/EEC of 14 June 1989 amending for the third time Directive 75/726/EEC on the approximation of the laws of the Member States concerning fruit juices and certain similar products. |
| *(3) Contents* | 1. Definition of 'fruit nectar' as the unfermented, but fermentable product obtained by the addition of water, with or without the addition of sugar, to fruit juice, concentrated fruit juice, fruit purée or a mixture of these products.<br>2. Freedom to replace sugars by honey.<br>3. Citric acid may be used in the production of fruit nectars obtained from apples, pears, or peaches.<br>4. Restrictions on the use of sweeteners; there is a maximum percentage limit on the added sugar content; sweetening (for fruit juice only) must be indicated in the name.<br>5. The Directive will be updated to take account of technical progress. The Commission and, where appropriate, the Council will adopt these amendments after consulting the Standing Committee on Foodstuffs. |
| *(4) Deadline for implementation of the legislation in the Member States* | — 14.6.1990: permit trade in products which meet the requirements of the Directive;<br>— 14.6.1991: prohibit trade in products which do not meet the requirements of this Directive. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 186, 30.6.1989 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 4. FOODSTUFFS

## 4.21. Fruit jams, jellies, marmalades and chestnut purée

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|---|---|
| *(1) Objective* | To update existing legislation on fruit jams, jellies and similar products in the light of technical developments in their production (Council Directive 79/693/EEC published in Official Journal L 205, 13.8.1979). |
| *(2) Community measures* | Council Directive 88/593/EEC of 18 November 1988 amending Directive 79/693/EEC on the approximation of the laws of the Member States relating to fruit jams, jellies and marmalades and chestnut purée. |
| *(3) Contents* | 1. Minor changes in the wording of the English and Spanish versions of the Directive, e.g. 'chestnut purée' is changed to 'sweetened chestnut purée'.<br>2. Identity and purity criteria must be determined where necessary, in accordance with the procedure laid down.<br>3. Amendments needed to adapt the annexes to progress must be adopted in accordance with the procedure laid down. The Commission and, where appropriate, the Council will adopt these amendments after consulting the Standing Committee on Foodstuffs.<br>4. Amendments to annexes, e.g. to allow the use of red fruit juices for the colouring of jams. |
| *(4) Deadline for implementation of the legislation in the Member States* | — 31.12.1989 to permit trade in products complying with the Directive;<br>— 1.1.1991 to prohibit trade in products not complying with the Directive. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 318, 25.11.1988 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | In December 1990 the Commission presented a communication on the approximation of the laws of the Member States relating to fruit jams, jellies and marmalades and chestnut purée (COM(90) 508 final).<br>In the communication the Commission informed the Council and Parliament that the current market situation, with a growing number of reduced-energy products, did not encourage the drafting of a proposal on the use of Community names for jams, as provided for under Directive 79/693/EEC. |

# 4. FOODSTUFFS

## 4.22. Foodstuffs treated with ionizing radiation

*(1) Objective*

To harmonize Member State provisions concerning the irradiation of foodstuffs.

*(2) Proposal*

Proposal for a Council Directive on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionizing radiation.

*(3) Contents*

1. The Directive applies to the processing and marketing of foodstuffs and food ingredients treated with ionizing radiation. It does not apply to foodstuffs exposed to ionizing radiation emitted by measuring or inspection devices up to a specified limit, nor to foodstuffs prepared under medical supervision for patients requiring sterile diets.
2. Irradiated foodstuffs may only be marketed if they comply with the Directive and Member States may not prohibit, restrict or obstruct the marketing of foodstuffs which have been irradiated in conformity with the Directive.
3. Annex 1 of the Directive lists foodstuffs authorized for irradiation treatment and the maximum radiation doses. Permitted radiation sources are listed in Annex 2, and Annex 3 specifies how the overall absorbed dose is to be calculated. Provision is made for amending these annexes.
4. Foodstuffs may not be re-irradiated. However, the full needed dose for a specific technological function may be given as the sum of fractionated doses. Irradiation may be used in conjunction with other processes. A procedure is established for exceptions to these provisions.
5. Member States are to ensure that irradiated foodstuffs are only marketed if their packaging or containers bear specific information. Where products are intended for sale to the final consumer, the information requirements of Council Directive 79/112/EEC (Official Journal L 33, 8.2.1979) on the labelling, presentation and advertising of foodstuffs have to be complied with. Foodstuffs not intended for sale to the ultimate consumer must bear information such as the fact that the product has been irradiated and the name and address of the irradiation unit.
6. Provisions for the establishment of regulatory authorities in the Member States to control the irradiation of foodstuffs. The Directive specifies the authorities' responsibilities, the information they must send to the Commission and the standards of good practice which they must ensure are followed.
7. Units for the irradiation of foodstuffs will have to be approved by the designated authorities and be subject to control and inspection. Units must keep a record for each source of ionizing radiation containing specified information, e.g. the nature and quantity of foodstuffs irradiated and data for the control of the irradiation process. These records must be preserved for five years. Detailed rules concerning these records will be adopted.
8. Irradiated foodstuffs may not be imported from third countries unless they comply with the provisions of the Directive. Documents accompanying the foodstuffs must provide the name and address of the irradiation unit and the necessary records. It must be confirmed that

irradiation has been officially supervised ensuring that the irradiation conditions are equivalent to those required by the Directive. The Commission may make arrangements with third countries regarding mutual notification of irradiation plants and Community inspection in third countries.
9. Appropriate materials shall be used for the packaging of foodstuffs to be irradiated.
10. The Commission, after consultation of the Standing Committee on Foodstuffs and certain other standing committees where appropriate, is empowered to:
— amend the annexes to take account of scientific and technological developments;
— adopt detailed rules for the records to be kept by approved irradiation units;
— take appropriate measures should a Member State conclude that the irradiation of a foodstuff is harmful to human health, although conforming to the Directive.

*(4) Opinion of the European Parliament*

First reading: Parliament approved the proposal subject to amendments, some of which have been accepted by the Commission (amendment of the list of products for which ionizing radiation is authorized).

*(5) Current status*

An amended proposal including the amendments put forward by Parliament and accepted by the Commission is currently before the Council for a common position.

*(6) References*

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|---|---|
| Commission proposal<br>COM(88) 654 final | Official Journal C 336, 31.12.1988 |
| Amended proposal<br>COM(89) 100 final | Official Journal C 303, 2.12.1989 |
| European Parliament opinion<br>First reading | Official Journal C 291, 20.11.1989 |
| Economic and Social<br>Committee opinion | Official Journal C 194, 31.7.1989 |

# 4. FOODSTUFFS

## 4.23. Lot

*(1) Objective*

To provide a useful source of information when foodstuffs are the subject of a dispute or constitute a health hazard for consumers, by providing better information on the identity of products.

*(2) Community measures*

Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs.

Council Directive 91/238/EEC of 22 April 1991 amending Directive 89/396/EEC on indications or marks identifying the lot to which a foodstuff belongs.

Council Directive 92/11/EEC of 3 March 1992 amending Directive 89/396/EEC on indications or marks identifying the lot to which a foodstuff belongs.

*(3) Contents*

1. The Directives concern indications which allow identification of the lot to which a foodstuff belongs. The term 'lot' means a batch of sales units of a foodstuff produced, manufactured or packaged under the same conditions.
2. An easily visible and indelible indication of the lot must appear in all cases on foodstuffs.
3. Certain exceptions are provided for, because of technical problems concerning the indication of the lot.
4. The lot is determined by the producer, or the first seller within the Community.
5. When the date of minimum durability or 'use by' date appears on the label, the indication of the lot need not appear on the foodstuff, provided that the date consists at least of the indication of the day and the month.
6. The Directives apply without prejudice to the indications laid down by specific Community provisions. The Commission will publish and keep up to date a list of the provisions in question.

*(4) Deadline for implementation of the legislation in the Member States*

— 20.6.1990: permit trade in products which meet the requirements of the Directive;
— 1.7.1992: prohibit trade in products which do not meet the requirements of the Directive.

*(5) Date of entry into force (if different from the above)*

*(6) References*

Official Journal L 186, 30.6.1989
Official Journal L 107, 27.4.1991
Official Journal L 65, 11.3.1992

*(7) Follow-up work*

*(8) Commission implementing measures*

On 25 July 1991 the Commission presented a communication on the implementation of Directive 89/396/EEC (COM(91) 297/II final, published in Official Journal C 219, 22.8.1991).

# 4. FOODSTUFFS

## 4.24. Product quality: certificates of specific character

*(1) Objective*

To lay down rules whereby a Community certificate of specific character for agricultural products and foodstuffs may be obtained.

*(2) Community measures*

Council Regulation (EEC) No 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs.

*(3) Contents*

1. 'Community certificate of specific character' means recognition by all Member States that a foodstuff possesses specific characteristics which distinguish it clearly from similar products in the same category.
2. The foodstuff whose specific character has been recognized is entered in a register kept by the Commission.
3. In order to appear in the register, the foodstuff must possess specific characteristics due to its raw materials and/or production methods but not to its provenance or to application of a technological innovation; it is not sufficient therefore for such foodstuff simply to meet the criteria laid down for a category of products.
4. Only groups of producers who have drawn up a product specification for the foodstuff may apply for registration. The product specification must include the trade description of the foodstuff, the rules governing its production, a description of the final foodstuff giving its main characteristics, the aspects allowing appraisal of traditional character and the minimum requirements and inspection procedures to which specific character is subject.
5. The application is submitted to the competent authority in the Member State which, after having checked that the necessary requirements are met, forwards it to the Commission which forwards it to the other Member States within a period of six months and publishes it in the *Official Journal of the European Communities*. Within five months from the date of publication any natural or legal person concerned may notify the competent national authorities of its opposition to registration. If no objections are notified within six months the Commission makes the entry in the register and proceeds with publication in the *Official Journal of the European Communities*. If objections are notified the Commission then invites the Member States concerned to seek agreement between themselves. If no agreement is reached, the Commission, assisted by a committee of an advisory nature, takes a decision. This procedure must be followed also if a group of producers wishes to amend its product specification.
6. From the date of publication in the *Official Journal of the European Communities* the trade description referring to specific character is reserved for the foodstuff corresponding to the product specification. The expression 'registered specific character' and, where applicable, a Community symbol may be used in the labelling, presentation and advertising of the registered foodstuff. In order to safeguard established rights these trade descriptions referring to specific character may be used simultaneously with descriptions already reserved under national provisions or sanctioned by use.
7. Member States must introduce stringent inspection arrangements to ensure that foodstuffs carrying a reference to their registered specific character comply with the product specification.

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| | 8. A third country may, on the initiative of its producers, apply for a Community certificate of specific character for a foodstuff offering equivalent guarantees to those laid down in the Regulation. The Commission has authority to initiate negotiations with a view to concluding international agreements.<br>9. Member States are to take the necessary measures to ensure legal protection against abusive or fallacious use or imitation of registered trade descriptions. Registered names are protected against all practices constituting unfair competition.<br>10. The Commission is to be assisted by a regulatory committee (of an advisory nature) composed of the representatives of the Member States. |
| *(4) Deadline for implementation of the legislation in the Member States* | Not required. |
| *(5) Date of entry into force (if different from the above)* | 24.7.1993 |
| *(6) References* | Official Journal L 208, 24.7.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 4. FOODSTUFFS

## 4.25. Product quality: geographical indications and designations of origin

*(1) Objective*

To lay down rules on the protection of geographical indications and designations of origin for certain agricultural products.

*(2) Community measures*

Council Regulation (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs.

*(3) Contents*

1. The Regulation applies to agricultural products, whether or not processed, and to foodstuffs.
2. A distinction is made between two classes of names:
— protected geographical indication (PGI), meaning the name of a region, specific place or country describing a product originating in that region, specific place or country and possessing a quality or reputation which may be attributed to the geographical environment with its inherent natural and/or human components;
— protected designation of origin (PDO), meaning the name of a region, specific place or country referring to a product originating in that region, specific place or country and whose quality or other characteristics are essentially or exclusively due to a particular geographical environment.
3. To qualify for a PGI or PDO designation, a product must comply with a specification containing the following: the name and description of the product, the definition of the geographical area, the methods of preparation, factors relating to the geographic environment, the inspection bodies, details of labelling and any legislative requirements that must be met. The type of link between the product and the geographical location is more stringent in the case of the PDO designation, the quality or other characteristics being due essentially or exclusively to its geographical environment.
4. An application for registration of a PGI or PDO may be made by any group of producers irrespective of its legal form or composition or, in exceptional circumstances, a natural or legal person. The application is sent to the Member State in which the geographical area in which the product originates is located. The Member State checks that it satisfies the requirements and forwards it to the other Member States and the Commission. The latter examines it and publishes it in the *Official Journal of the European Communities*. If no objections are notified within three months, the PGI or PDO is entered in a register kept by the Commission. Where objections are notified the Commission examines the reasons given before taking a decision.
5. An inspection body offering adequate guarantees of objectiveness and impartiality checks whether the product meets the criteria laid down in the specification. It withdraws the right of a producer or processor of a product which fails to meet those criteria to use the PGI or PDO designation. Any Member State may submit that a product no longer meets the criteria laid down in the specification. In such a case, the Commission decides whether to suspend or withdraw the PGI or PDO.
6. A third country may apply for the registration of a designation in its territory by following a similar procedure.

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| | 7. The Commission has authority to negotiate agreements with third countries for the reciprocal protection of designations.<br>8. Registered PGIs and PDOs are legally protected against any misuse or false or misleading indication.<br>9. The Commission is assisted by a regulatory committee composed of the representatives of the Member States and chaired by the representative of the Commission.<br>10. Within six months of the entry into force of the Regulation, Member States are to inform the Commission which of their legally protected names or, in those Member States where there is no protection system, which of their names established by usage they wish to register pursuant to the Regulation.<br>11. Member States may maintain national protection of the names communicated until such time as a Decision on registration has been taken. |
| *(4) Deadline for implementation of the legislation in the Member States* | Not required. |
| *(5) Date of entry into force (if different from the above)* | 24.7.1993 |
| *(6) References* | Official Journal L 208, 24.7.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | Commission Decision of 21 December 1992 on the creation of a scientific committee for geographical indications, designations of origin and certificates of specific character.<br>This Decision sets up a committee responsible for helping the Commission to implement a consistent policy on labelling and designations of origin. |

# 4. FOODSTUFFS

## 4.26. Assistance and cooperation with scientific examination

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| *(1) Objective* | To permit cooperation between the administrations of the Member States and the Commission to give necessary assistance for scientific examinations |
| *(2) Proposal* | Proposal for a Council Directive on assistance and cooperation to the Commission by the Member States in the scientific examination of questions relating to food. |
| *(3) Contents* | 1. The Directive applies when a Council act requires the opinion of the Scientific Committee for Food and when problems relating to the protection of the health and safety of persons arise from the consumption of food.<br>2. The Member States are required to take the necessary measures, including financial measures, to enable their competent authorities and bodies to cooperate with the Commission and lend it the scientific assistance it needs in such fields as medicine, toxicology, biology, microbiology, biotechnology, novel foods and processes, methods of analysis, risk assessment techniques, physics and chemistry.<br>3. The Member States are required to designate the authorities or bodies which will be responsible for cooperation with the Commission and for the distribution of work to appropriate institutes within Member States as regards such main tasks as drawing up risk assessment protocols in relation to foods and methods of nutritional evaluation. They must notify the Commission accordingly.<br>4. The Commission is authorized to open negotiations with a view to concluding agreements with third countries guaranteeing their participation in certain forms of cooperation laid down in the Directive, including the establishment of work programmes and definition of the rules for the administrative management of such cooperation. |
| *(4) Opinion of the European Parliament* | First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments. |
| *(5) Current status* | The Council adopted a common position on 22 September 1992. Under the cooperation procedure this is now before Parliament for a second reading. |
| *(6) References* | Commission proposal<br>COM(91) 16 final — Official Journal C 108, 13.4.1991<br>Amended proposal<br>COM(92) 128 final — Not yet published in the Official Journal<br>European Parliament opinion<br>First reading — Not yet published<br>Economic and Social Committee opinion — Official Journal C 14, 20.1.1992 |

# 4. FOODSTUFFS

## 4.27. Hygiene of foodstuffs

*(1) Objective*

To improve food hygiene standards in the Community.

*(2) Proposal*

Proposal for a Council Directive on the hygiene of foodstuffs.

*(3) Contents*

1. This Directive supplements Council Directive 89/397/EEC on the official control of foodstuffs (summary 4.15).
2. Food businesses are required to comply with the rules governing the hygiene for foodstuffs, as set out in an annex, during the preparation, processing, manufacture, packaging, storage, transport, distribution, handling, sale and supply of foodstuffs. They must also use HACCPS (hazard analyses and critical control points).
3. To help businesses comply with food hygiene Regulations, Member States are urged to draw up, in collaboration with the representatives of the sectors concerned, guides to good hygiene practices to which food businesses in the food industry will be able to refer. These guides may be drawn up at European level if that proves necessary for the purposes of harmonization.
4. Application of the EN 29 000 series of European standards (ISO 9 000 series) is recommended, wherever appropriate, as a means of ensuring compliance with general food hygiene Regulations and the guides to good practice.
5. The competent authorities (designated by the Member States and notified to the Commission) must satisfy themselves that food businesses are complying with hygiene Regulations by observing good hygiene practice.
6. Subject to certain conditions, Member States will be allowed to maintain, amend or introduce national hygiene provisions which are more specific than those laid down in this Directive.

*(4) Opinion of the European Parliament*

First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments.

*(5) Current status*

The Council adopted a common position on 17 December 1992. Under the cooperation procedure this is now before Parliament for a second reading.

*(6) References*

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| Commission proposal | |
| COM(91) 525 final | Official Journal C 24, 31.1.1992 |
| Amended proposal | |
| COM(92) 547 final | Official Journal C 347, 31.12.1992 |
| European Parliament opinion | |
| First reading | Not yet published |
| Economic and Social Committee opinion | Official Journal C 223, 31.8.1992 |

# 4. FOODSTUFFS

## 4.28. Contaminants

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| *(1) Objective* | To establish a procedure for assessing the permissible toxicity levels for contaminants in foodstuffs, considering all possible sources. |
| *(2) Proposal* | Proposal for a Council Regulation (EEC) laying down Community procedures for contaminants in foodstuffs. |
| *(3) Contents* | 1. No foodstuffs containing a toxicologically unacceptable amount of a contaminant may be marketed. Contaminants, i.e. any substance unintentionally added to food during production, manufacture, processing, preparation, treatment, packing, packaging, transport or storage or as a result of environmental contamination, must be kept at the lowest possible levels.<br>2. The maximum tolerances for specific contaminants will be established by the Standing Committee on Foodstuffs, after consultation with the Scientific Committee for Food.<br>3. Draft technical standards and regulations on contaminants must continue to be notified to the Commission under the procedure laid down in Council Directive 83/189/EEC (Official Journal L 109, 26.4.1983), as amended by Council Directive 88/182/EEC (summary 1.1).<br>4. Member States may not prohibit trade in foods which comply with this Regulation for any reason related to the aspects covered by the provisions of this Regulation.<br>5. The Regulation includes a safeguard clause: Member States may temporarily suspend or restrict marketing on their territory of any foodstuff suspected of containing contaminants which would endanger human health. |
| *(4) Opinion of the European Parliament* | First reading: Parliament approved the Commission's proposal without amendment. |
| *(5) Current status* | The Council adopted a common position on 22 September 1992. Under the cooperation procedure this is now before Parliament for a second reading. |
| *(6) References* | Commission proposal<br>COM(91) 523 final — Official Journal C 57, 4.3.1992<br>European Parliament opinion<br>First reading — Official Journal C 125, 18.5.1992<br>Economic and Social Committee opinion — Official Journal C 223, 31.8.1992 |

# 4. FOODSTUFFS

## 4.29. Novel foods and novel food ingredients

*(1) Objective*

To lay down provisions for certain novel food products which have not hitherto been covered by specific legislation in most of the Member States in order to avoid the creation of new national technical barriers to the free movement of these products in the single market and, at the same time, to protect consumers while taking account of prospects for advances in biotechnology in Europe.

*(2) Proposal*

Proposal for a Council Regulation on novel foods and novel food ingredients.

*(3) Contents*

1. Novel foods and novel food ingredients are foods which have been produced using processes which give rise to significant changes in composition and/or nutritive value and/or the intended use. Examples of such products are proteins obtained from certain types of mould, products similar to non-metabolizable fats or food fibres, genetically modified potatoes immunized against viruses, tomatoes with better keeping qualities, and yeast with better performance as regards the speed of fermentation. The Regulation does not apply to food additives or other food ingredients which are already covered by other specific Community laws.
2. It aims to establish a Community assessment procedure to determine whether such novel foods and food ingredients are suitable for human consumption.
3. The Regulation provides for a system for submitting a notification to the Commission of any novel food or food ingredient together with a scientific report. Furthermore, if there is any serious doubt supported by scientific evidence or if the food is consumed in the form of a living organism, an authorization procedure has to be followed during which the Commission refers the matter to the Standing Committee on Foodstuffs.
4. 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.
5. Member States are authorized 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 human health hazard. They inform the Commission, which immediately expresses its opinion and, if necessary, initiates the authorization procedure.

*(4) Opinion of the European Parliament*

Not yet delivered.

*(5) Current status*

The proposal has been sent to the European Parliament and the Economic and Social Committee for their opinions.

*(6) References*

Commission proposal
COM(92) 295 final/II — Official Journal C 190, 29.7.1992

# 5. PHARMACEUTICAL PRODUCTS

## 1992 target: current position and outlook

The EC market for pharmaceutical products is still divided into separate national markets. Although there is a body of Community legislation on the manufacture, testing and marketing of pharmaceuticals, backed up by procedures for consultation between the national regulatory authorities, marketing licensing remains national. National price control and social security refund systems add to this partitioning of the markets.

Since the publication of the 1985 White Paper 'Completing the internal market', which marked a new stage in the development of the Community legislation on pharmaceutical products, the Commission's strategy has revolved around two chief ideas.

Firstly, the Commission has sought to consolidate and complete the existing legislation by extending its scope, delegating the power to adopt technical amendments, making the national price control and refund schemes more transparent, acceding to the European Pharmacopoeia, harmonizing the conditions for administering medicines to patients and providing patients with fuller information on medicinal products.

Secondly, the Commission has proposed a reform of the marketing licensing procedure for medicinal products in the Community. The Council has accepted this proposal, enabling the new system to become operational in 1995. The procedure will consist of a combination of central authorization of new medicinal products and decentralized mutual recognition of national authorizations granted in the past for existing medicinal products. A European Agency for the Evaluation of Medicinal Products will be set up to coordinate these new procedures (summary 5.25).

The Agency will have various responsibilities in connection with the inspection of the manufacture and monitoring of medicinal products; it will coordinate the performance by the Community and Member States of their tasks relating to manufacture and testing of medicinal products, including good manufacturing, laboratory and clinical testing practice, and will continuously monitor the medicinal products authorized in the Community, issuing opinions on appropriate measures to be taken. The question of the location of the Agency has still to be decided.

The Council has adopted all the measures contained in the White Paper and more, if Directive 92/28/EEC on advertising of medicinal products is included. These measures concern:

— high-technology medicinal products (summaries 5.1 and 5.2);
— proprietary medicinal products (summaries 5.4 to 5.6 and 5.14);
— veterinary medicinal products (summaries 5.7 to 5.11);
— pricing of medicinal products (summaries 5.12 and 5.13);
— immunological pharmaceutical products (summary 5.15);
— pharmaceutical products derived from human blood or plasma (summary 5.16);
— radiopharmaceuticals (summary 5.17);
— rational use of medicinal products (summaries 5.18 to 5.21);
— supplementary protection certificate for medicinal products (summary 5.22);
— homeopathic medicines for human and veterinary use (summaries 5.23 and 5.24).

Transposal by Member States has proceeded satisfactorily, except for the most recent technical measures which should, however, despite their complexity, be transposed throughout the Community by the beginning of 1993.

This harmonization has enabled the European Community to engage in a trilateral programme of harmonizing testing of medicinal products with the USA and Japan, in order to reduce the overall cost of global pharmaceutical research.

## 5. PHARMACEUTICAL PRODUCTS

### 5.1. High-technology medicinal products: marketing authorization

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| *(1) Objective* | To protect public health by creating conditions for the introduction of a single market in high-technology medicinal products. |
| *(2) Community measures* | Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology. |
| *(3) Contents* | 1. The Directive covers such products as those developed by means of DNA technology; genetic engineering; any high technology process which is deemed to be a significant innovation by the relevant authority.<br>2. Before any Member State takes a decision on an application for marketing authorization or a decision to withdraw or suspend an authorization it must first consult either the Committee for Proprietary Medicinal Products or the Committee for Veterinary Medicinal Products, as appropriate.<br>3. When applying for marketing authorization the producer must provide information concerning the characteristics of the product, reports of the analytical, pharmaco-toxicological and clinical experts, and all available evaluation reports.<br>4. The Committee must issue its opinion within a specified time period; the Member State must then inform the Committee of any action it will take (for example, granting, refusal or withdrawal of marketing authorization). |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.7.1987 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 15, 17.1.1987 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 5. PHARMACEUTICAL PRODUCTS

## 5.2. High-technology medicinal products: marketing authorization

*(1) Objective*

Introduction of Community procedures for the authorization and monitoring of high-technology medicinal products for human and veterinary use and establishment of a European agency responsible for assessing such products.

*(2) Proposal*

Proposal for a Council Directive repealing Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology.

*(3) Contents*

1. Directive 87/22/EEC (summary 5.1) is repealed with effect from 1 January 1995.
2. Member States shall take the measures necessary to comply with this Directive not later than 1 January 1995. They shall forthwith inform the Commission thereof.
3. Marketing authorization applications which were submitted by the Member States to the Committee for Proprietary Medicinal Products or the Committee for Veterinary Medicinal Products pursuant to Directive 87/22/EEC and in respect of which no decision has been reached by 1 January 1995 shall be examined in accordance with the new Regulations introducing Community procedures for the authorization and monitoring of medicinal products for human and veterinary use (summary 5.25).

*(4) Opinion of the European Parliament*

First reading: Parliament approved the Commission's proposal without amendments.

*(5) Current status*

On 17 December 1992 the Council reached political agreement on a common position. Formal adoption of this common position is scheduled for the next meeting.

*(6) References*

| | |
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| Commission proposal<br>COM(90) 283/IV final | Official Journal C 330, 31.12.1990 |
| European Parliament opinion<br>First reading | Official Journal C 183, 15.7.1992 |
| Economic and Social<br>Committee opinion | Official Journal C 269, 14.10.1991 |

## 5. PHARMACEUTICAL PRODUCTS

### 5.3. Proprietary medicinal products: standards and protocols for testing

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| *(1) Objective* | To adopt a new procedure for making technical updates to the legislation on the testing of pharmaceuticals. This will make it more effective. |
| *(2) Community measures* | Council Directive 87/19/EEC of 22 December 1986 amending Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products. |
| *(3) Contents* | 1. The Directive delegates power to the Commission to adapt the legislation on testing to technical progress. It sets up a Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Proprietary Medicinal Products Sector, which the Commission must consult prior to making any changes. Only if the Commission does not agree with the Committee does the matter have to be referred to the Council.<br>2. This Directive also makes changes to the requirements for single-dose toxicity, physico-chemical, biological or microbiological, and toxicological and pharmacological tests. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.7.1987 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 15, 17.1.1987 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 5. PHARMACEUTICAL PRODUCTS

## 5.4. Proprietary medicinal products: simplified procedure

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| *(1) Objective* | To avoid repetitive testing on humans and animals by relaxing those requirements where similar products have already been authorized. |
| *(2) Community measures* | Council Directive 87/21/EEC of 22 December 1986 amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. |
| *(3) Contents* | The applicant does not have to supply the results of pharmacological, toxicological and clinical tests if he can prove either:<br>— that the new product is essentially similar to a product already on the market in that country, and the person responsible for the existing product is willing to allow the use of his clinical information in the examination of the new product;<br>— or, that there is detailed scientific evidence available showing that the constituents of the product have an acceptable level of safety and recognized efficacy;<br>— or, that the new product is essentially similar to a product that has been authorized elsewhere in the Community for six or 10 years, and is marketed in the Member State in question.<br>This period now becomes 10 years automatically for high-technology medicinal products covered by Council Directive 87/22/EEC (summary 5.1). However, if the product is to be used differently, new tests must be performed and results provided. |
| *(4) Deadline for implementation of the legislation in the Member States* | — 1.7.1987<br>— 1.1.1992: Greece, Portugal and Spain. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 15, 17.1.1987 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 5. PHARMACEUTICAL PRODUCTS

### 5.5. Proprietary medicinal products: free movement

*(1) Objective*

To define criteria concerning the quality, safety and efficacy of proprietary medicinal products, and the role of the Products Agency in applying the criteria, in order to allow free movement of such products in the Community.

*(2) Proposal*

Proposal for a Council Directive amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products.

*(3) Contents*

1. No medicinal product for human use may be placed on the market of a Member State unless an authorization has been obtained in accordance with Community rules.
2. This Directive does not affect the powers of the Member States as regards either the fixing of the prices of medicinal products or their inclusion under national health insurance schemes.
3. The person responsible for placing the medicinal product on the market must be established in the Community; temporary exceptions will be permitted in the case of medicinal products already authorized on the date of entry into force of the Directive.
4. The application for authorization must be accompanied by a copy of any authorization obtained in another Member State or in a third country to place the relevant medicinal product on the market, together with a list of those Member States in which an application for authorization submitted in accordance with this Directive is under examination.
5. When the marketing authorization is issued, the person responsible for placing the product on the market is informed by the competent authorities of the Member State concerned of the summary of the product characteristics as approved by them. A copy of this summary is forwarded to the European Agency for the Evaluation of Medicinal Products (summary 5.25). Furthermore, the competent authorities draw up an assessment report and comment on the dossier as regards the results of the analytical, pharmaco-toxicological and clinical tests of the medicinal product concerned.
6. Member States will take appropriate measures to ensure that the procedure for granting an authorization to place a medicinal product on the market is completed within 210 days of the date on which the application was submitted.
7. Mutual recognition of authorizations: European marketing authorizations will be valid throughout the Community. With effect from 1 January 1998, where a Member State is informed that another Member State has authorized a medicinal product which is the subject of an application for authorization in the Member State concerned, it will request the authorities of the Member State which have granted the authorization to forward to it the assessment report.
8. The person responsible for placing the product on the market must take account of technical and scientific progress to enable the medicinal product to be manufactured in accordance with accepted scientific methods.

9. Authorization is valid for five years and is renewable for five-year periods, on application at least three months before the expiry date and after consideration of a dossier containing up-to-date information on pharmacological vigilance.
10. A Committee for Proprietary Medicinal Products attached to the European Agency for the Evaluation of Medicinal Products is set up in order to facilitate the adoption of common decisions by Member States on the authorization of medicinal products on the basis of the scientific criteria of quality, safety and efficacy.
11. Each Member State concerned will recognize the marketing authorization granted by the first Member State within 90 days of receipt of the application. It will inform that Member State, the other Member States concerned, the Committee and the person responsible for marketing the product.
12. If several applications have been made for marketing authorization for a particular medicinal product, and Member States have adopted different decisions concerning the product's authorization, suspension or withdrawal from the market, any Member State, the person responsible for marketing the product or the Commission may refer the matter to the Committee.
13. The Member States will establish a pharmacological vigilance system for collecting information about adverse reactions to medicinal products and for the scientific evaluation of such information, such that the information about adverse reactions is systematically related to the information on the consumption of medicinal products.
14. The Commission, in consultation with the Agency and interested parties, will draw up guidelines for the collection, verification and presentation of adverse reaction reports. Such guidance shall take into account the format used by the World Health Organization. In case of urgency, the Member State concerned may suspend the marketing of a medicinal product, provided the Agency is informed.

*(4) Opinion of the European Parliament*

First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments.

*(5) Current status*

The Council adopted a common position on 17 December 1992. Under the cooperation procedure this is now before Parliament for a second reading.

*(6) References*

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| Commission proposal<br>COM(90) 283/II final | Official Journal C 330, 31.12.1990 |
| Amended proposal<br>COM(91) 382/II final | Official Journal C 310, 30.11.1991 |
| European Parliament opinion<br>First reading | Official Journal C 183, 15.7.1991 |
| Economic and Social Committee opinion | Official Journal C 269, 14.10.1991 |

## 5. PHARMACEUTICAL PRODUCTS

### 5.6. Proprietary medicinal products: standards for testing

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| *(1) Objective* | To adopt new explanatory notes containing the principles and methods for use by applicants in the marketing of proprietary medicines to facilitate their movement within the Community. |
| *(2) Community measures* | Council Recommendation 87/176/EEC of 9 February 1987 concerning tests relating to the placing on the market of proprietary medicinal products. |
| *(3) Contents* | The recommendation requests the Member States to ensure that the notes are adhered to and to process and evaluate requests for authorization in accordance with the notes, including:<br>(a) procedures for testing the mutagenic potential of pharmaceuticals,<br>(b) clinical investigation of oral contraceptives and information to be provided to users,<br>(c) presentation of information on proprietary medicinal products,<br>(d) testing procedures for a range of proprietary medicinal products and guidelines on interpreting the results of such tests. |
| *(4) Deadline for implementation of the legislation in the Member States* | Not applicable. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 73, 16.3.1987 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 5. PHARMACEUTICAL PRODUCTS

## 5.7. Veterinary medicinal products: residues

*(1) Objective*

To lay down a procedure for the establishment of tolerance levels for residues of veterinary medicinal products in foodstuffs of animal origin and a single high-quality scientific assessment.

*(2) Community measures*

Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

*(3) Contents*

1. Definitions of 'residues of veterinary medicinal products' and 'tolerance' for the purposes of this Regulation.
2. The Regulation introduces a general system for establishing tolerance levels for residues. In the case of veterinary medicinal products for which application for marketing authorization is made after the Regulation comes into force, a tolerance must be established before authorization is granted. In the case of products already on the market, tolerances are to be established before 1 January 1997. They will be inserted in the annexes to the Regulation when established. The Regulation lays down the procedure for this.
3. A tolerance expressed in terms of micrograms per kilogram on a fresh meat basis will be established after consideration of all available information and in accordance with generally recognized principles of safety assessment. This tolerance may however be reduced in certain circumstances, e.g. if residues cause difficulties for the industrial processing of foodstuffs. Specific tolerances may be established for particular foodstuffs, e.g. liver, kidneys, eggs. The list of substances used as active ingredients in veterinary medicinal products for which tolerances are established is contained in Annex 1 to the Regulation.
4. Annex 2 to the Regulation gives a list of substances for which it is not necessary to establish a tolerance because their residues are harmless to consumers. A substance will be included in Annex 2 according to the procedure laid down in this Regulation.
5. A provisional tolerance may be adopted for a substance used as an active ingredient in veterinary medicines as long as there is no evidence that the level of its residues presents a hazard to the consumer. A provisional tolerance may remain in force for a defined period of time which shall not exceed five years and which shall be renewable, exceptionally and once only, for a further period not exceeding two years. The list of substances for which provisional tolerances have been established is given in Annex 3 to the Regulation.
6. Annex 4 contains a list of substances used as active ingredients in veterinary medicinal products for which a tolerance level cannot be established because residues of the substance constitute a hazard to the health of the consumer at whatever level. The administration of such substances to food-producing animals is prohibited throughout the Community.
7. Member States may not authorize the marketing of veterinary medicinal products which are intended for administration to food-producing animals and which contain an active substance which was not yet authorized for use in such products at the date of entry into force of this Regulation unless the substances concerned have been included in Annexes 1, 2 or 3 to the Regulation.

8. A person responsible for placing products on the market wishing to have an active substance referred to in point 7 above included in Annexes 1, 2 or 3 should submit an application to the Commission of the European Communities which shall process the application according to the rules and within the time-limits set down in this Regulation.
9. If a Member State considers that the urgent amendment of a provision of Annexes 1 to 4 is necessary in order to protect human or animal health, it may temporarily suspend the operation of that provision in its territory immediately notifying the Commission and the other Member States and giving reasons for its action. The Commission will examine the Member State's reasons and, after consultation of the Member States in the Committee for Veterinary Medicinal Products, it will take appropriate measures. Any Member State may refer the Commission's decision to the Council within 15 days of such notification. The Council may, by qualified majority, take a different decision within 30 days of such referral.
10. Member States may not prohibit or impede the putting into circulation within their territory of foodstuffs of animal origin on the ground that they contain residues of veterinary medicinal products if this residue does not exceed the tolerance provided for in Annexes 1 or 3, or if the substance concerned is listed in Annex 2.
11. With effect from 1 January 1997, the administration to food-producing animals of veterinary medicinal products which contain active substances not mentioned in Annexes 1, 2 or 3 shall be prohibited within the Community except in clinical trials which have been approved by the competent authorities.

*(4) Deadline for implementation of the legislation in the Member States*

1.1.1992

*(5) Date of entry into force (if different from the above)*

*(6) References*

Official Journal L 224, 18.8.1990

*(7) Follow-up work*

*(8) Commission implementing measures*

Regulation (EEC) No 675/92 — Official Journal L 73, 19.3.1992
Commission Regulation of 18 March 1992 amending Annexes 1 and 3 to Council Regulation No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

Regulation (EEC) No 762/92 — Official Journal L 83, 28.3.1992
Commission Regulation of 27 March 1992 amending Annex 5 to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

Regulation (EEC) No 3093/92 — Official Journal L 311, 28.10.1992
Commission Regulation of 27 October 1992 amending Annex 3 to Council Regulation No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

# 5. PHARMACEUTICAL PRODUCTS

## 5.8. Veterinary medicinal products: free movement

*(1) Objective*

To remove remaining barriers to trade in veterinary medicinal products.

*(2) Community measures*

Council Directive 90/676/EEC of 13 December 1990 amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products.

*(3) Contents*

1. Obligation on Member States to ensure that no person has substances which may be used as veterinary medicinal products on his premises unless national legislation expressly permits it. Member States shall maintain a register of producers, dealers and others who are permitted to be in possession of active substances used in the manufacture of veterinary medicinal products which are available only on prescription. These persons will be required to maintain detailed records of the use made by them of these substances and to make these records available for inspection by the competent authorities for a period of at least three years.
2. No veterinary medicinal product may be marketed or administered to animals in a Member State unless it has been previously authorized by the competent authorities of that Member State. Certain exceptions to this rule are allowed, e.g. if the medical condition requires it, a Member State may authorize the marketing or administration to animals of veterinary medicinal products authorized by another Member State.
3. No veterinary medicinal product intended for administration to animals, the meat or products of which are intended for human consumption, may be marketed in a Member State unless it has been authorized in accordance with Community legislation. Certain exceptions to this rule are allowed: the Member States shall authorize the marketing of foodstuffs obtained from animals treated during such tests only if it is certified that the foodstuffs do not contain any residues which might constitute a hazard to human health.
4. Where no medicinal products have been authorized for the treatment of a disease, the Member States may authorize the administration of a medicinal product to a particular animal or a small group of animals from a given establishment, in order to avoid undue suffering, provided that:
— if administered to animals, the meat or products of which are intended for human consumption, the medicinal products contain substances only authorized for use in such animals in the Member State in question;
— the veterinarian responsible fixes a suitable withdrawal period for the animals in question, in order to ensure that foodstuffs obtained from treated animals do not contain residues harmful to consumers.
5. The Committee for Veterinary Medicinal Products set up by the earlier Directive will facilitate the adoption of common positions by the Member States on applications for marketing authorization. At the request of the Commission or a Member State, the Committee shall examine questions relating to the granting, suspension or withdrawal of an authorization.

6. To protect innovation, a second applicant for a marketing authorization for a product already authorized in the name of the original manufacturer will have to wait 10 years from the first authorization unless he either has the consent of the original manufacturer for use of the application file references or himself provides the required information.
7. Obligation on Member States to ensure that the manufacture of veterinary medicinal products is subject to a manufacturing authorization even if the products being manufactured are for export only. When issuing a certificate of manufacturing authorization, Member States shall have regard to the prevailing administrative arrangements of the World Health Organization and shall supply a summary of product characteristics as approved for veterinary medicinal products intended for export which are already authorized on their territory. Obligations relating to application for a manufacturing authorization are outlined in the Directive. Obligation on companies and Member States to consider the potential impact of the use of a veterinary product on the environment.
8. The person responsible for the marketing of a veterinary medicinal product shall be obliged to notify the Member States of his reasons should he suspend the marketing of a product or withdraw it from the market.
9. The Directive contains amendments to Council Directive 81/851/EEC (Official Journal L 317, 6.11.1981) in respect of labelling and package inserts of veterinary medicinal products.
10. Obligation on Member States to ensure that wholesale dealing in veterinary medicinal products is subject to the holding of an authorization. They must ensure that the time taken for granting an authorization does not exceed 90 days.
11. Obligation on persons applying for wholesale authorization to have sufficient and suitable premises at their disposal for storage and handling of products. The holder of an authorization shall be required to keep detailed records regarding matters outlined in the Directive.
12. Obligation on Member States to ensure that wholesalers supply veterinary medicinal products only to persons permitted to carry out retail activities or permitted to receive veterinary medicinal products from wholesalers.
13. Obligation on Member States to ensure that the retail supply of veterinary medicinal products is carried out only by persons expressly permitted to do so by national legislation. Obligation on retailers to maintain detailed records in respect of all incoming and outgoing transactions. Member States may dispense with this requirement in respect of domestic animals, e.g. cats and dogs.

*(4) Deadline for implementation of the legislation in the Member States*

1.1.1992

*(5) Date of entry into force (if different from the above)*

*(6) References*

Official Journal L 373, 31.12.1990

*(7) Follow-up work*

*(8) Commission implementing measures*

Directive 91/412/EEC — Official Journal L 228, 17.8.1991
Commission Directive of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products.
Date of entry into force: 23.7.1993.

# 5. PHARMACEUTICAL PRODUCTS

## 5.9. Veterinary medicinal products: free movement

*(1) Objective*

To define criteria concerning the quality, safety and efficacy of veterinary medicinal products, and the role of the Products Agency in applying the criteria, in order to allow free movement of such products in the Community.

*(2) Proposal*

Proposal for a Council Directive amending Directives 81/851/EEC and 81/852/EEC relating to veterinary medicinal products.

*(3) Contents*

1. No veterinary medicinal product may be placed on the market of a Member State unless authorization has been obtained in accordance with Community Measures.
2. The person responsible for placing the veterinary medicinal product on the market must be established in the Community; temporary exceptions will be permitted for veterinary medicinal products already authorized on the date of entry into force of this Directive.
3. The application for authorization must be accompanied by a copy of any authorization obtained in another Member State or in a third country to place the relevant veterinary medicinal product on the market, together with a list of those Member States in which an application for authorization submitted in accordance with this Directive is under examination.
4. When the marketing authorization is issued, the person responsible for placing the product on the market is informed by the competent authorities of the Member State concerned of the summary of the product characteristics as approved by them. A copy of this summary is forwarded to the European Agency for the Evaluation of Medicinal Products (summary 5.25). Furthermore, the competent authorities draw up an assessment report and comment on the dossier as regards the results of the analytical, pharmaco-toxicological and clinical tests of the veterinary medicinal product concerned.
5. Member States will take appropriate measures to ensure that the procedure for granting an authorization to place a veterinary medicinal product on the market is completed within 210 days of the date on which the application was submitted.
6. Mutual recognition of authorizations: European marketing authorizations will be valid throughout the Community. With effect from 1 January 1998, where a Member State is informed that another Member State has authorized a veterinary medicinal product which is the subject of an application for authorization in the Member State concerned, it will request the authorities of the Member State which have granted the authorization to forward to it the assessment report.
7. The person responsible for placing the product on the market must take account of technical and scientific progress to enable the veterinary medicinal product to be manufactured in accordance with accepted scientific methods.
8. Authorization is valid for five years and is renewable for five-year periods, upon application at least three months before the expiry date and following examination of a dossier containing up-to-date information on pharmacological vigilance.

9. A Committee for Veterinary Medicinal Products attached to the European Agency for the Evaluation of Medicinal Products is set up in order to facilitate the adoption of common decisions by Member States on the authorization of veterinary medicinal products on the basis of the scientific criteria of quality, safety and efficacy.
10. Each Member State concerned will recognize the marketing authorization granted by the first Member State within 90 days of receipt of the application. It will inform that Member State, the other Member States concerned, the Committee and the person responsible for marketing the product.
11. If several applications have been made for marketing authorization for a particular veterinary medicinal product, and Member States have adopted different decisions concerning the product's authorization, suspension or withdrawal from the market, any Member State, the person responsible for marketing the product or the Commission may refer the matter to the Committee.
12. The Member States will establish a pharmacological vigilance system for collecting information about adverse reactions to veterinary medicinal products and for the scientific evaluation of such information with systematic correlation of the information on adverse reactions and the data on consumption of veterinary medicinal products.
13. The Commission, having consulted the Agency and the interested parties, will draw up guidelines for the collection, verification and presentation of adverse reaction reports. These guidelines will take account of the form used by the World Health Organization. In urgent cases, the Member State concerned may suspend the placing on the market of a veterinary medicinal product, provided the Agency is informed.

*(4) Opinion of the European Parliament*

First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments.

*(5) Current status*

The Council adopted a common position on 17 December 1992. Under the cooperation procedure this is now before Parliament for a second reading.

*(6) References*

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| Commission proposal<br>COM(90) 283/III final | Official Journal C 330, 31.12.1990 |
| Amended proposal<br>COM(91) 382/III final | Official Journal C 310, 30.11.1991 |
| European Parliament opinion<br>First reading | Official Journal C 183, 15.7.1991 |
| Economic and Social Committee opinion | Official Journal C 269, 14.10.1991 |

## 5. PHARMACEUTICAL PRODUCTS

### 5.10. Veterinary medicinal products: provisions for immunological products

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|---|---|
| *(1) Objective* | To remove hindrances to intra-Community trade in immunological veterinary medicines and maintain a high level of protection of public health. |
| *(2) Community measures* | Council Directive 90/677/EEC of 13 December 1990 widening the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products. |
| *(3) Contents* | 1. The Directive extends the field of application of Council Directive 81/851/EEC (Official Journal L 517, 6.11.1981) to include immunological veterinary medicinal products subject to the provisions laid down in the proposed Directive. The Directive does not apply to inactivated immunological veterinary products manufactured from pathogenic and antigenic organisms obtained from an animal or animals from the same holding and used for the treatment of that animal or the animals of that holding in the same locality.<br>2. Definition of 'immunological veterinary medicinal product', and redefinition of the expressions 'qualitative and quantitative particulars of the constituents' and 'qualitative and quantitative composition'.<br>3. Provision for expression of quantitative particulars in specified units as appropriate to the product concerned.<br>4. Provisions for competent authorities to ensure the validation of manufacturing processes and batch-to-batch consistency. The person responsible for marketing immunological products may be required by the competent authorities to produce copies of control reports and/or to provide them with samples from batches. He must ensure that samples of each batch of finished products are kept in stock, at least until their expiry date, for provision upon request to the competent authorities. The samples may also be submitted for examination by State or other designated laboratories, unless the batch in question has already been approved by another competent authority within the Community.<br>5. Use of an immunological veterinary medicinal product may be prohibited in the absence of specific Community legislation if certain facts are established, e.g. that the administration of the product to animals will interfere with the operation of a national or Community programme for the diagnosis, control or eradication of animal disease or will cause difficulties in certifying the absence of contamination of foodstuffs obtained from treated animals. The disease against which the medicinal product is intended to confer immunity will be substantially absent from the territory in question.<br>6. Procedure for amending the testing requirements for veterinary medicinal products in order to render them applicable to immunological medicinal products. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.4.1993 |

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| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 373, 31.12.1990 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 5. PHARMACEUTICAL PRODUCTS

### 5.11. Veterinary medicinal products: testing standards

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|---|---|
| *(1) Objective* | To adopt a new procedure for making technical updates to legislation covering testing. This will make it more effective. |
| *(2) Community measures* | Council Directive 87/20/EEC of 22 December 1986 amending Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products. |
| *(3) Contents* | 1. The Directive delegates power to the Commission to adapt the legislation on testing to technical progress. It sets up a 'Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector' which must be consulted by the Commission before any changes can be made. Only if the Commission does not agree with the Committee does the matter have to be referred to the Council.<br>2. The Directive also makes changes to the requirements for analytical, single-dose toxicity, physico-chemical, biological, microbiological, toxicological and pharmacological tests. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.7.1987 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 15, 17.1.1987 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 5. PHARMACEUTICAL PRODUCTS

## 5.12. Pricing: price control and reimbursements

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| *(1) Objective* | To set out Member States' obligations under Article 30 et seq. of the EEC Treaty in the area of price controls and reimbursement of medicinal products. |
| *(2) Community measures* | Communication from the Commission on the compatibility with Article 30 of the EEC Treaty of measures taken by Member States relating to price controls and reimbursement of medicinal products. |
| *(3) Contents* | 1. In the absence of Community provisions, Member States are free to adopt legislation which controls the prices of pharmaceutical products, provided that it does not represent an obstacle to free trade in such products within the Community.<br>2. The general principles to be observed when setting up price control systems are that they must be realistic and transparent: each product must have its own price, calculated on the basis of its real cost and it must be obvious as to how the price was arrived at.<br>3. Member States may not introduce price controls that discriminate against imported medicines. Price freezes may or may not be permitted in light of this depending on their precise terms.<br>4. When deciding which medicines can be supplied under their national health insurance scheme, Member States must not discriminate against imported products.<br>5. The Commission has the right to begin proceedings against any Member State which does not fulfil its obligations under the EEC Treaty. |
| *(4) Deadline for implementation of the legislation in the Member States* | Not required. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal C 310, 4.12.1986 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 5. PHARMACEUTICAL PRODUCTS

### 5.13. Pricing: price regulation

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| *(1) Objective* | To harmonize price controls on medicines (whether direct or indirect). |
| *(2) Community measures* | Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems. |
| *(3) Contents* | 1. The definition of medicinal products to be found in Council Directive 65/65/EEC (Official Journal L 22, 9.2.1965) applies to this Directive.<br>2. For those products which can only be marketed when the price of the product has been approved, the appropriate authority is obliged to take a decision within 90 days.<br>3. A list of medicines whose prices have been regulated must be published at least once a year.<br>4. Points 2 and 3 also apply to applications for price increases.<br>5. If a price freeze is imposed on all, or certain categories, of medicinal products, Member States shall carry out a review, at least once a year, to ascertain whether the macroeconomic conditions justify the freeze being continued unchanged. In exceptional cases, the holder of the marketing authorization may apply for a derogation from a price freeze.<br>6. Where a Member State adopts a system of controls on the profitability of persons responsible for placing medicinal products on the market, certain information must be published and communicated to the Commission, e.g. target profit, definition of profit, etc.<br>7. Member States must publish a complete list of all medicines covered by their national health insurance system, and inform the Commission. Likewise, if it is decided that certain medicines should not be included, this should also be published.<br>8. Member States must inform the Commission of the criteria concerning the therapeutic classification of medicinal products used for the purposes of the national social security system. In addition, the Commission will submit a proposal to the Council to eliminate any remaining obstacles to the free movement of medicines throughout the Community.<br>9. The Directive establishes the Consultative Committee for the implementation of the Directive. |
| *(4) Deadline for implementation of the legislation in the Member States* | 31.12.1989 |
| *(5) Date of entry into force (if different from the above)* | |

*(6) References*

Official Journal L 40, 11.2.1989

*(7) Follow-up work*

*(8) Commission implementing measures*

## 5. PHARMACEUTICAL PRODUCTS

### 5.14. Extension of legislation

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| *(1) Objective* | To amend previous Directives relating to proprietary medicinal products to cover non-proprietary medicinal products. |
| *(2) Community measures* | Council Directive 89/341/EEC of 3 May 1989 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. |
| *(3) Contents* | 1. Definitions of 'magistral formula' and 'official formula'.<br>2. Extension of the scope of previous Directives to include ready-made medicinal products. Some medicinal products remain exempt, e.g. those intended for research and development trials and those made up according to a 'magistral' or 'official' formula.<br>3. Information requirements are increased to include special precautions for the disposal of unused products or waste materials and batch numbers.<br>4. The inclusion of a package leaflet for all medicinal products is obligatory unless all information can be conveyed on the external packaging.<br>5. Measures relating to exports to non-EC countries. For example, supply to the destination country of proof of manufacturing authorization, product summaries, etc.<br>6. Competent authorities in Member States must carry out repeated inspections to ensure that legal provisions relating to medicinal products are being adhered to and report periodically on whether or not a manufacturer complies with principles and guidelines of good manufacturing practice. The manufacturer will be informed of the contents of these reports and may request a further inspection.<br>7. The principles and guidelines of good manufacturing practice are the subject of a Commission Directive (see heading 8).<br>8. The person responsible for the placing of a medicinal product on the market shall be obliged to notify the Member States of any action to suspend the marketing of a product or to withdraw it.<br>9. The Commission shall publish an annual list of medicinal products prohibited in the Community or subject to special restrictions. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.1.1992 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 142, 25.5.1989 |

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| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | Directive 91/356/EEC — Official Journal L 193, 17.7.1991<br>Commission Directive of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.<br>Date of entry into force: 1.1.1992.<br>In addition, the Commission has published detailed guidelines (*Guide to good manufacturing practice for medicinal products*, Office for Official Publications of the European Communities, CB-55-89-722). |

## 5. PHARMACEUTICAL PRODUCTS

### 5.15. Immunological medicinal products

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| *(1) Objective* | To include immunological medicinal products, allergen products, vaccines, toxins, and serums under the heading of proprietary medicinal products. |
| *(2) Community measures* | Council Directive 89/342/EEC of 3 May 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for immunological medicinal products consisting of vaccines, toxins or serums and allergens. |
| *(3) Contents* | 1. Definitions of 'allergen product', 'vaccines', 'toxins' and 'serums'. Previous Directives on the manufacturing and marketing of proprietary medicinal products now include these products within their scope.<br>2. The quantitative particulars of an immunological medicinal product shall be expressed by mass or by units of biological activity or by specific protein content where possible.<br>3. Requirement to include details about any special precautions to be taken by persons handling immunological products in information summaries about the product.<br>4. The name of an immunological medicinal product should also include the common or scientific name of the active constituents.<br>5. Member States are required to ensure that the manufacturing processes of these products are properly validated and that there is batch-to-batch consistency.<br>6. Power is delegated to the Commission to adapt Council Directive 75/318/EEC (Official Journal L 147, 9.6.1975) on analytical, pharmaco-toxicological and clinical standards and protocols to take account of the specific characteristics of these products. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.1.1992 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 142, 25.5.1989 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 5. PHARMACEUTICAL PRODUCTS

## 5.16. Medicinal products derived from human blood or plasma

*(1) Objective*

To introduce a tough system of control guaranteeing the quality and safety of medicinal products and to promote self-sufficiency of the Community in human blood and plasma.

*(2) Community measures*

Council Directive 89/381/EEC of 14 June 1989, extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or plasma.

*(3) Contents*

1. This Directive applies to medicinal products derived from blood components (albumin, coagulating factors, immunoglobins of human origin, etc.) industrially prepared by public or private establishments. It does not apply to whole blood, plasma or blood cells of human origin.
2. The quantitative particulars of a medicinal product derived from human blood or plasma shall be expressed by international units of mass or by units of biological activity.
3. Member States shall take measures to prevent the transmission of infectious diseases such as AIDS and hepatitis. These shall comprise the measures recommended by the Council of Europe and the World Health Organization in particular for the selection and testing of blood donors.
4. Member States shall ensure that in the case of trade in human blood, the origin of the blood donors and donation centre is always clearly identified.
5. All the guarantees mentioned in points 3 and 4 must be given in respect of imports of human blood from countries outside the Community.
6. Member States shall promote the self-sufficiency of the Community in human blood and plasma. Voluntary unpaid donation of blood shall be encouraged.
7. Member States are required to ensure that the manufacturing and purification processes of these products are properly validated, that there is batch-to-batch consistency, and to guarantee the absence of viral contaminants.
8. The procedure laid down in Directive 87/22/EEC relating to high-technology medicinal products (summary 5.1) shall be extended to medicinal products derived from human blood or plasma.
9. Power is delegated to the Commission to adapt the 1975 Directive on analytical, pharmaco-toxicological and clinical standards to take account of the specific characteristics of these products.

*(4) Deadline for implementation of the legislation in the Member States*

— 1.1.1992: new products
— 31.12.1992: existing products

*(5) Date of entry into force (if different from the above)*

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| *(6) References* | Official Journal L 181, 28.6.1989 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | Directive 91/507/EEC — Official Journal L 270, 20.9.1991 Commission Directive of 19 July 1991 amending the annex to Council Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products. |

# 5. PHARMACEUTICAL PRODUCTS

## 5.17. Radiopharmaceuticals

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| *(1) Objective* | To include radiopharmaceuticals under the heading of proprietary medicinal products. |
| *(2) Community measures* | Council Directive 89/343/EEC of 3 May 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for radiopharmaceuticals. |
| *(3) Contents* | 1. Definitions of 'radiopharmaceutical', 'generator', 'kit', 'precursor'. Previous Directives on the manufacture and marketing of proprietary medicinal products now include these radiopharmaceuticals within their scope.<br>2. Authorization shall be required for generators, kits, precursor radiopharmaceuticals and industrially prepared radiopharmaceuticals. Authorization shall not be required for a radiopharmaceutical prepared at the time of use by a person or establishment authorized by national legislation to use such products.<br>3. The application for authorization of a generator must also include the following information and documentation:<br>— a general description of the system;<br>— a detailed description of the components and the qualitative and quantitative particulars of the eluate or sublimate.<br>4. The summary of product characteristics for radiopharmaceuticals must include full details of radiation dosimetry, and additional instructions for extemporaneous preparation and quality control.<br>5. The outer packaging and containers of radionuclides shall be labelled in accordance with International Atomic Energy Agency regulations as well as EEC legislation.<br>6. Member States must ensure that a detailed instruction leaflet is enclosed with the packaging of radiopharmaceuticals, generators, kits, and precursor radiopharmaceuticals.<br>7. Power is delegated to the Commission to adapt Council Directive 75/318/EEC (Official Journal L 147, 9.6.1975) on analytical, pharmaco-toxicological and clinical standards and protocols to take account of the specific characteristics of these products. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.1.1992 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 142, 25.5.1989 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 5. PHARMACEUTICAL PRODUCTS

### 5.18. Rational use of medicinal products: wholesale distribution

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| *(1) Objective* | To guarantee optimum conditions for the preservation, transport and handling of medicinal products. |
| *(2) Community measures* | Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human consumption. |
| *(3) Contents* | 1. The Directive sets out to guarantee control of the entire distribution chain, from leaving the factory to being sold to the public.<br>2. This control concerns in particular wholesalers who, once they have a specific authorization from the State in which they are established, can, in application of the principle of mutual recognition, exercise their activity throughout the Community.<br>3. The granting of this authorization will be subject to compliance with certain essential requirements:<br>— account of entry and withdrawal transactions, records being verified at least once a year and kept for three years;<br>— proof of the qualifications of personnel;<br>— suitable premises for storage which are accessible for inspection;<br>— an emergency plan permitting participation in any withdrawal from the ordered market action by the authorities.<br>4. Granting of the authorization will not exceed 90 days from the date of receipt of the application. Any refusal, suspension or withdrawal must be notified to the party in question. The Member States and the Commission will be informed of any withdrawal or suspension. Control and inspection will be effected under the authority of the Member State which granted the authorization.<br>5. Dispensing chemists and persons expressly authorized to supply medicinal products to the public are exempted from the authorization on condition that they do not exercise any wholesale activity in a principal or secondary role. They are obliged to keep records of each entry for three years for inspection purposes.<br>6. If need be, the Commission will publish guidelines on good distribution practice and, where appropriate, will consult for this purpose the Pharmaceutical Committee. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.1.1993 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 113, 30.4.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 5. PHARMACEUTICAL PRODUCTS

## 5.19. Rational use of medicinal products: legal status surrounding the supply of medicinal products

*(1) Objective*

The harmonization of supply of medicinal products on open sale or supplied solely on medical prescription.

*(2) Community measures*

Council Directive 92/26/EEC of 31 March 1992 on the classification with regard to the supply of medicinal products for human consumption.

*(3) Contents*

1. The Directive concerns the classification with regard to the supply of medicinal products for human consumption in the Community.
2. The Directive imposes the approximation of the classification criteria for medicinal products used by the Member States, in particular toxicity, side effects, tolerance, risk of dependence, risk of abuse and drug addiction, novelty of the product, etc. Medicinal products which can be marketed shall be classified as 'medicinal products subject to medical prescription' and 'medicinal products not subject to medical prescription'. The subcategories of medicinal products which can only be supplied on medical prescription shall be classified as 'medicinal products available on renewable or non-renewable medical prescriptions', 'medicinal products subject to special medical prescription' and 'medicinal products available on restricted medical prescription reserved for certain specialized areas'.
3. The direct effect of this harmonization will be to establish the right of the European citizen to take with him or her on travel in Europe (reasonable) quantities of medicinal products obtained legally that he or she needs for his or her personal use. He or she may also have pharmaceutical products obtained legally for his or her personal use sent by post from another Member State.
4. Medicinal products shall be subject to medical prescription where:
— they present a danger directly or indirectly if taken without medical supervision;
— they are used frequently and to a very large extent under the wrong conditions and this is likely to cause a danger to health;
— they contain substances or preparations based on substances whose effects and/or side-effects require more detailed research;
— they are prescribed by a doctor to be administered parenterally.
5. Where Member States specify a subcategory of medicinal product subject to special medical prescription, account shall be taken of the following elements:
— the presence in the medicinal product of a substance classified as a psychotropic or a narcotic substance;
— the possibility that the medicinal product could, if improperly used, give rise to major risks of medicinal abuse, cause addiction or be misused for illegal purposes;
— the presence in the medicinal product of a substance which because of its novelty or properties, could be included in that category as a precautionary measure.
6. Where Member States specify a subcategory of medicinal products subject to limited medical prescription, they shall take account of the following elements:

— medicinal products which, by reason of their pharmacological characteristics or their novelty or in the interest of public health, are reserved for use in treatments which can only be carried out in hospitals;
— medicinal products employed in the treatment of illnesses which require diagnosis in a hospital or other institution with adequate facilities for diagnosis but where administration and follow-up can be carried out outside the hospital;
— medicinal products for use by out-patients which could produce severe adverse effects and which therefore call for supervised treatment.

7. The competent authority shall publish at least annually the list of medicinal products subject to medical prescription in their territory specifying the category of classification.

8. Within two years of adoption of this Directive, the Member States shall communicate to the Commission and to the other Member States, the list of medicines which are available only on medical prescription on their territory. They shall communicate amendments to this list every 12 months.

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| *(4) Deadline for implementation of the legislation in the Member States* | 1.1.1993 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 113, 30.4.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 5. PHARMACEUTICAL PRODUCTS

## 5.20. Rational use of medicinal products: labelling and package leaflet

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| *(1) Objective* | Rational use of medicinal products for human consumption. |
| *(2) Community measures* | Council Directive 92/27/EEC of 31 March 1992 on the labelling and package leaflet of medicinal products for human consumption. |
| *(3) Contents* | 1. So far, a harmonized list has existed of particulars which must appear on the packaging and containers of proprietary medicinal products (Council Directive 65/65/EEC, published in Official Journal 22, 9.2.1965 and Council Directive 75/319/EEC, published in Official Journal L 147, 9.6.1975, both amended by Council Directive 89/341/EEC — summary 5.14), but to ensure a high level of consumer protection and to facilitate the free movement of these products it has proved necessary to complete this provision with full and comprehensible information. The improvement concerns the labelling of medicinal products and the package leaflet for the user, on which the particulars must be clearly visible, indelible and readily comprehensible in the languages of the marketing country.<br>2. The outer package (or else the packaging) must show the following particulars: the name of the medicinal product, its composition, pharmaceutical form and content, a list of excipients that should be known about to ensure effective use of the medicinal product, the method of administration, the date of expiry, storage precautions, the name and address of the person responsible for marketing the products, and the number of the production batch, etc. Member States may demand that the price and conditions of reimbursement by social security organizations, etc. also appear.<br>3. The package leaflet must contain all information that may be useful to the user, including the name of the product, the therapeutic indications and the dose.<br>4. The package leaflet must be written in such a way as to be clear, easily legible and understandable for the user.<br>5. If need be, the Commission will publish guidelines on the formulation of certain precautionary measures, the particular need for information on self-medication, the legibility of the particulars, the use of bar codes and the excipients that must be indicated on the packaging and warnings referring to them that must be carried on the packaging.<br>6. From 1 January 1994 Member States are required to refuse to authorize the marketing of medicinal products whose labelling and package leaflet do not conform to the requirements of the Directive. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.1.1993 |
| *(5) Date of entry into force (if different from the above)* | |

*(6) References*

*(7) Follow-up work*

*(8) Commission implementing measures*

Official Journal L 113, 30.4.1992

# 5. PHARMACEUTICAL PRODUCTS

## 5.21. Rational use of medicinal products: advertising of medicinal products for human use

*(1) Objective*

To lay down common rules relating to the advertising of pharmaceuticals.

*(2) Community measures*

Council Directive 92/28/EEC of 31 March 1992 regarding advertising of medicinal products for human use.

*(3) Contents*

1. Generally speaking, all advertising relating to a medicinal product:
— is forbidden if the medicinal product has not been granted a marketing authorization;
— must be compatible with the information listed in the summary of the product's characterisitics;
— must encourage the rational administration of the medicinal product;
— must not be misleading, within the meaning of Council Directive 84/450/EEC (Official Journal L 250, 19.9.1984).
2. The following are prohibited:
— advertising to the general public of medicinal products which are only available on medical prescription;
— mentioning, when advertising to the general public, therapeutic indications where self-medication is not suitable;
— the distribution of free samples to the general public, as well as offers of gifts and bonuses.
3. Where authorized, advertising to the general public:
— must be set out in such a fashion that it is clear that the message is an advertisement, and that the product is clearly identified as a medicinal product;
— must include all the necessary information for correct administration of the medicinal product;
— must include an express invitation to read the instruction leaflet carefully;
— must not include elements incompatible with the rational administration of the medicinal product.
4. Any advertising to professionals and any documentation transmitted to them as part of the promotion of a medicinal product must include:
— essential information compatible with the summary of the product's characteristics;
— the classification of the medicinal product for supply purposes.
5. During each visit, medical sales representatives must provide the persons visited with the summaries of product characteristics in respect of each medicinal product which they present.
6. Inducements to prescribe or supply medicinal products (such as gifts, pecuniary advantages or benefits in kind, including invitations to travel or to congresses, with the exception of objects of an insignificant intrinsic value) are prohibited.
7. The supply of free samples to persons qualified to prescribe or supply medicinal products is subject to strict controls.
8. Pharmaceutical companies are required to establish within the company a scientific service in charge of information relating to medicinal products.

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| | 9. Provisions relating to the monitoring of pharmaceutical advertising are similar to those provided for in Directive 84/450/EEC on misleading advertising. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.1.1993 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 113, 30.4.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 5. PHARMACEUTICAL PRODUCTS

## 5.22. Supplementary protection certificate for medicinal products

*(1) Objective*

To create a supplementary protection certificate for medicinal products which have received authorization to be placed on the market.

*(2) Community measures*

Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.

*(3) Contents*

1. The Regulation lays down definitions of the terms 'medicinal product', 'product', 'basic patent' and 'certificate'. 'Medicinal product' means any substance for treating or preventing disease in human beings or animals and any substance which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions.
2. The certificate is available for any product which, firstly, is protected by a patent in the territory of a Member State and which, secondly, has been subject, prior to being placed on the market, to an administrative authorization procedure under Council Directive 65/65/EEC (Official Journal 22, 9.2.1965) or Council Directive 81/851/EEC (Official Journal L 317, 6.11.1981).
3. The certificate is issued if the following conditions are satisfied:
— firstly, the product must be protected by a patent in force, termed a 'basic patent' in the Member State in which the application is submitted;
— a valid authorization to place the product on the market must have been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC. This authorization must be the first authorization to place the product on the market, in the Member State in which the application is submitted;
— the product must not already have been the subject of a certificate.
4. The protection conferred by the certificate extends only to the product covered by the marketing authorization and for any use of the product authorized before expiry of the certificate.
5. The certificate confers the same rights as are conferred by the basic patent and is subject to the same limitations and obligations.
6. Entitlement to the certificate lies with the holder of the basic patent or his successor in title.
7. The application for a certificate must be lodged, within six months of the date on which the authorization referred to in point 3 was granted, with the appropriate industrial property office of the Member State which granted the basic patent. Member States may require that the application for a certificate is subject to payment of a fee. The application for a certificate is published.
8. The certificate takes effect from the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community reduced by a period of five years.
9. The duration of the certificate may not exceed five years. By this means, effective protection for innovative medicinal products will be extended to a maximum of 15 years.

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| | 10. The certificate is void if:<br>— it was granted contrary to the provisions of the Regulation;<br>— the basic patent has lapsed before its lawful term expires;<br>— the basic patent is revoked.<br>11. The certificate will be issued for any product for which the first authorization to place it on the market in the Community was obtained after 1 January 1985. This date is replaced by that of 1 January 1982 in Italy and Belgium and by that of 1 January 1988 for certificates issued in Denmark and Germany. An application for a certificate must be submitted within six months of the date on which the Regulation enters into force. |
| *(4) Deadline for implementation of the legislation in the Member States* | Not required. |
| *(5) Date of entry into force (if different from the above)* | 2.1.1993 |
| *(6) References* | Official Journal L 182, 2.7.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 5. PHARMACEUTICAL PRODUCTS

## 5.23. Homeopathic medicinal products: medicinal products for human use

*(1) Objective*

To cover all industrially prepared medicinal products for human use with a view to the completion of the internal market.

*(2) Community measures*

Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of the laws of the Member States on medicinal products and laying down additional provisions on homeopathic medicinal products.

*(3) Contents*

1. The Directive applies to homeopathic medicinal products for human use to the exclusion of those prepared in accordance with a magistral or an officinal formula as defined in Council Directive 65/65/EEC (Official Journal 22, 9.2.1965). The products must be identified by the inclusion on their labels of the words 'homeopathic medicinal product'. Anthrophosophic medicinal products described in an official pharmacopoeia and prepared in a homeopathic manner are treated on the same basis.
2. The term 'homeopathic medicinal product' designates all medicinal products obtained from products, substances or mixtures manufactured in accordance with a homeopathic procedure described by the European Pharmacopoeia or by the official pharmacopoeia of a Member State.
3. Member States must send one another the information necessary to ensure the quality and safety of homeopathic medicinal products manufactured and marketed in the Community.
4. The manufacture, control, importation and exportation of homeopathic medicinal products are subject to the provisions of Council Directive 75/319/EEC (Official Journal L 147, 9.6.1975). The surveillance measures and sanctions provided for in Directive 75/319/EEC are also applicable to these products.
5. Member States shall ensure that homeopathic medicinal products manufactured and marketed within the Community are registered or authorized by a Member State. Member States shall recognize registrations and authorizations by other Member States.
6. A Member State may refrain from setting up any system of registration or authorization for homeopathic medicinal products. In this case it must inform the Commission accordingly and must consequently allow the use in its territory of medicinal products registered or authorized in other Member States.
7. A simplified registration system is laid down for homeopathic medicinal products which are so diluted as to present no risk to the patient and which are administered orally. On the other hand those administered parenterally are excluded.
8. The labelling and packaging of the products referred to in point 7 above must bear no information other than that set out in the Directive, except for therapeutic indications.
9. Applications for simplified registration submitted by the person responsible for marketing may cover a series of preparations derived from the same homeopathic stock(s). Such applications must be accompanied by documents demonstrating the pharmaceutical quality and batch-to-batch consistency of the products concerned.

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| | 10. Other homeopathic and anthroposophic medicinal products are subject to the full procedure for the marketing authorization and labelling of products in the Community. However, a Member State may lay down specific rules for the pharmaceutical and toxicological tests and clinical trials of the homeopathic medicinal products subject to authorization.<br>11. On 31 December 1995, at the latest, the Commission will present a report on the application of this Directive to the Council and European Parliament. |
| *(4) Deadline for implementation of the legislation in the Member States* | 31.12.1993 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 297, 13.10.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 5. PHARMACEUTICAL PRODUCTS

## 5.24. Homeopathic medicinal products: veterinary medicinal products

*(1) Objective*

To cover all industrially prepared veterinary medicinal products, with a view to the completion of the internal market.

*(2) Community measures*

Council Directive 92/74/EEC of 22 September 1992 widening the scope of Directive 81/851/EEC on the approximation of the laws of the Member States on veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products.

*(3) Contents*

1. The Directive applies to homeopathic veterinary medicinal products to the exclusion of products prepared by a pharmacist or a veterinarian in accordance with a magistral or an officinal formula intended for administration to a single animal or a small number of animals. The products must be identified by the inclusion on their labels of the words 'homeopathic medicinal products, for animal treatment only'. The Directive does not apply to immunlological veterinary medicinal products.
2. The term 'homeopathic medicinal product' designates all pharmaceutical preparations manufactured in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or the official pharmacopoeia of a Member State.
3. Member States must send one another the information necessary to ensure the quality and safety of homeopathic veterinary medicinal products manufactured and marketed in the Community.
4. The manufacture, control, importation and exportation of homeopathic veterinary medicinal products are subject to the provisions of Council Directive 81/851/EEC (Official Journal L 317, 6.11.1981). The surveillance measures and sanctions provided for in Directive 81/851/EEC are also applicable to these products.
5. A Member State may refrain from setting up any system of registration or authorization for homeopathic medicinal products. In this case, it must inform the Commission accordingly and must consequently allow the use in its territory of medicinal products registered or authorized in other Member States.
6. A simplified registration system is laid down for homeopathic medicinal products which are so diluted as to present no risk to the patient and which are administered orally.
7. The labelling and packaging of the products referred to in point 5 above must bear no information other than that set out in the Directive, except for therapeutic indications.
8. Applications for simplified registration submitted by the person responsible for marketing may cover a series of preparations derived from the same homeopathic stock(s). Such applications must be accompanied by documents demonstrating the pharmaceutical quality and batch-to-batch consistency of the products concerned.
9. Other homeopathic medicinal products are subject to the full procedure for the marketing authorization and labelling of products in the Community.
10. On 31 December 1995, at the latest, the Commission will present a report on the application of this Directive to the Council and European Parliament.

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| *(4) Deadline for implementation of the legislation in the Member States* | 31.12.1993 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 297, 13.10.1992 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 5. PHARMACEUTICAL PRODUCTS

## 5.25. European Agency for the Evaluation of Medicinal Products

*(1) Objective*

To provide the Member States and the Community institutions with scientific opinions on all matters relating to the assessment of medicinal products intended for human or veterinary use and subject to the provisions of Community legislation.

*(2) Proposal*

Proposal for a Council Regulation laying down Community procedures for the authorization and monitoring of medicinal products for human and veterinary use and establishing a European agency responsible for assessing such products.

*(3) Contents*

1. No medicinal product derived from biotechnology and no culture medium used in veterinary medicine can be marketed in the Community unless an authorization has been issued by the Community in accordance with the provisions of this Regulation. The person responsible for marketing a medicinal product may apply for a marketing authorization to be issued by the Community. Such an authorization can be obtained by submitting an application to the European Agency for the Evaluation of Medicinal Products.
2. The Committee for Proprietary Medicinal Products is responsible for formulating the opinion of the Agency on all matters relating to the granting, amendment, suspension or withdrawal of marketing authorizations for medicinal products intended for human use.
3. Following a written request by the Committee, Member States are required to forward the information needed in order to verify that the manufacturer of a medicinal product from a third country is competent to manufacture the medicinal product in question. Authorization of a medicinal product will be refused, if:
— after verification of the information and documentation submitted, it transpires that the quality, safety or efficacy of the medicinal product has not been adequately demonstrated;
— the information and documentation supplied by the applicant are not correct, or the labelling or package insert proposed by the applicant do not comply with the provisions of Council Directive 75/318/EEC (Official Journal L 147, 9.6.1975).
4. Marketing authorizations are granted by the Commission. When an authorization is granted, an announcement to this effect is published, for information purposes, in the *Official Journal of the European Communities*.
5. Medicinal products authorized by the Community pursuant to this Regulation are covered by the 10-year protection period provided for under Council Directive 65/65/EEC (Official Journal 22, 9.2.1965).
6. Following the granting of an authorization, the person responsible for marketing the medicinal product must take due account of scientific and technical progress and make such changes as may be needed to manufacture the product.
7. The Regulation sets up a European Agency for the Evaluation of Medicinal Products. The Agency will collaborate with the World Health Organization on international pharmacological vigilance and send it information on activities in the Community which could affect public health protection in third countries.

8. The opinion of the Agency on medicinal products intended for human use is delivered by the Committee on Proprietary Medicinal Products. The opinion of the Agency on medicinal products intended for veterinary use is delivered by the Committee on Veterinary Medicinal Products. The Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products may request the opinion of the Scientific Committee on important matters of a general scientific or ethical nature. The Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products are each composed of scientific advisers appointed for a period of three years (renewable).
9. The Agency has legal personality and exercises the widest possible legal powers recognized under the law in all the Member States.
10. A Scientific Committee, answerable to the Agency, has also been set up to deliver opinions to the Committee on Proprietary Medicinal Products or to the Committee on Veterinary Medicinal Products on any matter submitted to it.

*(4) Opinion of the European Parliament*

First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments.

*(5) Current status*

On 10 November 1992 the Council reached political agreement on the adoption of this proposal. Formal adoption is scheduled for the next meeting.

*(6) References*

| | |
|---|---|
| Commission proposal<br>COM(90) 283/I final | Official Journal C 330, 31.12.1990 |
| Amended proposal<br>COM(91) 382/I final | Official Journal C 310, 30.11.1991 |
| European Parliament opinion<br>First reading | Official Journal C 183, 15.7.1991 |
| Economic and Social Committee opinion | Official Journal C 269, 14.10.1991 |

# 6. CHEMICAL PRODUCTS

## 1992 target: current position and outlook

Differing Regulations for chemical products gave rise to a multitude of problems. Divergent levels of health and safety protection were a clear obstacle to the creation of the internal market.

Free movement of chemical products throughout the Community cannot be guaranteed if classification, packaging and labelling requirements differ in the individual Member States.

In this area the emphasis is on protecting the health and safety of man and his environment, and, at the same time, ensuring that users are adequately provided with information about products placed on the market.

The measures undertaken by the Community have to be seen as part of a continuing process which already has a long history. For example, the Community first adopted a Directive on the classification, packaging and labelling of dangerous substances in 1967 and this has been amended and adapted to technical progress nine times.

Community legislation on the classification, packaging and labelling of dangerous preparations has a similar history, going back to 1973.

The Community has undertaken the following measures:

— restrictions on the marketing and use of certain dangerous substances and preparations (summaries 6.1 to 6.8).
On the basis of the Directives amending Directive 76/769/EEC, the Council and, in certain cases, the Commission prohibit or restrict the placing on the market of dangerous substances or preparations. This procedure has been used to ban products such as cadmium or Ugilec 121 and Ugilec 141 and to limit the use of PCBs and asbestos.
In such matters the Commission has a duty to ensure that the level of regulation is consistent with the protection requirements in each Member State. Since that requirement has not been fulfilled, the Commission has had to confirm German legislation imposing a total ban on PCBs under Article 100a(4);

— classification, packaging and labelling of dangerous substances (summary 6.10); the general Directive on the classification, packaging and labelling of dangerous preparations, which replaced the earlier Directives, has been in force for over a year. The preparatory work to include in it the assessment of environmental hazards started recently, and an amending proposal will be sent to the Council by the end of the first half of 1994. The Commission has made a start on implementing the Directive with regard to certain categories of packaging and the exchange of information between administrations.

— approximation of the laws relating to detergents (summary 6.11);

— marketing of fertilizers (summaries 6.12 to 6.14).

It will be for the Commission to administer them by means of Commission directives in some cases and proposals to the Council in others.

# 6. CHEMICAL PRODUCTS

## 6.1. Marketing and use of dangerous substances: polychlorinated biphenyls and terphenyls — sixth amendment

| | |
|---|---|
| *(1) Objective* | To restrict the marketing and use of PCBs and PCTs (polychlorinated biphenyls and polychlorinated terphenyls). |
| *(2) Community measures* | Council Directive 85/467/EEC of 1 October 1985 amending for the sixth time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (PCBs/PCTs). |
| *(3) Contents* | 1. Prohibition of the use of PCBs and PCTs except under certain conditions:<br>— closed-system electrical equipment transformers, resistors and inductors;<br>— large condensers (with a total weight equal to or over 1 kg);<br>— in certain small condensers;<br>— heat-transmitting fluids in closed-circuit heat-transfer installations;<br>— hydraulic fluids for underground mining equipment.<br>These uses of PCBs and PCTs will come to an end on 30 June 1986.<br>2. New labelling requirements: Member States may prescribe that equipment and plants containing PCBs and PCTs must display instructions concerning their disposal, maintenance and use. |
| *(4) Deadline for implementation of the legislation in the Member States* | 30.6.1986 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 269, 11.10.1985 |
| *(7) Follow-up work* | On 9 September 1991 the Commission presented a proposal for a Council Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations.<br>This proposal relates to the legislative consolidation of the field. It replaces the various Directives now being consolidated, including Directive 85/467/EEC. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made. |
| *(8) Commission implementing measures* | |

# 6. CHEMICAL PRODUCTS

## 6.2. Marketing and use of dangerous substances: asbestos — seventh amendment

| | |
|---|---|
| *(1) Objective* | To prohibit certain uses of asbestos in order to ensure adequate public health protection throughout the Community. |
| *(2) Community measures* | Council Directive 85/610/EEC of 20 December 1985 amending for the seventh time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (asbestos). |
| *(3) Contents* | Prohibition of the marketing and use of asbestos for:<br>— toys;<br>— materials and preparations applied by spraying;<br>— products in powder form;<br>— items for smoking;<br>— filters and insulation devices for use in catalytic heaters using liquified gas;<br>— paints and varnishes. |
| *(4) Deadline for implementation of the legislation in the Member States* | 31.12.1987 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 375, 31.12.1985 |
| *(7) Follow-up work* | On 9 September 1991 the Commission presented a proposal for a Council Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations.<br>This proposal relates to the legislative consolidation of the field. It replaces the various Directives now being consolidated, including Directive 85/610/EEC. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made. |
| *(8) Commission implementing measures* | |

## 6. CHEMICAL PRODUCTS

### 6.3. Marketing and use of dangerous substances: eighth amendment

| | |
|---|---|
| *(1) Objective* | To add to the existing list new dangerous substances and/or preparations covered by the restrictions on marketing and/or use. |
| *(2) Community measures* | Council Directive 89/677/EEC of 21 December 1989 amending for the eighth time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. |
| *(3) Contents* | This amendment concerns restrictions on the marketing and use of 11 chemical substances or families of substances, in particular:<br>— five carcinogenic substances the marketing of which is strictly regulated;<br>— lead sulphates and lead carbonates which may not be used as constituents of paints;<br>— mercury compounds, arsenic compounds and organostannic compounds which may no longer be used as constituents of preparations used to prevent the fouling of the hulls of boats or of any totally or partly submerged appliances or equipment. |
| *(4) Deadline for implementation of the legislation in the Member States* | 21.6.1991 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 398, 30.12.1989 |
| *(7) Follow-up work* | On 9 September 1991 the Commission presented a proposal for a Council Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations.<br>This proposal relates to the legislative consolidation of the field. It replaces the various Directives now being consolidated, including Directive 89/677/EEC. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made. |
| *(8) Commission implementing measures* | |

# 6. CHEMICAL PRODUCTS

## 6.4. Marketing and use of dangerous substances: committee procedure

| | |
|---|---|
| *(1) Objective* | To provide the Community with means of adapting to technical progress the Community legislation on the marketing and use of dangerous substances. |
| *(2) Community measures* | Council Directive 89/678/EEC of 21 December 1989 amending for the eighth time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. |
| *(3) Contents* | This amendment concerns the manner in which decisions on the adaptation of the Directive's annexes to technical progress are to be taken. |
| *(4) Deadline for implementation of the legislation in the Member States* | Not applicable. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 398, 30.12.1989 |
| *(7) Follow-up work* | On 9 September 1991 the Commission presented a proposal for a Council Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations.<br>This proposal relates to consolidation of the legislation in this field. It replaces the various Directives now being consolidated, including Directive 89/678/EEC. It maintains the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made. |
| *(8) Commission implementing measures* | |

## 6. CHEMICAL PRODUCTS

### 6.5. Marketing and use of dangerous substances: pentachlorophenol and its compounds — ninth amendment

| | |
|---|---|
| *(1) Objective* | To strictly regulate the marketing of pentachlorophenol and its compounds with a view to ensuring adequate protection of public health in the whole of the Community. |
| *(2) Community measures* | Council Directive 91/173/EEC of 21 March 1991 amending for the ninth time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. |
| *(3) Contents* | Prohibition of the use of pentachlorophenol and its compounds in concentration equal to or greater than 0.1% by mass in substances or preparations intended for use in industrial installations:<br>— for the treatment of wood;<br>— for the impregnation of heavy-duty textiles;<br>— as a synthesizing and/or processing agent. |
| *(4) Deadline for implementation of the legislation in the Member States* | 31.12.1991 |
| *(5) Date of entry into force (if different from the above)* | 1.7.1992 |
| *(6) References* | Official Journal L 85, 5.4.1991 |
| *(7) Follow-up work* | On 9 September 1991 the Commission presented a proposal for a Council Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations.<br>This proposal relates to the legislative consolidation of the field. It replaces the various Directives now being consolidated, including Directive 91/173/EEC. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made. |
| *(8) Commission implementing measures* | |

# 6. CHEMICAL PRODUCTS

## 6.6. Marketing and use of dangerous substances: cadmium — 10th amendment

| | |
|---|---|
| *(1) Objective* | To prohibit certain uses of cadmium with a view to protecting the environment and human health. |
| *(2) Community measures* | Council Directive 91/338/EEC of 18 June 1991 amending for the 10th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. |
| *(3) Contents* | 1. Ban on the use of cadmium and its compounds in three areas of application: pigments, stabilizers and plating.<br>2. A general derogation clause is provided to cover reasons of safety and reliability and situations where the use of cadmium may be essential.<br>3. The Council will reassess the situation within three years of the date of adoption of the Directive. |
| *(4) Deadline for implementation of the legislation in the Member States* | 31.12.1992 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 186, 12.7.1991 |
| *(7) Follow-up work* | On 9 September 1991 the Commission presented a proposal for a Council Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations.<br>This proposal relates to the legislative consolidation of the field. It replaces the various Directives now being consolidated, including Directive 91/338/EEC. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made. |
| *(8) Commission implementing measures* | |

## 6. CHEMICAL PRODUCTS

### 6.7. Marketing and use of dangerous substances: Ugilec 141, Ugilec 121, DBBT — 11th amendment

| | |
|---|---|
| *(1) Objective* | To lay down rules on the marketing and use of certain dangerous substances and preparations with a view to protection of the environment and human health. |
| *(2) Community measures* | Council Directive 91/339/EEC of 18 June 1991 amending for the 11th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. |
| *(3) Contents* | 1. A ban on the use of Ugilec 141 except in, or for the maintenance of, plant and machinery already in service until such plant and machinery is disposed of or reaches the end of its service life.<br>2. A ban on the use of Ugilec 121 and DBBT. |
| *(4) Deadline for implementation of the legislation in the Member States* | 18.6.1992 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 186, 12.7.1991 |
| *(7) Follow-up work* | On 9 September 1991 the Commission presented a proposal for a Council Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations.<br>This proposal relates to consolidation of the legislation in this field. It replaces the various Directives now being consolidated, including Directive 91/339/EEC. It maintains the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made. |
| *(8) Commission implementing measures* | |

# 6. CHEMICAL PRODUCTS

## 6.8. Marketing and use of dangerous substances: polybromobiphenyl ethers — 12th amendment

| | |
|---|---|
| *(1) Objective* | To update the placing on the market of polybromobiphenyl ethers for the purposes of protecting human health and the environment. |
| *(2) Proposal* | Proposal for a Council Directive amending Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. |
| *(3) Contents* | A ban on the use of polybromobiphenyl ether and its compounds in concentrations by mass equal to or greater than 0.1%, with an exemption for a period of five years from the adoption of this Directive for decabromobiphenyl ether, octabromobiphenyl ether and pentabromobiphnenyl ether, which must not be present in concentrations greater than those specified above. |
| *(4) Opinion of the European Parliament* | Not yet delivered. |
| *(5) Current status* | The proposal has been forwarded to the European Parliament for its opinion. |
| *(6) References* | Commission proposal COM(91) 7 final — Official Journal C 46, 22.2.1991<br>Economic and Social Committee opinion — Official Journal C 191, 22.7.1991 |

## 6. CHEMICAL PRODUCTS

### 6.9. Marketing and use of dangerous substances: creosote, chlorinated solvents, CMT substances and preparations — 13th amendment

| | |
|---|---|
| *(1) Objective* | To regulate the marketing and use by the general public of dangerous preparations in order to ensure protection of the environment and health. |
| *(2) Proposal* | Proposal for a Council Directive amending for the 13th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. |
| *(3) Contents* | The Directive amends the annex to Council Directive 76/769/EEC (Official Journal L 762, 27.9.1976) which established an *ad hoc* system to restrict the marketing and use of dangerous substances and preparations, such as creosote and wood treated with creosote, any substance classified as carcinogenic, mutagenic and teratogenic and preparations containing such substances, plus certain chlorinated solvents. |
| *(4) Opinion of the European Parliament* | Not yet delivered. |
| *(5) Current status* | The proposal has been sent to the European Parliament for its opinion. |
| *(6) References* | Commission proposal COM(92) 195 final — Official Journal C 157, 24.6.1992<br>Economic and Social Committee opinion — Official Journal C 332, 16.12.1992 |

# 6. CHEMICAL PRODUCTS

## 6.10. Classification, packaging and labelling of dangerous preparations

*(1) Objective*

To harmonize national measures on classification, packaging and labelling of dangerous preparations to facilitate the establishment of a single market and to provide protection for public health.

*(2) Community measures*

Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

*(3) Contents*

1. The Directives apply to dangerous preparations as defined in Article 1(2) of Directive 88/379/EEC which have been placed on the market with certain exceptions, e.g. medicinal or veterinary products, foodstuffs, substances in transit which are under customs supervision, etc.
2. Classification of preparations such as 'explosive', 'oxidizing', 'extremely flammable', 'highly flammable', etc. with an extra provision on aerosols.
3. Provisions relating to the marketing of dangerous preparations.
4. Provision for the assessment of the health hazards of a product, i.e. those considered to be toxic, harmful, corrosive, irritant, carcinogenic, mutagenic, teratogenic, and as having special effects on health.
5. Packaging requirements, e.g. containers of dangerous preparations sold to the public must not have a shape and/or graphic design likely to attract children. They must be strong and resistant and have a suitable fastening system.
6. Labelling requirements including clear and indelible marking of the package with:
— the trade name of the preparation,
— the chemical name of the substance, etc.
Also, provision for the labelling of a product which has not yet been fully tested.
7. Manufacturers or those responsible for placing the preparation on the market shall hold the data used for the classification and labelling of the preparation at the disposal of the authorities of the Member States. Member States will appoint bodies responsible for receiving and ensuring the confidentiality of this information.
8. Member States shall set up a system of specific information (in safety data-sheet form) relating to dangerous products. This will primarily be used by industry to ensure health and safety at work.
9. Member States may temporarily suspend or make subject to special conditions the sale of a dangerous preparation on their territory. They may do so if it constitutes a hazard by reason of its classification, packaging or labelling. The Member State must immediately notify the Commission and other Member States of such action.

10. Member States may not prohibit, restrain or hinder the marketing of goods which comply with this Directive.
11. Annexes containing concentration limits of dangerous substances and special provisions on the labelling of certain preparations.
12. Directive 92/32/EEC amends Directive 88/379/EEC in the way it classifies preparations by category.

*(4) Deadline for implementation of the legislation in the Member States*

— Directive 88/379/EEC: 7.6.1991
— Directive 92/32/EEC: 31.10.1993

*(5) Date of entry into force (if different from the above)*

*(6) References*

| | |
|---|---|
| Amended opinion | Official Journal L 187, 16.7.1988<br>Official Journal L 110, 1.5.1991<br>Official Journal L 154, 5.6.1992 |

*(7) Follow-up work*

*(8) Commission implementing measures*

Directive 89/178/EEC — Official Journal L 64, 8.3.1989
Commission Directive of 22 February 1989 adapting to technical progress Council Directive 88/379 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

Directive 90/35/EEC — Official Journal L 19, 24.1.1990
Commission Directive of 19 December 1989 defining in accordance with Article 6 of Directive 88/379/EEC the categories of preparations the packaging of which must be fitted with child-resistant fastenings and/or carry a tactile warning of danger.
Date of entry into force: 10.6.1991.

Directive 91/155/EEC — Official Journal L 76, 22.3.1991
Commission Directive of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC. This Directive sets up a more detailed information system for industrial users.
Date of entry into force: 8.6.1991.

Publication by the Commission (Official Journal L 180A, 8.7.1991) of a guide to the labelling of dangerous substances and preparations.

Directive 91/442/EEC — Official Journal L 238, 27.8.1991
Commission Directive of 23 July 1991 on dangerous preparations the packaging of which must be fitted with child-resistant fastenings.
This Directive describes certain dangerous preparations as being likely to present a danger for children even if they do not fall into the categories of danger defined by Directive 90/35/EEC. The packaging must, therefore, be fitted with child-resistant fastenings.

Recommendation 92/214/EEC — Official Journal L 101, 16.4.1992
Commission Recommendation of 3 March 1992 concerning the information to be provided by the person responsible for placing a dangerous preparation on the market when making use of the provisions relating to the confidentiality of the chemical name of a substance to protect the true identity.
This Recommendation specifies the information to be provided to the national authorities. It also contains a lexical guide to the establishment of alternative names.
This Recommendation was repealed, by a Commission Decision on 30 November 1992 with retroactive effect from 15 April 1992, as a result of proceedings by the German authorities to have it annulled.

# 6. CHEMICAL PRODUCTS

## 6.11. Detergents

| | |
|---|---|
| *(1) Objective* | To extend until 31 December 1989 the existing exemptions from the requirement of a minimum biodegradability level for certain detergents. |
| *(2) Community measures* | Council Directive 86/94/EEC of 10 March 1986 amending for the second time Directive 73/404/EEC on the approximation of the laws of the Member States relating to detergents. |
| *(3) Contents* | Extension of the exemption period quoted in the original Directive until 31 December 1989 for a range of detergents including:<br>— low-foaming alkene oxide additives in such substances as alcohols, alkyphenols, glycols, polyols, fatty acids, amides or amines used in dish-washing products;<br>— alkali-resistant terminally blocked alkyl and alkylaryl polyglycol ethers and substances of the type referred to in the paragraph above, used in cleaning agents for the food, beverage and metallurgical industries. |
| *(4) Deadline for implementation of the legislation in the Member States* | Exemptions for certain detergents extended until 31 December 1989. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 80, 25.3.1986 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 6. CHEMICAL PRODUCTS

## 6.12. Marketing of fertilizers: liquid fertilizers

| | |
|---|---|
| *(1) Objective* | To extend the laws on the marketing of fertilizers to include liquid fertilizers. |
| *(2) Community measures* | Council Directive 88/183/EEC of 22 March 1988 amending Directive 76/116/EEC in respect of fluid fertilizers. |
| *(3) Contents* | 1. Marketing requirements for liquid fertilizers. Only fertilizers listed in this Directive may be designated EEC fertilizers. Fluid fertilizers may only be marketed if directions for their correct storage and prevention of accidents are provided.<br>2. An annex containing a list of fluid fertilizers. |
| *(4) Deadline for implementation of the legislation in the Member States* | 25.3.1989 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 83, 29.3.1988 |
| *(7) Follow-up work* | On 5 December 1991 a consolidated version of Directive 76/116/EEC was presented by the Commission.<br>It relates to the legislative consolidation of the field and will replace the various Directives now being consolidated. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made. |
| *(8) Commission implementing measures* | |

## 6. CHEMICAL PRODUCTS

### 6.13. Marketing of fertilizers: solid and fluid fertilizers

| | |
|---|---|
| *(1) Objective* | To extend the existing legislation on fertilizers to include their calcium, magnesium, sodium and sulphur content or to market them as EEC fertilizers. |
| *(2) Community measures* | Council Directive 89/284/EEC of 13 April 1989 supplementing and amending Directive 76/116/EEC in respect of the calcium, magnesium, sodium and sulphur content of fertilizers. |
| *(3) Contents* | 1. A declaration of the magnesium, sodium and sulphur content of fertilizers may be made, provided that these elements are present in quantities at least equal to the minimum values laid down.<br>2. A declaration of calcium content considered to be a nutrient need only be made for calcium sulphate and calcium chloride solution fertilizers.<br>3. Fertilizers complying with the Directive may be marked 'EEC fertilizer'.<br>4. Required marking for identification purposes includes:<br>— 'EEC fertilizer',<br>— the designation of the type of fertilizer and the guaranteed nutrient content.<br>5. List of fertilizers containing calcium, magnesium and sulphur as principal nutrients. |
| *(4) Deadline for implementation of the legislation in the Member States* | 17.4.1990 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 111, 22.4.1989 |
| *(7) Follow-up work* | On 5 December 1991 a consolidated version of Directive 89/284/EEC was adopted by the Commission.<br>It relates to the legislative consolidation of the field and will replace the various Directives now being consolidated. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made. |
| *(8) Commission implementing measures* | |

# 6. CHEMICAL PRODUCTS

## 6.14. Marketing of fertilizers: trace elements

| | |
|---|---|
| *(1) Objective* | To extend existing Community legislation on fertilizers (summaries 6.12 and 6.13) to include specific nutrients in fertilizers. |
| *(2) Community measures* | Council Directive 89/530/EEC of 18 September 1989 supplementing and amending Council Directive 76/116/EEC (Official Journal L 24, 30.1.1976) on the approximation of the laws of the Member States in respect of the trace elements boron, cobalt, copper, iron, manganese, molybdenum and zinc contained in fertilizers. |
| *(3) Contents* | 1. Solid or fluid fertilizers complying with the existing Directive and containing one or more of the trace elements boron, cobalt, copper, iron, manganese, molybdenum and zinc may be marked 'EEC fertilizer', provided they meet the technical requirements detailed in the annex. A mixture of at least two of these trace elements may be termed 'EEC fertilizer'. These fertilizers must be packaged.<br>2. The content of the trace elements must be declared when they are present above a specified minimum and when they satisfy the requirements of Directive 76/116/EEC on fertilizers.<br>3. Compulsory markings for the identification of fertilizers, e.g. the words 'EEC fertilizer'; trace elements must be listed in alphabetical order of chemical symbol.<br>4. A Member State may authorize further information on labels within its territory; this would contain suitable dose rates and conditions of use for a fertilizer applied to a particular crop and soil condition.<br>5. Tolerance allowances for declared trace element content. |
| *(4) Deadline for implementation of the legislation in the Member States* | 18.3.1991 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 281, 30.9.1989 |
| *(7) Follow-up work* | On 5 December 1991 a consolidated version of Directive 89/530/EEC was adopted by the Commission.<br>It relates to the legislative consolidation of the field and will replace the various Directives now being consolidated. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made. |
| *(8) Commission implementing measures* | |

# 7. CONSTRUCTION

## 1992 target: current position and outlook

The construction sector raises problems of two kinds. Firstly, there is the problem of obstacles to the free movement between Member States of construction equipment. Secondly, there is the problem of differing standards for buildings, which can mean different levels of protection for occupants.

The lack of common standards for construction equipment restricts manufacturers to national rather than Community-wide markets. In order to promote their products throughout the Community costly modifications have to be made, frustrating the ideal of the internal market.

As with motor vehicles and agricultural machinery, the lack of EEC type-approval procedures leads to repeated testing and certification of components. Costs mount and valuable resources are wasted.

The completion of the internal market is intended to remove all these barriers, and, at the same time, lay down Community-wide minimum standards of health, safety and environment.

Safety requirements are essential not only for construction equipment but also for buildings. For this reason the Commission has proposed measures in three areas, namely:

— construction equipment: a Directive on admissible acoustic levels for tower cranes and another on earth-moving equipment have been adopted (summaries 7.1 and 8.3);

— construction products (summary 7.3): the Directive is based on the new approach principles (summary 1.1). The Commission will have to adopt implementing measures for the purpose of putting it into effect;

— safety measures in hotels (summary 7.2): safety in hotels is particularly important because many hotels are old buildings and because of the number of persons at risk.

The entire programme has been completed.

# 7. CONSTRUCTION

## 7.1. Tower cranes: sound levels

| | |
|---|---|
| *(1) Objective* | To consolidate into one Directive all the technical provisions required to determine the sound levels of tower cranes. |
| *(2) Community measures* | Council Directive 87/405/EEC of 25 June 1987 amending Directive 84/534/EEC on the approximation of the laws of the Member States relating to the permissible sound-power level of tower cranes. |
| *(3) Contents* | 1. This Directive applies to the permissible sound-power level, and sound-pressure level at the operator's position, of noise emitted from tower cranes used on industrial and building sites.<br>2. EC type-examination certificates shall be issued to tower cranes which satisfy the following requirements: the lifting mechanism must emit less than 102 dB(A)/1pW (to be reduced to 100 dB(A)/1pW in 1992); the sound-pressure level at the operator's position must not exceed 85 dB/20 µ pA (to be reduced to 80 dB/20 µ pA in 1992).<br>3. Cranes which satisfy the requirements must bear a mark indicating the sound-power and sound-pressure levels guaranteed by the manufacturer, and the symbol 'epsilon'.<br>4. The annexes contain technical information on the measurement of airborne noise and diagrams of the marks to be put on complying cranes. |
| *(4) Deadline for implementation of the legislation in the Member States* | 26.6.1989 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 220, 8.8.1987 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 7. CONSTRUCTION

### 7.2. Fire safety in hotels

| | |
|---|---|
| *(1) Objective* | To lay down a minimum fire safety level for all hotels in the Member States. |
| *(2) Community measures* | Council Recommendation 86/666/EEC of 22 December 1986 on fire safety in existing hotels. |
| *(3) Contents* | 1. Member States are recommended to take action to ensure that hotels are subject to provisions based on the principles set out in the Recommendation. For example:<br>— safe escape routes should be available, unobstructed and clearly marked;<br>— buildings should be stable at least as long as necessary to allow safe evacuation of occupants;<br>— warning systems should be installed and in full working order;<br>— staff should be given suitable instructions and training.<br>2. The annex contains technical guidelines in particular for the construction of hotel buildings.<br>3. Member States are recommended to inspect hotels periodically.<br>4. Member States must inform the Commission of the national regulations which they intend to introduce in the next five years to ensure that hotels meet the requirements of the Recommendation. |
| *(4) Deadline for implementation of the legislation in the Member States* | Not applicable. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 384, 31.12.1986 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 7. CONSTRUCTION

## 7.3. Construction products

| | |
|---|---|
| *(1) Objective* | To harmonize national legislation with respect to the health and safety requirements applicable to construction products. |
| *(2) Community measures* | Council Directive 89/106/EEC of 21 December 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to construction products. |
| *(3) Contents* | 1. The Directive applies to construction products, which are defined as any products produced with a view to their incorporation in a permanent manner in construction works.<br>2. Products may only be placed on the market if they are fit for their intended use. They must be such that works in which they are incorporated satisfy the essential requirements with regard to mechanical strength and stability, safety in case of fire, hygiene, health and the environment, safety in use, protection against noise and energy economy and heat retention for an economically reasonable working life.<br>3. Harmonized European standards for construction products shall be established by the European standardization bodies after consulting the Standing Committee on Construction (which was set up by the Directive).<br>4. A system of European technical approval designed to assess new products in terms of whether they satisfy the essential requirements set out in point 2 above.<br>5. Where neither a European standard nor guidelines for European technical approval yet exist, construction products may be assessed in terms of their compliance with national requirements.<br>6. Products which bear the EC mark shall be assumed to conform to requirements. Procedures for inspecting for conformity shall be laid down in accordance with the relevant decisions by the Standing Committee.<br>7. Products conforming to standards, but which are thought to pose a safety threat, may be temporarily withdrawn from the market.<br>8. Annexes containing detailed information on the essential requirements, European technical approval, attestation of conformity with technical specifications, certification bodies, inspection bodies and testing laboratories. |
| *(4) Deadline for implementation of the legislation in the Member States* | 27.6.1991 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 40, 11.2.1989 |

| | |
|---|---|
| *(7) Follow-up work* | Interpretative documents will be drawn up by technical committees by the end of June 1991 and submitted to the Standing Committee for approval by a qualified majority (Article 148(2)) before the end of 1991 and then published by the Commission in the 'C' series of the Official Journal. |
| *(8) Commission implementing measures* | |

# 8. OTHER AREAS

## 1992 target: current position and outlook

All of the proposals contained in the White Paper have now been tabled by the Commission; one of these remains to be adopted by the Council.

The emphasis is on providing a high level of health and safety for all European citizens and to protect the environment.

Thus the measures cover areas such as noise from household appliances and lawnmowers (summaries 8.1 and 8.2); good laboratory practice in chemical laboratories (summary 8.4), which is necessary not only for safety reasons but also to allow for mutual recognition of test results throughout the Community; prohibitions on marketing dangerous substances which could be confused with food (summary 8.5); and noise emissions from construction products (summary 8.3).

There are also three measures (summaries 8.6 to 8.10) which aim to protect the consumer and harmonize national regulations for product pricing (both for food and non-food items) and for cosmetics (colouring agents, adaptation to technical progress, constituents).

In addition, there are Community measures on the elimination of waste: general waste disposal, toxic and dangerous wastes, as well as the incineration of these (summaries 8.11 to 8.14).

Other measures cover the disposal of polychlorobiphenels (PCBs) and polychloroterphenels (PCTs) (summary 8.15), the disposal of spent batteries and accumulators (summary 8.16) and the disposal of waste oil (summary 8.20).

Similarly, there are measures on the disposal of pollution from titanium dioxide industrial waste (summary 8.17) and the procedures for the surveillance and monitoring of environments concerned by waste from such an industry (summary 8.18).

A Directive laying down the terms of harmonization programmes for the reduction of pollution caused by industrial waste of titanium dioxide was adopted on 15 December 1992 (summary 8.19).

# 8. OTHER AREAS

## 8.1. Noise: household appliances

| | |
|---|---|
| *(1) Objective* | To provide the public with information on levels of noise emitted by household appliances, harmonizing only those requirements necessary for measuring noise. |
| *(2) Community measures* | Council Directive 86/594/EEC of 1 December 1986 on airborne noise emitted by household appliances. |
| *(3) Contents* | 1. The Directive covers: the general principles relating to the publication of information on noise levels emitted from household appliances; methods of measuring noise; arrangements for monitoring noise emitted by household appliances.<br>2. Where Member States require information to be published on the noise level of such appliances it shall be the responsibility of the manufacturer (or the importer if the manufacturer is outside the Community) to supply such information and ensure its accuracy.<br>3. The information supplied may be subject to spot checks. If it is found to be inaccurate, Member States must ensure that appropriate action to correct it without delay is taken by the manufacturer (or importer).<br>4. Where appliances have to have labels detailing other types of information, information on the noise emitted shall also be included.<br>5. Member States must inform the Commission of their national regulations.<br>6. The Directive also gives details of the testing methods to be used for determining levels of noise. |
| *(4) Deadline for implementation of the legislation in the Member States* | 4.12.1989 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 344, 6.12.1986 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 8. OTHER AREAS

## 8.2. Noise: lawnmowers

| | |
|---|---|
| *(1) Objective* | To harmonize legislation relating to noise emissions from lawnmowers so as to remove any barriers to trade that exist due to differences in national provisions. |
| *(2) Community measures* | Council Directive 88/180/EEC and Council Directive 88/181/EEC of 22 March 1988 amending Directive 84/538/EEC on the approximation of the laws of the Member States relating to the permissible sound-power level of lawnmowers. |
| *(3) Contents* | *Directive 88/180/EEC*<br>1. The Directive enlarges the field of application of Council Directive 84/538/EEC (Official Journal L 300, 19.11.1984) by including motorized cylinder mowers.<br>2. The cutting devices of cylinder lawnmowers shall be adjusted with a cylinder/cutting edge gap specified by the manufacturer according to three different criteria.<br>*Directive 88/181/EEC*<br>1. The Directive establishes common standards for noise emission from lawnmowers.<br>2. The permitted sound-power level ranges between 96 dB/pW and 105 dB/pW according to the corresponding cutting width of the lawnmower.<br>3. Lawnmowers shall display clearly visible marks identifying the manufacturer and to be guaranteed by him, describing the type and indicating the maximum sound-power level expressed in dB(A)/pW. Lawnmowers with a cutting width exceeding 120 cm shall indicate the sound-pressure level expressed in dB(A)/20 μ P at the operator's position.<br>4. Two annexes containing the method of measuring airborne noise emitted by lawnmowers with a cutting width exceeding 120 cm at the operator's position and giving the model for a mark stating the sound-pressure level at the operator's position. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.7.1991 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 81, 26.3.1988 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 8. OTHER AREAS

### 8.3. Noise: emissions from construction plant

| | |
|---|---|
| *(1) Objective* | To harmonize national legislation on the control of noise emitted from construction equipment to ensure adequate environmental and health protection. |
| *(2) Community measures* | Council Directive 86/662/EEC of 22 December 1986 on the limitation of noise emitted by hydraulic excavators, rope-operated excavators, dozers, loaders and excavator-loaders. |
| *(3) Contents* | 1. The Directive applies to the sound-power level of noise emitted into the environment, and the sound-pressure level of noise emitted at the operator's position of earth-moving machines used to perform work on civil-engineering and building sites. The four particular types of earth-moving machines are defined in detail.<br>2. The permitted sound-power level is between 106 dB(A)/1pW and 118 dB(A)/1pW according to the net installed power in kW of the machinery. All machines that comply will be issued with an EC type-examination certificate.<br>3. Member States must ensure that the marketing and use of earth-moving machines that do not comply with the Directive are prohibited.<br>4. Member States may limit the use of these machines in certain areas.<br>5. Six annexes containing technical information. |
| *(4) Deadline for implementation of the legislation in the Member States* | 30.12.1988. The level of noise fixed by the Commission must be respected six years after the entry into force of the Directive. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 384, 31.12.1986 |
| *(7) Follow-up work* | The Commission has still to submit to the Council a proposal aimed at introducing the real, dynamic method of measurement of airborne noise thus superseding the stationary method. |
| *(8) Commission implementing measures* | Directive 89/514/EEC — Official Journal L 253, 30.8.1989<br>Commission Directive of 2 August 1989 adapting to technical progress Council Directive 86/662/EEC on the limitation of noise emitted by hydraulic excavators, rope-operated excavators, dozers, loaders and excavator-loaders. |

# 8. OTHER AREAS

## 8.4. Good laboratory practice (GLP)

| | |
|---|---|
| *(1) Objective* | To set up a harmonized system for the verification of studies and for inspections of laboratories, ensuring that the latter comply with good laboratory practice (GLP) in order to allow for mutual recognition of tests carried out in these laboratories. |
| *(2) Community measures* | Council Directive 88/320/EEC of 9 June 1988 on the inspection and verification of good laboratory practice (GLP). |
| *(3) Contents* | 1. The Directive applies to the inspection and verification of the conditions under which non-clinical tests are performed on chemical products in order to assess health and safety implications for humans, animals and the environment. The principles of good laboratory practice (GLP) to be followed are found in Council Directive 87/18/EEC (Official Journal L 15, 17.1.1987).<br>2. Member States must designate particular authorities to carry out inspections of laboratories.<br>3. Every year a report must be produced by Member States containing a list of inspected laboratories and a summary of the conclusions of the inspections.<br>4. Commercially sensitive and confidential information will be made available only to specified bodies, e.g. the Commission, national regulatory and designated authorities, etc., but GLP compliance status will be publicly available.<br>5. If it is thought that a laboratory has not carried out a test according to GLP, further information may be sought by the Member States from the inspecting authorities. A further inspection of the laboratory may be necessary. Member States shall inform the Commission of laboratories claiming GLP status but which fail to meet the requirements.<br>6. Amendments to the technical clauses of the Directive can be made by the Commission in consultation with the relevant committee.<br>7. Annex referring to OECD guidelines containing detailed information on the procedures to be followed when carrying out inspections. |
| *(4) Deadline for implementation of the legislation in the Member States* | 1.1.1989 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 145, 11.6.1988 |
| *(7) Follow-up work* | |

*(8) Commission implementing measures*

Directive 90/18/EEC — Official Journal L 11, 13.1.1990
Commission Directive adapting to technical progress the annex to Directive 88/320/EEC on the approximation of the laws of the Member States relating to the permissible sound-power level of lawnmowers.
This Directive is to incorporate into the Directive OECD guidelines on procedures for laboratory inspection verification and the carrying out of inspections.
The Member States must undertake to implement the Directive before 1 July 1990.

# 8. OTHER AREAS

## 8.5. Dangerous products resembling foodstuffs

| | |
|---|---|
| *(1) Objective* | To harmonize all national legislation relating to the marketing of such products so that consumers are protected equally in all Member States. |
| *(2) Community measures* | Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers. |
| *(3) Contents* | 1. The Directive applies to products which are not edible but could easily be confused with foodstuffs by their appearance, smell or packaging.<br>2. Member States must take all the measures necessary to prohibit the marketing, import and manufacture of such products.<br>3. Checks must be carried out to ensure that no such products are marketed.<br>4. If a Member State bans a product under the terms of this Directive it must inform the Commission and provide the details needed to inform the other Member States. |
| *(4) Deadline for implementation of the legislation in the Member States* | 26.6.1989 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 192, 11.7.1987 |
| *(7) Follow-up work* | The Directive may be updated by the Council to extend its scope. |
| *(8) Commission implementing measures* | |

# 8. OTHER AREAS

## 8.6. Cosmetic products: labelling and colouring agents — fourth amendment

| | |
|---|---|
| *(1) Objective* | To improve Community provisions on labelling. |
| *(2) Community measures* | Council Directive 88/667/EEC of 21 December 1988 amending for the fourth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products. |
| *(3) Contents* | 1. The Directive gives an extensive Community list of colouring agents used in cosmetic products. Colouring agents intended solely to colour hair are excluded.<br>2. New requirements for labelling are laid down, including provisions concerning the manufacturer or the party responsible for placing the product on the market as well as nominal content specifications except for very small packets of less than 5 g or 5 ml (e.g. samples). There will be future provisions concerning special measures to be taken concerning cosmetic products intended for professional use, particularly those used in hairdressing.<br>3. Member States must ensure that no cosmetics that do not comply with the new requirements are marketed after 1 January 1992. |
| *(4) Deadline for implementation of the legislation in the Member States* | 31.12.1989 |
| *(5) Date of entry into force (if different from the above)* | Cosmetic products whose labelling does not comply with the provisions of the Directive may not be marketed after 1 January 1992. Products not complying with the Directive may not be sold to the final consumer after 31 December 1993. |
| *(6) References* | Official Journal L 382, 31.12.1988 |
| *(7) Follow-up work* | See summaries 8.7 and 8.8.<br>A proposal for a consolidated version of Directive 76/768/EEC was presented by the Commission in October 1990 (SEC(90) 1985 final, published in Official Journal C 322, 21.12.1990).<br>It consolidates the existing Community provisions concerning the harmonization of cosmetic products. |
| *(8) Commission implementing measures* | |

# 8. OTHER AREAS

## 8.7. Cosmetic products: adaptation to technical progress — fifth amendment

| | |
|---|---|
| *(1) Objective* | To extend the period during which the procedure involving the Committee on the Adaptation to Technical Progress applies. |
| *(2) Community measures* | Council Directive 89/679/EEC of 21 December 1989 amending for the fifth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products. |
| *(3) Contents* | The procedure involving the Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Cosmetic Products Sector has been extended indefinitely in the case of Annexes III to VII (list of substances which cosmetic products must not contain except subject to the restrictions and conditions laid down; list of substances provisionally allowed, etc.). |
| *(4) Deadline for implementation of the legislation in the Member States* | Not required. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 398, 30.12.1989 |
| *(7) Follow-up work* | See summary 8.8.<br>A proposal for a codified version of Directive 76/768/EEC was presented by the Commission in October 1990 (SEC(90) 1985 final, published in Official Journal C 322, 21.12.1990).<br>A codification containing Community provisions exists in the harmonization of cosmetic products. |
| *(8) Commission implementing measures* | |

## 8. OTHER AREAS

### 8.8. Cosmetic products: labelling and constituents — sixth amendment

*(1) Objective*

To increase consumer protection; to remove the remaining barriers to free movement; to ban experiments involving animals in the cosmetic products industry.

*(2) Proposal*

Proposal for a Council Directive amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products.

*(3) Contents*

1. The Commission is to draw up, not later than 18 months following the adoption of the proposal by the Council, a guideline list of the constituents used in cosmetic products. This list, periodically updated and published by the Commission, must contain various items of information and, in particular, information relating to the identity of the constituent and any compulsory warnings to be included on the labelling.
2. Cosmetic products may be placed on the Community market only if their constituents are listed clearly, legibly and indelibly on their containers and packages. However, provision has been made for exemptions.
3. The manufacturer or his authorized representative must, if requested by the competent authorities of the Member State concerned, make available, in the language of that Member State, information relating in particular to physico-chemical and microbiological specifications, purity and microbiological monitoring criteria and the method of manufacture.
4. Before the cosmetic products are placed on the Community market, the manufacturer or his authorized representative — or, in the case of imported products, the person responsible for placing them on the market — must notify the competent authorities of the address of the place of manufacture or point of initial importation of these products.
5. The Directive lays down a new deadline of 1 January 1998 for the banning of experiments involving animals. However, this time-limit could be extended in specific circumstances.

*(4) Opinion of the European Parliament*

First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments.

*(5) Current status*

The Council adopted a common position on 17 December 1992. Under the cooperation procedure this is now before Parliament for a second reading.

*(6) References*

| | |
|---|---|
| Commission proposal<br>COM(90) 488 final | Official Journal C 52, 28.2.1991 |
| Amended proposal<br>COM(92) 364 final | Official Journal C 249, 26.9.1992 |
| European Parliament opinion<br>First reading | Not yet published |
| Economic and Social<br>Committee opinion | Official Journal C 269, 14.10.1991 |

# 8. OTHER AREAS

## 8.9. Foodstuff prices

*(1) Objective*

To inform and protect consumers whilst liberalizing trade in food within the Community by harmonizing requirements for indicating unit prices on labels.

*(2) Community measures*

Council Directive 88/315/EEC of 7 June 1988 amending Directive 79/581/EEC on consumer protection in the indication of the prices of foodstuffs.

Council Resolution 88/611/EEC of 7 June 1988 regarding the protection of consumers on prices of foodstuffs and non-foodstuffs.

*(3) Contents*

*Directive 88/315/EEC*

1. The Directive does not apply to foodstuffs sold in hotels, cafés, etc., or to food which is purchased for trade or commercial activities, or to food supplied in the course of the provision of a service.
2. Definitions:
— 'prepackaged foodstuffs' means foodstuffs packaged other than in the consumer's presence;
— 'unit price', means the price per litre for products sold by volume, and the price per kilo for products sold by weight.
3. Member States may waive the obligation to indicate the unit price of prepackaged foodstuffs in a series of cases, particularly for foodstuffs sold by certain small retail businesses. They may provide that the Directive will not apply to foodstuffs sold on the farm or to private sales.
4. Prices, and where appropriate unit prices, must be indicated on all foodstuffs offered for sale to the final consumer.
5. The Directive gives details of which products must display unit prices and those which are exempt, in particular foodstuffs prepacked in pre-established quantities.
6. Advertisements or catalogues must mention the unit price as well as the selling price.
7. An annex contains a list of the products prepackaged in pre-established quantities referred to in the Directive.

*Resolution 88/611/EEC*

The resolution requests further proposals from the Commission as soon as possible to extend the range of categories of products covered by the Directive and to revise the existing range.

*(4) Deadline for implementation of the legislation in the Member States*

7.6.1990

*(5) Date of entry into force (if different from the above)*

7.6.1995. Transitional measures have been included in respect of the imperial system used in the UK and in Ireland.

*(6) References*

Official Journal L 142, 9.6.1988
Official Journal C 153, 11.6.1988

*(7) Follow-up work*

*(8) Commission implementing measures*

# 8. OTHER AREAS

## 8.10. Non-food product prices

| | |
|---|---|
| *(1) Objective* | To inform and protect consumers whilst liberalizing trade in non-food products within the Community and by harmonizing the obligations to indicate the retail price and the unit price. |
| *(2) Community measures* | Council Directive 88/314/EEC of 7 June 1988 on consumer protection in the indication of prices for non-food products.<br>Council Resolution 88/611/EEC of 7 June 1988 regarding the protection of consumers on prices of foodstuffs and non-foodstuffs. |
| *(3) Contents* | *Directive 88/314/EEC*<br>1. The Directive does not apply to products bought for trade or supplied in connection with a service, private sale, sale by auction, or the sale of objects of art or antiques.<br>2. The retail prices and the unit prices must be indicated in an unambiguous, easily identifiable and clearly legible manner on products offered for sale to the ultimate consumer.<br>3. Definitions of 'unit price', e.g. price per litre for products sold by volume, price per kilo for products sold by weight, and of prepackaged products as products packaged other than in the consumer's presence.<br>4. The Directive gives details of which products must display unit prices and those which are exempt, in particular products prepacked in pre-established quantities.<br>5. Annex containing list of products prepackaged in pre-established quantities referred to in the Directive.<br>*Resolution 88/611/EEC*<br>The resolution requests further proposals from the Commission as soon as possible to extend the range of categories of products covered by the Directive and to revise the existing range. |
| *(4) Deadline for implementation of the legislation in the Member States* | 7.6.1990 |
| *(5) Date of entry into force (if different from the above)* | 7.6.1995. Transitional measures exist in respect of the imperial system used in the UK and in Ireland. |
| *(6) References* | Official Journal L 142, 9.6.1988<br>Official Journal C 153, 11.6.1988 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 8. OTHER AREAS

## 8.11. Waste disposal

*(1) Objective*

To set up a system for the coordinated management of waste within the Community in order to limit waste production.

*(2) Community measures*

Council Directive 75/442/EEC of 15 July 1975 on waste.

Council Directive 91/156/EEC of 18 March 1991 amending Directive 75/442/EEC on waste.

*(3) Contents*

*Directive 75/442/EEC*

1. The Directive applies to all substances or objects which the holder disposes of or is obliged to dispose of in pursuance of the national provisions in force in the Member States. It does not apply to radioactive waste, mineral waste, annual carcasses and agricultural waste, waste water, gaseous effluents and wastes that are subject to specific Community regulations.
2. (Member) States shall promote the prevention, recycling and conversion of wastes with a view to their reuse. They shall inform the Commission of any draft regulations which may involve the use of products which can give rise to technical difficulties and excessive disposal costs and which may encourage decreasing as regards the quantities of certain wastes, the treatment of waste for the purpose of their recycling or their reuse, the use of energy deriving from certain wastes or the use of natural resources which may be replaced by reclamation materials.
3. The disposal of wastes must not constitute a hazard to human beings in the environment. It is not a question of causing hazard for water, air, the soil, flora and fauna or noise or smell nuisances or any impairment of beauty spots and landscapes.
4. Member States shall ensure that all holders of wastes shall hand them over to a private or public collection agency or to a disposal company, or else shall themselves conduct the disposal in compliance with the requirements of this Directive.
5. Companies or establishments treating, storing or dumping waste for another party must obtain an authorization from the competent authority which concerns, in particular, the types and quantities of waste to be treated, the general technical requirements and the precautions to be taken. The competent authorities may routinely check compliance with those authorization conditions. The same monitoring by the competent authority is reserved for transport, collection, storage, dumping or treatment companies working on their own account or for third parties.
6. The cost of disposal of waste must be borne by its holder, who will hand over his waste to a collector or company and/or else by earlier holders or by the producer who has generated the waste in accordance with the 'polluter pays' principle.

*Directive 91/156/EEC*

This Directive substantially amends Directive 75/442/EEC. The following requirements have been added:

1. Member States must prohibit the uncontrolled discarding, discharge and disposal of waste.

2. The Directive provides for cooperation between the Member States with a view to setting up an integrated, adequate network of disposal installations (taking account of the best technologies available) which would enable the Community itself to dispose of its wastes and the Member States individually to work towards that aim. That network would have to enable waste to be disposed of in one of the closest installations that guaranteed a high level of environmental protection.
3. The competent authorities appointed by the Member States in order to implement the Directive shall draw up at least one management plan governing, in particular, the types, quantities and origins of the wastes to be upgraded or disposed of, the general technical requirements, all of the special arrangements concerning specific wastes, and the appropriate locations and installations for the disposal.
4. The Directive identifies the disposal and upgrading operations and adds to Directive 75/442/EEC a requirement that upgrading centres and companies disposing of their own wastes be authorized.

*(4) Deadline for implementation of the legislation in the Member States*

— Directive 75/442/EEC: 24 months from the date of notification
— Directive 91/156/EEC: 1.4.1993

*(5) Date of entry into force (if different from the above)*

*(6) References*

Official Journal L 194, 25.7.1975
Official Journal L 78, 26.3.1991

*(7) Follow-up work*

On 1 April 1996 the Commission will for the first time publish a summary report concerning the measures taken in order to ensure implementation of the Directive by the Member States. Before entry into force of Directive 91/156/EEC the Commission must draw up a list of the wastes covered by that Directive.

*(8) Commission implementing measures*

# 8. OTHER AREAS

## 8.12. Disposal of toxic and dangerous wastes

*(1) Objective*

Approximation of the laws on the disposal of toxic and dangerous wastes in order to safeguard the competition rules and the operation of the common market.

*(2) Community measures*

Council Directive 78/319/EEC of 20 March 1978 on toxic and dangerous wastes.

*(3) Contents*

1. The Directive applies to all waste containing or contaminated by substances or materials in quantities or concentrations such that they constitute a health or environmental hazard. It does not apply to radioactive waste, animal carcasses, explosives, hospital wastes, effluents discharged into sewers and water courses, household wastes, mining wastes and other toxic and dangerous wastes that are subject to specific Community regulations.
2. The international conventions on the carriage of dangerous products apply to the Member States only if the measures contained therein are not less stringent than those required for implementation of the Directive.
3. Member States shall promote the prevention, recycling and conversion of toxic and dangerous wastes into raw materials or energy, together with any reuse.
4. They shall ensure that wastes are disposed of without endangering human health and the environment within the complex.
5. Member States shall designate the competent authority(s) responsible for managing the toxic and dangerous waste disposal operations.
6. They must ensure that those wastes are, if necessary, separated from other substances and residues during the disposal operations, are appropriately labelled and that it is possible to record them and identify them when they are disposed of.
7. They may take more stringent action than that provided for by the Directive.
8. Only facilities, establishments or undertakings which have received an authorization from the competent authorities may dispose of toxic and dangerous wastes. Those authorizations, granted for a specific, but renewable, period relate especially to the types and quantities of waste.
9. The cost of disposing of toxic and dangerous wastes must be borne by the holder of the waste and/or earlier holders or the producer of the waste-generating product.
10. Waste disposal programmes relating, in particular, to the types and quantities of waste to be disposed of will be drawn up and updated by the competent authorities, and will be published and passed on to the Commission, which will regularly compare these programmes together with the Member States in order to check the stage reached in the harmonization of the Directive.
11. In the event of urgency or serious danger to the population or the environment the Member States may temporarily depart from this Directive.

| | |
|---|---|
| | 12. The competent authorities shall monitor and check the facilities, establishments and undertakings holding or disposing of wastes, which will cooperate fully. |
| *(4) Deadline for implementation of the legislation in the Member States* | Twenty-four months from the date of notification;<br>Exemption up to 31 December 1995 in implementation of Council Directive 90/656/EEC (Official Journal L 353, 17.12.1990) for the older facilities in the former GDR, which do not comply with Directive 78/319/EEC. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 84, 31.3.1978 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 8. OTHER AREAS

## 8.13. Disposal of hazardous waste

| | |
|---|---|
| *(1) Objective* | To manage the correct disposal of hazardous waste. |
| *(2) Community measures* | Council Directive 91/689/EEC of 12 December 1991 on hazardous waste. |
| *(3) Contents* | This Directive will replace Directive 78/319/EEC, which it repeals with effect from 12 December 1993 (summary 8.12).<br>1. A list of the hazardous wastes covered by the Directive will be drawn up on the basis of the categories, constituents and properties set out in the annexes to the Directive by 12 June 1993. Domestic waste is not covered by the Directive. Waste not covered by the Directive is subject to Directive 75/442/EEC (summary 8.11).<br>2. Member States ensure that hazardous waste is recorded and identified; they also ensure that different categories of hazardous waste are not mixed and that hazardous waste is not mixed with non-hazardous waste, save where the necessary measures have been taken to safeguard human health and the environment.<br>3. Any establishment or undertaking which carries out disposal operations must obtain a permit. This applies also in the case of operations which may lead to recovery. However, the permit requirement may be waived in the latter case if the method of recovery is such that there is no danger to human health or the environment, or if the Member State has adopted general measures laying down conditions for various methods of recovery, provided the conditions have been communicated to the Commission.<br>4. Establishments or undertakings which carry out disposal operations or operations which may lead to recovery and producers of hazardous waste are subject to periodic inspections covering in particular the origin and destination of the waste. Transporters, producers, establishments and undertakings keep a record of their activities and make this information available to the competent authorities designated by each State.<br>5. The competent authorities publish plans for the management of hazardous waste and the Commission evaluates these plans.<br>6. In case of emergency or grave danger, Member States may derogate temporarily from the Directive. They must inform the Commission of any such derogations.<br>7. The annexes to the Directive can be adapted to scientific and technical progress in accordance with the procedure referred to in Article 18 of Directive 75/442/EEC. |
| *(4) Deadline for implementation of the legislation in the Member States* | 12.12.1993 |
| *(5) Date of entry into force (if different from the above)* | |

*(6) References* Official Journal L 377, 31.12.1991

*(7) Follow-up work* Every three years, and for the first time on 1 April 1995, the Member States send the Commission a report on implementation of the Directive. By 12 December 1994 the Member States must send the Commission particulars of every establishment or undertaking which carries out disposal and/or recovery of hazardous waste and which is likely to form part of the integrated network which must eventually enable the Community to become self-sufficient in waste disposal. The Commission reports to Parliament every three years on the implementation of the Directive.

*(8) Commission implementing measures*

# 8. OTHER AREAS

## 8.14. Incineration of dangerous waste

*(1) Objective*

To prevent or reduce the effects of dangerous-waste incineration on the environment and the ensuing risks for public health.

*(2) Proposal*

Proposal for a Council Directive on the incineration of dangerous waste.

*(3) Contents*

1. The Directive defines the following concepts:
— dangerous waste, solid or liquid, of Council Directive 91/689/EEC (summary 8.13). Municipal waste and liquid combustible waste (including waste oils) are excluded on the grounds that the levels of harmful emissions from such waste are characteristically negligible;
— dangerous-waste incineration plant (whether new or existing), and any installation using such waste as an additional fuel.
2. Before an incineration plant can become operational, a licence must be obtained from the competent authorities designated by each Member State. The issuing of such licences is subject to the conditions laid down in the Directive. Steps must be taken as swiftly as possible to employ the best available technologies in both the new and the existing plants. A licence is also required for the discharge of waste water from an incineration plant. Licences will be reviewed every five years.
3. Licensing procedures and emission inspection results must be made public.
4. The plant operator will be required to draw up an analytical report each time waste is delivered and accepted and to provide a detailed description of the waste in question. The same rules will apply in the case of interim storage and pretreatment.
5. The Directive lays down general and specific conditions governing the design and operation of incineration plants. Annex TN III gives details of the technologies currently available. Fuelling the furnace with dangerous waste will be permitted only if the main operating parameters fall within the prescribed limits.
6. The Directive lays down emission threshold values comparable to those obtainable through the use of the best available technologies. Emissions of dioxins and furans must be reduced to a minimum by means of the most advanced technologies. A guideline value of 0.1 ng TE/$m^3$ is laid down in respect of these emissions.
7. Incineration residues left over from the treatment of combustion gases must be disposed of in accordance with the provisions of the Directive on dangerous and other waste (Council Directive 75/442/EEC — summary 8.11, and Council Directive 91/689/EEC — summary 8.13).
8. Measuring equipment and techniques must meet high technological standards in order to ensure that compliance with the threshold values and operating conditions can be effectively monitored (see Annexes TN IV and VI for relevant information and specifications).
Measurements must be taken on an ongoing basis in respect of the quantitatively significant emissions, and the results set against standard operating conditions. Emissions which cannot at present be measured on an ongoing basis (dioxins, furans, heavy metals) must be checked once a month. In the event of the threshold values being exceeded, the plant must cease operation until the situation has been

rectified and the plant complies once more with the requirements laid down in the Directive.
9. Existing plants must either take steps to comply with the provisions of the Directive before 30 June 1997 and inform the Commission accordingly or must notify the competent authority of their intention to terminate their activities in the short term.

*(4) Opinion of the European Parliament*

Not yet delivered.

*(5) Current status*

The proposal has been sent to the European Parliament for its opinion.

*(6) References*

| | |
|---|---|
| Commission proposal COM(92) 9 final | Official Journal C 130, 21.5.1992 |
| Economic and Social Committee opinion | Official Journal C 332, 16.12.1992 |

## 8. OTHER AREAS

### 8.15. Disposal of PCBs and PCTs

| | |
|---|---|
| *(1) Objective* | To enable the same conditions to be met for the disposal for PCBs and PCTs throughout the Community. |
| *(2) Community measures* | Council Directive 76/403/EEC of 6 April 1976 on the disposal of polychlorobiphenyls and polychloroterphenyls. |
| *(3) Contents* | 1. Member States shall ban the uncontrolled discharge, discarding and dumping of PCBs, together with objects and appliances containing these. They shall ensure that spent PCBs or PCBs contained in disused objects or appliances will be disposed of.<br>2. No disposal shall threaten human health or the environment.<br>3. Member States shall promote the reclamation of spent PCBs or PCBs contained in disused objects or appliances.<br>4. The authorities in the Member States shall set up or designate the installations, establishments or undertakings that have been approved for the disposal of PCBs.<br>5. Their holder must be in possession of an approval by the competent authorities before any disposal of PCBs.<br>6. Under the 'polluter pays' principle the Directive provides that the cost of disposing of PCBs shall be borne by their holder and/or the previous holder or producer.<br>7. Member States may lay down any particular requirements which must be met by holders of PCBs, whether installations, establishments or undertakings. |
| *(4) Deadline for implementation of the legislation in the Member States* | Twenty-four months from notification date. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 108, 26.4.1976 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 8. OTHER AREAS

## 8.16. Disposal of spent batteries and accumulators

| | |
|---|---|
| *(1) Objective* | To introduce measures for the upgrading and controlled disposal of spent batteries and accumulators containing dangerous materials in the Community. |
| *(2) Community measures* | Council Directive 91/157/EEC of 18 March 1991 on batteries and accumulators containing certain dangerous substances. |
| *(3) Contents* | 1. With effect from 1 January 1993, the Member States must prohibit the placing on the market of:<br>— manganese alkaline batteries designed for prolonged use in extreme conditions and containing more than 0.05% by weight of mercury;<br>— any other alkaline battery with a mercury content of more than 0.025% by weight.<br>2. Batteries of the 'button' type or those composed of elements of the 'button' type are excluded from the scope of this Directive.<br>3. After 1 January 1994 the Member States will take steps to prevent batteries and accumulators from being incorporated in appliances, unless they can be easily removed by the user.<br>4. The Member States will draw up programmes aimed primarily at reducing the heavy-metal content of batteries and accumulators.<br>5. Under these programmes, the Member States must encourage the separate collection of batteries and accumulators with a view to their upgrading or ultimate disposal. The batteries and accumulators, or the appliances in which they are incorporated, must be marked in such a way as to indicate separate collection and recycling requirements and heavy-metal content. |
| *(4) Deadline for implementation of the legislation in the Member States* | 18.9.1992 |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 78, 26.3.1991 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

# 8. OTHER AREAS

## 8.17. Titanium dioxide: disposal

| | |
|---|---|
| *(1) Objective* | To prevent, gradually reduce and ultimately eliminate pollution from titanium dioxide industrial waste. |
| *(2) Community measures* | Council Directive 78/176/EEC of 20 February 1978 on titanium dioxide industrial waste. |
| *(3) Contents* | 1. The Member States will take steps to ensure that waste-disposal procedures take due account of human-health and environmental considerations. They will actively encourage waste prevention and recycling and the reuse of waste as raw materials.<br>2. Any discharge, dumping, storage, accumulation or injection of waste will require prior authorization, for a limited but renewable period, by the competent Member State authority:<br>— on whose territory the waste is produced;<br>— on whose territory the waste is discharged or dumped;<br>— from whose territory the waste is discharged or dumped.<br>3. Periodical checks will be carried out on the waste, and on the ambient environment in question, by bodies designated by the Member State responsible for issuing the licence, with a view to assessing the physical, chemical, biological and ecological aspects.<br>4. The Member States will draw up programmes for the gradual reduction, and ultimate elimination, of pollution caused by waste from old manufacturing facilities.<br>5. In the case of new manufacturing facilities, prior authorization must be obtained from the competent authorities in the Member State on whose territory it is planned to construct them. The issuing of any such authorization will be preceded by environmental impact studies and will be conditional on an undertaking by the companies concerned to use only those materials, procedures and technology that are least damaging to the environment.<br>6. Under the terms of the Directive, Member States are empowered to introduce more stringent rules. |
| *(4) Deadline for implementation of the legislation in the Member States* | Twelve months from the date of notification |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 54, 25.2.1978 |
| *(7) Follow-up work* | See summaries 8.18 and 8.19. |
| *(8) Commission implementing measures* | |

# 8. OTHER AREAS

## 8.18. Titanium dioxide: surveillance and monitoring

| | |
|---|---|
| *(1) Objective* | To fix common reference methods of measurement for sampling in order to conserve environments concerned by titanium dioxide waste. |
| *(2) Community measures* | Council Directive 82/883/EEC of 3 December 1982 on procedures for the surveillance and monitoring of environments concerned by waste from the titanium dioxide industry. |
| *(3) Contents* | 1. The Directive applies to the discharge into water, the land surface, underground strata and the air of waste from the manufacture of titanium dioxide.<br>2. The Member States carry out surveillance and monitoring of the environments affected, special account being taken of local environmental factors and the manner of disposal of the waste in question.<br>3. Detailed description of the sampling procedure and the sampling methods used.<br>4. Member States may lay down other parameters in addition to those laid down by the Directive.<br>5. Member States may derogate from the Directive in the event of flooding or natural disaster or on account of exceptional weather conditions. |
| *(4) Deadline for implementation of the legislation in the Member States* | Two years from the date of notification. |
| *(5) Date of entry into force (if different from the above)* | |
| *(6) References* | Official Journal L 378, 31.12.1982 |
| *(7) Follow-up work* | |
| *(8) Commission implementing measures* | |

## 8. OTHER AREAS

### 8.19. Titanium dioxide: programmes for the reduction of pollution

| | |
|---|---|
| *(1) Objective* | To eliminate distortions of competition and to protect the environment. |
| *(2) Community measures* | Council Directive 92/112/EEC of 15 December 1992 on procedures for harmonizing the programmes for the reduction and eventual elimination of pollution caused by waste from the titanium dioxide industry. |
| *(3) Contents* | 1. The Directive is intended to fill the legal void created by the annulment of Council Directive 89/428/EEC by the Court of Justice of the European Communities.<br>2. The Directive applies to solid waste, strong acid waste, weak acid waste, neutralized waste, treatment waste and dust. The processes covered are the sulphate process and the chloride process. The Directive also concerns dumping.<br>3. The dumping of any waste from ships or aircraft is prohibited from 15 June 1993.<br>4. Discharges into territorial waters and the high sea of solid waste and strong acid waste from existing industrial establishments using either process and of treatment waste from existing industrial establishments using the sulphate process are prohibited from 15 June 1993.<br>5. Discharges into any waters of waste other than that referred to at point 4 above is reduced to limit values laid down by the Directive. Member States may choose to make use of quality objectives coupled with appropriate limit values, provided they demonstrate, in a programme presented to the Commission, that the measures achieve an equivalent effect in terms of protecting the environment and avoiding distortion of competition. The Member States must ensure that this reduction is achieved by 31 December 1993 or, under certain conditions, by 31 December 1994 for the sulphate process, and by 15 June 1993 for the chlorine process.<br>6. The Member States must ensure that discharges into the atmosphere are reduced in accordance with limit values laid down by the Directive.<br>7. The Member States monitor compliance with the limit values.<br>8. The Member States are subject to the general obligation to avoid or reuse the waste referred to by the Directive or, failing that, to dispose of it. Their actions must not endanger human health or harm the environment. |
| *(4) Deadline for implementation of the legislation in the Member States* | 15.6.1993 |
| *(5) Date of entry into force (if different from the above)* | |

*(6) References*

*(7) Follow-up work*

*(8) Commission implementing measures*

Official Journal L 409, 31.12.1992

# 8. OTHER AREAS

## 8.20. Disposal of waste oil

*(1) Objective*

Prevention of unequal conditions of competition and improvements to environmental protection.

*(2) Community measures*

Council Directive 75/439/EEC of 16 June 1975 on the disposal of waste oil.

Council Directive 87/101/EEC of 22 December 1986 amending Directive 75/439/EEC on the disposal of waste oil.

*(3) Contents*

*Directive 75/439/EEC*

1. The Directive applies to all spent semi-liquid or liquid products consisting of mineral or synthetic oil including oily tank residues, water-oil mixtures and emulsions.
2. Member States must ensure that spent oils are collected and disposed of harmlessly, including their reuse.
3. They shall ban the discharge of waste oils into any water or into the ground, and the uncontrolled discharge of residues resulting from the processing of waste oils and any treatment of spent oils causing air pollution exceeding the permissible level.
4. Member States may make one or several undertakings responsible for collecting and disposing of the products offered by their holders. The undertaking performing the collecting and disposal operations shall do so on the authorization of the competent administration, without causing harm to water, the air or the ground.
5. Undertakings disposing of waste oils must supply the competent authorities with all necessary information regarding the disposal or dumping of oils or their residues.
6. Establishments producing, collecting and/or disposing of a certain quantity of waste oils as determined by each Member State (but which may not exceed 500 litres per year) must keep a register and/or provide information on these on request by the competent administration.
7. The collection and/or disposal undertakings may receive fees for their services, account being taken of compliance with the competition rules or a tax charged on products converted into waste oils after their use.
8. Member States shall regularly inform the Commission of their technical know-how and the results concerning implementation of the Directive. Every three years they shall draw up a report on the situation as regards the disposal of waste oils and shall send this to the Commission.

*Directive 87/101/EEC*

1. The Directive applies to all industrial oils or mineral-based lubricants that have become inappropriate for their original intended use.
2. Member States shall give priority to the treatment of waste oils by means of reclamation under the ecologically acceptable conditions laid down by this Directive.
3. Waste oils must be destroyed safely under controlled storage or dumping conditions.

4. Where appropriate Member States shall carry out public awareness and promotion campaigns aimed at ensuring efficient storage and collection.
5. Authorizations enabling companies to carry out collection and disposal operations may only be issued by the competent authorities where these have assured themselves that appropriate environmental and health protection measures have been taken.
6. When waste oils are reclaimed Member States shall take any action needed in order to avoid any damage to the environment which may be caused by operation of the facilities involved.
7. Where waste oils are burnt Member States shall ensure that the relevant facilities operate without polluting the atmosphere or exceeding the limit values for the substances laid down by this Directive or by any more stringent national requirements.
8. The Directive prohibits the mixture of waste oils with PCBs and PCTs (polychlorobiphenyls and polychloroterphenyls).
9. Member States may adopt measures that are more restrictive than those provided for in this Directive.

*(4) Deadline for implementation of the legislation in the Member States*

*Directive 75/439/EEC*
— Twenty-four months dating from the notification of the Directive;
— Four years from the date of notification of operating authorizations granted to companies on that date.

*Directive 87/101/EEC*
— 1.1.1990;
— Seven years from the date of notification in the case of operating authorizations granted to companies on that date.

*(5) Date of entry into force (if different from the above)*

*(6) References*

Official Journal L 194, 25.7.1975
Official Journal L 42, 12.2.1987

*(7) Follow-up work*

*(8) Commission implementing measures*

# 8. OTHER AREAS

## 8.21. Packaging and packaging waste

| | |
|---|---|
| *(1) Objective* | To prevent the production of packaging waste, to reduce the quantity of packaging waste arising and to promote the recovery of packaging waste, the production of which cannot be avoided. |
| *(2) Proposal* | Proposal for a Council Directive on packaging and packaging waste. |
| *(3) Contents* | 1. The Directive applies to all packaging and packaging waste, including that regarded as hazardous which will in addition be the subject of specific management plans.<br>2. The Directive sets targets for recovery and the minimization of final disposal for all packaging waste to be achieved no later than 10 years from the date of implementation of the Directive in national law. However, provision is made for a review of the targets on the basis of scientific research and progress achieved in the Member States, six years after the date by which the Directive must be implemented in national law.<br>3. The reuse of packaging and the recovery of packaging waste are two ways of reducing environmental impact to a minimum.<br>4. All packaging must bear a harmonized mark indicating that it is reusable or recoverable and showing the type of packaging materials used. The identification system is indicated in Annex I.<br>5. The Directive outlines essential requirements to be met by packaging and packaging waste which may replace the relevant national provisions; this presupposes the establishment of harmonized standards.<br>6. Provision is made for the establishment of databases for packaging and packaging waste; the formats for these are indicated in Annex III. In addition, consumers will be properly informed about the proposed arrangements for managing used packaging.<br>7. A series of measures, to be introduced on the basis of standardization, have to be taken at Community level concerning the manufacture and use of packaging.<br>8. The Member States will report to the Commission every three years. To adapt the provisions of the Directive to technical progress it is proposed that an Advisory Committee be set up. The same procedure will be used for primary packaging for medical devices and pharmaceutical products and for small packagings. |
| *(4) Opinion of the European Parliament* | Not yet delivered. |
| *(5) Current status* | The proposal has been sent to the European Parliament and the Economic and Social Committee for their opinions. |
| *(6) References* | Commission proposal<br>COM(92) 278 final — Not yet published |

# 8. OTHER AREAS

## 8.22. Landfill of waste

*(1) Objective*

To harmonize environmental and technical standards for the landfill of waste within the Community in order to establish a high level of environmental protection, with particular regard to soil and groundwater resources, and to prevent the creation of polluted sites.

*(2) Proposal*

Proposal for a Council Directive on the landfill of waste.

*(3) Contents*

1. The Directive contains a classification by 'types of waste' in relation to their origin or characteristics, while landfills are also categorized under 'classes of landfills'.
2. Definitions of 'municipal waste', 'industrial waste', 'hazardous waste', 'monolandfill', 'operator', etc.
3. The Directive lays down the requirements to be met by the various categories of landfill in order to avoid polluting the environment.
4. With regard to the permit procedure, the Directive refers to the application, conditions and content of the permit required for the establishment and operation of a landfill. The permit may be amended with the agreement of the competent authority and the landfill project must be compatible with waste disposal plans established for the region.
5. The Directive defines the types of waste which cannot be accepted in a landfill due to the problems they may cause in the landfill itself or due to the dangers that they might impose on their surroundings and/or on the health of persons. Liquid waste is only accepted if compatible with other waste or with the operating procedures of the site.
6. The mixture of different types of waste in order to reach acceptable criteria for landfilling is forbidden, except where beneficial interactive processes occur between the different types of waste when mixed.
7. In order to be able to direct the various types of waste to a suitable landfill, it is important to use the same acceptance criteria based on the characteristics of the eluate (a solution obtained during simulated leaching tests in the laboratory) as well as on the compatibility of the various types of waste in the case of joint disposal. The Directive lays down criteria for the eluate and for compatibility. It also establishes rules for the disposal of waste in a monolandfill and for the joint disposal of certain types of waste with municipal waste.
8. The Directive lays down the obligations of the operator and the procedures for accepting waste at the site. An important point is that the operator is responsible for applying a programme of sampling and analysis of the waste under the provisions of Annex III.
9. The Directive requires the implementation by the site operator of a measuring programme, as set out in Annex IV, during the operational and after-care phases on landfills. Where landfill operation causes damage to the environment, corrective measures, to be paid for by the operator, are to be taken.
10. The conditions and procedures required for the closure of a landfill are set out, as are the procedures required following closure.

11. A landfill operator is liable under civil law for damage and impairment of the environment caused by landfilled waste, irrespective of fault on his part.
12. Existing landfills may continue to operate as long as future operation of the remaining part of the site meets the conditions laid down in this Directive. Following the entry into force of the Directive, the operator will have five years to condition the site.
13. The price to be charged for the disposal of any type of waste in a landfill is to cover all the costs arising from the setting up and operation of the site, as well as the estimated costs of closure and after-care.
14. The operator is to provide a financial guarantee, the purpose of which is to cover the estimated costs of landfill closure procedures and after-care operations. The establishment and administration by the competent authorities in the Member States of landfill after-care funds will provide an additional financial instrument.
15. Member States are to forward to the Commission an annual report on the landfill of waste, with the aim of developing an appropriate policy on waste management.

*(4) Opinion of the European Parliament*

First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments.

*(5) Current status*

An amended proposal including Parliament's amendments accepted by the Commission is awaited.

*(6) References*

| | |
|---|---|
| Commission proposal<br>COM(91) 102 final | Official Journal C 263, 12.10.1992 |
| European Parliament opinion<br>First reading | Not yet published |
| Opinion of the Economic and Social Committee | Official Journal C 40, 17.2.1992 |

# 8. OTHER AREAS

## 8.23. Labelling of footwear

*(1) Objective*

To lay down the means to be used for the labelling of footwear, and as a result provide general, harmonized information for consumers throughout the Community.

*(2) Proposal*

Proposal for a Council Directive on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to a final consumer.

*(3) Contents*

1. The provisions concerning labelling apply to the materials used in footwear, a detailed definition of which is given in the proposal.
2. Labels must convey information relating to the upper, the lining and insole sock, and the outersole of the footwear article. The information must be conveyed by means of agreed pictograms, as defined and illustrated in the annex to the Directive, and must relate to the material which constitutes at least 85% of the surface area of the upper, the lining and insole sock of the footwear article, and at least 85% of the volume of the outersole. However, if no one material accounts for at least 85%, information must be given concerning the two principal materials in the composition of the article.
3. Given that the aim of the above measures is to provide information, the label must be legible, firmly secured and accessible, and the manufacturer or his authorized agent established in the Community is responsible for supplying the label and for the accuracy of the information contained in it. Only the information provided for in the Directive has to be supplied, but there is nothing to prevent the Member States from recommending additional information in their national provisions.
4. Distance selling is also covered by the proposal.
5. The Member States must bring into force the provisions necessary to comply with the Directive by 31 December 1993. The provisions concerning the labelling of the materials used in the main components of footwear articles need not be introduced until 30 June 1994.

*(4) Opinion of the European Parliament*

First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments.

*(5) Current status*

An amended proposal including Parliament's amendments accepted by the Commission is awaited.

*(6) References*

| | |
|---|---|
| Commission proposal<br>COM(91) 529 final | Official Journal C 74, 25.3.1992 |
| European Parliament opinion<br>First reading | Not yet published |
| Economic and Social<br>Committee opinion | Official Journal C 287, 4.11.1992 |

# Eastern Europe and the USSR

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25/11/92

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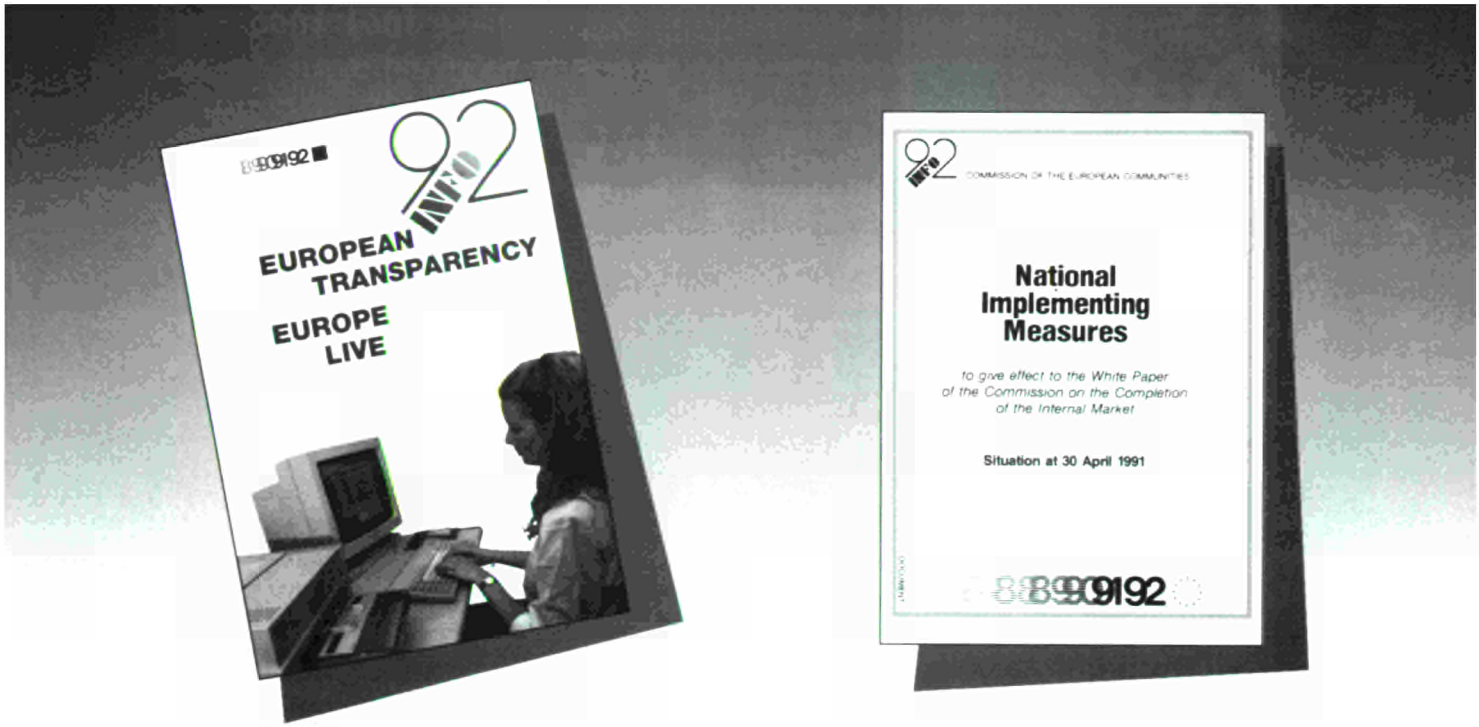


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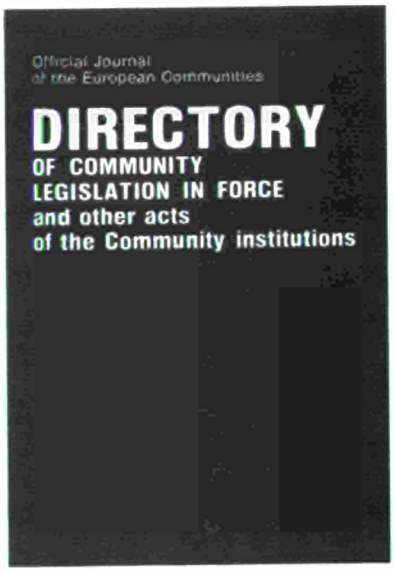


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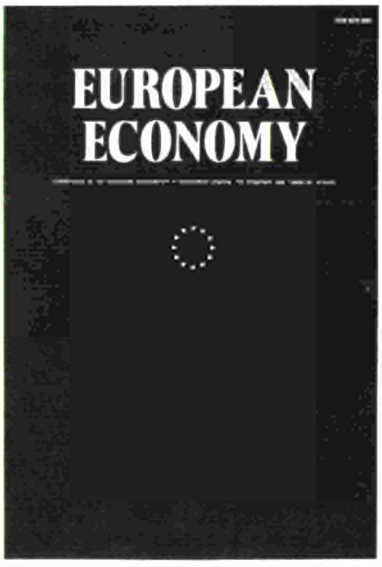


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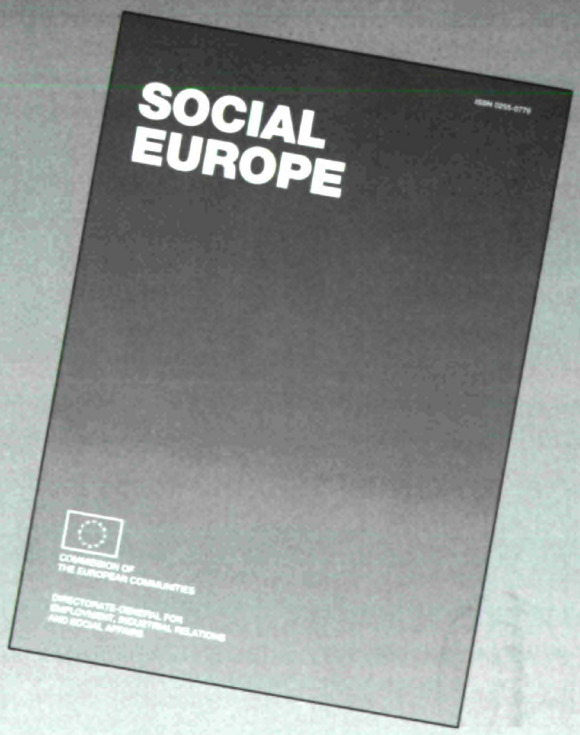


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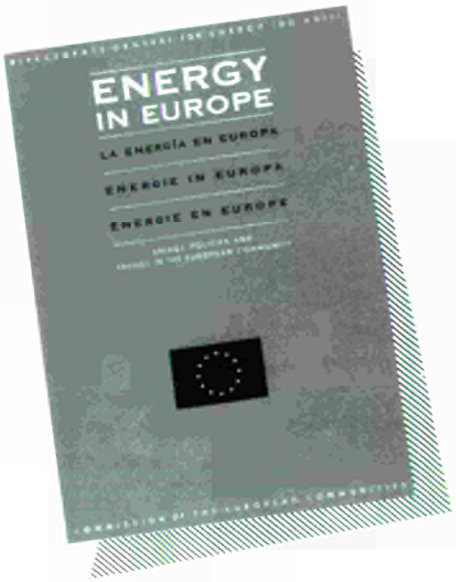


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