ENGLISH

COMPLETING THE INTERNAL MARKET

1992

CURRENT STATUS 1 JANUARY 1992

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 1992

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 June 1991, the Commission issued its 'Sixth 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.

This booklet is one of a series of six publications.

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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 in 1992.

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 fo 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 1992, of a situation which is evolving all the time.

The reader should understand that the text is provisional, also from a linguistic and terminological point of view. It will be revised and consolidated as and when measures are adopted in their definitive form.

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)

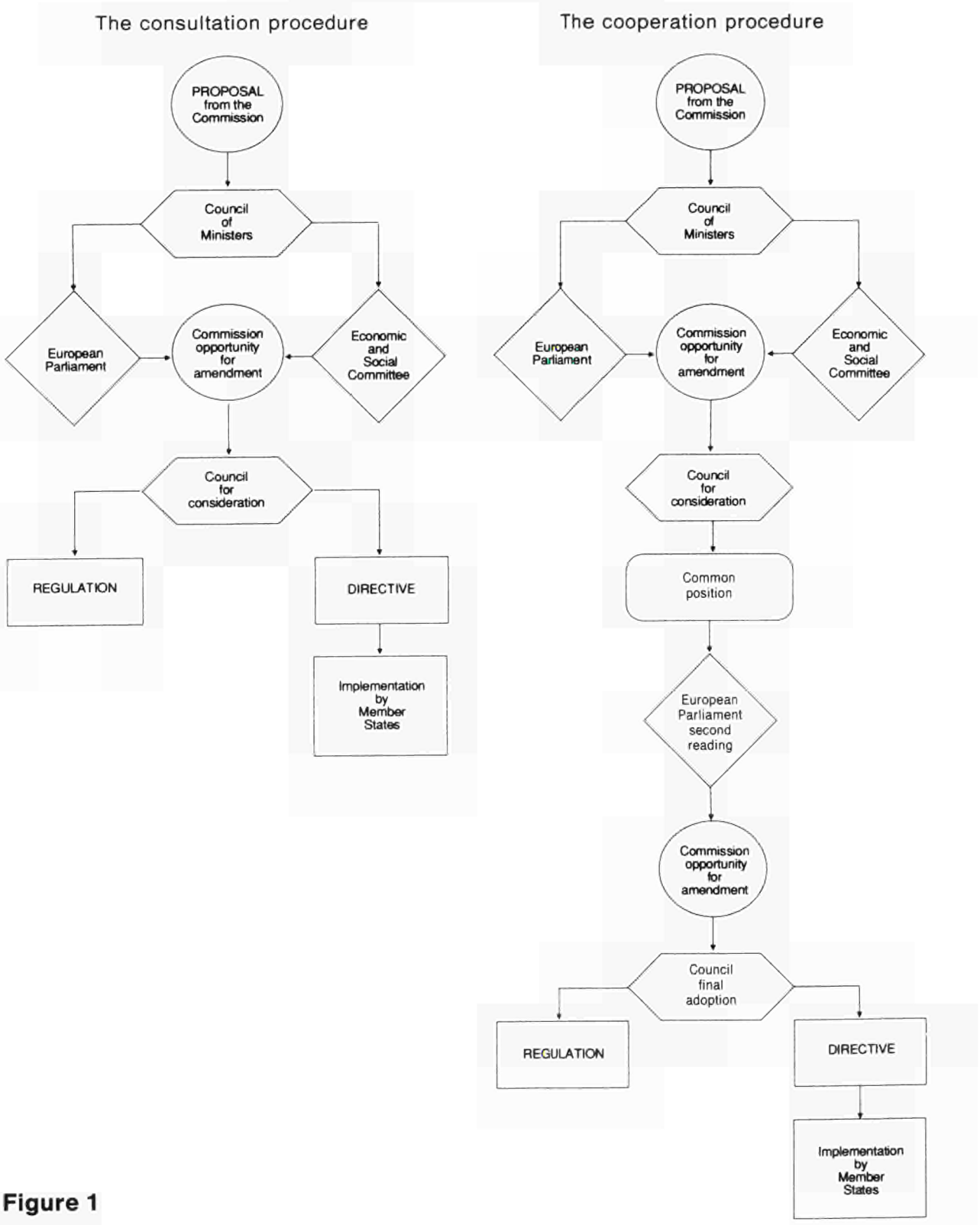

Figure 1

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 1991.

A NEW COMMUNITY STANDARDS POLICY

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INTRODUCTION

WHY HARMONIZATION OF STANDARDS AND TECHNICAL REGULATIONS?

1957 — Treaty of Rome

This was intended to create a single market across the European Community, with 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.

1985 — White Paper

The continued maintenance of internal barriers perpetuated the costs and disadvantages of separate national markets. Only when these barriers are eliminated will the Community have a genuine single market. 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 modified the EEC Treaty, and therefore had to be ratified by the governments and parliaments of all Community countries, confirmed the objective 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 a type of qualified majority (as opposed to unanimous) voting in the Council. The Single European Act has facilitated the adoption of the measures set out in the White Paper.

1991 — Current status

The Commission has developed the principle of the mutual recognition of national rules, in principle limiting as a rule the harmonization of laws to those points involving 'essential requirements' concerning health, safety, consumer protection, the working environment and the environment.

This is the area in which most progress has been made. Approximately 90% of the legislative proposals drawn up by the Commission to harmonize technical standards and regulations have been adopted. The new approach in harmonization (see below) has increased the pace of legislation on essential technical requirements, especially in the field of health and safety, but the parallel development of European standards undertaken by the standardization bodies to back up these measures has speeded up. In the case of measures which have had to follow the earlier approach of detailed legislative harmonization, the improved decision-making procedure introduced by the 1987 Single European Act has allowed the White Paper programme to be completed in some areas and has provided new impetus in others.

1992 — Single market

1992 is the deadline set by the 1987 Single European Act for complete elimination of all obstacles to a genuine single market.

Standards and technical regulations

Differing technical regulations and national standards in the individual Member States are a very real obstacle to the creation of the internal market. The effects are widespread, adding real costs and wasting valuable resources, restricting consumer choice and impeding the development of Europe's full competitive potential.

The existence of differering technical regulations in the individual Member States forces manufacturers to concentrate on national rather than Community-wide markets. It is necessary to have different production lines for the different Member States, and so the opportunities to reap economies of scale are reduced. As a result, costs are higher; indeed, a recent Commission publication cited a manufacturer of elevators as saying that the existence of different national regulations within his industry accounts for between 8% and 10% of total production costs. The same publication points out that the existence of separate national testing and type-approval procedures for telephone switchboards in the Community means that costs are 8% higher than in the United States.

These barriers result from differences between Member States in three types of arrangements:

— technical regulations lay down the legal requirements enacted by the national parliaments mainly in the interests of health and safety and the environment: often these regulations refer to standards;

— standards are produced by private national standardization bodies (like DIN in Germany or BSI in Britain): while they are only voluntary codes they often assume a quasi-legal status because of their use as a reference in technical regulations or insurance policies;

— type testing and certification is used to check that a product complies either with voluntary standards or with statutory regulations: a typical problem is that one Member State does not recognize another's type-testing, entailing the costs and delays of additional testing. The original approach to dismantling these barriers was to attempt to harmonize national regulations across the Community. However, this proved a very difficult and protracted process; the relevant technology had sometimes even changed by the time that eventual agreement was reached. At the same time, increased concern for health, safety and the environment, and the rapid growth in technical innovation were adding to the occasions on which differences in national approaches and regulations were occurring.

The Community responded to this challenge with a new approach. The key elements of this approach, which is described in more detail in Chapter 1 are:

— establishment of compulsory requirements essential to the marketing of products;

— the creation of harmonized European standards by European standardization bodies;

— as a transitional measure, the mutual recognition of national standards until appropriate European standards are created.

This brochure contains examples from both the new approach and previous approaches to harmonization. As yet, the new approach has only been in operation for a short time but there is already evidence that it is effective in reducing the time it takes to adopt new legislation. The other measures on technical regulations contained in the White Paper are grouped into

various industry sectors and in general are primarily concerned with the protection of the health and safety of consumers, guaranteed by compulsory certification mechanisms.

Harmonization of these requirements, combined with mutual recognition of tests, test results and certification will remove the barriers to trade due to differing standards within these industry sectors.

Such harmonization of the rules on the manufacture and marketing of products is supplemented by minimum harmonization of the rules on the protection of workers at the workplace (including minimum health and safety requirements for the use of machinery, minimum requirements for the use of personal protective equipment at the workplace).

1. THE NEW APPROACH IN HARMONIZATION

Current problems and 1992 objectives

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 notify 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 and CENELEC).

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 to technical harmonization and standards

On 7 May 1985 the Council adopted a resolution setting out a new approach to technical harmonization and standards (Official Journal C 136, 4.6.1985). This resolution provides a significant, effective means of implementing the programme to remove technical barriers, as set out in the White Paper on completing the internal market (COM(85) 310 final).

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

— legislative harmonization is limited to the adoption, by means of Directives based on Article 100 of the EEC Treaty, of the essential safety requirements (or other requirements in the general interest) with which products put on the market must conform in order to 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 (summary 1.4);
— mobile machinery and lifting and loading appliances (summary 1.5);
— electromagnetic compatibility (summary 1.6);
— non-automatic weighing instruments (summary 1.7);
— active implantable medical devices (summaries 1.8 and 1.9);
— gas appliances (summary 1.10);
— personal protective equipment (summary 1.11);
— testing and certification: conformity assessment procedures (summary 1.12);
— lifts (summary 1.13); and
— electrical equipment for use in potentially explosive atmospheres (summary 1.14).

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

1. THE NEW APPROACH IN HARMONIZATION

1.1. Extension of information procedures on standards and technical rules

(1) Objective	The Community adopted a Directive in 1983 (Directive 83/189/EEC, published in Official Journal L 109, 26.4.1983) which required Member States to inform the Commission of new standards and regulations for industrial products prior to their enactment. The Directive aims at preventing the creation of new barriers to trade by imposing on all Member States an absolute obligation to notify all draft standards and regulations before their adoption and allow time for comment on them. It gives 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 Commission initiative. This amendment extends the coverage of that legislation to all products.
(2) Community measures	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 broadens the definition of 'product' in the 1983 Directive to include agricultural products, foodstuffs, medicinal products and cosmetics, so that standards and technical rules applying to these are now subject to the information procedures. 2. If the Commission has submitted a proposal concerned with a particular product to the Council, Member States must not adopt technical regulations on that product for 12 months from the date of submission.
(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 81, 26.3.1988
(7) Follow-up work	
(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 Directive 83/189/EEC in 1988 and 1989 (COM(91) 102 final).

1. THE NEW APPROACH IN HARMONIZATION

1.2. Simple pressure vessels

(1) Objective	The primary aim of this Directive is to ensure a minimum level of safety throughout the Community for simple pressure vessels. The harmonization of safety standards will also aid the free movement of such products. In addition, a universally recognized testing procedure and mark of conformity will prevent wasteful checks being carried out in each Member State.
(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.
(3) Contents	1. This Directive applies to simple pressure vessels manufactured in series, i.e. any welded vessel 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, 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. 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. 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.
(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)	1.7.1990

(6) References

Official Journal L 220, 8.8.1987

(7) Follow-up work

On 17 September 1990, the Council adopted a Directive amending Directive 87/404/EEC on the harmonization of the laws of the Member States relating to simple pressure vessels (Directive 90/488/EEC, published in the Official Journal L 270, 2.10.1990).
This Directive introduces a transitional period up to 1 July 1992 during which the Member States will permit the placing on the market and/or in service of vessels conforming to the rules in force on their territory before 1 July 1990.

On 17 May 1991 the Commission presented a proposal for a Council Regulation on the affixing and use of the EC mark of conformity on industrial products (COM(91) 145 final, published in Official Journal C 160, 20.6.1991).
This proposal is aimed (a) at aligning the provisions already existing in respect of the affixing of the EC mark to products that comply and (b) at drawing up a reference document on any future Community regulations in this area.

(8) Commission implementing measures

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

(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

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 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 'CE'.
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.
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. 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	Official Journal L 187, 16.7.1988 Corrigendum Official Journal L 37, 9.2.1991
(7) Follow-up work	On 17 May 1991 the Commission presented a proposal for a Council Regulation on the affixing and use of the EC mark (COM(91) 145 final, published in Official Journal C 160, 20.6.1991). This proposal is aimed (a) at aligning the provisions already in existence in respect of the affixing of the EC mark to products complying with that mark and (b) at drawing up a reference document for all future Community regulations in that area .
(8) Commission implementing measures	List of approved bodies published in the Official Journal of the European Communities to date: Official Journal C 154, 23.6.1990 Official Journal C 162, 3.7.1990 Official Journal C 278, 6.11.1990 Official Journal C 34, 9.2.1991 Official Journal C 68, 16.3.1991 Official Journal C 264, 10.10.1991 Official Journal C 272, 17.10.1991 Official Journal C 279, 26.10.1991 Official Journal C 282, 29.10.1991

1. THE NEW APPROACH IN HARMONIZATION

1.4. Machine safety

(1) Objective	Member States have national legislation to ensure the health and safety of workers and other people using hazardous machinery. The Directive aims to harmonize these national laws concerning the obligation to ensure the health and safety of 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. There are exemptions, e.g. mobile equipment and lifting equipment. 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. 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 and accompanied by the EC declaration of conformity must be considered to be compatible with the essential health and safety requirements. 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. 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. 6. In order to certify machinery in accordance with certain standards 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. 7. The EC mark will consist of the symbol 'CE'. 8. Wood-working machines are included. A more stringent certification procedure is proposed for machine types considered to present greater hazards (e.g. chain saws, metal shears). 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

(5) Date of entry into force (if different from the above)	31.12.1992
(6) References	Official Journal L 183, 29.6.1989
(7) Follow-up work	On 17 May 1991 the Commission presented a proposal for a Council Regulation on the affixing and use of the EC mark on industrial products (COM(91) 145 final — published in Official Journal C 160, 20.6.1991). This proposal is aimed (a) at aligning the provisions already in existence in respect of the affixing of the EC mark to products complying with that mark and (b) at drawing up a reference document for all future Community regulations in that area. On 20 June 1991 the Council adopted a Directive covering mobile machinery and lifting and loading equipment (summary 1.5). This Directive amends Council Directive 89/392/EEC. The Commission will also be submitting a proposal for a Directive on second-hand machinery.
(8) Commission implementing measures	

1. THE NEW APPROACH IN HARMONIZATION

1.5. Mobile machinery and lifting appliances

(1) Objective	To implement the new approach to technical harmonization and standardization. To approximate the laws of the Member States on machinery and to include rules on machinery which creates hazards as a result of its mobility and load-raising capacity. To introduce Community legislation therefore on safety at the workplace and to eliminate the barriers to trade resulting from the differences in these provisions.	
(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 (this being independent 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, such as machinery that is stationary or mobile, self-propelled, drawn, pushed or carried by other machinery or a tractor. 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. 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. 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	1.1.1993	
(5) Date of entry into force (if different from the above)		
(6) References	Amending opinion	Official Journal L 198, 22.7.1991 Official Journal L 305, 6.11.1991
(7) Follow-up work		
(8) Commission implementing measures		

1. THE NEW APPROACH IN HARMONIZATION

1.6. Electromagnetic compatability

(1) Objective

To harmonize national provisions on electromagnetic disturbance levels by establishing basic 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.

(3) Contents

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. 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 basic 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 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. 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, instructions for use or 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.
(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	Adoption by the Council — Official Journal L 139, 23.5.1989 Amending opinion — Official Journal L 144, 27.5.1989
(7) Follow-up work	On 17 May 1991 the Commission presented a proposal for a Council Regulation concerning the affixing and use of the EC mark (COM(91) 145 final, published in Official Journal C 160, 20.6.1991). This proposal is aimed (a) at aligning the provisions already in existence in respect of the affixing of the EC mark to products complying with that mark and (b) at providing a reference document for all future Community Regulations in that area. On 31 May 1991 the Commission presented a proposal for a Council Directive amending Council Directive 89/336/EEC of 3 May 1989 on the harmonization of the laws of the Member States relating to electromagnetic compatibility (COM(91) 126 final, published in Official Journal C 162, 21.6.1991). On 19 December 1991 the Council adopted a common position on this proposal. This Directive provides for a transitional 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 31 December 1991 shall be permitted.
(8) Commission implementing measures	

1. THE NEW APPROACH IN HARMONIZATION

1.7. Non-automatic weighing instruments

(1) Objective

To ensure a single Community market in non-automatic weighing instruments by setting the essential metrological and performance requirements necessary for effective protection of users and consumers, and by laying 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.
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 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

	compliance with the essential requirements is mandatory must undergo EC unit verification. 6. Provision for control of instruments in service, re-verification, etc. 7. Annexes to the Directive including essential metrological requirements, essential design and construction requirements, details of 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	On 17 May 1991 the Commission presented a proposal for a Council Regulation concerning the affixing and use of the EC mark of conformity on industrial products (COM(91) 145 final, published in Official Journal C 160, 20.6.1991). This proposal is aimed (a) at aligning the provisions already in existence in respect of the affixing of the EC mark to products complying with that mark and (b) at providing a reference document for all future Community regulations in that area.
(8) Commission implementing measures	

1. THE NEW APPROACH IN HARMONIZATION

1.8. Active implantable medical equipment

(1) Objective	To ensure that active implantable electromedical devices used in human medicine, e.g. cardiac stimulators, meet a high and clearly defined level of safety both for the users of such equipment and for those receiving treatment. To harmonize the national provisions ensuring such a safety level so as to guarantee a single Community market in implantable electromedical devices without lowering existing levels of safety.
(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'. 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. 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. 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. 4. Devices shall be subject to a conformity assessment procedure. Member States shall designate bodies responsible for such procedures. 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	Official Journal L 189, 20.7.1990
(7) Follow-up work	On 17 May 1991 the Commission presented a proposal for a Council Regulation on the affixing and use of the EC mark of conformity on industrial products (COM(91) 145 final — Official Journal C 160, 20.6.1991). This proposal is aimed (a) at aligning the provisions already in existence in respect of the affixing of the EC mark to products complying with that mark and (b) at drawing up a reference document for all future Community regulations in that area.
(8) Commission implementing measures	

1. THE NEW APPROACH IN HARMONIZATION

1.9. 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 1.8).
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. 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	Not yet issued.
(5) Current status	The proposal has been submitted to the European Parliament and to the Economic and Social Committee for endorsement.
(6) References	Commission proposal COM(91) 287 final Official Journal No C 237, 12.9.1991

1. THE NEW APPROACH IN HARMONIZATION

1.10. Gas appliances

(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: — 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; — 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'. 2. Appliances designed specifically for use in an industrial process are excluded from the scope of the Directive. 3. Definitions of 'gaseous fuel' and of 'appliance under normal conditions of use'. 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. 5. The appliances and equipment must satisfy the essential requirements stipulated in Annex I. 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. 7. If a Member State finds that, under normal conditions of use, an appliance fitted with an EC mark 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. 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. 9. Obligation on Member States to publish national standards implementing the relevant harmonized standards and to communicate these to the Commission. 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	Official Journal L 196, 26.7.1990
(7) Follow-up work	On 17 May 1991 the Commission presented a proposal for a Council Regulation on the affixing and use of the EC mark on industrial products (COM(91) 145 final published in Official Journal C 160, 20.6.1991). This proposal is aimed (a) at aligning the provisions already in existence in respect of the affixing of the EC mark to products complying with that mark and (b) at drawing up a reference document for all future Community regulations in that area .
(8) Commission implementing measures	

1. THE NEW APPROACH IN HARMONIZATION

1.11. 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. EEC 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. 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.
(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	On 17 May 1991 the Commission presented a proposal for a Council Regulation on the affixing and use of the EC mark on industrial products (COM(91) 145 final published in Official Journal C 160, 20.6.1991). This proposal is aimed (a) at aligning the provisions already in existence in respect of the affixing of the EC mark to products complying with that mark and (b) at drawing up a reference document for all future Community regulations in that area.
(8) Commission implementing measures	

1. THE NEW APPROACH IN HARMONIZATION

1.12. Certification and testing: procedures for assessing conformity of products

(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. 2. As a rule, the product should pass inspections during both phases before it can be placed on the market. 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. 4. The Directives will have to lay down requirements governing the conditions under which the manufacturer chooses the modules most appropriate to his products. 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. 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

1.13. Lifts

(1) Objective	To extend the scope of Council Directive 84/529/EEC (Official Journal L 300, 19.11.1984) on electrically operated lifts to include 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 EC type-examination procedures which lay down the necessary technical requirements also apply to oil and hydraulic lifts. 2. The scope of the Directive and definition of the term 'lift'. 3. 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. 4. Annexes containing the technical requirements and procedures for the EC 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

1.14. Electrical equipment for use in potentially explosive atmospheres

(1) Objective	To extend the scope of Council Directive 79/196/EEC (Official Journal L 43, 20.2.1979), which has made possible the free movement of electrical equipment for use in potentially explosive atmospheres, 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'. 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	On 13 December 1991, the Commission presented a new proposal for a Council Directive on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (COM(91) 516 final). The Directive applies to equipment and protective systems and also to devices not in potentially explosive atmospheres but having repercussions on equipment installed in such atmospheres. It replaces, from 1 July 1996, Council Directive 90/487/EEC, which applies to the electrical field only.
(8) Commission implementing measures	

2. MOTOR VEHICLES

Current problems and 1992 objectives

1. EEC type-approval and road safety

The Community has been striving for many years to bring about a comprehensive EEC type-approval for passenger cars. This will allow a car approved in one Member State to be marketed in another without having to obtain new type-approval, which is both costly and time-consuming.

Since 1970, the Community has adopted a series of measures harmonizing technical standards and type-approval of individual vehicle components (summaries 2.1 and 2.2).

However, for the complete type-approval procedure to be introduced for cars, further measures must be adopted concerning dimensions and weight, tyres, safety glass (summaries 2.3 to 2.6). The adoption of common positions relative to these three Directives will complete the EEC type-approval of motor vehicles (a total of 43 Directives).

2. EEC type-approval and pollution

It is important that the Community keeps up to date appropriate measures to safeguard the environment from pollution caused by engine exhaust emissions. This must be uniform throughout the Community, both to ensure full protection for citizens and the environment, and to prevent emission requirements becoming a non-trade barrier, necessitating modifications to engines sold in different national markets.

The Commission has taken action on the following in this area:

— gaseous emissions from petrol and diesel engines (summaries 2.9 and 2.10);
— gaseous emissions from cars below 1400 cc (summary 2.12);
— air pollution by motor vehicle emissions (summary 2.13);
— gaseous emissions from buses, coaches, lorries, taxis, ambulances and commercial vehicles (summary 2.15);
— particulate emissions from diesel engines (summary 2.11);
— emissions from diesel engines in vehicles, except those in category M_1 (summary 2.14).

3. EEC type-approval and noise pollution

With the same aim of environmental protection in mind, the Community has taken action to reduce noise from motorcycle exhausts (summary 2.7).

Pending completion of this work, the Commission has published a communication stating that it considers that duplication of the roadworthiness testing of vehicles which have already been tested in another Member State is contrary to Article 30 of the Treaty.

Many of the proposals and measures in this section are optional, which means that Member States may maintain national standards in their domestic markets in parallel with the Community standards which they must accept.

Thus, in practice, a producer exporting to a given market has a choice of standards. For safety reasons, and to protect the environment, the Commission has stated that it plans to ensure that these Directives are adopted by 31 December 1992.

2. MOTOR VEHICLES

2.1. EEC type-approval: motor vehicles and trailers

(1) Objective	To abolish the existing 12 national type-approvals for motor vehicles and trailers and replace them with one Community-wide type-approval. This will simplify the administrative burden for the industry and facilitate the free movement and use of motor vehicles.
(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. 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. This proposal for a framework Directive constitutes the basis for Community type-approval procedures for vehicles or for components intended for use in these vehicles.

(2) Proposal

Proposal for a Council Directive on the type-approval of two- or three-wheel motor vehicles.

(3) Contents

1. This 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.

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) Opinion of the European Parliament

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

(5) Current status

The Council adopted a common position on 19 December 1991. Within the framework of the cooperation procedure this is now before Parliament for a second reading.

(6) References	Commission proposal COM(90) 669 final	Official Journal C 110, 25.4.1991
	Economic and Social Committee opinion	Not yet published in the Official Journal
	European Parliament opinion First reading	Not yet published

2. MOTOR VEHICLES

2.3. Weights and dimensions

(1) Objective	To harmonize the national laws concerning the weights and dimensions of motor vehicles; thereby to ensure free movement of motor vehicles within the Community.
(2) Proposal	Proposal for a Council Directive 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. 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. 3. The Directive also contains requirements for the maximum towed weight authorized for motor vehicles.
(4) Opinion of the European Parliament	First reading: Parliament approved the proposal of the Commission with amendments. The Commission accepted all of the proposed amendments.
(5) Current status	The Council adopted a common position on 19 December 1991. Within the framework of the cooperation procedure this is now before Parliament for a second reading.
(6) References	Commission proposal COM(89) 653/II final — Official Journal C 95, 12.4.1990 Amended proposal COM(91) 38/II final — Official Journal C 51, 27.2.1991 European Parliament opinion First reading — Official Journal C 284, 12.11.1990 Economic and Social Committee opinion — Official Journal C 225, 10.9.1990

2. MOTOR VEHICLES

2.4. Tyres

(1) Objective

To harmonize the national type-approval for tyres and their fitting to motor vehicles and their trailers.

(2) Proposal

Proposal for a Council Directive 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 categories O_1 and O_2 (categories in note (B) to Annex 1 to Directive 70/156/EEC published in Official Journal L 42, 23.2.1970).
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) Opinion of the European Parliament

First reading: Parliament approved the proposal of the Commission with amendments. The Commission accepted all of the proposed amendments.
First reading (continued): Parliament approved the proposal of the Commission with amendments.

(5) Current status

The Council adopted a common position on 19 December 1991. Within the framework of the cooperation procedure this is now before Parliament for a second reading.

(6) References

Commission proposal	
COM(89) 653/III final	Official Journal C 95, 12.4.1990
Amended proposal	
COM(91) 38/III final	Official Journal C 51, 27.2.1991
European Parliament opinion	
First reading	Official Journal C 284, 12.11.1990
First reading (continued)	Not yet published
Economic and Social Committee opinion	Official Journal C 225, 10.9.1990

2. MOTOR VEHICLES

2.5. Tyres: tyre pressure gauges for motor vehicles

(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. 2. To obtain an EC mark, pressure gauges are subject to EC pattern-approval and verification. Requirements that they must satisfy include: — the metrological characteristics specified in paragraph 2 of the annex; — robust and careful construction to maintain their metrological characteristics; — guaranteed direct and accurate reading of pressure measured; — 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. 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

2.6. Safety glass and glazing materials

(1) Objective

To bring into line the national provisions relating to safety glass and glazing materials used in motor vehicles and their trailers; thereby to ensure the free movement of goods within the Community.

(2) Proposal

Proposal for a Council Directive 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.
2. The proposal also lays down the materials permitted for use in windscreens and for glass other than windscreens.

(4) Opinion of the European Parliament

First reading: Parliament approved the proposal of the Commission with amendments. The Commission accepted all of the proposed amendments.

(5) Current status

The Council adopted a common position on 19 December 1991. Within the framework of the cooperation procedure this is now before Parliament for a second reading.

(6) References

Commission proposal COM(89) 653/I final	Official Journal C 95, 12.4.1990
Amended proposal COM(91) 38/I final	Official Journal C 51, 27.2.1991
European Parliament opinion First reading	Official Journal C 284, 12.11.1990
Economic and Social Committee opinion	Official Journal C 225, 10.9.1990

2. MOTOR VEHICLES

2.7. Motorcycle exhaust system noise

(1) Objective	There is an existing Directive which regulates the permissible sound levels of motorcycle exhaust systems (Council Directive 78/1015/EEC, published in Official Journal L 349, 13.12.1978). This proposed amendment aims at bringing existing national type-approval for motorcycle exhaust systems closer together and including replacement exhaust systems within its scope.
(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: — Belgium: agréation par type; — Denmark: standardtypegodkendelse. 2. The national model certificate shall be replaced by the model EEC type-approval certificate in Annex IV of the Directive. 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. 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. 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. 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

2.8. Lateral protection for goods vehicles

(1) Objective	In certain accidents, unprotected road-users, i.e. pedestrians and cyclists, are often caught under the wheels of heavy goods vehicles and thereby killed or seriously injured. In order to minimize risks, the Directive requires that sides of goods vehicles should be built or equipped with continuous surfaces or rails.
(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. 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. 3. Annexes containing technical requirements for lateral protection and application form for EC type-approval. Appendix containing model of annex to type-approval certificate with information on lateral protection. 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 1.5.1991
(6) References	Official Journal L 124, 5.5.1989
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.9. Air pollution: exhaust gases

(1) Objective	To reduce pollution caused by cars in order to avoid adverse effects such as acid rain. To this end the legislation in the field of pollution control has been adapted to US testing methods. Technical specifications have also been adapted in order to permit the use of lead-free petrol.
(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. 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. 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. 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. 1.10.1989 for refusing type-approval for other vehicles whose engines do not comply with the Directive. 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 2.12.
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.10. 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 and promote the free movement of goods.
(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. 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. 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. 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). 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 2.14.
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.11. Air pollution: emissions of gaseous pollutants from diesel engines

(1) Objective	To extend the previous legislation relating to passenger cars to include particulate emissions from diesel engines and to adopt the dates for the implementation of the new Community requirements.
(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. 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. 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	
(8) Commission implementing measures	

2. MOTOR VEHICLES

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

(1) Objective

To amend the previous Directive by introducing 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

(8) Commission implementing measures

2. MOTOR VEHICLES

2.13. Air pollution: new standards

(1) Objective

To consolidate Community Regulations on emissions of air pollutants by private cars, in accordance with the guidelines laid down by the Council.

(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 Directive 70/220/EEC, as amended.
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)	
(6) References	Official Journal L 242, 30.8.1991
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

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

(1) Objective

The Directive provides for a further reduction in limits for emissions of three gaseous pollutants (carbon monoxide, hydrocarbons and nitrogen oxides) from commercial vehicles. It also lays down limits for emissions of particles from such vehicles. This will take place in two stages.

(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

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

(1) Objective

To amend point 8.2 of Annex II of Directive 77/143/EEC (Official Journal L 47, 18.2.1977) such as 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) Proposal

Proposal for a Council Directive 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).
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.
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.).
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 diesel engines.
5. The provisions of this Directive do not apply to vehicles with petrol or diesel engines manufactured prior to 1 January 1970.

(4) Opinion of the European Parliament

Not yet issued.

(5) Current status

The proposal is currently under examination by the European Parliament and the Economic and Social Committee.

(6) References

Commission proposal
COM(91) 244 final — Official Journal C 189, 20.7.1991

2. MOTOR VEHICLES

2.16. 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. 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. 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. 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. 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. 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

2.17. 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) Proposal

Proposal for a Council Directive 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.
2. Type-approval is granted for vehicles equipped with a drive axle weighing 11.5 tonnes and put into circulation from January 1995 onwards, on condition that the axle is equipped with twin tyres and air suspension or a recognized equivalent.
3. If the drive axles of the vehicles under consideration are not equipped with twin tyres and air suspension or a recognized equivalent, the maximum authorized weight may not exceed 10.5 tonnes.
4. The annexes to Directive 85/3/EEC specifying the authorized dimensions and weights are amended accordingly.

(4) Opinion of the European Parliament

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

(5) Current status

On 17 December 1991 the Council released a political agreement concerning the adoption of this proposal. The formal adoption will take place during the next session.

(6) References

Commission proposal COM(90) 486 final	Official Journal C 292, 22.11.1990
Amended proposal COM(91) 417 final	Official Journal C 313, 4.12.1991
European Parliament opinion	Official Journal C 183, 15.7.1991
Economic and Social Committee opinion	Official Journal C 159, 17.6.1991

2. MOTOR VEHICLES

2.18. 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). 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. 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	

3. TRACTORS AND AGRICULTURAL MACHINERY

Current problems and 1992 objectives

The existence of differing national product regulations and standards was a major problem in the manufacture of agricultural machinery. Production lines could not be centralized which prevented manufacturers from taking advantage of economies of scale. A further problem was the absence of Community-wide type-approval procedures. Individual Member States thus required national testing and certification for components; a costly and wasteful process.

Measures for a Community-wide type-approval procedure are covered by summaries 3.1 and 3.2: the first measure harmonizes technical requirements throughout the Community and ensures recognition of a single type test and the second provides for an EEC-wide type-approval standard. A further measure tackles the specific area of front-mounted roll-over protection structures (summary 3.3).

Work on the White Paper was completed in December 1988. Since 31 December 1989 any national type-approval is recognized in all Community countries; it is now possible to market tractors without additional formalities in every Member State.

Proposals are currently being drawn up with a view to changing over from 'optional' harmonization to 'total' harmonization and for the adaptation to technical progress of a number of Directives already in force.

3. TRACTORS AND AGRICULTURAL MACHINERY

3.1. EEC type-approval: components and characteristics

(1) Objective	To harmonize the technical requirements of tractors in all Member States to permit, in particular, implementation of the type-approval procedure laid down in previous legislation (Council Directive 74/150/EEC, published in Official Journal L 84, 28.3.1974), and to promote free trade within the Community.
(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. 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. 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. 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. 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. 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

(1) Objective	To harmonize the technical requirements for front-mounted roll-over protection structures on narrow-track tractors. This will both improve safety and also ensure that the EEC type-approval procedure can be uniformly applied throughout the Community, as a prerequisite for mutual recognition of testing procedures in all the Member States.
(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. 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. 3. All tractors covered by the Directive must be fitted with a roll-over protection structure. 4. The Directive will be adapted to technical progress. 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). 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

Current problems and 1992 objectives

One of the fundamental principles of the European Community, laid down in the Treaty of Rome, is the free movement of goods. The Court of Justice of the European Communities has consistently upheld this principle, ruling that the Treaty prohibits any national measure which hinders intra-Community trade.

In its much-quoted judgment in Case 120/78, 'Cassis de Dijon', (ECR 1979, p. 649), the Court ruled that the Treaty prohibits national legislation which prevents the marketing of a product that has been lawfully produced and marketed in another Member State. This means mutual recognition by the Member States of each others' product standards.

However, this legal principle established by the Court does not eliminate all the practical problems encountered by exporting manufacturers. The Cassis de Dijon judgement does not prohibit the adoption of national measures that seek to protect public health and consumer interests. Community-level harmonization of regulations in these areas is necessary.

The Commission subsequently developed a strategy which combines the adoption of harmonized rules at Community level, which are applicable to all foodstuffs marketed in the Community, with the principle of mutual recognition of national regulations and standards which do 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' (COM(85) 603 final). What the Commission proposed was to strike a new balance between the legislative powers retained by the Council and the matters which could be delegated to the Commission. This entails delegating to the Commission, assisted by the Standing Committee for 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 horizontal framework Directives laying down the essential requirements (protection of public health, consumer protection, fairness of commercial transactions and protection of the environment).

The Commission's explanatory communication on the free movement of foodstuffs within the Community (Official Journal C 271, 21.10.1989) deals on the one hand with the rules applicable in the absence of Community provisions and, on the other, with the barriers to the free movement of foodstuffs relating to public health protection, and also to labelling, trade decription, packaging of products, ranges of pre-packages and substitute products.

As regards the first point, the Commission clarifies the extent of the residual powers of the Member States.

As regards the second point, the Commission recognizes the protection of public health as the only essential requirement which can justify infringing the principle of the free movement of goods. It makes it clear, however, that national legislation conflicting with that principle must be compatible either with relevant secondary Community law or, in the absence of Community rules, with a legitimate health policy objective and with the conditions necessary to apply Article 36 of the Treaty as it has been interpreted by the Court.

The Commission's explanatory communication on the names under which foodstuffs are sold (Official Journal C 270, 15.10.1991) spells out the conditions under which a trade description other than that used in the Member State of manufacture can be imposed in the importing Member State. It also defines what is meant by 'characteristics'.

As part of its horizontal harmonization, the Community has taken action in the following areas:

— additives (summaries 4.1 to 4.6);
— materials coming into contact with foodstuffs (summaries 4.7 and 4.8);
— labelling (summaries 4.9 and 4.10, 4.12 and 4.13 ;
— food for particular nutritional uses (summary 4.14);
— official control of foodstuffs (summary 4.15);
— sampling and methods of analysis (summary 4.16);
— deep-frozen foodstuffs (summary 4.17);
— irradiation of foodstuffs (summary 4.21);
— identification of the lot to which a foodstuff belongs (summary 4.22);
— product quality (summaries 4.23 and 4.24).

Under the heading of vertical harmonization the Community has taken measures in the following areas:

— labelling of spirituous beverages (summary 4.11);
— coffee and chicory extracts (summary 4.18);
— fruit juices and similar products (summary 4.19);
— jams, jellies, marmalades and chestnut purees (summary 4.20).

On 4 December 1990 the Council adopted transitional measures applicable in the new *Länder* of the Federal Republic of Germany, having regard to German unification, preparing the way for progressive application of all Community legislation to the territory of the former German Democratic Republic (Council Directives 90/650/EEC and 90/657/EEC published in Official Journal L 353, 17.12.1990 — summaries 4.1, 4.3, 4.4, 4.6, 4.8, 4.9, 4.10, 4.14, 4.16 to 4.19 and 4.22).

4. FOODSTUFFS

4.1. Authorized food additives

(1) Objective

To ensure that the free movement of food within the Community is not compromised by different national regulations on food additives. This is to be accomplished by:
— the Directive on food additives;
— specific Directives on certain categories of food additives.

(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 is part of the finished product (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 Directive prohibits the use of substances not appearing in Annex 1. 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 Derogation until 31.12.1992, pursuant to Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990), for products from the former GDR which do not comply with Directive 89/107/EEC. These products may be marketed in the new *Länder,* but not on other Community markets.
(5) Date of entry into force (if different from the above)	The Member States must, if necessary, amend their laws, regulations and administrative provisions so as to: permit trade in products which meet the requirements of this Directive by 28 December 1990 at the latest; prohibit trade in products which do not meet the requirements of this Directive by 28 December 1991 at the latest.
(6) References	Official Journal L 40, 11.2.1989
(7) Follow-up work	See summary 4.2.
(8) Commission implementing measures	On 10 December 1991 the Commission presented a Council Directive concerning colouring for foodstuffs (COM(91) 444 final).

4. FOODSTUFFS

4.2. Authorized food additives: sweeteners

(1) Objective

To lay down maximum levels for the use of sweeteners in foodstuffs in order to protect the health of consumers.

(2) Proposal

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

(3) Contents

1. The Directive is a specific Directive forming part of the comprehensive Directive within the meaning of Article 3 of Directive 89/107/EEC (summary 4.1). It applies to food additives (sweeteners) used to impart a sweet taste to foodstuffs.
2. It does not apply to foodstuffs with sweetening properties, such as monosaccharides, disaccharides and honey.
3. Table-top sweeteners are considered as additives sold to the final consumer and will be subject to particular labelling provisions as set out in Directive 89/107/EEC and in Article 2 (4a) of this Directive.
4. This Directive applies to sugar-free and energy-reduced food. A foodstuff is considered to be energy-reduced if its calorific value has been reduced by 33% by comparison with a reference foodstuff of the same weight.
5. Sweeteners may not be used in foods intended for particular nutritional use by infants and young children.
6. Table-top sweeteners containing polyols (E 420, E 421, E 953, E 965, E 966, E 967) shall be labelled with the following: 'excessive consumption may induce laxative effects'. Those containing aspartame (E 951) shall be labelled with the following: 'contains a source of phenylalanine — counter-indicated in the case of phenylketonuria'.
7. Sweeteners may only be used in certain foodstuffs and under certain conditions.
8. The maximum levels indicated in the annex refer to ready-for-consumption foodstuffs prepared according to the manufacturer's instructions.
9. The Directive applies without prejudice to specific Directives permitting additives listed in the annex to be used for functions other than sweetening.

(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 19 December 1991. Within the framework of the cooperation procedure this is now before Parliament for a second reading.

(6) References

Commission proposal COM(90) 381 final	Official Journal C 242, 27.9.1990
Amended proposal COM(91) 195 final	Official Journal C 175, 6.7.1991
European Parliament opinion First reading	Official Journal C 129, 20.5.1991
Economic and Social Committee opinion	Official Journal C 120, 6.5.1991

4. FOODSTUFFS

4.3. Additives: flavourings

(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. 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. 3. Provision for the adoption of specific Directives applicable to certain groups of flavourings, e.g. chemically synthesized flavouring substances. 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. 5. By 1 July 1990 labelling rules for flavourings intended for sale to the final consumer will be adopted. 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. 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. 8. Procedures for updating the Directives. 9. Technical annexes on maximum limits for certain substances found in flavourings.
(4) Deadline for implementation of the legislation in the Member States	21.12.1989 Derogation until 31.12.1992, pursuant to Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990), for products from the former GDR which do not comply with Directive 88/388/EEC. These products may be marketed in the new *Länder,* but not on other Community markets.
(5) Date of entry into force (if different from the above)	22.6.1990: authorization of flavourings complying with the Directive. 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 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

4.4. 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.

(3) Contents

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 Item 7 'Follow-up work').
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 that 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.

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

13.6.1991
Derogation until 31.12.1992, pursuant to Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990), for products from the former GDR which do not comply with Directive 88/344/EEC. These products may be marketed in the new *Länder,* but not on other Community markets.

(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 157, 24.6.1988
(7) Follow-up work	On 9 December 1991, the Commission presented a proposal for a Council Directive (COM(91) 502 final) amending the Directive for the first time. This amendment (as provided for in point 6 of the 'Contents') is intended to regulate certain substances subject so far to national legislation on the basis of a recent opinion of the Scientific Committee for Food and to revise the existing provisions.
(8) Commission implementing measures	

4. FOODSTUFFS

4.5. Additives: preservatives (potassium bisulphite and thiabendazole)

(1) Objective	To include potassium acid sulphite (potassium bisulphite) which is used in wine production in the list of permitted preservatives. To fully authorize the use of thiabendazole (E 233).
(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. 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

4.6. Additives: emulsifiers, stabilizers, thickeners and gelling agents

(1) Objective	To extend the period of temporary authorization for certain emulsifiers, stabilizers, thickeners and gelling agents. To prohibit the use after 31 March 1987 of polyoxyethylene (8) stearate, polyoxyethylene (40) stearate, lactylated fatty acid esters of glycerol and propylene glycol, and dioctyl sodium sulphosuccinate.
(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: 1. New temporary authorization period for the substances listed in Annex II. Tragacanth and Karaya gum are pending a Commission enquiry. 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	26.3.1988 Derogation until 31.12.1992, pursuant to Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990), for products from the former GDR which do not comply with Directive 86/102/EEC. These products may be marketed in the new *Länder,* but not on other Community markets.
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 88, 3.4.1986
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.7. Materials in contact with foodstuffs

(1) Objective	To supplement existing legislation on food packagings, wrappings etc. This is to be accomplished by: — this framework Directive which lays down general principles; — specific Directives on certain groups of materials and articles coming 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	Commission Directive 90/128/EEC of 23 February 1990 relating to plastic materials and articles intended to come into contact with foodstuffs (Official Journal L 75, 21.3.1990). 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. Definition of 'plastics'. Only those monomers and other starting substances listed in Annex 2, Sections A and B may be used for the manufacture of plastic materials and articles, subject to certain restrictions specified. The list may be supplemented, subject to certain restrictions. From the date of notification of this Directive no Member State will authorize any new substance for use within its territory except under the procedure in Article 4 of Directive 89/109/EEC. Verification of compliance with the migration limits will be carried out in accordance with the rules laid down in Directives 82/711/EEC (Official Journal L 297, 23.10.1982) and 85/572/EEC (summary 4.8) and the further provisions set out in Annex 1. Member States will: permit trade in and the use of plastic materials and articles complying with this Directive before 1 January 1991; prohibit trade in and the use of plastic materials and articles intended to come into contact with foodstuffs and which do not comply with this Directive as from 1 January 1993.

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4.8. Materials in contact with foodstuffs: testing

(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. 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). Derogation until 31.12.1992, pursuant to Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990), for products from the former GDR which do not comply with Directive 85/572/EEC. These products may be marketed in the new *Länder,* but not on other Community markets.
(5) Date of entry into force (if different from the above)	Member States are required: to permit trade in plastics, articles and materials complying with this Directive as from 1 January 1991; to prohibit trade in and the use of plastics, articles and materials which come into contact with foodstuffs and which do not comply with this Directive as from 1 January 1993.
(6) References	Official Journal L 372, 31.12.1985
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.9. Labelling: labelling, presentation and advertising

(1) Objective	To amend existing legislation on the labelling of foodstuffs so as to eliminate national derogations. This will improve the flow of information throughout the Community, improve consumer awareness and facilitate trade. This is to be accomplished by: — amendment of the existing framework Directive on labelling; — specific Directives on certain categories of foodstuffs.
(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. However, any foodstuff or ingredient treated in this way must bear a suitable indication. 2. Clarification of requirements for labelling and listed ingredients. 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. 4. Updating of the annex to the earlier Directive to include flavouring agents among products requiring the designation of flavouring ingredients. 5. The Commission will adopt specific Community provisions after consulting the Standing Committee on Foodstuffs, in accordance with the procedure laid down. 6. Indication on the labelling of the drained net weight of foodstuffs presented in a liquid medium (definition of 'liquid medium'). 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. 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	Derogation until 31 December 1992, pursuant to Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990), for products from the former GDR which do not comply with Directive 89/395/EEC. These products may be marketed in the new *Länder*, but not on other Community markets.
(5) Date of entry into force (if different from the above)	The Member States will, if necessary, amend their laws, regulations and administrative provisions so as to: permit trade in products conforming to this Directive by 20 December 1990 at the latest; prohibit trade in products not conforming to this Directive as from 20 June 1992.
(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.

(8) Commission implementing measures

4. FOODSTUFFS

4.10. Labelling: alcoholic drinks

(1) Objective	To extend food labelling requirements to include the percentage of alcohol in alcoholic drinks to ensure that consumers are adequately informed. The original proposal has been only partially adopted. Some points are still under consideration, including additions to the list of ingredients that need not be specifically indicated.
(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 Derogation until 31 December 1992, pursuant to Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990), for products from the former GDR which do not comply with Directive 86/197/EEC. These products may be marketed in the new *Länder*, but not on other Community markets.
(5) Date of entry into force (if different from the above)	The Member States will, if necessary, amend their laws, regulations and administrative provisions so as to: permit trade in products conforming to this Directive by 1 May 1988 at the latest; prohibit trade in products not conforming to this Directive from 1 May 1989.
(6) References	Official Journal L 144, 29.5.1986
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.11. 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 while ensuring that consumers receive adequate information about their origin, alcohol content and certain other characteristics.
(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.
(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. Annexes setting out the characteristics of ethyl alcohol of agricultural origin and geographical designations for different categories of products. 6. 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)	15.12.1989 15.6.1989: for Articles 13 to 16.
(6) References	Official Journal L 160, 12.6.1989
(7) Follow-up work	On 31 October 1991, the Commission presented a proposal for a Regulation (EEC) amending for the first time Regulation (EEC) No 1576/89 laying down general rules on the definition, description and presentation of spirit drinks (COM(91) 422 final). This proposal bans the use of capsules or foil containing lead as a covering for closing devices of containers in which spirit drinks are placed on the market and makes provision for a period of adjustment for the manufacturers and users of such capsules and foil.

(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.

4. FOODSTUFFS

4.12. Labelling: compulsory nutrition labelling

(1) Objective	To lay down rules on nutrition labelling which are to be compulsory when a Member State decides to introduce such labelling. This measure follows the trend in consumer habits, which is towards low-calorie foodstuffs. The Commission has proposed two Directives in this area. The first is summarized below and the second proposal is summarized in summary 4.13.
(2) Proposal	Proposal for a Council Directive on the introduction of compulsory nutrition labelling of foodstuffs intended for sale to the ultimate consumer.
(3) Contents	1. The Commission is granted powers to adopt appropriate legislation at the request of a Member State or on its own initiative, when compulsory nutritional labelling is necessary. It will submit its draft legislation to a Standing Advisory Committee. The Commission will take account of the Committee's opinion but will not be bound by it. 2. The Commission will base its decision as to the need for compulsory nutrition labelling on evidence of links between certain foods and specific diseases among the population, the need to improve the nutrition status of the population in general or substantial groups. 3. The Commission's choice of measures will take account of different means of achieving the desired objective.
(4) Opinion of the European Parliament	First reading: Parliament approved the proposal subject to amendments, which were not accepted by the Commission.
(5) Current status	The proposal is currently before the Council for a common position.
(6) References	Commission proposal COM(88) 489/I final — Official Journal C 282, 5.11.1988 European Parliament opinion First reading — Official Journal C 158, 26.6.1989 Economic and Social Committee opinion — Official Journal C 159, 26.6.1989

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 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. 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. 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 amend and at the same time redraft the existing Council Directive 77/94/EEC published in Official Journal L 26, 31.1.1977 which established the general principles governing foodstuffs for particular nutritional uses. To identify the categories of foods for particular nutritional uses for which specific Directives are needed. To define procedures for the adoption of these Directives. To eliminate national derogations where these still exist under the existing Directive. To regulate the free movement of foodstuffs for particular nutritional uses which will not be covered by existing Directives. This is to be accomplished by:

— this framework Directive on foodstuffs intended for particular nutritional uses;
— specific Directives on certain categories of foods 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

Derogation until 31.12.1992, pursuant to Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990), products from the former GDR which do not meet the requirements of Directive 89/398/EEC. These products may be marketed in the new *Länder*, but not elsewhere in the Community.

(5) Date of entry into force (if different from the above)	The Member States shall amend their laws, regulations and administrative provisions so as to: permit, from 16 May 1990 onwards, trade in products which meet the requirements of this Directive; prohibit, as from 16 May 1991, trade in products which do not meet the requirements of this Directive.
(6) References	Official Journal L 186, 30.6.1989
(7) Follow-up work	On 11 November 1991, the Commission presented a proposal for a Council Directive on infant formulas and follow-on formulas intended for export to third countries (COM(91) 441/I final). 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 Commission also presented a proposal for a Council Resolution on the marketing of breast milk substitutes by Community manufacturers in developing countries (COM(91) 441/II final).
(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.

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4.15. Official inspection of foodstuffs

(1) Objective	To provide for official inspections of food in order to protect the health and economic interests of consumers, while upholding the legitimate rights of businesses, e.g. the right to manufacturing secrecy and the right of appeal. To harmonize legislation, thus facilitating the free movement of foodstuffs within the Community by establishing mutual confidence between the various systems of inspection in the Member States.
(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. 2. Procedures concerning the carrying out of inspections both on a regular basis and in those instances when non-compliance is suspected. 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. 4. Analysis of samples is entrusted to official laboratories. 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: — training provision for food inspectors; — quality standards for laboratories involved in inspection and sampling; — the possibility of establishing a Community inspection service, including opportunities for all institutions and persons involved in the inspections to exchange information. 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.
(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

(8) Commission implementing measures

On 13 September 1990 the Commission adopted a communication to the Council and to the European Parliament relating to the uniform application of Directive 89/397/EEC in all Member States (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).

4. FOODSTUFFS

4.16. Sampling and analysis of foodstuffs

(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: — the need to ensure that Community law is uniformly applied; — the existence of barriers to intra-Community trade. 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. 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 Derogation until 31 December 1992, pursuant to Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990), for products from the former GDR which do not comply with Directive 85/591/EEC. These products may be marketed in the new *Länder*, but not on other Community markets.
(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

4.17. Quick-frozen food

(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). 2. Quick freezing must be carried out with the aid of appropriate equipment immediately after the product has been processed. 3. A list of authorized cryogenic fluids is included. 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. 5. Member States must conduct random checks on quick-freezing equipment and on temperature levels. 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'. 7. Procedure for adopting methods of sampling, monitoring temperatures and storage. 8. Transitional period of eight years for retail display cabinets.
(4) Deadline for implementation of the legislation in the Member States	Derogation until 31.12.1992, pursuant to Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990), for products from the former GDR which do not comply with Directive 89/108/EEC. These products may be marketed in the new *Länder*, but not on other Community markets.
(5) Date of entry into force (if different from the above)	The Member States must, if necessary, amend their laws, regulations and administrative provisions so as to: permit trade in products which meet the requirements of the Directive by 10 July 1990 at the latest; prohibit trade in products which do not meet the requirements of this Directive by 10 January 1991 at the latest.
(6) References	Official Journal L 40, 11.2.1989
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.18. Coffee and chicory extracts

(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. 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. 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. Once the existing stocks are disposed of, as of 1 July 1988 products not meeting the requirements of the Directive should no longer be sold. Derogation until 31.12.1992, pursuant to Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990), for products from the former GDR which do not comply with Directive 85/573/EEC. These products may be marketed in the new *Länder*, but not on other Community markets.
(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

4.19. Fruit juices and similar products

(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. 2. Freedom to replace sugars by honey. 3. Citric acid may be used in the production of fruit nectars obtained from apples, pears, or peaches. 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. 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	Derogation until 31.12.1992, pursuant to Council Directive 90/650/EEC (Official Journal L 353, 17.12.1990), for products from the former GDR which do not comply with Directive 89/394/EEC. These products may be marketed in the new *Länder*, but not on other Community markets.
(5) Date of entry into force (if different from the above)	The Member States must take the necessary steps to comply with this Directive, which they will apply so as to: permit trade in products which meet the requirements of this Directive by 14 June 1990 at the latest; prohibit trade in products which do not meet the requirements of this Directive as from 14 June 1991.
(6) References	Official Journal L 186, 30.6.1989
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.20. Fruit jams, jellies, marmalades and chestnut purée

(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'. 2. Identity and purity criteria must be determined where necessary, in accordance with the procedure laid down. 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. 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	
(5) Date of entry into force (if different from the above)	31.12.1989 to permit trade in products complying with the Directive; 1.1.1991 to prohibit trade in products not complying with the Directive.
(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). 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

4.21. Foodstuffs treated with ionizing radiation

(1) Objective

To harmonize Member State provisions concerning the irradiation of foodstuffs so as to eliminate barriers to free movement of foodstuffs and unequal conditions of competition, whilst ensuring protection of human health.

(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 for 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, of which some 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

Commission proposal COM(88) 654 final	Official Journal C 336, 31.12.1988
Amended proposal COM(89) 576 final	Official Journal C 303, 2.12.1989
European Parliament opinion First reading	Official Journal C 291, 20.11.1989
Economic and Social Committee opinion	Official Journal C 194, 31.7.1989

4. FOODSTUFFS

4.22. 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.

(3) Contents

1. The Directive concerns 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 Directive applies 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

See also the second paragraph under heading 'Follow-up Work'.

Derogation until 31 December 1992, pursuant to Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990), for products from the former GDR which do not comply with Directive 89/396/EEC. These products may be marketed in the new *Länder* but not on other Community markets.

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

Where necessary, Member States will have to amend their laws, regulations or administrative provisions so as to authorize trade in products complying with the Directive and prohibit trade in products not complying with the Directive. In the first instance the deadline is 20 June 1991. Trade in products placed on the market before 20 June 1991 may continue until stocks run out.

(6) References

Official Journal L 186, 30.6.1989

(7) Follow-up work

On 22 April 1991 the Council adopted a Directive completing Directive 89/396/EEC in such a way that the lot identification rule does not apply to individual portions of ice cream, provided that the lot is indicated on the combined packages (Official Journal L 107, 27.4.1991).

On 19 December 1991 the Council adopted a common position on a proposal for a Council Directive amending Directive 89/396/EEC (COM(91) 297/I final, published in Official Journal C 219, 22.8.1991).

The aim of this proposal is to postpone the implementation date for the lot Directive by one year as a result of technical problems encountered by manufacturers in the purchase of appropriate labelling equipment.

(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

4.23. Product quality: certificates of specific character

(1) Objective

To create a Community instrument enabling producers to obtain recognition of the specific character of their products. To promote a quality policy for products. To inform consumers, clearly and succinctly, of the method of production and special characteristics of foodstuffs.

(2) Proposal

Proposal for a Council Regulation on certificates of specific character for 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 geographical origin; 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, and the minimum requirements and inspection procedures to which production 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 publishes it in the *Official Journal of the European Communities*. Within three months from the date of publication any other Member State may notify to the competent national authorities its opposition to registration. 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.

8. Where a national certificate has been issued prior to the Community certificate, the simultaneous use of the two certificates for a given foodstuff is authorized for five years only.
9. 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.
10. Member States are to take the necessary measures to ensure legal protection against abusive or fallacious use or imitation of registered trade descriptions.
11. The Commission is to be assisted by a committee of an advisory nature composed of the representatives of the Member States.
12. Provision is made for financial measures to provide information for consumers, promote foodstuffs bearing a certificate of specific character and assist groups starting activities arising from the application of the Regulation.

(4) Opinion of the European Parliament

Parliament approved the 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

Commission proposal SEC(90) 2414 final	Official Journal C 30, 6.2.1991
European Parliament opinion	Not yet published
Economic and Social Committee opinion	Not yet published in the Official Journal

4. FOODSTUFFS

4.24. Product quality: geographical indications and designations of origin

(1) Objective

To establish a system for the protection of geographical indications and designations of origin of agricultural products and foodstuffs whose quality and characteristics are attributable to their geographical origin. To promote a quality policy for products. To assist rural society by maintaining specific products.

(2) Proposal

Proposal for a Council Regulation 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 a group of producers 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. 7. The Commission has authority to negotiate agreements with third countries for the reciprocal protection of designations. 8. Registered PGIs and PDOs are legally protected against any misuse or false or misleading indication. 9. The Commission is to adopt financial provisions to promote products displaying a PGI or PDO. 10. The Commission is to be assisted by an advisory committee composed of the representatives of the Member States. 11. Each Member State is to send to the Commission within three months from the date this Regulation enters into force details of the authority responsible for approving inspection bodies. The list of inspection bodies will be published in the *Official Journal of the European Communities.* 12. The Member States may maintain geographical indications or designations of origin issued in their territory before the entry into force of this Regulation until they have been published in the *Official Journal of the European Communities.*
(4) Opinion of the European Parliament	Parliament approved the 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	Commission proposal SEC(90) 2415 final — Official Journal C 30, 6.2.1991 European Parliament opinion — Not yet published Economic and Social Committee opinion — Not yet published in the Official Journal

5. PHARMACEUTICAL PRODUCTS

Current problems and 1992 objectives

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 on 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. In future, 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.

In the same context, the Community has definitively adopted measures on:
— high-technology medicinal products (summaries 5.1 and 5.2);
— proprietary medicinal products (summaries 5.3 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).

Common positions have been adopted on:
— rational use of medicinal products (summaries 5.18 to 5.21);
— supplementary protection certificate for medicinal products (summary 5.22);
— homeopathic medicines (summary 5.23).

Proposals on the future system for the authorization of medicinal products and on the European Agency for the Evaluation of Medicinal Products are now being discussed (summary 5.25) in the light of the Commission's reports to the Council on the activities of the Committee for Proprietary Medicinal Products (COM(91) 39 final) and of the Veterinary Medicinal Products Committee (SEC(91) 1403).

5. PHARMACEUTICAL PRODUCTS

5.1. High-technology medicinal products: marketing authorization

(1) Objective	To coordinate procedures in the Member States for authorizing high-technology medicines, especially those based on biotechnology. Whilst the primary purpose of the Directive is to protect public health, it is also intended to enable a single market in high-technology medical products to be set up.
(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. 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. 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. 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 1993. 2. Member States shall take the measures necessary to comply with this Directive not later than 1 January 1993. 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 1993 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	The proposal is currently before the Council for a common position.
(6) References	Commission proposal COM(90) 283/IV final — Official Journal C 330, 31.12.1990 European Parliament opinion First reading — Not yet published Economic and Social Committee opinion — Official Journal C 269, 14.10.1991

5. PHARMACEUTICAL PRODUCTS

5.3. Proprietary medicinal products: standards and protocols for testing

(1) Objective	Technology is advancing very quickly in this area, and the aim of the Directive is to adopt a new, quicker 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. 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

(1) Objective	When seeking marketing authorization for a new proprietary medicinal product, manufacturers have to provide detailed results of tests performed, even though there may be many similar products already on the market. The Directive seeks 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: — 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; — or, that there is detailed scientific evidence available showing that the constituents of the product have an acceptable level of safety and recognized efficacy; — 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. 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 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 medicinal products 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. 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.
3. 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 comments on the dossier as regards the results of the analytical, pharmaco-toxicological and clinical tests of the medicinal product concerned.
4. 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 140 days of the date on which the application was submitted.
5. Mutual recognition of authorizations: European marketing authorizations will be valid throughout the Community. With effect from 1 January 1996, 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 has granted the authorization to forward to it the assessment report.
6. 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.
7. 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.
8. 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.

9. 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.
10. 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.
11. 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.
12. 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 amended proposal is currently before the Council for a common position.

(6) References

Commission proposal COM(90) 283/II final	Official Journal C 330, 31.12.1990
Amended proposal COM(91) 382/II final	Official Journal C 310, 30.11.1991
European Parliament opinion First reading	Not yet published
Economic and Social Committee opinion	Official Journal C 269, 14.10.1991

5. PHARMACEUTICAL PRODUCTS

5.6. Proprietary medicinal products: standards for testing

(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: (a) procedures for testing the mutagenic potential of pharmaceuticals, (b) clinical investigation of oral contraceptives and information to be provided to users, (c) presentation of information on proprietary medicinal products, (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 medicines: residues

(1) Objective

To lay down a procedure for the establishment of tolerance levels for residues of veterinary medicines in foodstuffs of animal origin and a single high-quality scientific assessment. This is necessary in order to eliminate the hindrances to the free movement of veterinary medicinal products and foodstuffs of animal origin which could result from different national tolerance levels.

(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 will have to be established before authorization is granted. In the case of products already on the market, tolerances will be established for groups of compounds over a period estimated at about eight years. 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 shall 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 to be established will be contained in Annex 1 to the Regulation.
4. Annex 2 to the Regulation will give a list of substances for which it is not necessary to establish a tolerance having regard to their nature and pattern of use. A substance shall 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 residue presents a hazard to the consumer. A provisional tolerance may remain in force for a defined period of time which shall not exceed three years and which shall be renewable, exceptionally and once only, for a further period not exceeding three years. The list of substances for which provisional tolerances have been established will be inserted in Annex 3 to the Regulation.
6. Annex 4 shall contain 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 shall be prohibited throughout the Community.
7. Member States shall 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 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 of the Regulation.
8. An individual wishing to have an active substance referred to in point 7 above included in Annexes 1, 2 or 3 shall 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 shall examine the Member State's reasons and, after consultation of the Member States in the Committee for Veterinary Medicinal Products, it shall 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 a further 15 days.
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

5. PHARMACEUTICAL PRODUCTS

5.8. Veterinary medicines: 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 medicines: free movement

(1) Objective

To abolish the remaining barriers to the free movement of veterinary medicinal 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 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.
3. 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 comments on the dossier as regards the results of the analytical, pharmaco-toxicological and clinical tests of the veterinary medicinal product concerned.
4. 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 140 days of the date on which the application was submitted.
5. Mutual recognition of authorizations: European marketing authorizations will be valid throughout the Community. With effect from 1 January 1996, 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 has granted the authorization to forward to it the assessment report.
6. 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.
7. 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 file of the latest pharmacological vigilance data.
8. 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.
9. 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.
10. 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.
11. 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.
12. 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 amended proposal is currently before the Council in view of a common position.

(6) References

Commission proposal COM(90) 283/III final	Official Journal C 330, 31.12.1990
Amended proposal COM(91) 382/III final	Official Journal C 310, 30.11.1991
European Parliament opinion 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 medicines: provisions for immunological products

(1) Objective	To remove hindrances to intra-Community trade in immunological veterinary medicines and maintain a high level of protection of public health by extending to these products the provisions of existing Directives relating to veterinary medicinal products.
(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 317, 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. 2. Definition of 'immunological veterinary medicinal product', and redefinition of the expressions 'qualitative and quantitative particulars of the constituents' and 'qualitative and quantitative composition'. 3. Provision for expression of quantitative particulars in specified units as appropriate to the product concerned. 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. 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. 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	1.1.1992

(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	

5. PHARMACEUTICAL PRODUCTS

5.11. Veterinary medicines: testing standards

(1) Objective	The technology of veterinary medicines is making rapid advances and the aim of the Directive is to adopt a new, quicker 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. 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

(1) Objective	The communication sets out Member States' obligations under the EEC Treaty, in particular Article 30 *et seq.* as interpreted by the Court of Justice, and as the Commission intends to apply them 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. 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. 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. 4. When deciding which medicines can be supplied under their national health insurance scheme, Member States must not discriminate against imported products. 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

(1) Objective

Most Member States have adopted some sort of price controls on medicines (whether direct or indirect), usually to ensure that products are available to all at reasonable prices and to control the cost of health services. The Directive seeks to begin the harmonization of such measures so that they do not constitute barriers to trade.

(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 22, 9.2.1965) applies to this Directive.
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.
3. A list of medicines whose prices have been regulated must be published at least once a year.
4. Points 2 and 3 also apply to applications for price increases.
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.
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.
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.
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.
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

(1) Objective	To amend previous Directives relating to proprietary medicinal products to cover non-proprietary medicinal products. To improve the information available to consumers about medicinal products. To lay down certain provisions governing the export of medicinal products. To improve the guarantees of the quality, safety and efficiency of all 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'. 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. 3. Information requirements are increased to include special precautions for the disposal of unused products or waste materials and batch numbers. 4. The inclusion of a package leaflet for all medicinal products is obligatory unless all information can be conveyed on the external packaging. 5. Measures relating to exports to non-EC countries. For example, supply to the destination country of proof of manufacturing authorization, product summaries, etc. 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. 7. The principles and guidelines of good manufacturing practice are the subject of a Commission Directive (see heading 8). 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. 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

(7) Follow-up work

(8) Commission implementing measures

Directive 91/356/EEC — Official Journal L 193, 17.7.1991
Commission Directive of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.
Date of entry into force: 1.1.1992.
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

(1) Objective	To extend the scope of Council Directives 65/65/EEC (Official Journal 22, 9.2.1965 — special Greek edition: chapter 13, volume 1) and 75/319/EEC (Official Journal L 147, 9.6.1975 — special Greek edition: chapter 13, volume 3) relating to proprietary medicinal products to include immunological medicinal products, allergen products, vaccines, toxins, and serums.
(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. 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. 3. Requirement to include details about any special precautions to be taken by persons handling immunological products in information summaries about the product. 4. The name of an immunological medicinal product should also include the common or scientific name of the active constituents. 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. 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 production control and severe tests guaranteeing the quality, safety and efficacy of medicinal products before they are placed on the market, in order to prevent in particular the transmission of infectious diseases such as AIDS and hepatitis. The Directive also encourages voluntary and unpaid donation of human blood and plasma with a view to self-sufficiency in the supply of human blood throughout the Community.
(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. Definition of 'medicinal products derived from human blood or plasma'. These products include in particular albumen, coagulating factors and immunoglobins of human origin. The Directive will 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. 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

(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 181, 28.6.1989
(7) Follow-up work	
(8) Commission implementing measures	

5. PHARMACEUTICAL PRODUCTS

5.17. Radiopharmaceuticals

(1) Objective	To extend the scope of Council Directives 65/65/EEC (Official Journal 22, 9.2.1965 — special Greek edition: chapter 13, volume 1) and 75/319/EEC (Official Journal L 147, 9.6.1975 — special Greek edition: chapter 13, volume 3) relating to proprietary medicinal products to include radiopharmaceuticals.
(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. 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. 3. The application for authorization of a generator must also include the following information and documentation: — a general description of the system; — a detailed description of the components and the qualitative and quantitative particulars of the eluate or sublimate. 4. The summary of product characteristics for radiopharmaceuticals must include full details of radiation dosimetry, and additional instructions for extemporaneous preparation and quality control. 5. The outer packaging and containers of radionuclides shall be labelled in accordance with International Atomic Energy Agency regulations as well as EEC legislation. 6. Member States must ensure that a detailed instruction leaflet is enclosed with the packaging of radiopharmaceuticals, generators, kits, and precursor radiopharmaceuticals. 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

(7) Follow-up work

(8) Commission implementing measures

Official Journal L 142, 25.5.1989

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5. PHARMACEUTICAL PRODUCTS

5.18. Rational use of medicinal products: wholesale distribution

(1) Objective

Rational use of medicinal products for human consumption. The Directive is designed to guarantee optimum conditions for the preservation, transport and handling of medicinal products, to remove barriers to their free movement and to permit the withdrawal from the market of imperfect or dangerous products.

(2) Proposal

Proposal for a Council Directive 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.
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.
3. The granting of this authorization will be subject to compliance with certain essential requirements:
— account of entry and withdrawal transactions, records being verified at least one a year and kept for three years;
— proof of the qualifications of personnel;
— suitable premises for storage which are accessible for inspection;
— an emergency plan permitting participation in any withdrawal from the ordered market action by the authorities.
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.
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.
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) 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 October 1991. Within the framework of the cooperation procedure this is now before Parliament for a second reading.

(6) References	Commission proposal COM(89) 607/I final	Official Journal C 58, 8.3.1990
	Amended proposal COM(91) 245/I final	Official Journal C 207, 8.8.1991
	European Parliament opinion First reading	Official Journal C 183, 15.7.1991
	Economic and Social Committee opinion	Official Journal C 225, 10.9.1990

5. PHARMACEUTICAL PRODUCTS

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

(1) Objective

More rational use of medicinal products for human consumption through the harmonization of supply of medicinal products on open sale or supplied solely on medical prescription.

(2) Proposal

Proposal for a Council Directive 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.

(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 October 1991. Within the framework of the cooperation procedure this is now before Parliament for a second reading.

(6) References

Commission proposal COM(89) 607/II final	Official Journal C 58, 8.3.1990
Amended proposal COM(91) 245/II final	Official Journal C 207, 8.8.1991
European Parliament opinion First reading	Official Journal C 183, 15.7.1991
Economic and Social Committee opinion	Official Journal C 225, 10.9.1990

5. PHARMACEUTICAL PRODUCTS

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

(1) Objective

Rational use of medicinal products for human consumption. Improved information on medicinal products for patients to allow them to use them correctly.

(2) Proposal

Proposal for a Council Directive 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.
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.
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.
4. The package leaflet must be written in such a way as to be clear, easily legible and understandable for the user.
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.

(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 October 1991. Within the framework of the cooperation procedure this is now before Parliament for a second reading.

(6) References	Commission proposal COM(89) 607/III final	Official Journal C 58, 8.3.1990
	Amended proposal COM(91) 245/III final	Official Journal C 207, 8.8.1991
	European Parliament opinion First reading	Official Journal C 183, 15.7.1991
	Economic and Social Committee opinion	Official Journal C 225, 10.9.1990

5. PHARMACEUTICAL PRODUCTS

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

(1) Objective

To improve the protection of public health and facilitate the free movement within the Community of medicinal products by laying down common rules relating to the advertising of pharmaceuticals.

(2) Proposal

Proposal for a Council Directive on 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. 9. Provisions relating to the monitoring of pharmaceutical advertising are similar to those provided for in Directive 84/450/EEC on misleading advertising.
(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 October 1991. Within the framework of the cooperation procedure this is now before Parliament for a second reading.
(6) References	Commission proposal COM(90) 212 final — Official Journal C 163, 4.7.1990 Amended proposal COM(91) 245/IV final — Official Journal C 207, 8.8.1991 European Parliament opinion First reading — Official Journal C 183, 15.7.1991 Economic and Social Committee opinion — Official Journal C 60, 8.3.1991

5. PHARMACEUTICAL PRODUCTS

5.22. Supplementary protection certificate for medicinal products

(1) Objective

To improve protection of innovation in the pharmaceutical sector. To ensure additional protection for new medicinal products for a maximum period of five years by means of the creation of a supplementary protection certificate which will take effect immediately on expiry of the corresponding patent. To encourage research in the pharmaceutical sector in Europe.

(2) Proposal

Proposal for a Council Regulation concerning the creation of a supplementary protection certificate for medicinal products.

(3) Contents

1. Definitions of the terms 'product', 'product protected by a patent' and 'certificate' used in the proposed Regulation. The supplementary certificate covers 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. A consultative document on the legal protection of industrial designs was published in July 1991. During the course of 1992, this document will be the subject of wide-ranging consultations with interested parties, enabling the Commission to present legislative proposals to the Council and Parliament by the end of the year.
4. 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. Secondly, 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. Thirdly, this authorization must be the first authorization to place the product on the market. Finally, the product must not already have been the subject of a certificate.
5. The protection conferred by the certificate extends only to the product covered by the authorization to place it on the market and for any authorized use of the product before the expiry of the certificate.
6. The certificate confers the same rights as are conferred by the basic patent and is subject to the same limitations.
7. The application for a certificate must be lodged with the central 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 on the day following 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.
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.
10. The certificate is void if:
— it was granted contrary to the provisions of the Regulation;
— the basic patent is no longer in force when its lawful term expires;
— the basic patent is cancelled.

(4) Opinion of the European Parliament

First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission did not accept these amendments.

(5) Current status

The Council adopted a common position on 19 December 1991. Within the framework of the cooperation procedure this is now before Parliament for a second reading.

(6) References

Commission proposal COM(90) 101 final	Official Journal C 114, 8.5.1990
European Parliament opinion First reading	Official Journal C 19, 28.1.1991
Economic and Social Committee opinion	Official Journal C 69, 18.3.1991

5. PHARMACEUTICAL PRODUCTS

5.23. Homeopathic medicinal products: medicinal products for human use

(1) Objective

To improve the protection of public health; to introduce legislation covering all industrially prepared medicinal products for human use, with a view to the completion of the internal market.

(2) Proposal

Proposal for a Council Directive 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 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'.
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 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. 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 at 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 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.

	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.
(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 19 December 1991. Within the framework of the cooperation procedure this is now before Parliament for a second reading.
(6) References	

Commission proposal COM(90) 72/I final	Official Journal C 108, 1.5.1990
Amended proposal COM(91) 313/I final	Official Journal C 244, 19.9.1991
European Parliament opinion First reading	Official Journal C 183, 15.7.1991
Economic and Social Committee opinion	Not yet published in the Official Journal

5. PHARMACEUTICAL PRODUCTS

5.24. Homeopathic medicinal products: veterinary medicinal products

(1) Objective

To improve the protection of public health; to introduce legislation covering all industrially prepared veterinary medicinal products, with a view to the completion of the internal market.

(2) Proposal

Proposal for a Council Directive 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 official 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 at 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.
(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 now before the Council pending adoption of a common position.
(6) References	Commission proposal COM(90) 72/II final — Official Journal C 108, 1.5.1990 Amended proposal COM(91) 313/II final — Official Journal C 244, 19.9.1991 European Parliament opinion First reading — Official Journal C 183, 15.7.1991 Economic and Social Committee opinion — Not yet published in the Official Journal

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

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

(6) References

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

6. CHEMICAL PRODUCTS

Current problems and 1992 objectives

Differing regulations for chemical products give rise to a multitude of problems. Divergent levels of health and safety protection are 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.

Likewise, a Directive relating to restrictions on marketing and use of dangerous substances and preparations was adopted in 1976 and has been amended 12 times.

The Community has, therefore, undertaken the following measures:

— amendment of the basic Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (summaries 6.1 to 6.8);

— classification, packaging and labelling of dangerous substancs (summary 6.9);

— detergents (summary 6.10);

— marketing of fertilizers (summaries 6.11 to 6.13).

It will be for the Commission to administer them by means of Commission Directives in some cases and proposals to the Council in others (e.g. fertilizers).

In addition, on 4 December 1990, the Council adopted transnational measures applicable in the territory of the former German Democratic Republic having regard to the unification of Germany to take account of the progressive application of all Community laws in that territory (Directive 90/657/EEC published in Official Journal L 353, 17.12.1990 — summaries 6.2, 6.3, 6.9 and 6.10).

6. CHEMICAL PRODUCTS

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

(1) Objective	To update previous legislation to prohibit the marketing and use of PCBs and PCTs (polychlorinated biphenyls and polychlorinated terphenyls) except in special circumstances. Substitutes have been developed which are considered less dangerous to human beings and the environment.
(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: — closed-system electrical equipment transformers, resistors and inductors; — large condensers (with a total weight equal to or over 1 kg); — in certain small condensers; — heat-transmitting fluids in closed-circuit heat-transfer installations; — hydraulic fluids for underground mining equipment. These uses of PCBs and PCTs will come to an end on 30 June 1986. 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. 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 update previous legislation in order to prohibit certain uses of asbestos. This will 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: — toys; — materials and preparations applied by spraying; — products in powder form; — items for smoking; — filters and insulation devices for use in catalytic heaters using liquified gas; — paints and varnishes.
(4) Deadline for implementation of the legislation in the Member States	31/12/1987 Derogation until 31 December 1992, pursuant to Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990), for products from the former GDR which do not comply with Directive 85/610/EEC. These products may be marketed in the new *Länder,* but not on other Community markets.
(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. 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	The purpose of this Directive is to amend Annex 1 to Council Directive 76/769/EEC (Official Journal L 262, 27.9.1976) by adding new dangerous substances and/or preparations covered by 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: — five carcinogenic substances the marketing of which is strictly regulated; — lead sulphates and lead carbonates which may not be used as constituents of paints; — 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 Derogation until 31 December 1992 on the implementation of Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990) for the products from the former German Democratic Republic in Directive 89/677/EEC. These products may be marketed in the new *Länder* but not on the other markets of the Community.
(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. 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	The Directive, which is based on Article 100a of the EEC Treaty; inserts a new article into Council Directive 76/769/EEC (Official Journal L 262, 27.9.1976) providing for a procedure designed to enable the Directive to be adapted rapidly to technical progress in close collaboration between the Member States and the Commission, using the committee procedure.
(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. This proposal relates to the legislative consolidation of the field. It replaces the various Directives now being consolidated, including Directive 89/678/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

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

(1) Objective	To amend Council Directive 76/769/EEC (Official Journal L 262, 27.9.1976) in order to regulate strictly 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: — for the treatment of wood; — for the impregnation of heavy-duty textiles; — 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. 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 amend Council Directive 76/769/EEC (Official Journal L 262, 27.9.1976) in order 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. 2. A general derogation clause is provided to cover reasons of safety and reliability and situations where the use of cadmium may be essential. 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. 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 update Council Directive 76/769/EEC (Official Journal L 262, 27.9.1976) in respect of the marketing of Ugilec 141, Ugilec 121 and DBBT so as to guarantee the 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. 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. This proposal relates to the legislative consolidation of the field. It replaces the various Directives now being consolidated, including Directive 91/339/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

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

(1) Objective	To update Council Directive 76/769 (Official Journal L 262, 27.9.1976) with a view to restricting 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 Economic and Social Committee opinion — Official Journal C 191, 22.7.1991

6. CHEMICAL PRODUCTS

6.9. 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.

(3) Contents

1. The Directive applies to dangerous preparations as defined in Article 1 (2) of the Directive 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.

(4) Deadline for implementation of the legislation in the Member States	7.6.1991 Derogation until 31 December 1992 on the implementation of Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990) for the products from the former German Democratic Republic in Directive 88/379/EEC. These products may be marketed in the new *Länder* but not on the other markets of the Community.
(5) Date of entry into force (if different from the above)	Preparations in conformity with Council Directive 73/173/EEC (Official Journal L 189, 11.7.1973) and Council Directive 77/728/EEC (Official Journal L 303, 28.11.1977) may be marketed until 7 June 1992.
(6) References	Official Journal L 187, 16.7.1988 Corrigendum Official Journal L 110, 1.5.1991
(7) Follow-up work	The Commission will put forward a new draft proposal for a labelling guide.
(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. 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.

6. CHEMICAL PRODUCTS

6.10. 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: — low-foaming alkene oxide additives in such substances as alcohols, alkyphenols, glycols, polyols, fatty acids, amides or amines used in dish-washing products; — 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	Derogation until 31 December 1992 on the implementation of Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990) for the products from the former German Democratic Republic in Directive 86/94/EEC. These products may be marketed in the new *Länder* but not on the other markets of the Community.
(5) Date of entry into force (if different from the above)	Exemptions for certain detergents extended until 31 December 1989.
(6) References	Official Journal L 80, 25.3.1986
(7) Follow-up work	
(8) Commission implementing measures	

6. CHEMICAL PRODUCTS

6.11. 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. 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. 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

6.12. 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. 2. A declaration of calcium content considered to be a nutrient need only need be made for calcium sulphate and calcium chloride solution fertilizers. 3. Fertilizers complying with the Directive may be marked 'EEC fertilizer'. 4. Required marking for identification purposes includes: — 'EEC fertilizer', — the designation of the type of fertilizer and the guaranteed nutrient content. 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. 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: trace-elements

(1) Objective	To extend existing Community legislation on fertilizers (summaries 6.11 and 6.12) 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. 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. 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. 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. 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. 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

Current problems and 1992 objectives

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. Safety in hotels is particularly important because of the number of persons at risk, particularly at night, and due to the fact that many hotels are older buildings.

The entire programme has been completed; it relates to noise levels of tower cranes (summary 7.1), safety measures in hotels (summary 7.2) and construction products (summary 7.3). This last Directive is based on the new approach principles described in summary 1.1. The Commission will have to adopt implementing measures for the purpose of putting it into effect.

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. 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/1pW (to be reduced to 100 dB/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). 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'. 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: — safe escape routes should be available, unobstructed and clearly marked; — buildings should be stable at least as long as necessary to allow safe evacuation of occupants; — warning systems should be installed and in full working order; — staff should be given suitable instructions and training. 2. The annex contains technical guidelines in particular for the construction of hotel buildings. 3. Member States are recommended to inspect hotels periodically. 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. To lay down the essential requirements which will eventually form the basis for the preparation of standards harmonized at European level. To enable the Commission to adopt guidelines in line with the new approach to harmonization before the current standardization process is complete.
(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. 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. 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). 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. 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. 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. 7. Products conforming to standards, but which are thought to pose a safety threat, may be temporarily withdrawn from the market. 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. On 17 May 1991 the Commission presented a proposal for a Council Regulation on the affixing and use of the EC mark on industrial products (COM(91) 145 final, published in Official Journal C 160, 20.6.1991). This proposal is aimed (a) at aligning the provisions already existing in respect of the affixing of the EC mark to products that comply and (b) to draw up a reference document on any future Community Regulations in this area.
(8) Commission implementing measures	

8. OTHER AREAS

Current problems and 1992 objectives

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).

In addition, there are three measures (summaries 8.6 to 8.8) which aim to protect the consumer and harmonize national regulations for product pricing (both for food and non-food items) and for labelling of cosmetics.

On 4 December 1990 the Council adopted transitional measures applicable in the new *Länder* of the Federal Republic of Germany, having regard to German unification, preparing the way for progressive application of all Community legislation to the territory of the former German Democratic Republic (Council Directive 90/657/EEC published in Official Journal L 353, 17.12.1990 — summary 8.6).

8. OTHER AREAS

8.1. Noise: household appliances

(1) Objective	The Directive aims to: — ensure that the public get as much information as possible about the household products they are buying, and — aid the free movement of household appliances throughout the Community. It is not intended to harmonize national standards at present; rather to ensure that national regulations follow a common pattern.
(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. 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. 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). 4. Where appliances have to have labels detailing other types of information, information on the noise emitted shall also be included. 5. Member States must inform the Commission of their national regulations. 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 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. 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. Directive 88/181/EEC 1. The Directive establishes common standards for noise emission from lawnmowers. 2. The permitted sound-power level ranges between 96 dB/pW and 105 dB/pW according to the corresponding cutting width of the lawnmower. 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 pA at the operator's position. 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	Differences in national requirements concerning the limitation of noise from construction equipment effectively act as a barrier to free trade in these products. The Directive aims to harmonize national legislation whilst ensuring 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. 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. 3. Member States must ensure that the marketing and use of earth-moving machines that do not comply with the Directive are prohibited. 4. Member States may limit the use of these machines in certain areas. 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. 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. Non-clinical laboratory tests (GLP)

(1) Objective

To ensure that laboratories in all Member States carrying out tests on chemical products comply with good laboratory practice (GLP). This will allow for mutual recognition of test results throughout the Community.

(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).
2. Member States must designate particular authorities to carry out inspections of laboratories.
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.
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.
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.
6. Amendments to the technical clauses of the Directive can be made by the Commission in consultation with the relevant committee.
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 good laboratory practice (GLP).
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	Some toys which look like sweets, or can be confused with foodstuffs, present a significant danger to children. The aim of the Directive is 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. 2. Member States must take all the measures necessary to prohibit the marketing, import and manufacture of such products. 3. Checks must be carried out to ensure that no such products are marketed. 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

(1) Objective	To amend Council Directive 76/768 EEC (Official Journal L 262, 27.9.1976) relating to the labelling of cosmetic products.
(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. 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. 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 Derogation until 31.12.1992, pursuant to Council Directive 90/657/EEC (Official Journal L 353, 17.12.1990), for products from the former GDR which do not comply with Directive 88/667/EEC. These products may be marketed in the new *Länder*, but not on other Community markets.
(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	In December 1989 the Council adopted a fifth amendment of Directive 76/768/EEC (Council Directive 89/679/EEC published in Official Journal L 398, 30.12.1989). A sixth amended proposal was adopted by the Commission on 5 February 1991 (COM(90) 488 final, published in Official Journal C 52, 28.2.1991). A proposal for a consolidated version of Directive 76/768/EEC was presented by the Commission in October 1990. It consolidates the existing Community provisions concerning the harmonization of cosmetic products (SEC(90) 1985 final, published in Official Journal C 322, 21.12.1990).
(8) Commission implementing measures	

8. OTHER AREAS

8.7. 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.
(3) Contents	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.
(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
(7) Follow-up work	On 7 June 1988 the Council adopted a Resolution regarding the protection of consumers on prices of foodstuffs and non-foodstuffs (Official Journal C 153, 11.6.1988). 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.
(8) Commission implementing measures	

8. OTHER AREAS

8.8. 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.
(3) Contents	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. 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. 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. 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. 5. Annex containing list of products prepackaged in pre-established quantities referred to in the Directive.
(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
(7) Follow-up work	On 7 June 1988 the Council adopted a Resolution regarding the protection of consumers on prices of foodstuffs and non-foodstuffs (Official Journal C 153, 11.6.1988). 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.
(8) Commission implementing measures	

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