ENGLISH

COMPLETING THE INTERNAL MARKET

1992

CURRENT STATUS 31 DECEMBER 1990

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

DECEMBER 1990

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 March 1990, the Commission issued its 'Fifth 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 five summarizing the current problems, the 1992 objectives and the measures and proposals necessary for the implementation of the single market.

The complete series of booklets covers

A common market for services

The elimination of frontier controls

Conditions for business cooperation
Public procurement

A new Community standards policy

Veterinary and plant health controls

These booklets will be updated and reissued at regular intervals up to 1992. Details of availability are given on the inside back cover.

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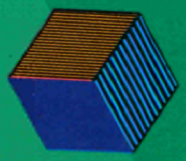

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A NEW COMMUNITY STANDARDS POLICY

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 as 31 December 1990, 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)

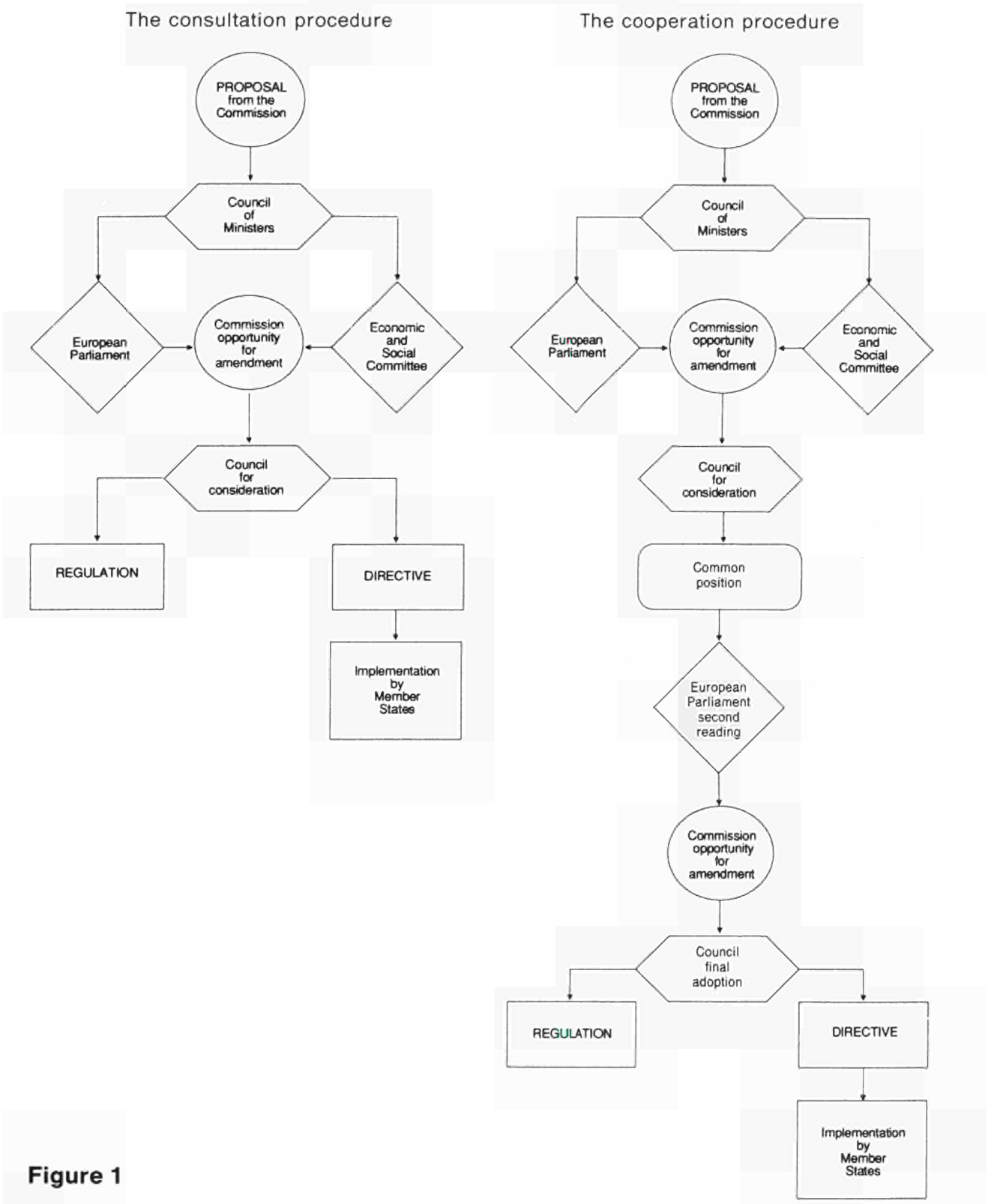

Figure 1

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 1990.

A NEW COMMUNITY STANDARDS POLICY

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; 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 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.

1990 — 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.

Approximately 80% of the legislative proposals drawn up by the Commission to harmonize technical standards and regulations have been adopted, while 20% are still under consideration. The new approach to harmonization (see below) has increased the pace of legislation on essential technical requirements, especially in the field of health and safety, and 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 booklet 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 and minimum requirements for the use of personal protective equipment at the workplace). Some of the proposals were adopted in 1989 and 1990.

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 elimination of such barriers to trade. However, if the creation of the internal market is to be completed by 1992 then more rapid progress must be made than has been the case in the past.

In 1983, the Community adopted a Directive which required Member States to notify the Commission of new technical regulations for certain products prior to their enactment. The Commission was given the power to freeze introduction of these new regulations for up to a year if it decided that a Community initiative would be more appropriate.

An identical mechanism applies between national standardization bodies and European bodies as regards the preparation of national standards. This system, which originally covered only certain products, was extended in 1989 to all industrial and agricultural products and will also apply to all EFTA (European Free Trade Association) countries — see summary 1.1.

To speed up the process of removing technical barriers to trade a new approach has been developed. It is based on the following principles:

— a distinction will be drawn in future internal-market initiatives between what it is essential to harmonize in legislation and what may be left to be harmonized by European standardization bodies;
— legislative harmonization will, in the future, be restricted to laying down health, safety and other essential requirements;
— harmonization of industrial standards will be achieved by the elaboration of European standards. These European standards will be developed by the European Committee for Standards (CEN) or the European Committee for Electrotechnical Standardization (Cenelec) as appropriate (see end of introduction for the list of addresses of the European standards organizations). As a transitional measure, and in so far as harmonized standards do not yet exist, national standards may be recognized as equivalent through an appropriate procedure of approval by the Commission. The result will be that a product manufactured in one Member State in conformity with EEC legislation as regards its essential safety requirements and with a standard in other respects will be guaranteed automatic access to the markets of all other Member States.

In 1987 and 1988 the Council adopted two Directives based on the new approach: one on pressure vessels (summary 1.2) and the other on toys (summary 1.3).

This year it has already adopted three further Directives, one on machine safety (summary 1.4), one on electromagnetic compatibility (summary 1.6) and personal protective equipment (summary 1.10).

Another set of proposals based on the new approach have also been adopted in the year 1990, including those concerning non-automatic weighing instruments, electromedical equipment and gas appliances (summaries 1.7, 1.8 and 1.9).

A new proposal covering all mobile machinery (civil engineering equipment, lifting and loading appliances), amending the Directive adopted on machine safety, was drawn up by the Commission in December 1989 (summary 1.5).

All of these new-approach Directives take account of the objectives contained within the Single European Act which commits the Commission to table proposals based on a high level of health, safety, consumer and environmental protection.

In July 1989 the Commission, as requested by the Council resolution of 7 May 1988, completed the 'new approach' with a communication entitled 'A global approach to certification and testing — quality measures for industrial products', which includes a proposal for a Council Decision concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization Directives (see summary 1.11).

On 3 October 1990 the Commission adopted a Green Paper on the development of European standardization (COM(90) 456 final) with the following objectives:

— to involve a wider range of participants in the debate on the future of standardization in Europe;

— to accelerate the delivery of European standards;

— to stimulate debate on how to ensure long-term dynamism and stability in European standardization.

The Green Paper examines a number of issues relating to the organizational structure, financing, and policies and practices of standarization bodies, both at European and national level.

It is divided into two parts:

— Part One identifies the challenges and problems facing European standardization;

— Part Two puts forward possible solutions to the challenges and problems facing European standardization in the 1990s.

The European standards organizations:

— CEN (European Standardization Committee)
Rue de Stassart, 36
B-1050 Brussels
Tel: 322-519 68 11

— Cenelec (Committee for Electrotechnical Standardization)
Rue de Stassart, 35
B-1050 Brussels
Tel: 322-519 68 71

— ETSI (European Telecommunications Standards Institute)
Boîte postale 52
F-Cedex 06561 Valbonne
Tel: 33 92-94 42 00

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 — Official Journal L 109, 26.4.1983) which required Member States to inform the Commission of new standards and regulations in certain fields 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 measure	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 implementing Member State legislation	1.1.1989
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 81, 26.3.1988
(7) Follow-up work	
(8) Commission implementing measure	Commission Decision of 3 May 1990 amending the lists of standards institutions contained in the Annex to Directive 83/189/EEC.

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 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 measure	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, 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. Those designed for nuclear use, for installation on ships and aircraft, and fire extinguishers are excluded from the scope of the Directive. 2. Vessels must conform with certain 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 assume conformity with essential safety requirements. 4. Manufacturers can either submit their design for inspection prior to production, or submit a prototype vessel to EC type-examination followed by a verification to ensure that manufactured vessels conform with the approved prototype. 5. If a prototype vessel passes the type-examination a type-examination certificate is issued. Type-examination has to be carried out by an approved body. 6. Verification that manufactured vessels conform with the approved prototype is carried out on batches of vessels submitted by the manufacturer. Tests are performed to ensure compliance. The EC mark is affixed to complying vessels. 7. If an EC mark is wrongly affixed (if, for example, manufactured vessels do not conform to the standards or the approved prototype) then the body responsible must report to the Member State concerned and, where appropriate, withdraw the EC type-examination certificate. 8. The EC mark must be visible, easily legible and indelible. Any other inscription which is likely to be confused with it is prohibited.
(4) Deadline for implementing Member State legislation	1.7.1990
(5) Date of entry into force (if different from 4)	
(6) Reference	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 approximation of the laws of the Member States relating to simple pressure vessels. This Directive provides for acceptance of the marketing of vessels in stock which still do not meet the requirements of Directive 87/404/EEC during the transitional period ending on 1 July 1992 (Directive 90/488/EEC, published in the Official Journal L 270, 2.10.1990).

(8) Commission implementing measure

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 products for which essential requirements have been adopted.

(2) Community measure

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, excluded from the scope of the Directive, including Christmas decorations, fireworks, playground equipment, and sports equipment.
2. Toys can only be marketed if they do not jeopardize the health and/or safety of their users or third parties; these essential safety requirements are defined in an annex.
3. If a toy satisfies the requirements of the Directive, no Member State may prohibit its sale, distribution or placing on the market. Any toy bearing an EC mark will be assumed to conform to the essential requirements or to a model examined by an approved body.
4. If a Member State feels that a toy is wrongly bearing the EC mark action shall be taken to withdraw it from the market.
5. Before being marketed, toys manufactured in accordance with harmonized standards or conforming to an examined model must have an EC mark attached to them by the manufacturer or his authorized representative established within the Community.
6. The manufacturer or his representative in the Community shall keep information on the product for inspection by authorities, e.g. product design and manufacture details, EC certificates, etc. Authorities shall ensure the confidentiality of this information.
7. Provision for the establishment of approval bodies.
8. Procedure for EC type-examination and certification of a product.
9. Member States are required to perform random checks to ensure that toys comply with the Directive.
10. The EC mark and the name and address of the manufacturer (or his representative) 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. Provision for changing harmonized standards where a Member State considers that they do not meet the Directive's requirements.
12. The annexes contain detailed essential 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 only be made of materials that are not readily flammable; they should not contain dangerous substances which are used to operate the toy; they must not be explosive, etc.
13. The annexes also contain conditions to be fulfilled by approved bodies (e.g. technically qualified personnel must carry out the relevant tests), and precautions to be taken when using toys (e.g. not to give unsuitable toys to very young children).

(4) Deadline for implementing Member State legislation	30.6.1989
(5) Date of entry into force (if different from 4)	1.1.1990
(6) Reference	Official Journal L 187, 16.7.1988
(7) Follow-up work	
(8) Commission implementing measure	

1. THE NEW APPROACH IN HARMONIZATION

1.4. Machine safety

(1) Objective	Member States have existing 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 responsibility for ensuring the health and safety of people using machinery.
(2) Community measure	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 safety and health requirements. Machinery means a powered assembly with mechanically linked parts of which at least one is movable. There are exemptions, e.g. mobile site equipment and lifting equipment. 2. Member States must ensure that appropriate measures are taken to ensure that machinery is only marketed if it complies with the Directive, that is if it does not endanger the health or safety of persons, animals or property. 3. The marketing and use of machinery which complies with the Directive, bears the EC mark and is accompanied by the EC declaration of conformity must be permitted by Member States. 4. Where a Member State considers that the harmonized standards do not satisfy the objectives in point 2 the matter will be brought to a standing committee who shall deliver an opinion. The Commission will then inform the Member State as to whether or not the machine must be withdrawn. 5. Where a Member State ascertains that a machine bearing the EC mark is liable to endanger the safety of persons it shall 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 shall 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 as presenting higher risks and greater hazards (e.g. chain-saws, metal shears). 9. Annexes containing the safety and health requirements, an EC declaration of conformity form and a model EC mark.
(4) Deadline for implementing Member State legislation	1.1.1992
(5) Date of entry into force (if different from 4)	31.12.1992

(6) Reference	Official Journal L 183, 29.6.1989
(7) Follow-up work	A new proposal also covering lifting and loading instruments was presented by the Commission in December 1989 in the form of an amendment to this Directive (see summary 1.5). The Commission will be submitting a proposal for a Directive on second-hand machinery.
(8) Commission implementing measure	

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) Proposal	Proposal for a Council Directive amending Council Directive 89/392/EEC on the approximation of the laws of the Member States on machinery.
(3) Contents	1. This proposal 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 of Directives 73/361/EEC, 76/434/EEC, 86/295/EEC, 86/296/EEC, 86/663/EEC and 89/240/EEC. 3. Annex 1 to this proposal 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 proposal also lays down essential health and safety requirements to reduce the specific hazards inherent in lifting operations. These requirements refer first to measures to protect against 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) Opinion of the European Parliament	First reading: The European Parliament approved the Commission proposal with three amendments. The Commission accepted one of these amendments, purely for a technical reason.
(5) Current status	The Council adopted a common position on 13 December 1990. In the framework of the cooperation procedure, this is currently before European Parliament for a second reading.

(6) Reference

Commission proposal COM(89) 624 final	Official Journal C 37, 17.2.1990
Amended proposal COM(90) 462 final	Official Journal C 268, 24.10.1990
European Parliament opinion First reading	Official Journal C 175, 16.7.1990
Economic and Social Committee opinion	Official Journal C 168, 10.7.1990

1. THE NEW APPROACH IN HARMONIZATION

1.6. Electromagnetic compatibility

(1) Objective	To harmonize national provisions on permissible electromagnetic disturbance and immunity levels caused by electronic apparatus in order to guarantee the free movement of these goods.
(2) Community measure	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 apparatus liable to cause or be affected by electromagnetic disturbance. Definitions of 'apparatus', 'electromagnetic disturbance', 'immunity' and 'electromagnetic compatibility'. 2. Member States shall ensure that: — the electromagnetic disturbance generated by the apparatus will not exceed a level which allows radio and telecommunications equipment and other apparatus to operate as intended; — the apparatus has an adequate level of intrinsic immunity to electromagnetic disturbance. 3. The conformity of apparatus with the Directive shall be certified by a Community declaration of conformity. This will be issued either by the manufacturer or an authorized representative established within the Community. An EC conformity mark shall be affixed to the apparatus or the packaging. 4. Where a Member State considers that the harmonized standards do not satisfy the objectives in point 2 the matter will be brought to a standing committee which shall deliver an opinion. The Commission will then inform the Member State as rapidly as possible as to whether standards must be withdrawn. 5. Where a Member State determines that an apparatus accompanied by a declaration of conformity does not comply, it shall 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. Provisions for a technical file describing apparatus to which standards have not yet been applied and including a technical report obtained from a technical body.
(4) Deadline for implementing Member State legislation	1.7.1991
(5) Date of entry into force (if different from 4)	1.1.1992
(6) Reference	Official Journal L 139, 23.5.1989
(7) Follow-up work	
(8) Commission implementing measure	

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 measure

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 implementing Member State legislation	1.7.1992
(5) Date of entry into force (if different from 4)	1.1.1993
(6) Reference	Official Journal L 189, 20.7.1990
(7) Follow-up work	
(8) Commission implementing measure	

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 measure	Council Directive 90/385/EEC, of 20 June 1990 on the approximation for the laws of the Member States relating to active implantable medical equipment.
(3) Contents	1. Definition of 'medical device', 'active implantable electromedical device', 'permanently implanted'. 2. Member States shall not impede the placing on the market, the free circulation 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 relevant national standards implementing the harmonized standards and to communicate these to the Commission. Member States shall presume that devices conforming 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 or of a standard. 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, EEC type-examination, EEC verification, EEC declaration of conformity to type, declaration on devices intended for special use, clinical assessment, minimum criteria governing the appointment of the bodies to be notified, copy of the EC conformity mark.
(4) Deadline for implementing Member State legislation	1.7.1992
(5) Date of entry into force (if different from 4)	1.1.1993
(6) Reference	Official Journal L 189, 20.7.1990
(7) Follow-up work	
(8) Commission implementing measure	

1. THE NEW APPROACH IN HARMONIZATION

1.9. 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 measure	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. Definition 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 implementing Member State legislation	1.7.1991
(5) Date of entry into force (if different from 4)	1.1.1992

(6) Reference	Official Journal L 196, 26.7.1990
(7) Follow-up work	
(8) Commission implementing measure	

1. THE NEW APPROACH IN HARMONIZATION

1.10. 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 measure	Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to the design of personal protective equipment.
(3) Contents	1. PPE means any device or appliance designed to be worn or held by an individual for protection against one or more safety and health hazards. The Directive applies to all PPE intended for professional and private use (sport, leisure, domestic use) except PPE covered by another Directive with the same objectives and PPE specifically referred to in Annex I. 2. This Directive, which runs parallel to the Directive dealing with the choice and use of PPE at the workplace, does not contain detailed design and manufacturing provisions but defines the basic safety requirements which the PPE must meet. 3. It defines the general requirements applicable to all PPE, additional requirements specific to certain types of PPE (e.g. equipment to protect eyes must not restrict the field of vision) and also additional requirements specific to particular risks. 4. Basic safety requirements may be satisfied either by national standards which implement harmonized standards, or by other technical specifications assessed by an approved inspection body as giving equivalent protection. 5. The harmonized standards may be changed should a Member State consider that they do not meet the Directive's basic safety requirements. 6. EC type-approval of product models prior to manufacture will be required for most PPE, although a simple declaration of the manufacturer is sufficient for PPE providing protection against minimal risks. However, in the case of PPE providing protection against lethal risks, the basic procedure is supplemented by a surveillance of the production. 7. Member States may not hinder the marketing of PPE or PPE components bearing the EC mark. 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 implementing Member State legislation	31.12.1991

(5) Date of entry into force (if different from 4)	1.7.1992
(6) Reference	Official Journal L 399, 30.12.1989
(7) Follow-up work	
(8) Commission implementing measure	

1. THE NEW APPROACH IN HARMONIZATION

1.11. 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 measure	Council Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases pf 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 implementing Member State legislation	Not applicable.
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 380, 31.12.1990
(7) Follow-up work	

2. MOTOR VEHICLES

Current problems and 1992 objectives

The Community has been striving for many years to bring about a comprehensive EC 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 adopted a series of measures harmonizing technical standards and type-approval of individual vehicle components in order to bring this about.

However, for the complete type-approval procedure to be introduced for cars, further measures must be adopted concerning safety glass, tyres, dimensions and weight (summaries 2.2, 2.3 and 2.5).

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.

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 adopted a series of important measures for gaseous emissions from petrol and diesel engines (summaries 2.8 and 2.9), gaseous emissions from cars below 1 400 cc (summary 2.11) and particulate emissions from diesel engines (summary 2.10).

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 circulation and use of motor vehicles.
(2) Community measure	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, and its trailers, with the exception of vehicles which run on rails and agricultural tractors and machinery. EC type-approval is defined as the procedure where one Member State certifies that a vehicle type satisfies the technical requirements of appropriate Directives. 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 appropriate Directives; spot checks should be carried out to ensure that production models conform to the approved type; Member States have to inform others, on a regular basis, of the type-approvals they have granted and refused.
(4) Deadline for implementing Member State legislation	1.10.1988
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 192, 11.7.1987
(7) Follow-up work	
(8) Commission implementing measure	

2. MOTOR VEHICLES

2.2. 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 proposal for a 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 proposal 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	An amended proposal including the amendments of Parliament withheld by the Commission, is awaited.

(6) Reference	Commission proposal COM(89) 653/II final	Official Journal C 95, 12.4.1990
	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

2.3. 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 proposal for a Directive applies to original and replacement tyres fitted to motor vehicles in category M_1 and trailers in categories 0_1 and 0_2 (categories in note (B) to Annex I to Directive 70/156/EEC — 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.
(5) Current status	An amended proposal including the amendments of Parliament withheld by the Commission, is awaited.

(6) Reference

Commission proposal COM(89) 653/III final	Official Journal C 95, 12.4.1990
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: tyre pressure gauges for motor vehicles

(1) Objective	To bring national provisions relating to tyre pressure gauges, including technical specification, closer together so as to facilitate intra-Community trade in these products.
(2) Community measure	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 robust and careful construction so that they maintain their metrological characteristics; ability to accurately read off the pressure measured; the dial must specify the symbol for the quantity measured, and the symbol for the unit of measurement. (More detail is found in the technical annex). 3. No Member State may refuse, prohibit or restrict the marketing and use of tyre pressure gauges if they bear the EC pattern-approval mark.
(4) Deadline for implementing Member State legislation	30.11.1987
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 152, 6.6.1986
(7) Follow-up work	
(8) Commission implementing measure	

2. MOTOR VEHICLES

2.5. 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 EC 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	An amended proposal including the amendments of Parliament withheld by the Commission, is awaited.	
(6) Reference	Commission proposal COM(89) 653/I final	Official Journal C 95, 12.4.1990
	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

2.6. Motorcycle exhaust system noise

(1) Objective	There is an existing Directive which regulates the permissible sound levels of motorcycle exhaust systems. This proposed amendment aims to bring existing national type-approval for motorcycle exhaust systems closer together and to include replacement exhaust systems within its scope.
(2) Community measure	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 EC type-approval certificate. 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 refuse to grant type-approval to a motorcycle which does not comply with the Directive. 5. From 1 October 1990, Member States may prohibit the entry into service of motorcycles whose sound and exhaust levels do not comply with the Directive. 6. Annex containing new conformity testing methods, application for type-approval and markings.
(4) Deadline for implementing Member State legislation	1.10.1989
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 98, 11.4.1989
(7) Follow-up work	
(8) Commission implementing measure	

2. MOTOR VEHICLES

2.7. 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 proposed Directive requires that sides of goods vehicles should be built or equipped with continuous surfaces or rails.
(2) Community measure	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 the 1970 Directive on type-approval of motor vehicles and their trailers) 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 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 referred to in the Annex shall be transmitted to the Member State which carried out the EC type-approval. The Member State may then decide whether to hold fresh tests on the modified type. 3. Annexes containing technical requirements for side protection and application for EC type-approval. Appendix containing model of annex to type-approval certificate with information on side protection. 4. Consultation of a standing committee by the Commission when adapting the Annex to technical progress.
(4) Deadline for implementing Member State legislation	30.10.1989
(5) Date of entry into force (if different from 4)	1.6.1990 and 1.5.1991
(6) Reference	Official Journal L 124, 5.5.1989
(7) Follow-up work	
(8) Commission implementing measure	

2. MOTOR VEHICLES

2.8. Air pollution: exhaust gases

(1) Objective	To reduce car pollution in order to avoid adverse effects such as acid rain. To this end legislation in the field of pollution control was adapted in line with US testing methods. Technical specifications were adapted in order to permit the use of lead-free petrol.
(2) Community measure	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 of earlier legislation 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 refuse to grant type-approval or prevent the entry into service of any vehicle that conforms with the requirements of this Directive. 3. National type-approvals for vehicles whose engines 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. The Commission is to table a new proposal which will further reduce the permitted pollution levels.
(4) Deadline for implementing Member State legislation	1.7.1988
(5) Date of entry into force (if different from 4)	— 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) Reference	Official Journal L 36, 9.2.1988
(7) Follow-up work	See summary 2.11
(8) Commission implementing measure	

2. MOTOR VEHICLES

2.9. Air pollution: exhaust gases from diesel engines

(1) Objective	To approximate the technical requirements of diesel vehicle engines within the Community to combat exhaust pollution and promote the free movement of goods.
(2) Community measure	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, excluding those which run on rails, agricultural tractors and machines, and public works vehicles. 2. From 1 July 1988 Member States may not refuse to grant EC type-approval or prohibit the entry into service of vehicles whose engines satisfy the requirements of this Directive. From 1 October 1990 Member States may prohibit the entry into service of vehicles whose engines do not comply with this Directive. 3. If an engine which has received type-approval is modified, Member States must decide whether fresh tests need to be performed and take appropriate action. If the engine then fails subsequent tests the modifications will not be approved. 4. The procedure to be followed for updating the annexes to take account of technical progress is that laid down in the original 1970 Directive on type-approval of motor vehicles. 5. The technical annexes include detailed information on type-approval procedures; testing procedures (with specification of limits for emission of toxic gases).
(4) Deadline for implementing Member State legislation	1.7.1988
(5) Date of entry into force (if different from 4)	30.9.1990 for particular diesel engines as specified in the Annex.
(6) Reference	Official Journal L 36, 9.2.1988
(7) Follow-up work	On 15 June 1990 the Commission adopted a proposal for a Council Directive amending Council Directive 88/77/EEC (COM(90) 174 final — Official Journal C 187, 27.7.1990). This proposal was drawn up following consultation with experts from the relevant national administrations and from industrial, environmental and consumer protection organizations. The aim of the proposal is to ensure proper protection in the Community for public health and for the environment, to set realistic objectives and to create a firm framework of rules and regulations. The measures being

proposed should impose stricter limits on gaseous pollutants and set limits for particulate emissions. This operation will take place in two stages (1992/93 and 1996/97 respectively).

(8) Commission implementing measure

2. MOTOR VEHICLES

2.10. Air pollution: gas emission standards from diesel engines

(1) Objective	To extend 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 measure	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 pollutant particulate 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 refuse to grant EC type-approval or prohibit the entry into service of vehicles whose engines comply with the Directive. 3. From 1 October 1989, according to the type of vehicle, Member States must refuse EC type-approval and may refuse national type-approval and prohibit entry into service of vehicles whose engines do not comply.
(4) Deadline for implementing Member State legislation	1.10.1988
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 214, 6.8.1988
(7) Follow-up work	See summary 2.12.
(8) Commission implementing measure	

2. MOTOR VEHICLES

2.11. Air pollution: gas emission standards for cars below 1 400 cc

(1) Objective

To amend a previous Directive by introducing more stringent limit values for exhaust gas emissions from cars.

(2) Community measure

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

(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.
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 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 stabilize and subsequently 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 implementing Member State legislation

1.1.1990

(5) Date of entry into force (if different from 4)

(6) Reference

Official Journal L 226, 3.8.1989

(7) Follow-up work	See summary 2.12, also for cars above 1 400 cc
(8) Commission implementing measure	

2. MOTOR VEHICLES

2.12. 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) Proposal

Proposal for a Council Directive amending Directive 70/220/EEC on the approximation of the laws of the Member States relating to measures to be taken against air pollution by emissions from motor vehicles.

(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 Directive 70/220/EEC, 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 Directive 70/156/EEC 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 fot the approval of new types of vehicles are:
CO: 2.72 g/km; HC + NOx: 0.97 g/km; particulates: 0.14 g/km and for any new car:
CO: 3.16 g/km; HC + NOx: 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.

(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 20 December 1990. In the framework of the cooperation procedure, the common position is presently before the European Parliament for a second reading.

(6) Reference	Commission proposal COM(89) 662 final	Official Journal C 81, 30.3.1990
	Amended proposal COM(90) 493 final	Official Journal C 281, 9.11.1990
	Opinion of the European Parliament First reading	Official Journal C 260, 15.10.1990

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 EC-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. From 31 December 1989 any national type-approval will be recognized in all Community countries; it will thus be 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: elements and characteristics

(1) Objective	To harmonize the technical requirements of tractors in all Member States to allow, in particular, implementation of the type-approval procedure laid down in previous legislation, and to promote free trade within the Community.
(2) Community measure	Council Directive 89/173/EEC of 21 December 1988 concerning the approximation of the laws of Member States relating to certain elements 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 of a tractor, refuse its registration or prohibit its entry into service if it complies with the provisions of this Directive. 3. Any amendments that have to be made to the Directive to take account of technical progress shall be adopted by the Commission after it has obtained the opinion of the relevant committee. 4. The annexes contain detailed technical requirements. These include minimum safety margins, weights and dimensions, requirements for the main elements and characteristics of tractors (brakes, engine stopping device, windscreen, etc.)
(4) Deadline for implementing Member State legislation	31.12.1989
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 67, 10.3.1989
(7) Follow-up work	
(8) Commission implementing measure	

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 measure	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 implementing Member State legislation	31.12.1988
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 126, 20.5.1988
(7) Follow-up work	
(8) Commission implementing measure	

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 EC type-approval procedure can be uniformly applied throughout the Community, allowing reciprocal recognition of testing procedures in all the Member States
(2) Community measure	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. those with axle widths of less than 1 150 mm, and unladen weight of between 600 and 3 000 kg. 2. No Member State can prevent the marketing of a tractor, or refuse to grant type-approval, if it satisfies the requirements of the Directive. 3. All tractors covered by the Directive must be fitted with a roll-over protective structure. 4. The Directive will be amended where necessary to take account of technical advances. 5. The annexes deal with type-approval and testing procedures.
(4) Deadline for implementing Member State legislation	26.6.1989
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 220, 8.8.1987
(7) Follow-up work	The Commission presented in 1989 a proposal modifying Directive 87/402/EEC (COM(88) 629 final published in Official Journal C 305, 30.11.1988) which was adopted by the Council on 21 December 1989 (Directive 89/681/EEC, published in Official Journal L 398 30.12.1989).
(8) Commission implementing measure	

4. FOODSTUFFS

Current problems and 1992 objectives

One of the fundamental principles of the European Community, laid down in the EEC Treaty of 1957, is the free movement of goods. The European Court of Justice has upheld this principle on numerous occasions, ruling that the Treaty prohibits any national measure which hinders intra-Community trade. In the well-known 'Cassis de Dijon' case (1979), the Court ruled that the Treaty does not permit Member State laws which prevent the marketing of a product 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 does not eliminate all practical difficulties for exporting manufacturers. The 'Cassis de Dijon' case does not prohibit national laws necessary for the protection of public health and consumer interests. Clearly, such rules cannot always easily be applied to a given set of circumstances. Community-level harmonization of regulations in these areas is necessary. For these reasons, the Community had adopted directives in a number of areas prior to 1985.

However, in the Commission's White Paper of 1985, it was recognized that a genuine common market for food could not be achieved by 1992 if the Community relied exclusively on past methods.

In its communication 'Completion of the internal market: Community legislation on foodstuffs' issued in November 1985, the Commission therefore recommended a new strategy combining:

— sufficient harmonization of national regulations and standards to:
  — protect public health;
  — provide consumers with clear labelling and protection in matters other than health;
  — ensure fair trading;
  — provide for the necessary public controls;
— in all other respects mutual recognition of each Member State's regulations and standards, so that a product acceptable for sale in one country should be acceptable throughout the Community. This follows from the European Court's case-law discussed above.

This new approach was to be implemented in the first instance by horizontal framework directives which lay down the philosophy and controls for a particular area, e.g. additives. These directives would be complemented by specific horizontal directives detailing how these requirements are to be applied to specific segments of a wider area, e.g. flavourings as a category of additives.

In addition, there is a need for commodity or product directives on certain types of foods, e.g. jams. Finally, it is necessary to keep up to date the existing Community management directives in the light of technical progress.

The division of legislative powers between the Council and Commission is of major practical importance. The Commission, advised by the Scientific Committee for Food, draws up and manages the technical and detailed aspects of the directives. This then leaves the Council free to concentrate on the essential political criteria forming the basis of the directives.

To this end seven framework measures were included in the White Paper, all proposed by the Commission (some being amendments to existing horizontal measures). These cover the areas of:

— summaries 4.1 to 4.7: additives;
— summaries 4.8 and 4.9: materials coming into contact with foodstuffs;

— summaries 4.10 to 4.14: labelling;
— summaries 4.15 and 4.16: food for particular nutritional uses;
— summary 4.17: official inspection of foodstuffs;
— summary 4.23: irradiation of foodstuffs.

The Council has now adopted most of these framework measures.

Two further important directives have been adopted on indications or marks identifying the batch to which a foodstuff belongs (Directive 89/396/EEC, Official Journal L 186, 30.6.1989) and on the making-up by volume of certain prepackaged liquids (Directive 89/676/EEC, Official Journal L 398, 30.12.1989)

Proposals for specific directives have been adopted for several categories of additives, as well as the proposal amending provisions on labelling, advertising and packaging.

Further Commission proposals or directives should be adopted over the next two years to provide an accurate expression of the framework directives adopted.

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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 proposal for the framework directive on food additives;
— directives on all specific food additives.

(2) Community measure

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 (a food additive being any substance not normally consumed as a food itself).
2. The Directive prohibits the use of substances not appearing in lists to be established for purposes specified in Annex I, 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 in agreement with 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 which are subsequently considered to carry a health risk.
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 provided that certain conditions are respected, e.g. maximum limit of three years' circulation, official inspection of foodstuffs in which the particular additive is used. Information requirements on labelling and packaging of additives for sale to both the consumer and the manufacturer.

(4) Deadline for implementing Member State legislation

28.6.1990

(5) Date of entry into force (if different from 4)	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) Reference	Official Journal L 40, 11.2.1989
(7) Follow-up work	See summary 4.2. On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	

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 (see 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. Sweeteners may not be used in foods intended for particular nutritional use by infants and young children. 4. Sweeteners may only be used in certain foodstuffs and under certain conditions. 5. The maximum levels indicated in the Annex refer to ready-for-consumption foodstuffs prepared according to the manufacturer's instructions. 6. 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	Not yet delivered.
(5) Current status	The proposal is at present before the European Parliament and the Economic and Social Committee for their opinions.
(6) Reference	Commission proposal COM(90) 381 final — Official Journal C 242, 27.9.1990

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 measure	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 out in the Directive such as purity criteria and percentage composition by weight of additive. 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 additives and where necessary, criteria and methods of analysis of flavourings. 5. By 1 July 1990 labelling rules for flavourings intended for sale to the final consumer will be issued. 6. Procedures to be followed if a Member State believes an authorized flavouring to be dangerous to human health. 7. Labelling requirements for flavourings 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 implementing Member State legislation	21.12.1989
(5) Date of entry into force (if different from 4)	— 22.6.1990 authorization of flavourings complying with the Directive. — 22.6.1991 prohibition of flavourings not complying with the Directive.
(6) Reference	Official Journal L 184, 15.7.1988
(7) Follow-up work	See summary 4.4. On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	

4. FOODSTUFFS

4.4. Additives: flavourings (identification)

(1) Objective

To decide the terms under which flavourings should be identified and rules for using the word 'natural'.

(2) Proposal

Proposal for a Council Directive supplementing 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.

(3) Contents

1. Flavourings intended for sale to the final consumer may not be marketed, unless their labels bear the following required information, which should be easily visible, clearly legible and indelible:
- — either the word 'flavouring' or a more specific name or description of the flavouring;
- — either the statement 'for foodstuffs' or a more specific reference to the foodstuff for which the flavouring is intended;
- — the date of minimum durability;
- — any special requirements in respect of storage and use;
- — instructions for use where required to ensure proper use of the flavouring;
- — the net quality expressed in units of mass or volume;
- — the name or business name and address of the manufacturer or packer, or of a vendor established within the Community;
- — an indication or code identifying a consignment;
- — where the flavouring, or flavourings, are mixed with other substances, a list in descending order of weight in the mixture of:
  - — the flavouring or flavourings in question;
  - — the names of each of the other substances or materials or, where necessary, their EEC numbers.

2. The word 'natural' may be used only for flavourings in which the flavouring component contains exclusively flavouring preparations as defined in the directive.

3. If the sales description of the flavouring contains a reference to a foodstuff or a flavouring source, the word 'natural', or any other word having substantially the same meaning, may not be used unless the flavouring component has been isolated by appropriate physical processes, enzymatic or microbiological processes or traditional food-preparation processes solely or almost solely from the foodstuff or the flavouring source concerned.

4. The particulars provided for in this directive shall be given in terms easily understood by purchasers unless other measures have been taken to ensure that the purchaser is informed.

(4) Opinion of the European Parliament

Not yet required.

(5) Current status

The proposal has now been sent to the Council. The 'net' procedure does not require the opinion of the European Parliament nor that of the Economic and Social Committee.

(6) Reference	Commission proposal COM(90) 408 final	Not yet published in the Official Journal

4. FOODSTUFFS

4.5. Additives: extraction solvents

(1) Objective	To harmonize laws relating to extraction solvents so as to facilitate the free movement of food within the Community, whilst protecting health.
(2) Community measure	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 not listed in the Annex to the Directive nor to those 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. Definition 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. 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 implementing Member State legislation	12.6.1991
(5) Date of entry into force (if different from 4)	

(6) Reference	Official Journal L 157, 24.6.1988
(7) Follow-up work	
(8) Commission implementing measure	

4. FOODSTUFFS

4.6. 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). 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.
(2) Community measure	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. The use of thiabendazole (E 233) is now fully authorized and will no longer be 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 implementing Member State legislation	31.12.1986
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 372, 31.12.1985
(7) Follow-up work	On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	

4. FOODSTUFFS

4.7. 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. This will allow for the re-evaluation of an additive in the light of any new information, the completion of an investigation of a temporarily authorized additive or 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.
(2) Community measure	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	1. Extension of the temporary authorization period for Tragacanth and Karaya gum pending an enquiry. 2. Extension of the temporary authorization 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.
(4) Deadline for implementing Member State legislation	26.3.1988
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 88, 3.4.1986
(7) Follow-up work	On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	

4. FOODSTUFFS

4.8. Materials in contact with foodstuffs

(1) Objective	To supplement existing legislation on food packagings, wrappings etc. This is to be accomplished by: — the proposal for this framework directive on materials in contact with foodstuffs; — directives on certain specific materials coming into contact with foodstuffs.
(2) Community measure	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 and coating substances such as cheese rinds or skins on meat products which may be consumed together with the food do not belong to this category. 2. Materials 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 food. 3. Specific directives will be adopted for plastics, regenerated cellulose film, elastomers and rubber, paper and board, ceramics, glass, metals and alloys and paraffin wax or microcrystalline wax. The directives will include such topics as a list of the authorized substances, conditions of use, purity standards, etc. 4. The Commission will adopt these specific directives after consulting with the Standing Committee on Foodstuffs. 5. When a Member State has grounds to believe that a material endangers human health although it complies with a specific directive that Member State may temporarily suspend the use of that material. The Commission will then examine the grounds and take appropriate action. 6. Requirements for marketing materials and articles coming into contact with foodstuffs, e.g. they must bear an indication that they are for use with food, 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 in indelible ink.
(4) Deadline for implementing Member State legislation	Member States shall, where appropriate, amend their laws, regulations and administrative provisions to ensure that: — trade in products in conformity with the Directive is authorized by 10 July 1990; — trade in products not in conformity with the Directive is prohibited from 10 January 1992.
(5) Date of entry into force (if different from 4)	31.12.1990
(6) Reference	Official Journal L 40, 11.2.1989

(7) Follow-up work	On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	Commission Directive 90/128 of 23 February 1990 concerning 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, as finished products, are intended to or do come into contact with foodstuffs.

4. FOODSTUFFS

4.9. 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 measure	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 implementing Member State legislation	Same as for Directive 82/711/EEC.
(5) Date of entry into force (if different from 4)	Member States are required: — to allow as from 1 January 1991 trade in plastics, articles and materials in conformity with the Directive; — to prohibit as from 1 January 1993 trade in and the use of plastics, articles and materials which come into contact with foodstuffs and are not in conformity with the Directive.
(6) Reference	Official Journal L 372, 31.12.1985
(7) Follow-up work	
(8) Commission implementing measure	

4. FOODSTUFFS

4.10. Labelling: labelling, presentation and advertising

(1) Objective

To amend existing legislation on the labelling of food to end national exemptions. This will improve the flow of information throughout the Community, improve consumer awareness and facilitate trade. This is accomplished by:
— the proposal of this amendment to the existing framework directive on labelling;
— directives on certain specific groups of food.

(2) Community measure

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 mass catering establishments such as restaurants, hospitals and canteens as well as for sale to the final consumer. It does not apply to the authorization or prohibition of the ionizing radiation of foodstuffs. However, any food or ingredient treated in this way must bear a suitable indication.
2. Clarification of requirements for labelling and listed ingredients.
3. Dating regulations do not apply to food such as fresh fruit and vegetables, wines, beverages containing 10% or more by volume of alcohol, solid sugar, etc.
4. Update of annex to the earlier Directive to include aromatizers among products requiring the designation of flavouring.
5. The Commission will adopt specific provisions following consultation with the Standing Committee on Foodstuffs.
6. Indication on the labelling of the drained net weight of foodstuffs presented in a liquid medium (definition of 'liquid medium').
7. Member States may permit until 11 December 1992 the minimum durability period to be expressed in their own territories otherwise than in terms of the date of minimum durability.
8. Ireland, the Netherlands and the United Kingdom may lay down special conditions applicable to milk and milk products in returnable glass bottles.

(4) Deadline for implementing Member State legislation

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 from 20 June 1992.

(5) Date of entry into force (if different from 4)

(6) Reference

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 (document SEC(89) 2151).
(8) Commission implementing measure	On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.

4. FOODSTUFFS

4.11. 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 named.
(2) Community measure	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 implementing Member State legislation	1.5.1988
(5) Date of entry into force (if different from 4)	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) Reference	Official Journal L 144, 29.5.1986
(7) Follow-up work	
(8) Commission implementing measure	

4. FOODSTUFFS

4.12. Labelling: spirituous beverages

(1) Objective	To set out common rules for describing alcoholic drinks. This will facilitate the free movement of these products within the Community whilst ensuring that consumers receive adequate information about the origin, alcohol content and certain other characteristics of products.
(2) Community measure	Council Regulation (EEC) No 1576/89 of 30 May 1989 laying down general rules on the definition, description and presentation of spirituous beverages.
(3) Contents	1. Definitions of generic terms including 'gin', 'rum', 'whisky', and of general terms including 'spirit drink', 'sweetening', 'mixing', 'blending', etc. Spirituous beverages marketed for human consumption may not be described by associating words or phrases such as 'like', 'type'. Certain spirituous beverages will lose their generic names if mixed with ethyl alcohol. 2. Restrictions on the sale of spirituous beverages, 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 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. Regulations concerning the naming and labelling of the products with particular reference to origin and method of manufacture, e.g. the alcoholic strength must be expressed to the nearest half per cent, the name under which the drinks are sold must be supplemented by the term 'mixture' or the term 'blend' where the product has undergone these procedures. 5. Annexes containing maximum levels of impurities in ethyl alcohol of agricultural origin and geographical descriptions for different categories of products. 6. Establishment of a list of geographical indications.
(4) Deadline for implementing Member State legislation	None required.
(5) Date of entry into force (if different from 4)	— 15.12.1989 — 15.6.1989 for Articles 13 to 16.
(6) Reference	Official Journal L 160, 12.6.1989
(7) Follow-up work	

(8) Commission implementing measure	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 spirituous beverages. 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.

4. FOODSTUFFS

4.13. 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 4.14.	
(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 nutrition 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, some of which were accepted by the Commission.	
(5) Current status	The proposal is currently before the Council for a common position.	
(6) Reference	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

4.14. 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 measure

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 five years from the date of notification of this Directive, 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 implementing Member State legislation	— Member States are to permit no later than 1 April 1992 the sale of goods conforming to the present directive. — Member States are to prohibit from 1 October 1993 the sale of goods not conforming to the present directive.
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 276, 6.10.1990
(7) Follow-up work	On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	

4. FOODSTUFFS

4.15. Foodstuffs for particular nutritional uses

(1) Objective

To amend and at the same time replace an existing Directive (77/94/EEC) which has 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 when they are still permitted under the existing Directive. To regulate the free circulation of foodstuffs for particular nutritional uses which will not be covered by existing Directives. This is to be accomplished by:

— this framework directive on food for particular nutritional purposes;
— directives on certain specific groups of food for particular nutritional uses.

(2) Community measure

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 should satisfy the 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. Labelling, presentation and advertising of normal foodstuffs may not use the words 'dietetic' or 'dietary'.
3. Specific provisions for groups of food shall be laid down in specific Directives. These may include compositional requirements, hygienic requirements, list of additives, purity criteria, etc. Specific labelling requirements in addition to those required for foodstuffs in general, e.g. declaration of energy, cabohydrate and fat content.
4. Procedures to be followed if a particular foodstuff, although complying with a specific Directive, is believed to endanger human health.
5. Provisions for the adoption of future specific Directives.

(4) Deadline for implementing Member State legislation

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;
— to prohibit, as from 16 May 1992, trade in products which do not meet the requirements of this Directive.

(5) Date of entry into force (if different from 4)

(6) Reference

Official Journal L 186, 30.6.1989

(7) Follow-up work

On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.

(8) Commission implementing measure

4. FOODSTUFFS

4.16. Foodstuffs for particular nutritional uses: infant and follow-up milks

(1) Objective

To protect infant health by setting the compositional criteria for baby milks, by extending the rules relating to labelling, presentation and advertising of foodstuffs for general consumption as necessary to cover these products conforming with the aims and principles of the International Code of Marketing of Breast-Milk Substitutes.

(2) Proposal

Proposal for a Council Directive on the approximation of the laws of the Member States relating to infant formulas and follow-up milks.

(3) Contents

1. Infant formulas are foodstuffs intended for use as the sole source of nourishment by infants during the first four to six months of their life. Follow-up milks are foodstuffs intended for infants over the age of four months and constituting the milk element in a diversified diet.
2. Marketing of these foodstuffs within the Community shall be permitted only if the products are suitable for the particular nutritional requirements of infants.
3. Infant formulas and follow-up milks must comply with compositional criteria detailed in the Directive.
4. Restrictions on additives to those listed.
5. Labelling requirements, e.g. in the case of follow-up milks, a statement to the effect that the product is only suitable for particular nutritional use by infants over the age of four months.
6. Advertising restrictions for infant formulas, e.g. advertisements shall contain only factual information and shall not create the impression that bottle feeding is equivalent or superior to breast-feeding.
7. Requirement on Member States to keep the public informed about infant and young child feeding.
8. If an authorized substance is believed to endanger human health a Member State may temporarily restrict its use. The Commission will then examine the grounds for its restriction and deliver its opinion and take the appropriate measures.

(4) Opinion of the European Parliament

First reading: Parliament welcomed the spirit of the proposal but stressed that it did not go far enough and recommended several amendments. All of these were incorporated into the amended proposal including a number of restrictions on marketing and advertising.

(5) Current status

(6) Reference

Commission proposal COM(84) 703 final	Official Journal C 28, 30.1.1985
Amended proposal COM(86) 564 final	Official Journal C 285, 12.11.1986
European Parliament opinion First reading	Official Journal C 120, 20.5.1986
Economic and Social Committee opinion	Official Journal C 303, 25.11.1985

4. FOODSTUFFS

4.17. Official inspection of foodstuffs

(1) Objective	To provide for official inspections of food in order to protect the health and economic interests of consumers. To harmonize legislation which will facilitate the free movement of foodstuffs within the Community by establishing mutual confidence between the various systems of inspection in the Member States.
(2) Community measure	Council Directive 89/397/EEC of 14 June 1989 on the official inspection of foodstuffs.
(3) Contents	1. The Directive lays down the general principles for the performance of official inspections of foodstuffs. These consist of the inspection of foodstuffs and materials coming into contact with them to ensure that they conform with the provisions aimed at preventing risks to public health or fraud in the matter of risks and presentation. 2. Procedures concerning the carrying out of inspections both on a regular basis and in those instances when non-conformity is suspected. 3. Items subject to inspection include raw materials, semi-finished products, finished products, cleaning and maintenance products used in the production of foodstuffs, etc. 4. Analysis of samples shall be carried out at official laboratories. 5. Those responsible for carrying out the inspections 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 shall make a report on: — the training provision for food inspectors; — the quality standards for laboratories in charge of inspection and sampling; — the exchange of information between laboratories and persons involved in these inspections. 6. Each year Member States shall draw up forward programmes for sampling of foodstuffs.
(4) Deadline for implementing Member State legislation	20.6.1990
(5) Date of entry into force (if different from 4)	20.6.1991
(6) Reference	Official Journal L 186, 30.6.1989
(7) Follow-up work	On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	In conformity with the measures foreseen by Directive 89/397/EEC, the Commission presented to the Council and the European Parliament, in September 1990, a report relating to the uniform application of this Directive in all Member States (COM(90) 392 final).

4. FOODSTUFFS

4.18. Sampling and analysis of foodstuffs

(1) Objective	To allow the Commission to adopt Community methods for the sampling and analysis of food where necessary.
(2) Community measure	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 should be adopted by the Commission when: — there is a need to ensure that Community law is uniformly applied; — without them there would be a barrier to intra-Community trade. 2. Member States have the right to apply their own testing procedures provided this does not hinder the free movement of products recognized as complying with the Community's regulations. 3. Testing methods believed to be inappropriate may be temporarily suspended pending examination by the Commission.
(4) Deadline for implementing Member State legislation	23.12.1987
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 372, 31.12.1985
(7) Follow-up work	On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	

4. FOODSTUFFS

4.19. Quick-frozen food

(1) Objective

To harmonize Member State laws on quick-frozen foods to facilitate their free movement within the Community.

(2) Community measure

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 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. Compulsory temperatures for quick-frozen foods during storage (3° C), transport and retail display (6° C).
5. Member States shall 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 sales name shall be supplemented by the term 'quick-frozen'.
7. Procedure for adopting methods of sampling and analysis.
8. Transitional period of eight years for local distribution and retail display cabinets.

(4) Deadline for implementing Member State legislation

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.

(5) Date of entry into force (if different from 4)

(6) Reference

Official Journal L 40, 11.2.1989

(7) Follow-up work

On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.

(8) Commission implementing measure

4. FOODSTUFFS

4.20. 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 measure	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 percentage by weight must be stated. 3. Annex containing descriptions and definitions of coffee and chicory extracts to which the Directive applies.
(4) Deadline for implementing Member State legislation	1.1.1987. Products not meeting the requirements of the Directive may nevertheless be sold until 1 July 1988 in order to allow for disposal of existing stocks.
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 372, 31.12.1985
(7) Follow-up work	On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	

4. FOODSTUFFS

4.21. Fruit juices and similar products

(1) Objective	To update existing legislation on fruit juices in the light of technical developments in the production of some juices.
(2) Community measure	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, fruit purée or to 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 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 will decide on these amendments after consulting with the Standing Committee on Foodstuffs.
(4) Deadline for implementing Member State legislation	The Member States shall take the necessary steps to meet the requirements of 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 from 14 June 1991.
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 186, 30.6.1989
(7) Follow-up work	On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	

4. FOODSTUFFS

4.22. 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.
(2) Community measure	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 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 shall be determined where necessary in accordance with Commission procedures. 3. The Directive will be updated to take account of technical progress. The Commission will decide on these amendments after consulting the Standing Committee on Foodstuffs. 4. Obligation on the Commission to propose new Directives on jams containing less than 60% of dried matter. 5. Amendments to annexes, e.g. to allow the use of red fruit juices for the colouring of jams.
(4) Deadline for implementing Member State legislation	— 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.
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 318, 25.11.1988
(7) Follow-up work	On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	

4. FOODSTUFFS

4.23. 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 Directive 79/112/EEC 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 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) Reference

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

4.24. 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 measure

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 implementing Member State legislation

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.

(5) Date of entry into force (if different from 4)

(6) Reference

Official Journal L 186, 30.6.1989

(7) Follow-up work

In September 1990 the Commission adopted a proposal to amend 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 (COM(90) 440 final — Official Journal C 267, 27.10.1990). On 13 December 1990, the Council adopted a common position concerning this proposal.

On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.

(8) Commission implementing measure

5. PHARMACEUTICAL PRODUCTS

Current problems and 1992 objectives

The EC market for pharmaceutical products is still divided into distinct national markets. Although there is a body of Community legislation on the manufacture, testing and marketing of pharmaceuticals and procedures for consultation among the national regulatory authorities, marketing authorizations remain national. National price control and social security refund systems also contribute to the partitioning of the markets.

Since the publication in 1985 of the White Paper 'Completing the internal market', the Council has adopted most of the proposals which constitute a major step towards the establishment of a single European market in pharmaceutical products. In particular, there are new Community rules on the marketing and development of medicines produced by biotechnology and the protection of highly innovative pharmaceutical products (summaries 5.1, 5.2, 5.3 and 5.11).

As well as encouraging research in the pharmaceutical sector, the Commission presented in April 1990 a new proposal which ensures additional protection for new medicinal products by means of the creation of a supplementary protection certificate (summary 5.21).

Another important area that has been tackled by the Commission is the pricing of pharmaceuticals and reimbursement by national social security schemes (summary 5.12).

Two further measures relate to the marketing of proprietary medicinal products (summaries 5.4 and 5.6).

A further package of four Directives adopted in 1989, which was presented to the Council early in 1988, is intended to extend the current Community rules to cover immunological products, products derived from human blood or plasma, radiopharmaceuticals used for diagnostic purposes and generic medicines.

In addition, one of the measures will improve the guarantees of the quality of medicines manufactured in Europe and package information for patients (summaries 5.14 to 5.17).

During 1990, the Council adopted a number of measures amending the current rules relating to veterinary medicines in order to eliminate barriers to trade and improve the guarantees of safety both for the animals treated and for consumers of foodstuffs of animal origin (summaries 5.7 to 5.10).

The Commission has again presented new proposals aimed at improving:

— the protection of innovation in the pharmaceutical sector (summary 5.21);

— the protection of public health by laying down common rules relating to the advertising of medicinal products for human use (summary 5.22);

— the protection of human health by extending Community legislation to include homoeopathic medicines (summaries 5.23 and 5.24).

In addition, the Commission presented on 14 November 1990 a series of four new proposals introducing, in particular, 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 (summary 5.25).

These proposals also seek to promote the marketing and free movement of medicinal products and veterinary medecines (summaries 5.5 and 5.9). The fourth measure will repeal Directive 87/22/EEC, while at the same time introducing interim measures for the authorization and monitoring of high-technology medicinal products (summary 5.2).

5. PHARMACEUTICAL PRODUCTS

5.1. High-technology medicinal products: marketing authorization

(1) Objective	To coordinate Member State procedures 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 liberalize the European market in high-tech medical products.
(2) Community measure	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 coding; any biotechnological process which is deemed to be a significant innovation. 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 on the pharmoco-toxicological analysis, and all available evaluation reports. 4. The Committee has to issue its opinion within a specified time period; the Member State must then inform the Committee of any action it will take (for example, grant, refusal or withdrawal of marketing authorization).
(4) Deadline for implementing Member State legislation	1.7.1987
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 15, 17.1.1987
(7) Follow-up work	
(8) Commission implementing measure	

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 (Official Journal L 15, 17.1.1987) is hereby 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 (COM(90) 283 final — SYN 312) introducing Community procedures for the authorization and monitoring of medicinal products for human and veterinary use (see summary 5.25).
(4) Opinion of the European Parliament	Not yet delivered.
(5) Current status	The proposal is currently being examined by the European Parliament and the Economic and Social Committee prior to the delivery of an opinion.
(6) Reference	Commission proposal COM(90) 283/IV final — Official Journal C 330, 31.12.1990

5. PHARMACEUTICAL PRODUCTS

5.3. Proprietary medicinal products: testing

(1) Objective	Technology advances 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 measure	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 update the legislation on testing to keep pace with technical advancement. It sets up a Committee on 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 implementing Member State legislation	1.7.1987
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 15, 17.1.1987
(7) Follow-up work	
(8) Commission implementing measure	

5. PHARMACEUTICAL PRODUCTS

5.4. Proprietary medicinal products

(1) Objective	When seeking marketing authorization for a new pharmaceutical, the producers 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 measure	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	Cases in which detailed test results are not required to be supplied with applications for marketing authorization: — when 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; — if there is detailed scientific evidence available showing that the constituents of the pharmaceutical have an acceptable level of safety; — when the new product is essentially similar to a product that has been authorized elsewhere in the Community for 6 or 10 years, and is marketed in the Member State in question. However, if the product is to be used differently, new tests must be performed and results provided.
(4) Deadline for implementing Member State legislation	— 1.7.1987 — 1.1.1992 Greece, Portugal and Spain.
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 15, 17.1.1987
(7) Follow-up work	On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	

5. PHARMACEUTICAL PRODUCTS

5.5. Proprietary medicinal products: free circulation

(1) Objective

To harmonize laws, regulations and administrative provisions relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products.

(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 issued by the competent authority of that Member state or by the Community.
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 (see 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 210 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.
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 Agency, in consultation with Member States and interested parties, will draw up guidelines for the collection, verification and presentation of adverse reaction reports. In case of urgency, the Member State concerned may suspend the marketing of a medicinal product, provided the Agency is informed. 12. The Member States will establish a pharmacovigilance system for collecting information about adverse reactions to medicinal products and for the scientific evaluation of such information.	
(4) Opinion of the European Parliament	Not yet given.	
(5) Current status	The proposal is currently before the European Parliament and the Economic and Social Committee for their opinions.	
(6) Reference	Commission proposal COM(90) 283/II final	Official Journal C 330, 31.12.1990

5. PHARMACEUTICAL PRODUCTS

5.6. Proprietary medicinal products: marketing

(1) Objective	To adopt new guidance measures for the marketing of proprietary medicines to facilitate their movement within the Community.
(2) Community measure	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 sets out notes for guidance for the relevant authorities concerning the granting of marketing authorization for pharmaceuticals, 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 pharmaceuticals, (d) testing procedures for a range of pharmaceuticals and guidelines on interpreting the results of such tests.
(4) Deadline for implementing Member State legislation	Not applicable.
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 73, 16.3.1987
(7) Follow-up work	
(8) Commission implementing measure	

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 measure

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. Definition 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, kidney, 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 I to the Regulation.
4. Annex II 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 II 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 III to the Regulation.
6. Annex IV 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 I, II or III of the Regulation.
8. An individual wishing to have an active substance referred to in point 7 above included in Annexes I, II or III 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 I to IV 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 I or III, or if the substance concerned is listed in Annex II.
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 I, II or III shall be prohibited within the Community except in clinical trials which have been approved by the competent authorities.

(4) Deadline for implementing Member State legislation 1.1.1992

(5) Date of entry into force (if different from 4)

(6) Reference Official Journal L 224, 18.8.1990

(7) Follow-up work

(8) Commission implementing measure

5. PHARMACEUTICAL PRODUCTS

5.8. Veterinary medicines: free circulation

(1) Objective

To remove remaining barriers to trade in veterinary medicinal products.

(2) Community measure

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. 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 Directive 81/851/EEC 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 implementing Member State legislation

1.1.1992

(5) Date of entry into force (if different from 4)

(6) Reference

(7) Follow-up work

(8) Commission implementing measure

5. PHARMACEUTICAL PRODUCTS

5.9. Veterinary medicines: free circulation

(1) Objective

To harmonize the laws of the Member States relating to veterinary medicinal products in order 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 in respect of veterinary medicinal products.

(3) Contents

1. No veterinary medicinal product may be placed on the market of a Member State unless an authorization has been issued by the competent authority of that Member State or by the Community.
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 (see 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 210 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, on application at least three months before the expiry date.
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 Agency, in consultation with Member States and interested parties, will draw up guidelines for the collection, verification and presentation of adverse reaction reports. In case of urgency, the Member State concerned may suspend the placing on the market of a veterinary medicinal product, provided the Agency is informed. 12. The Member States will establish a pharmaco-vigilance system for collecting information about adverse reactions to veterinary medicinal products and for the scientific evaluation of such information.
(4) Opinion of the European Parliament	Not yet given.
(5) Current status	The proposal is currently before the European Parliament and the Economic and Social Committee for their opinions.
(6) Reference	Commission proposal COM(90) 283/III final — Official Journal C 330, 31.12.1990

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 measure

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 Directive 81/851/EEC 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 implementing Member State legislation

1.1.1992

(5) Date of entry into force (if different from 4)

(6) Reference

Official Journal L 373, 31.12.1990

(7) Follow-up work

(8) Commission implementing measure

5. PHARMACEUTICAL PRODUCTS

5.11. Veterinary medicines: testing standards

(1) Objective	The technology of veterinary medicines advances very quickly 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 measure	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 update the legislation to take account of scientific advances. 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, and toxicological and pharmacological tests.
(4) Deadline for implementing Member State legislation	1.7.1987
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 15, 17.1.1987
(7) Follow-up work	
(8) Commission implementing measure	

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, as interpreted by the Court of Justice, and as the Commission intends to apply them in the area of price controls and reimbursement of medical products.
(2) Community measure	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 medical 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: that is to say they must be based on their 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 implementing Member State legislation	Not required.
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal C 310, 4.12.1986
(7) Follow-up work	
(8) Commission implementing measure	

5. PHARMACEUTICAL PRODUCTS

5.13. Pricing

(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 measure	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 within the scope of the national health insurance systems.
(3) Contents	1. The definition of medicinal products to be found in Directive 65/65/EEC 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 fixed must be published at least twice a year. 4. Points 2 and 3 also apply to applications for price increases. 5. If a price freeze is imposed on all, or just certain categories, of medicinal products, Member States must ensure that prices are adjusted at least once a year, or when the retail price index increases by more than 10%. Manufacturers may request exemptions from price freezes. 6. Where a Member State imposes controls on the profitability of pharmaceutical manufacturers or importers, certain information has to be given to the Commission, e.g. target profitability, definition of profit etc. 7. Member States have to publish a list of all medicines where the cost is reinvested or otherwise borne 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 their systems of classification of medicinal products; the Commission may produce future legislation to harmonize such classification systems. In addition, the Commission will table a proposal 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 implementing Member State legislation	31.12.1989
(5) Date of entry into force (if different from 4)	

(6) Reference

Official Journal L 40, 11.2.1989

(7) Follow-up work

(8) Commission implementing measure

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 measure	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 the prescription of an authorized health care professional for an individual patient. 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 itself. 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 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 demand a second inspection. 7. The principles and guidelines of good manufacturing practice will be the subject of a future Commission directive and detailed guidelines to be published by the Commission. 8. The person responsible for the marketing of a medicinal product 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 implementing Member State legislation	1.1.1992
(5) Date of entry into force (if different from 4)	

(6) Reference

Official Journal L 142, 25.5.1989

(7) Follow-up work

(8) Commission implementing measure

5. PHARMACEUTICAL PRODUCTS

5.15. Immunological medicinal products

(1) Objective	To extend the scope of previous directives relating to proprietary medicinal products to include immunological medicinal products, allergen products, vaccines, toxins, and serums.
(2) Community measure	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. Product documents using 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 the 1975 Directive on analytical, pharmaco-toxicological and clinical standards and protocols to take account of the specific characteristics of these products.
(4) Deadline for implementing Member State legislation	1.1.1992
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 142, 25.5.1989
(7) Follow-up work	
(8) Commission implementing measure	

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 measure	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 plasma.
(3) Contents	1. Definition of medicinal products derived from human 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 plasma shall be expressed by mass or by units of biological activity. 3. Member States shall take measures to prevent the transmission of infectious diseases. These shall at least 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 when human blood is traded, the origin of the blood donation centre is always clearly identified. 5. Every guarantee must be given as to the safety and purity of imports of human blood from countries outside the Community. 6. Member States shall promote the self-sufficiency of the Community in human blood. Voluntary unpaid donation of blood shall be encouraged. 7. Member States are required to ensure that the manufacturing 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 implementing Member State legislation	1.1.1992
(5) Date of entry into force (if different from 4)	

(6) Reference	Official Journal L 181, 28.6.1989
(7) Follow-up work	
(8) Commission implementing measure	

5. PHARMACEUTICAL PRODUCTS

5.17. Radiopharmaceuticals

(1) Objective	To extend the scope of previous directives relating to proprietary medicinal products to include radiopharmaceuticals.
(2) Community measure	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. Definition 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 has a further information requirement. This is a general description of the system, a detailed description of the components and qualitative and quantitative particulars of the eluate. 4. The summary of product characteristics for radiopharmaceuticals must include full details of radiation dosimetry, instructions for preparation and storage. 5. 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 the 1975 Directive on analytical, pharmaco-toxicological and clinical standards and protocols to take account of the specific characteristics of these products
(4) Deadline for implementing Member State legislation	1.1.1992
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 142, 25.5.1989
(7) Follow-up work	
(8) Commission implementing measure	

5. PHARMACEUTICAL PRODUCTS

5.18. Rational use of medicinal products: wholesale distribution

(1) Objective	Rational use of medicinal products for human consumption. The proposal for a 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 proposal 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. They are obliged to keep records of each entry for three years for inspection purposes. 6. If need be, the Commission will publish guidelines on good practice and, where appropriate, will consult for this purpose the Pharmaceutical Committee.
(4) Opinion of the European Parliament	Not yet delivered.
(5) Current status	The proposal is currently before the European Parliament for opinion.
(6) Reference	Commission proposal COM(89) 607/I final — Official Journal C 58, 8.3.1990 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 legal status surrounding the supply of medicinal products for human consumption.
(3) Contents	1. The proposal concerns the legal status surrounding the supply of medicinal products for human consumption, these being defined in Directive 65/65/EEC. It sets out the concepts of 'legal status surrounding supply' and 'medical prescription'. 2. The directive will prescribe the approximation of the classification criteria for medicinal products used by the Member States, these being, amongst others, toxicity, side effects, tolerance, risk of dependence, risk of abuse and drug addiction, novelty of the product, etc. It will classify in four categories the medicinal products which may only be supplied on prescription in the marketing authorization: renewable issue, non-renewable issue unless expressly stated on the prescription, special prescription (medicinal products containing substances classified as narcotics or psychotropic), restricted prescription (hospital environment and specialists). 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. When authorizing the marketing of a medicinal product the competent authorities will lay down the legal status surrounding the supply of the medicinal product. 5. Within a period of two years the Member States must communicate to the Commission and the other Member States a list of medicinal products requiring medical prescription. Any changes are notified each year. Within a period of four years the Commission will report to the Council on the application of the Directive.
(4) Opinion of the European Parliament	Not yet delivered.
(5) Current status	The proposal is currently before the European Parliament for its opinion.
(6) Reference	Commission proposal COM(89) 607/II final — Official Journal C 58, 8.3.1990 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 (Directive 65/65/EEC, as amended by Directive 89/341/EEC, and Directive 75/319/EEC, as amended by Directive 89/341/EEC), 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, 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 in particular the name of the product, its composition, the name and address of the person responsible for marketing the product, the side effects, the precautions on use, the medicinal interactions, the particular situation of different categories of user (infants, pregnant women, elderly persons, etc.), the dose, the method and frequency of administration, the length of treatment, what action to take in the case of an overdose, the way to terminate the treatment, a description of undesirable effects and the expiry date.
4. If need be, the Commission will publish guidelines on the formulation of certian precautionary measures, the particular need for information on self-medication, the legibility of the particulars and the use of bar codes. To this end the Commission will consult the Committee for Proprietary Medicinal Products.

(4) Opinion of the European Parliament

Not yet delivered.

(5) Current status

The proposal is currently before the European Parliament for its opinion.

(6) Reference

Commission proposal COM(89) 607/III final	Official Journal C 58, 8.3.1990
Economic and Social Committee opinion	Official Journal C 225, 10.9.1990

5. PHARMACEUTICAL PRODUCTS

5.21. 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 10 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. Definition 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 Directive 65/65/EEC or Directive 81/851/EEC.
3. The certificate is issued if the following conditions are satisfied: firstly, the product must be protected by a patent in force, termed a 'basic patent' in the Member State in which the application is submitted. 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.
4. 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 basic patent.
5. The certificate confers the same rights as are conferred by the basic patent and is subject to the same limitations.
6. 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.
7. 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.
8. The duration of the certificate may not exceed 10 years. By this means, effective protection for innovative medicinal products will be extended to a maximum of 16 years.
9. 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 subject of the certificate is not covered by a basic patent.

(4) Opinion of the European Parliament	First reading: Parliament approved the Commissions proposal including certain amendments. The Commission did not accept these amendments.	
(5) Current status	The proposal is before the Council for a common position.	
(6) Reference	Commission proposal COM(90) 101 final	Official Journal C 114, 8.5.1990
	European Parliament opinion First reading	Not yet published.

5. PHARMACEUTICAL PRODUCTS

5.22. 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:
— must be compatible with the particulars listed in the summary product characterisitics;
— must encourage the rational use of the medicinal product;
— must not be misleading, within the meaning of Council Directive 84/450/EEC.
2. The following are prohibited:
— advertising to the general public of medicinal products which are only available on medical prescription;
— the mention in advertising to the general public of therapeutic indications for which self-medication is not suitable;
— the distribution of samples free of charge to the general public.
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 the information necessary for correct usage of the medicinal product or, failing this, an express invitation to read the package leaflet carefully;
— must not contain elements incompatible with the rational use 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:
— the particulars listed in the summary of product characteristics;
— the legal prescription status;
— the retail price;
— conditions of coverage by social security systems.
Advertising relating to recall is, however, authorized.
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	Not yet given.	
(5) Current status	The proposal is currently before Parliament for its opinion.	
(6) Reference	Commission proposal COM(90) 212 final	Official Journal C 163, 4.7.1990
	Economic and Social Committee opinion	Not yet published in the Official Journal.

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 Directive 65/65/EEC. The products must be identified by the inclusion on their labels of the words 'homeopathic medicinal product'. 2. 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. 3. The manufacture, control, importation and exportation of homeopathic medicinal products are subject to the provisions of Directive 75/319/EEC. The surveillance measures and sanctions provided for in Directive 75/319/EEC are also applicable to these products. 4. 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. 5. 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. 6. The labelling and packaging of the products referred to at 5 above must bear no information other than that set out in the directive, except for therapeutic indications. 7. Applications for simplified registration submitted by the person responsible for marketing may cover a series of preparations derived from the same homeopathic stock. Such applications must be accompanied by documents demonstrating the pharmaceutical quality and batch-to-batch consistency of the products concerned. 8. Other homeopathic 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.
(4) Opinion of the European Parliament	Not yet delivered.
(5) Current status	The proposal is currently before Parliament for its opinion.
(6) Reference	Commission proposal — Official Journal C 108, 1.5.1990 COM(90) 72 final 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. 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. 3. The manufacture, control, importation and exportation of homeopathic veterinary medicinal products are subject to the provisions of Directive 81/851/EEC. The surveillance measures and sanctions provided for in Directive 81/851/EEC are also applicable to these products. 4. 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. 5. 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. 6. The labelling and packaging of the products referred to at 5 above must bear no information other than that set out in the directive, except for therapeutic indications. 7. Applications for simplified registration submitted by the person responsible for marketing may cover a series of preparations derived from the same homeopathic stock. Such applications must be accompanied by documents demonstrating the pharmaceutical quality and batch-to-batch consistency of the products concerned. 8. Other homeopathic 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.
(4) Opinion of the European Parliament	Not yet delivered.
(5) Current status	The proposal is currently before Parliament for its opinion.

(6) Reference	Commission proposal COM(90) 72 final	Official Journal C 108, 1.5.1990
	Economic and Social Committee opinion	Not yet published in the Official Journal

5. PHARMACEUTICAL PRODUCTS

5.25. European agency for assessing medicinal products

(1) Objective

Establishment of a European agency responsible for assessing medicinal products ('the Agency'), with a view to providing the Member States and the Community institutions with the best possible scientific advice 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 assessment 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 shall 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 Directive 75/318/EEC.
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 Directive 65/65/EEC.
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. A European agency for the assessment of medicinal products is hereby set up under this regulation. 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.

	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 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	Not yet delivered.
(5) Current status	The proposal is currently being examined by the European Parliament and the Economic and Social Committee prior to the delivery of an opinion.
(6) Reference	Commission proposal COM(90) 283/I final — Official Journal C 330, 31.12.1990

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 appearing in the White Paper 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.

The Community's legislation on the classification, packaging and labelling of dangerous preparations has a similar history, going back to 1973. Again, a Directive relating to restrictions on marketing and use of dangerous substances and preparations was adopted in 1976 and has been amended seven times.

Thus, the measures summarized here represent the latest stage in a dynamic process which must keep pace with the advances in scientific knowledge.

The White Paper programme consists of:

— the implementation of the framework directive in order to extend to the Community some national protection for health purposes (such as polychlorinated biphenyls and asbestos which are covered in summaries 6.1 and 6.2);

— the reorganization of the 1973 Directive in order to cover all dangerous preparations and to update labelling by taking into account any new risks (summary 6.3 covers the Directive in this area which was adopted by the Council in June 1988);

— specific measures for individual chemical products such as detergents and fertilizers (summaries 6.4 to 6.7).

All these proposals have been adopted. 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).

6. CHEMICAL PRODUCTS

6.1. Restrictions on marketing and use of dangerous substances: polychlorinated biphenyls and terphenyls

(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 measure	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 on the use of PCBs and PCTs except under certain conditions: — closed-system electrical equipment transformers, resistors and inductors; — large 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: equipment and plant containing PCBs and PCTs must display instructions concerning their disposal and maintenance.
(4) Deadline for implementing Member State legislation	30.6.1986
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 269, 11.10.1985
(7) Follow-up work	The Commission has put forward an 11th amendment to Directive 76/769/EEC to restrict the marketing and use of certain substitutes developed to replace PCBs and PCTs (COM(89) 665 final, published in Official Journal C 24, 1.2.1990). On 4 December 1990 the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	

6. CHEMICAL PRODUCTS

6.2. Restrictions on marketing and use of dangerous substances: asbestos

(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 measure	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 on the use of asbestos for: — toys; — preparations applied by spraying; — products in powder form; — items for smoking; — filters and insulation devices for use in catalytic heaters using liquefied gas; — paints and varnishes.
(4) Deadline for implementing Member State legislation	31.12.1987
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 375, 31.12.1985
(7) Follow-up work	On 10 November 1989 the Commission put forward a 10th amendment to Directive 76/769/EEC more especially concerning cadmium (COM(89) 548 final — Official Journal C 304, 4.12.1990). On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	

6. CHEMICAL PRODUCTS

6.3. 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 measure	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, teragenic, 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 indelible marking of the package with the trade name of the preparation and 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 the sale of a product believed to be harmful. 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 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 implementing Member State legislation	26.6.1989

(5) Date of entry into force (if different from 4)	Preparations in conformity with Directives 73/173/EEC and 77/728/EEC may be marketed until 7 June 1992.
(6) Reference	Official Journal L 187, 16.7.1988
(7) Follow-up work	The Commission will put forward a new draft proposal for a labelling guide. On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	— 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. — Commission Directive 90/35/EEC 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 (Official Journal L 19, 24.1.1990). Containers of whatever capacity containing preparations offered or sold to the general public and labelled as very toxic, toxic or corrosive in accordance with Article 7 of Directive 88/379/EEC must be fitted with child-resistant fastenings and carry a tactile warning of danger. Containers of whatever capacity containing preparations offered or sold to the general public and labelled as harmful, extremely flammable or highly flammable in accordance with Article 7 of Directive 88/379/EEC must carry a tactile warning of danger. These fastenings and warnings must conform to the specifications in Parts A and B of Annex IX to Directive 67/548/EEC (Official Journal 196, 16.8.1967). Date of entry into force: 10.6.1991.

6. CHEMICAL PRODUCTS

6.4. 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 measure	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, ployols, 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 metal-working industries.
(4) Deadline for implementing Member State legislation	
(5) Date of entry into force (if different from 4)	Exemptions for certain detergents extended until 31 December 1989.
(6) Reference	Official Journal L 80, 25.3.1986
(7) Follow-up work	On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	

6. CHEMICAL PRODUCTS

6.5. Marketing of fertilizers: liquid fertilizers

(1) Objective	To extend the laws on the marketing of fertilizers to include liquid fertilizers.
(2) Community measure	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. Lists of fluid fertilizers, type designation, data on method of production, minimum content of nutrients, nutrient content to be declared and any other relevant data.
(4) Deadline for implementing Member State legislation	25.3.1989
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 83, 29.3.1988
(7) Follow-up work	
(8) Commission implementing measure	

6. CHEMICAL PRODUCTS

6.6. 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 measure	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. Declaration of the magnesium, sodium and sulphur content of fertilizers must be made. 2. Declaration of calcium content considered to be a nutrient need only 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. Annex containing list of fertilizers containing calcium, magnesium and sulphur as principal nutrients.
(4) Deadline for implementing Member State legislation	17.4.1990
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 111, 22.4.1989
(7) Follow-up work	
(8) Commission implementing measure	

6. CHEMICAL PRODUCTS

6.7. Marketing of fertilizers: trace elements

(1) Objective	To extend existing Community legislation on fertilizers (see summaries 6.5 and 6.6) to include specific nutrients in fertilizers.
(2) Community measure	Council Directive 89/530/EEC of 18 September 1989 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 implementing Member State legislation	18.3.1991
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 281, 30.9.1989
(7) Follow-up work	
(8) Commission implementing measure	

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 EC 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	The aim of this Directive is to harmonize national legislation relating to tower cranes, so as to remove differences that constitute trade barriers. It is also intended to consolidate all the legislation relating to this subject into one Directive making the requirements more comprehensible.
(2) Community measure	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/pW (to be reduced to 100 dB/pW in 1992); the sound pressure level at the operator's position must not exceed 85 dB/Pa (to be reduced to 80 dB/Pa in 1992). 3. Cranes which satisfy the requirements must bear a mark indicating the sound-power and sound-pressure levels, 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 implementing Member State legislation	— 26.12.1988 for standards of 102 dB (pW) — 26.6.1989 for standards of 85 dB (Pa) — 26.6.1992 for standards of 100 dB (pW) and 80 dB (Pa)
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 220, 8.8.1987
(7) Follow-up work	
(8) Commission implementing measure	

7. CONSTRUCTION

7.2. Fire safety in hotels

(1) Objective	To ensure that all hotels throughout the Community are covered by minimum safety requirements.
(2) Community measure	Council Recommendation 86/666/EEC of 22 December 1986 on fire safety in existing hotels.
(3) Contents	1. Member States are recommended to ensure that fire precautions in hotels should, at the very least, satisfy certain minimum requirements. For example, safe escape routes should be available, unobstructed, and clearly marked; buildings should be stable enough to allow adequate time for the evacuation of occupants; warning systems should be installed and in full working order; staff should be given suitable training. 2. The annex contains technical guidelines for the construction of hotel buildings. 3. Member States are advised 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 meet the above requirements.
(4) Deadline for implementing Member State legislation	Not applicable.
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 384, 31.12.1986
(7) Follow-up work	
(8) Commission implementing measure	

7. CONSTRUCTION

7.3. Construction products

(1) Objective	To harmonize national legislation in the domain of health and safety requirements of construction products. To set out those essential requirements which will eventually form the basis of European standards. To enable the Commission to adopt guidelines in line with the new approach to harmonization before the actual standardization process is complete.
(2) Community measure	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 products with a view to their incorporation in construction works, e.g. cement, tiles, doors, drainage, etc. 2. All products must be fit for their intended use and meet other essential requirements concerning stability, safety in the case of fire, hygiene, safety in use, protection against noise and economy of energy during an economically reasonable working life. 3. European standards for construction products shall be established by the European standardization bodies following consultation with the Standing Committee for Construction (which is established by the Directive). 4. System of European technical approval designed to assess new products in the light of the essential requirements mentioned in point 2. 5. Where neither a European standard nor guidelines for European technical approval yet exist products may be assessed in compliance with national requirements. 6. Products which bear the EC mark shall be assumed to conform with requirements. Inspection for conformity according to the relevant decisions by the Standing Committee. 7. Products conforming with required standards, but which are thought to present a safety threat, may be temporarily withdrawn from the market. 8. Annexes containing information including details of the essential requirements, European technical approval procedure and procedures for ensuring that approved products conform with appropriate requirements.
(4) Deadline for implementing Member State legislation	27.6.1991
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 40, 11.2.1989

(7) Follow-up work	Interpretative documents will be drawn up by a standing committee and published by the Commission in the Official Journal, 'C' series.
(8) Commission implementing measure	

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.

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 measure	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 implementing Member State legislation	4.12.1989
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 344, 6.12.1986
(7) Follow-up work	
(8) Commission implementing measure	

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 measure	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 88/181/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 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. Directive 88/180/EEC 1. The Directive enlarges the field of application of Directive 84/538/EEC 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.
(4) Deadline for implementing Member State legislation	1.7.1991
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 81, 26.3.1988
(7) Follow-up work	
(8) Commission implementing measure	

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 measure	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. 6. The Commission will submit to the Council before 29 June 1990 a proposal aimed at introducing the real, dynamic method of measurement of airborne noise thus superseding the stationary method used at present.
(4) Deadline for implementing Member State legislation	24.12.1988. 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 4)	
(6) Reference	Official Journal L 384, 31.12.1986
(7) Follow-up work	
(8) Commission implementing measure	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. Good laboratory practice (GLP)

(1) Objective	To ensure that laboratories in all Member States claiming to follow good laboratory practice (GLP) are subject to regular controls by public authorities. This will allow for mutual recognition of test results throughout the Community.
(2) Community measure	Council Directive 88/320/EEC of 9 June 1988 on the inspection and verification of good laboratory practice.
(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. The principles of good laboratory practice (GLP) to be followed are found in Directive 87/18/EEC. 2. Member States must designate particular authorities to carry out inspections of laboratories. 3. Every year a report must be produced 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 implementing Member State legislation	1.1.1989
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 145, 11.6.1988
(7) Follow-up work	
(8) Commission implementing measure	In December 1989 the Commission adopted a Directive adapting to technical progress the Annex to Directive 88/320/EEC (Commission Directive 90/18/EEC, published in Official Journal L 11, 13.1.1990). 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	There are some toys which look like sweets, or can easily be confused with foodstuffs, which 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 measure	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 and 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 prohibit the marketing, import and manufacture or export of such products. 3. Checks must be carried out to ensure that such products are not sold. 4. If a Member State bans a product under the terms of this Directive it must inform the Commission and provide relevant information so that other Member States can be informed.
(4) Deadline for implementing Member State legislation	26.6.1989
(5) Date of entry into force (if different from 4)	
(6) Reference	Official Journal L 192, 11.7.1987
(7) Follow-up work	The Directive may be updated by the Council in 1991.
(8) Commission implementing measure	

8. OTHER AREAS

8.6. Cosmetic products

(1) Objective	To improve the existing EEC Regulations relating to the labelling of cosmetic products.
(2) Community measure	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 implementing Member State legislation	31.12.1989
(5) Date of entry into force (if different from 4)	Cosmetic products whose labelling does not comply with the provisions of the Directive may not be marketed after 1 Janaury 1992. Products not complying with the Directive may not be sold to the final consumer after 31 December 1992
(6) Reference	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 — Official Journal L 398, 30.12.1989). A sixth amendment should be adopted by the Commission shortly. A proposal for a consolidated version of Directive 76/768/EEC was adopted by the Commission in October 1990. It consolidates the existing Community provisions concerning the harmonization of cosmetic products (SEC(90) 1985 — Official Journal C 322, 21.12.1990). On 4 December 1990, the Council adopted a Commission proposal of August 1990 on the transitional measures applicable in the new *Länder* of the Federal Republic of Germany in the light of German reunification.
(8) Commission implementing measure	

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 measure	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 of prepackaged foodstuffs as foodstuffs packaged other than in the consumer's presence, and 'unit price', e.g. price per litre for products sold by volume, price per kilo for products sold by weight. 3. Member States may decide that this Directive shall not apply to foodstuffs sold on farms or to private sale. 4. Prices, and where appropriate unit prices, must be indicated on foodstuffs offered for sale to the ultimate 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. Annex containing list of products prepackaged in certain quantities referred to in the Directive.
(4) Deadline for implementing Member State legislation	7.6.1990
(5) Date of entry into force (if different from 4)	7.6.1997. Transitional measures exist in respect of the imperial system used in the UK and in Ireland.
(6) Reference	Official Journal L 142, 9.6.1988
(7) Follow-up work	A Council Resolution of 7 June 1988 requested 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 measure	

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 measure	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, private sale or sale by auction. 2. Prices, and where appropriate unit prices, must be indicated in an unambiguous, easily identifiable and clearly legible manner on products offered for sale to the ultimate consumer. 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. 3. The Directive gives details of which products must display unit prices and those which are exempt, in particular products prepacked in pre-established quantities. 4. Annex containing list of products prepackaged in pre-established quantities referred to in the Directive.
(4) Deadline for implementing Member State legislation	7.6.1990
(5) Date of entry into force (if different from 4)	7.6.1997. Transitional measures exist in respect of the imperial system used in the UK and in Ireland.
(6) Reference	Council adoption — Official Journal L 142, 9.6.1988
(7) Follow-up work	A Council Resolution of 7 June 1988 requested 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 measure	

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