ENGLISH

INTERNAL MARKET

CURRENT STATUS 1 JULY 1994

A NEW COMMUNITY STANDARDS POLICY

The new approach in harmonization

Motor vehicles

Tractors and agricultural machinery

Foodstuffs

Pharmaceutical products

Chemical products

Construction

Other areas

EUROPEAN COMMISSION

Volume 4

JULY 1994

This booklet is one of a series of six publications on the internal market.

The complete series of booklets covers

A common market for services

The elimination of frontier controls

Conditions for business cooperation
Public procurement
Internal market for energy

A new Community standards policy

Veterinary and plant health controls

Community social policy

Luxembourg: Office for Official Publications of
the European Communities, 1994

This booklet: ISBN 92-826-7261-1
Set of six booklets: ISBN 92-826-7298-0

Printed in Belgium

A NEW COMMUNITY STANDARDS POLICY

How to use this booklet

This series of booklets sets out:

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

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

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

This booklet contains:

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

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

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

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

The reader should:

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

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

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

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

Note to the reader

This publication provides a snapshot, as at 1 July 1994, of a situation which is evolving all the time. It was designed as a documentary tool and does not bind the Commission in any way.

EUROPEAN COMMUNITY LEGISLATIVE PROCEDURES

SUMMARY

To gain a better understanding of the information contained in the summaries, it is worthwhile learning about the Community's legislative procedures. Each summary refers to a specific measure desgned to facilitate the creation of the single market. In brief:

(i) the Commission, which enjoys decision-making and implementing powers, has a right of initiative: it draws up proposals, which it submits to the Council;

(ii) the Council consists of members representing each Member State at ministerial level. Jointly with Parliament and the Commission, the Council adopts Community instruments on the basis of these proposals;

(iii) the European Parliament (elected by the citizens of the Community) examines these proposals and participates, within the limits of its powers, in the adoption of Community acts;

(iv) the Economic and Social Committee (consisting of representatives of employers, trade unions and other interest groups) must be consulted on some of these proposals;

(v) the Committee of the Regions, consisting of representatives of local and regional authorities, also has a consultative role in some fields.

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 EC 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

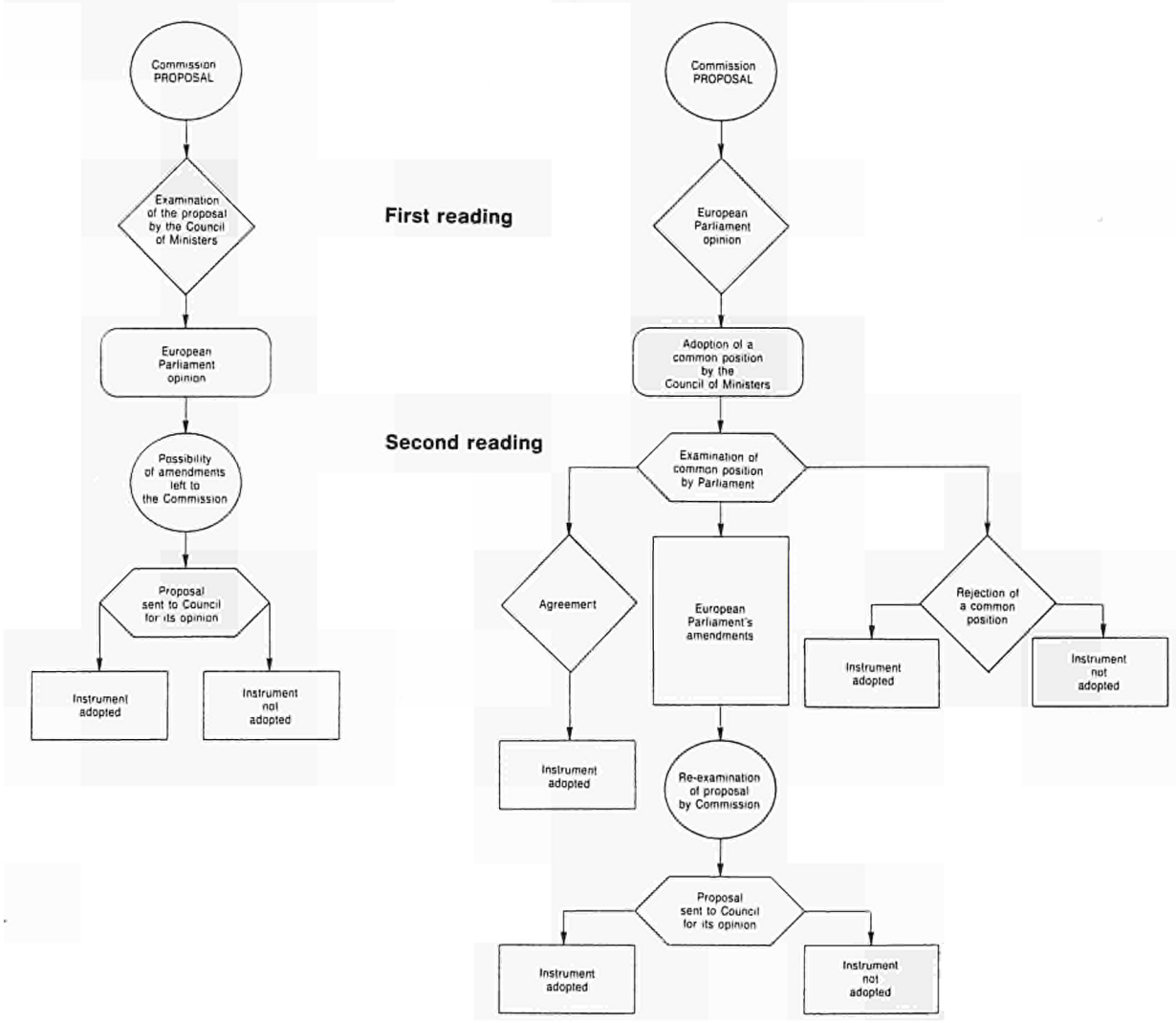
A decision is binding entirely on those to whom it is addressed. No national implementing legislation is required. The decisions summarized in this booklet are Council decisions although in certain cases the Commission has the power to adopt Commission decisions.

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.

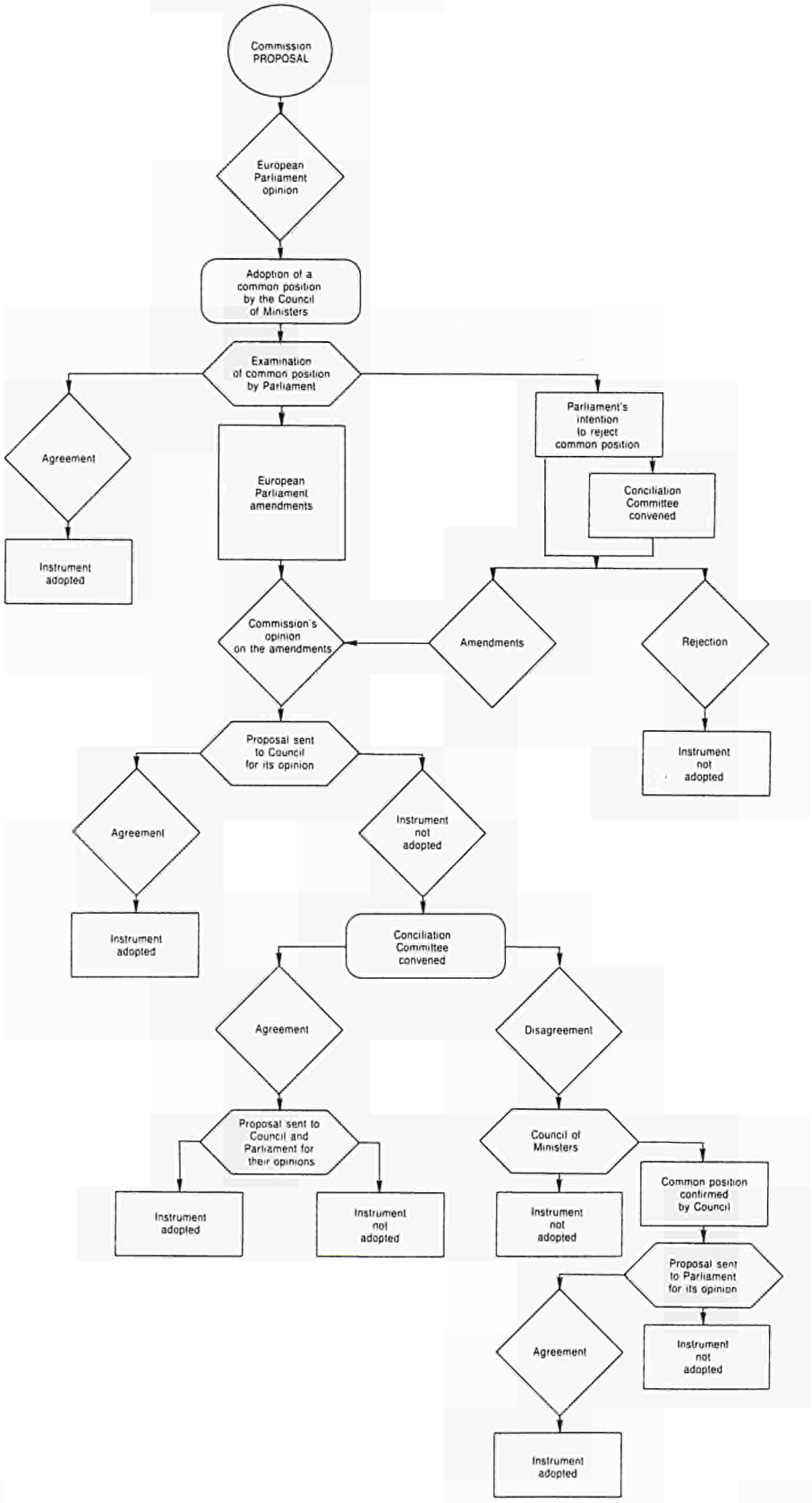
EC legislation from start to finish (directives and regulations)



Co-decision procedure

First reading

Second reading



2. LEGISLATIVE PROCEDURES

The best way of illustrating the Community decision-making procedures is to describe the route leading to the adoption of a legislative instrument. The following text should be read in conjunction with the charts set out above.

Since the Treaty on European Union entered into force on 1 November 1993, four different procedures have existed for the adoption of a legislative instrument: the consultation procedure, the assent procedure, the cooperation procedure and the co-decision procedure.

The procedure to be followed is determined by the article of the EC Treaty on which the proposal is based and each Council instrument starts from a proposal addressed by the Commission to the Council.

Under the consultation procedure, the Council seeks the opinion of the European Parliament and, in most cases, that of the Economic and Social Committee. Once these opinions have been delivered, the Commission may amend its proposal, if it so wishes. The proposal is then examined by the Council, which may adopt it as it stands or after amending it. It can happen that the Council does not reach agreement, in which case the proposal remains 'on the table'.

Parliamentary approval is obligatory in all cases subject to the assent procedure — as regards the exercise of Community citizens' rights of free movement and residence. The instrument is either adopted or rejected. Where it is rejected, the Council has to re-examine the proposal until such time as Parliament gives its assent. Although unable to amend the text submitted to it, Parliament thus enjoys to all intents and purposes a right of veto.

The cooperation procedure allows Parliament to amend a proposal submitted to it not on one, but on two occasions. After consulting Parliament and the Economic and Social Committee and, where appropriate, the Committee of the Regions, the Council has to adopt a common position. This is then transmitted to Parliament, which has three months in which to accept it, reject it or propose amendments in second reading. The Commission re-examines its proposal in the light of Parliament's amendments and sends it to the Council, which has to take a final decision within three months. In the absence of a decision, the proposal will lapse.

The co-decision procedure is a three-phase procedure enabling Parliament to veto the proposals placed before it. It follows the same course as the cooperation procedure up to the second parliamentary reading. It differs from the latter procedure only in so far as it allows for the convening of a committee to elucidate certain aspects of the Council's position in cases where Parliament intends to reject the common position. This committee, which is known as the Conciliation Committee, consists of representatives of the Council and Parliament and involves the Commission in its work. Where Parliament has proposed amendments to the common position, the Commission issues its opinion on those amendments and the text is forwarded to the Council. Within three months (third phase), the Council either adopts the act or convenes the Conciliation Committee, which then has six weeks in which to negotiate a compromise between Parliament and the Council. If an agreement is found, Parliament and the Council can only approve or reject the text. Where there is disagreement, there are two possibilities:

(i) either the proposal lapses;

(ii) or Parliament adopts or rejects the initial common position as reaffirmed, and possibly amended, by the Council.

Prior to the entry into force of the Treaty on European Union, most matters now subject to this procedure were covered by the cooperation procedure: this was the case, for example, with the harmonization of legislation relating to the internal market, the free movement of workers and the mutual recognition of qualifications. The following table provides a full list of the areas falling within the scope of the co-decision procedure.

Scope of co-decision procedure

- Free movement of workers
- Freedom of establishment
- Mutual recognition of qualifications
- Services
- Harmonization of legislation on the internal market
- Education (incentive measures)
- Culture (incentive measures)
- Health (incentive measures)
- Consumer protection
- Trans-European networks (guidelines)
- Research (multiannual framework programme)
- Environment (action programme of a general nature)

The voting procedure within the Council (qualified majority or unanimous vote) depends on the article of the Treaty on which the proposal is based. There are some instances where Council unanimity is automatically required, namely:

(i) where amendments are made to the proposal on the Council's own initiative except in the case of the co-decision procedure Conciliation Committee;

(ii) where amendments are being made which have been proposed by Parliament but not endorsed by the Commission;

(iii) where a measure is being accepted after Parliament has rejected the Council's common position adopted under the cooperation procedure.

Only a limited number of decisions are summarized in this brochure. The European Parliament delivers an opinion on some of them, as do the Economic and Social Committee and the Committee of the Regions.

The same is true of recommendations, the list of which is also limited. In some cases, the European Parliament delivers an opinion before they are adopted and the Economic and Social Committee and the Committee of the Regions are consulted.

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 30 June 1994.

A NEW COMMUNITY STANDARDS POLICY

5. PHARMACEUTICAL PRODUCTS

6. CHEMICAL PRODUCTS

INTRODUCTION

WHY HARMONIZATION OF TECHNICAL STANDARDS AND REGULATIONS?

1957 — Treaty of Rome

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

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

1985 — White Paper

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

1987 — Single European Act

This Act, which entered into force on 1 July 1987, and which amended the EEC Treaty, reaffirmed the aim of achieving an area without borders by 1992 in accordance with the timetable set out in the 1985 White Paper. It adapted the Community's decision-making procedures, and increased the scope for voting by a qualified majority (as opposed to unanimously) within the Council. The Single European Act has facilitated the adoption of the measures set out in the White Paper.

1993 — Treaty on European Union

The Treaty on European Union, which entered into force on 1 November 1993, is part of the process of completing the internal market. It will enable the policies and joint actions accompanying economic integration to be implemented by extending the Community's powers (environment, trans-European networks, consumer protection, education, culture, vocational training), adding to and amending the list of legislative procedures, and transferring responsibility to the Community in matters currently negotiated at intergovernmental level.

The harmonization of national legislation on the creation and functioning of the internal market henceforth comes under the co-decision procedure introduced by the Treaty on European Union.

Current status

Technical standards and regulations

The rules, under the EEC Treaty, intended to remove barriers to the free movement of goods (customs duties, taxes having an equivalent effect, quantitative restrictions and measures

having an equivalent effect, national monopolies, State aid and tax discrimination) do not in themselves enable the free movement of goods to be achieved within the Community.

The same applies to the principle of mutual recognition. According to this principle, all products lawfully manufactured in one Member State must be accepted by the others, even when they have been manufactured in accordance with technical regulations which differ from those laid down by the existing national legislation, provided they meet the conditions of marketing in the originating Member State. This principle is subject to the exception in Article 36 of the EEC Treaty which allows Member States to intervene at national level, in cases where this is justified in order to ensure the protection of their citizens. In the absence of Community-wide legislation each Member State retains the right, subject to certain conditions, to require that imported products which do not comply with the technical regulations laid down for national products, meet, for instance, a level of health or safety protection equivalent to that of national products.

Even where justified these disparities have an impact on the proper functioning of the internal market: the Community therefore turned its attention to eliminating barriers by harmonizing technical specifications for products. This led to the introduction of instruments which had to be highly technical in order to be able to meet the individual requirements of each product category. The Member States were responsible for issuing certificates of conformity before products could be placed on the market, in accordance with the procedures laid down in the Directives. The national authorities had entire responsibility for the type approval of products (checks on conformity). Mutual recognition therefore depended on the degree of confidence which national authorities had in one another.

In order to prevent the creation of fresh technical barriers to trade, therefore, the Community introduced two Community information procedures in 1983 which must be complied with prior to the adoption of any draft technical standards and regulations drawn up nationally. The Commission can issue a mandate to the European standardization bodies to draw up European standards for Community purposes, in particular to ensure compliance with essential requirements. These mandates have the effect of imposing a formal standstill period on all national activities in the field covered by the European mandate. To date, several standardization programmes have been introduced or are being prepared, notably under the 'new approach', with the bulk of standardization activities relating to product specifications. These procedures thus enabled the national authorities and the private sector to legislate or adopt standards at national level, but in a Community context. However, they did nothing to alter traditional methods of legislation, i.e. the very detailed specifications and type-approval procedures which are difficult to implement.

In a communication dated 31 January 1985 the Commission therefore put a new approach concerning technical harmonization and standardization to the Council, which approved this in its resolution of 7 May 1985. The Community legislation no longer contains specific technical rules. Instead, it confines itself to defining and harmonizing, in the technical harmonization Directives, the essential health and safety requirements which industrial products must meet before they can be marketed, leaving the European standardization bodies to devise the technical solutions enabling those aims to be achieved. Products which comply with the technical standards may move freely within the Community, as they are presumed to satisfy the essential requirements which lay down protection levels for the entire Community.

By 1986 it had become clear that, to ensure successful implementation of the 'new approach', the means of certifying products used by a Member State needed to be automatically recognized by the other Member States. This was the intention behind the Commission's communication on a global approach to certification and testing. In 1989 the Council adopted a resolution on conformity assessment which advocated the use of European quality assurance standards transposing international standards, and reorganization of the structures responsible for certification at European level. The Commission subsequently drew up

objective criteria for the functioning and technical evaluation of the testing laboratories and certification bodies in order to bolster the confidence of the authorities. Following this, it examined the conformity assessment procedures to be incorporated in the technical harmonization Directives which, as a general rule, propose a series of equivalent certification procedures, leaving the manufacturer free to choose one or more of them. Products which meet the essential requirements and which have undergone all the appropriate assessment procedures are given the 'EC' marking, the rules on the use of which were harmonized in 1993.

Numerous rules have been adopted under the 'new approach', notably relating to toy and machinery safety, gas appliances, construction products, pressure vessels, hot water boilers, electromagnetic compatibility, low-voltage electrical equipment and telecommunications terminal equipment.

The successful operation of the 'new approach' has led the Commission to apply the principle as systematically as possible, while reconciling it with the legislation existing prior to 1985 in other sectors such as:

— chemical products;
— pharmaceutical products;
— motor vehicles;
— tractors and agricultural machinery;
— foodstuffs and
— construction.

1. THE NEW APPROACH IN HARMONIZATION

Current position and outlook

The removal of technical barriers to trade is a precondition for the completion of the internal market. Since the adoption of the new approach to technical harmonization and standardization in 1985, the harmonization of European industrial standards in the 16 areas covered by European technical legislation has become an essential instrument for the achievement of this objective. This approach was subsequently complemented by a coherent policy on certification and tests, setting out clear, consistent and transparent principles which apply to the product certification procedures to be used at Community level (summary 1.13). The objective is to help establish a European policy on quality in cooperation with national and international standardization bodies to enable businesses to manufacture and sell their products throughout the Community with the aid of a system for the mutual recognition of trade marks and manufacturing processes.

Up to 1985, the texts adopted on technical harmonization were based on a case-by-case approach and contained very detailed specifications with type-approval procedures which were difficult to implement. It was, then, the responsibility of Member States to issue certificates of conformity on the basis of the procedures set out in the Directives in question. The results obtained were unsatisfactory, since the mutual recognition of the certificates depended on the confidence that the various national authorities were able to show in each other.

This new approach, the two fundamental elements of which are the essential requirements and the procedures for assessing conformity, has enabled precisely these difficulties to be overcome: Community legislation is now restricted to establishing the essential requirements that products must meet. These requirements fix thresholds or levels of protection for the whole of the Community in the area of health and safety.

Technical specifications which meet these essential requirements are drawn up on the basis of the Council Resolution of 7 May 1985 setting out a new approach to technical harmonization and to standardization (Official Journal C 136, 4.6.1985) and Directive 83/189/EEC (summary 1.1). This provides for an information procedure covering progress on standardization, as well as a mechanism whereby the Commission can empower the national standardization bodies (CEN, Cenelec, ETSI) to draw up those standards. The effect of this is to impose a 'standstill' on all national work falling within the scope of the European mandate.

These standards are voluntary; manufacturers therefore remain free to offer, on the Community market, products meeting other standards or not meeting any, provided that they satisfy the procedures for assessing conformity laid down by the Directive in question. Products manufactured in accordance with the standards, for their part, are presumed to conform to the essential requirements.

The harmonized certification procedures and the rules governing their use are set out in Decision 93/465/EEC (summary 1.13). These procedures are divided into modules which cover various functions relating to either design, production, or controls. It is, then, possible to carry out tests on a product in various ways. The choice may be made between one, two or more procedures selected for the same category of products.

Products meeting the essential requirements laid down by the Directive(s) in question may be recognized by the EC marking that they bear. The conditions governing the use and affixing of this marking were harmonized in 1993 by Decision 93/465/EEC. The marking thus indicates indirectly that the manufacturer has undergone all the assessment procedures laid down for his product and in return simplifies his obligations with regard to

marking. It makes it easier to carry out controls and above all allows the product to move freely, and be put up for sale and put into service on the Community market.

The Commission intends to continue to develop this policy on quality and, to this end, is currently working on an action plan (extension of the principles of the new approach to the services sector, closer cooperation with international standardization bodies, greater coordination of national actions, and due consideration to quality objectives in all Community policies).

European standardization bodies

CEN (European Committee for Standardization)
Rue de Stassart 36
B-1050 Brussels
Tel.: (02) 519 68 11
Fax: (02) 519 68 19

Cenelec (European Committee for Electrotechnical Standardization)
Rue de Stassart 35
B-1050 Brussels
Tel.: (02) 519 68 71
Fax: (02) 519 69 19

ETSI (European Telecommunications Standards Institute)
F-06921 Sophia Antipolis Cedex
Tel.: (33) 92 94 42 00
Fax: (33) 93 65 47 16

1. THE NEW APPROACH IN HARMONIZATION

1.1. Extension of information procedures on technical standards and regulations

(1) Objective

To eliminate or reduce the barriers to the free movement of goods which can arise from the adoption of national regulations, by encouraging transparency of action at the national level and discipline in the case of joint action.

(2) Community measures

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

Amended by the following measures:
Council Directive 88/182/EEC of 22 March 1988;
European Parliament and Council Directive 94/10/EC of 23 March 1994.

(3) Contents

1. The Directives lay down two information procedures, one for standards and the other for technical regulations on industrial, agricultural, pharmaceutical, cosmetic and food products.
2. Standards information procedure:
- each national standardization body informs the Commission and all the other standardization bodies of its draft standards or amendments to existing standards, except in the case of transposition of an international or European standard;
- the Commission may, after consulting the standing committee responsible for technical regulations and standards, ask the European standardization bodies to prepare specific standards;
- each national standardization body:
  - publishes its draft standards;
  - may take an active or a passive role in the standardization work of another national standardization body;
  - is entitled to receive the requested draft standards and to know what account is taken of comments on the drafts.

3. Technical regulations information procedure:
- notification procedure: each Member State notifies the Commission of:
  - any draft technical regulation and any subsequent amendments thereto, unless the regulation is an integral transposition of an international or European standard, in which case a simple note is sufficient;
  - the text of the basic laws and regulations concerned by the draft regulation;
- standstill period:
  - Member States must refrain from adopting any draft technical regulations for three months from the date of receipt by the Commission, so as to allow the Commission and the other Member States to react to the notification;
  - if the Member States and/or the Commission deliver a detailed opinion, the Member State concerned may not adopt the draft regulation until after the end of the three-month standstill period: it must postpone the adoption of the draft by four months (draft in

the form of a voluntary agreement) or six months (any other draft);
— if the Commission wishes to propose or adopt a Directive, regulation or decision in the same area, or if the draft concerns a subject already covered by a Commission proposal, the Member State concerned must suspend adoption of the draft for 12 months. If the Council adopts a common position during this period, the standstill period is extended by six months (18 months altogether).

4. Derogations from the notification and standstill requirements.

5. Commission report every two years on the implementation of Directive 94/10/EC.

6. List of organizations recognized as European and national standardization bodies.

7. Lists of the standardization work carried out by the European standardization bodies are published once a year in the Official Journal of the European Communities.

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

— Directive 83/189/EEC: 31.3.1984
— Directive 88/182/EEC: 1.1.1989
— Directive 94/10/EC: 1.7.1995

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

(6) References

Official Journal L 109, 26.4.1983
Official Journal L 81, 26.3.1988
Official Journal L 100, 19.4.1994

(7) Follow-up work

On 10 March 1994 the Council adopted a Directive amending for the second time Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations.
The Commission proposes a basic instrument to ensure the correct functioning of the internal market while increasing transparency by extending and making more explicit the scope of Directive 83/189/EEC, by clarifying some concepts and rules of procedure and by providing fuller information for economic operators.

(8) Commission implementing measures

— Commission Decisions amending the lists of standardization bodies contained in the Annex to Council Directive 83/189/EEC:
Decision 90/230/EEC — Official Journal L 128, 18.5.1990
Decision 92/400/EEC — Official Journal L 221, 6.8.1992

— On 8 December 1988 the Commission adopted a report on the implementation of Directive 83/189/EEC in 1984 and 1987 (COM(88) 722 final).

— On 5 April 1991 the Commission adopted a report on the implementation of Directive 83/189/EEC in 1988 and 1989 (COM(91) 108 final).

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

— Notifications of national draft technical regulations received by the Commission:
— Official Journal C 303, 10.11.1993;
— Official Journal C 311, 17.11.1993;
— Official Journal C 324, 1.12.1993;
— Official Journal C 332, 8.12.1993;
— Official Journal C 3, 5.1.1994;
— Official Journal C 8, 12.1.1994;
— Official Journal C 22, 26.1.1994;
— Official Journal C 31, 2.2.1994;
— Official Journal C 39, 9.2.1994;
— Official Journal C 86, 23.3.1994;
— Official Journal C 93, 30.3.1994;
— Official Journal C 95, 6.4.1994;
— Official Journal C 110, 20.4.1994;
— Official Journal C 116, 27.4.1994;
— Official Journal C 122, 4.5.1994;
— Official Journal C 129, 11.5.1994;
— Official Journal C 135, 18.5.1994;
— Official Journal C 143, 26.5.1994;
— Official Journal C 157, 10.6.1994;
— Official Journal C 163, 15.6.1994;
— Official Journal C 169, 22.6.1994;
— Official Journal C 176, 29.6.1994.

1. THE NEW APPROACH IN HARMONIZATION

1.2. Simple pressure vessels

(1) Objective

To ensure the free movement of simple pressure vessels within the Community market by completely harmonizing the safety requirements to which they must conform.

(2) Community measures

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

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

Council Directive 93/68/EEC of 22 July 1993 amending Directive 87/404/EEC, as well as Directives 88/378/EEC, 89/106/EEC, 89/336/EEC, 89/392/EEC, 89/686/EEC, 90/384/EEC, 90/385/EEC, 90/396/EEC, 91/263/EEC, 92/42/EEC and 73/23/EEC.

(3) Contents

1. These Directives apply to simple pressure vessels manufactured in series, i.e. any simple welded vessel:
— of non-alloy quality steel, non-alloy aluminium or non-age hardening aluminium alloys;
— subjected to an internal gauge pressure greater than 0.5 bar;
— which is intended to contain air or nitrogen;
— and which is not intended to be fired.
2. Excluded from the scope of the Directives are:
— vessels specifically designed for nuclear use;
— vessels for installation in or the propulsion of ships and aircraft;
— fire extinguishers.
3. The Directives determine the objectives or 'essential requirements' which simple pressure vessels must satisfy at the time of manufacture and before they are placed on the market.
4. Harmonized European standards are drawn up on the basis of essential requirements by European standardization bodies. These standards, which are not compulsory, are published in the *Official Journal of the European Communities* and transposed in the form of national standards with identical contents.
5. Any vessel manufactured in conformity with the harmonized standards is deemed to satisfy the essential requirements.
6. Procedures for the testing of vessels for conformity with the essential requirements are based on the modular approach set out in Council Decision 93/465/EEC (see summary 1.13). Conformity assessment is carried out:
— either by bodies designated by the Member States in accordance with common assessment criteria and communicated to the Commission and the other Member States;
— or by the manufacturers themselves.
7. Before being placed on the market, vessels must bear the EC conformity marking which:
— indicates their conformity with the provisions of these Directives;
— consists of the distinctive 'EC' initials;

— is affixed by the manufacturer or his authorized representative in the Community.
8. The vessel or data plate must bear, in addition to the EC marking, at least one of the seven additional inscriptions described in the Directive.
9. Where a vessel is the subject of other Directives which require the EC marking, affixation of the marking also indicates that the vessel complies with the requirements of these Directives.
10. Any other mark may be affixed on vessels, unless it risks being confused with the conformity marking.
11. Penalties adopted by the Member States in cases where the latter establish that the EC marking has been affixed unduly.
12. Transitional period from 1 January 1995 (date of entry into force of Directive 93/68/EEC) to 1 January 1997, during which the Member States shall authorize the placing on the market and/or putting into service of vessels which comply with the regulations in force on their territory before 1 January 1995.

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

— Directive 87/404/EEC: 1.1.1990
— Directive 90/488/EEC: 1.7.1991
— Directive 93/68/EEC: 1.7.1994

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

— Directive 87/404/EEC: 1.7.1990
— Directive 93/68/EEC: 1.1.1995

(6) References

Official Journal L 220, 8.8.1987
Official Journal L 270, 2.10.1990
Official Journal L 220, 30.8.1993

(7) Follow-up work

(8) Commission implementing measures

— Communication — Official Journal C 104, 24.4.1992
Commission Communication publishing the titles and references of harmonized standards under Council Directive 87/404/EEC relating to simple pressure vessels as amended by Council Directive 90/488/EEC.

— Communication — Official Journal C 328, 12.12.1992
Commission Communication in the framework of the implementation of Council Directive 87/404/EEC on simple pressure vessels, as amended by Directive 90/488/EEC. Publication of titles and references of harmonized standards under the Directive.

— Communication — Official Journal C 76, 18.3.1993
Commission Communication implementing Council Directive 87/404/EEC relating to simple pressure vessels.
Publication of the list of approved bodies responsible for carrying out the certification procedures referred to in Chapter II of Directive 87/404/EEC.

1. THE NEW APPROACH IN HARMONIZATION

1.3. Toy safety

(1) Objective

To ensure the free movement of toys in the Community market by completely harmonizing the essential safety and health requirements they must conform with.

(2) Community measures

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

Council Directive 93/68/EEC of 22 July 1993 amending Directive 88/378/EEC, as well as Directives 87/404/EEC, 89/106/EEC, 89/336/EEC, 89/392/EEC, 89/686/EEC, 90/384/EEC, 90/385/EEC, 90/396/EEC, 91/263/EEC, 92/42/EEC and 73/23/EEC.

(3) Contents

1. These Directives apply to toys, i.e. any product or material designed or clearly intended for use in play by children of less than 14 years of age.
2. They lay down the safety criteria or 'essential requirements' which toys must meet during manufacture and before being placed on the market.
3. Harmonized European standards have been drawn up on the basis of the essential requirements by the European standardization organizations. These (non-mandatory) standards are notified to the *Official Journal of the European Communities*.
4. Any toy manufactured in conformity with the harmonized standards is presumed to conform with the essential requirements.
5. The procedures for assessing the conformity of toys with the essential requirements are based on the modular approach set out in Council Decision 93/465/EEC (summary 1.13).
The toy conformity assessment must be carried out by:
— organizations designated by the Member States on the basis of common evaluation criteria, and notified to the Commission and the other Member States;
— or by the manufacturers themselves.
6. Before being marketed, toys must be provided with an EC conformity marking which
— symbolizes their conformity with the provisions of these Directives;
— consists of a unique seal or design, namely the EC seal;
— is affixed by the manufacturer or his authorized representative established in the Community.
7. When a toy falls within the purview of other Directives that stipulate the EC marking, the marking must also indicate that the toy conforms with the requirements of these Directives.
8. Any other mark may be affixed to the toy, provided there is no risk of confusion with the conformity marking.
9. Penalties provided for by the Member States if they ascertain that the EC marking has been improperly used.
10. A transitional period from 1 January 1995 (date of entry into effect of Directive 93/68/EEC) to 1 January 1997 during which the Member States authorize the placing on the market and/or in service of toys that conform with the regulations in force on their territory before 1 January 1995.

(4) Deadline for implementation of the legislation in the Member States	— Directive 88/378/EEC: 30.6.1989 — Directive 93/68/EEC: 1.7.1994	
(5) Date of entry into force (if different from the above)	— Directive 88/378/EEC: 1.1.1990 — Directive 93/68/EEC: 1.1.1995	
(6) References	Amending opinion	Official Journal L 187, 16.7.1988 Official Journal L 37, 9.2.1991 Official Journal L 220, 30.8.1993
(7) Follow-up work		
(8) Commission implementing measures	— List of approved bodies published in the *Official Journal of the European Communities* to date: Official Journal C 154, 23.6.1990 Official Journal C 162, 3.7.1990 Official Journal C 278, 6.11.1990 Official Journal C 320, 20.12.1990 Official Journal C 13, 19.1.1991 Official Journal C 32, 7.2.1991 Official Journal C 68, 16.3.1991 Official Journal C 264, 10.10.1991 Official Journal C 272, 17.10.1991 Official Journal C 279, 26.10.1991 Official Journal C 282, 29.10.1991 Official Journal C 307, 27.11.1991 Official Journal C 25, 1.2.1992 Official Journal C 73, 24.3.1992 Official Journal C 97, 16.4.1992 Official Journal C 264, 13.10.1992 Official Journal C 87, 27.3.1993 Official Journal C 237, 1.9.1993 — List of titles and references to harmonize standards under the terms of Directive 88/378/EEC published to date in the *Official Journal of the European Communities* (Official Journal C 129, 11.5.1994).	

1. THE NEW APPROACH IN HARMONIZATION

1.4. Machine safety

(1) Objective

To harmonize the design and manufacture of machinery so as to ensure the safety of workers and other people using machinery.

(2) Community measures

Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery.

Council Directive 93/68/EEC of 22 July 1993 amending Directive 89/392/EEC, as well as Directives 87/404/EEC, 88/378/EEC, 89/106/EEC, 89/336/EEC, 89/686/EEC, 90/384/EEC, 90/385/EEC, 90/396/EEC, 91/263/EEC, 92/42/EEC and 73/23/EEC.

(3) Contents

1. The Directives apply to machinery and lay down essential health and safety requirements. Machinery means a powered assembly with mechanically linked parts of which at least one is movable. Certain types of machinery are excluded from the scope of these measures.
2. Member States must take all appropriate measures to ensure that machinery is marketed and used only if it complies with the Directives, that is if it does not endanger the health or safety of persons, domestic animals or property.
3. Member States may not prohibit, restrict or hinder the marketing and use on their territory of machines which comply with the Directives. Machines bearing the EC marking (see summary 1.13 regarding the EC marking of conformity) and accompanied by the EC declaration of conformity must be considered to be compatible with the essential health and safety requirements.
4. Where a Member State or the Commission considers that the harmonized standards do not fully satisfy the essential health and safety requirements specified in Annex I, the Commission or the Member State will refer the matter to the Standing Committee which must deliver an opinion without delay. The Commission will then notify Member States whether or not it is necessary to withdraw the standards concerned from the relevant publications.
5. Where a Member State ascertains that a machine bearing the EC mark is liable to endanger the safety of persons, domestic animals or property, it must take all the measures necessary to withdraw it from the market. The Member State will then inform the Commission of its action and the reason for its decision.
6. In order to certify machinery in accordance with the essential requirements laid down in the annexes to the Directives, the manufacturer must draw up documentation including a technical construction file composed of overall drawings and detailed drawings, etc. When the machinery conforms to the requirements the manufacturer will issue an EC declaration of conformity.
7. The EC marking will consist of the symbol 'EC'.
8. A more stringent certification procedure is applied to categories of machinery regarded as potentially more hazardous and dangerous.
9. Annexes containing the essential health and safety requirements, an EC declaration of conformity form and a model EC marking.

(4) Deadline for implementation of the legislation in the Member States	— Directive 89/392/EEC: 1.1.1992 — Directive 93/68/EEC: 1.7.1994	
(5) Date of entry into force (if different from the above)	— Directive 89/392/EEC: 1.1.1993 — Directive 93/68/EEC: 1.1.1995	
(6) References		Official Journal L 183, 29.6.1989 Official Journal L 220, 30.8.1993
(7) Follow-up work	See summaries 1.5 and 1.6.	
(8) Commission implementing measures	Commission Communications pursuant to Council Directive 89/392/EEC on machinery, as amended by Directive 91/368/EEC: — Official Journal C 271, 20.10.1992; — Official Journal C 333, 17.12.1992; — Official Journal C 22, 26.1.1993; — Official Journal C 133, 12.5.1993; — Official Journal C 229, 25.8.1993. These Communications contain a list of bodies notified by France to carry out type-examinations under the Directive.	

1. THE NEW APPROACH IN HARMONIZATION

1.5. Machine safety: mobile machinery and lifting appliances

(1) Objective	To ensure protection at the workplace against risks associated with mobile machinery and lifting appliances.	
(2) Community measures	Council Directive 91/368/EEC of 20 June 1991 amending Council Directive 89/392/EEC on the approximation of the laws of the Member States on machinery.	
(3) Contents	1. This Directive concerns the following machinery: machinery creating a hazard as a result of its mobility (i.e. stand-alone mobile machinery and more complex systems such as machinery that is self-propelled, drawn, pushed or carried by other mobile machinery or a tractor), and machinery capable of raising loads comprising not only the independent lifting apparatus but also more complex systems. 2. Cancellation, with effect from 31 December 1994, of Directives 73/361/EEC (in part), 76/434/EEC, and with effect from 31 December 1995, Directives 86/295/EEC, 86/296/EEC, 86/663/EEC and 89/240/EEC. 3. Annex 1 to this Directive first lays down essential health and safety requirements to reduce the specific hazards arising from the mobility of the machinery. Safety requirements are then laid down for the workplace, the controls and indicators, and measures to protect against mechanical and other hazards are defined. 4. Annex 1 of the present Directive also lays down essential health and safety requirements to reduce the specific hazards inherent in lifting operations. These requirements refer first to general protection measures and then to appliances driven by a source of energy other than human power and to marking and the instruction manual.	
(4) Deadline for implementation of the legislation in the Member States	1.1.1992	
(5) Date of entry into force (if different from the above)	1.1.1993	
(6) References		Official Journal L 198, 22.7.1991
	Amended opinion	Official Journal L 305, 6.11.1991
(7) Follow-up work	See summaries 1.4 and 1.6.	
(8) Commission implementing measures		

1. THE NEW APPROACH IN HARMONIZATION

1.6. Machine safety: appliances for lifting persons

(1) Objective	To ensure protection at the workplace against risks associated with machinery for lifting persons.
(2) Community measures	Council Directive 93/44/EEC of 14 June 1993 amending Directive 89/392/EEC on the approximation of the laws of the Member States relating to machinery.
(3) Contents	1. This Directive concerns machinery specifically designed for lifting persons (elevating platforms used for the maintenance of façades of buildings, elevating platforms fitted on lorries, etc.) as well as machinery which, while not designed primarily for lifting persons, nevertheless causes the operator to be lifted in the course of the machine operations. 2. Machinery which entails the risk of falling from a height of more than 3 metres as well as machines for the manufacture of pyrotechnics and certain safety components (ROPs, FOPs, electronically sensitive devices to detect persons, etc.) are required to undergo an EC-type examination. The EC declaration of conformity procedure whereby the manufacturer states that the machinery placed on the market complies with all essential health and safety requirements applies to machinery which is not already mentioned above. 3. This Directive supplements Directive 89/392/EEC on machine safety (summary 1.4) as amended by Directive 91/368/EEC on the safety of mobile machinery and lifting appliances (summary 1.5).
(4) Deadline for implementation of the legislation in the Member States	30.6.1994 except for derogations
(5) Date of entry into force (if different from the above)	1.1.1995
(6) References	Official Journal L 175, 19.7.1993
(7) Follow-up work	See summary 1.4.
(8) Commission implementing measures	

1. THE NEW APPROACH IN HARMONIZATION

1.7. Electromagnetic compatibility

(1) Objective

To ensure the free movement of all electrical and electronic appliances on the Community market through full harmonization of the protection requirements with which they must comply.

(2) Community measures

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

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

Council Directive 93/68/EEC of 22 July 1993 amending Directive 89/336/EEC, as well as Directives 87/404/EEC, 88/378/EEC, 89/106/EEC, 89/392/EEC, 89/686/EEC, 90/384/EEC, 90/385/EEC, 90/396/EEC, 91/263/EEC, 92/42/EEC and 73/23/EEC.

(3) Contents

1. The Directives apply to all electrical and electronic appliances together with equipment and installations containing electrical and/or electronic components likely to create electromagnetic disturbance or whose functioning is liable to be affected by such disturbance.
2. They define the objectives or 'essential requirements' of protection to be complied with in the manufacture of the abovementioned equipment and before marketing.
3. Harmonized European standards are drawn up by the European standardization bodies on the basis of the essential requirements. These standards, which are not mandatory, are published in the *Official Journal of the European Communities* and transposed in their entirety into national standards.
4. Any apparatus manufactured in accordance with harmonized standards is presumed to meet the essential requirements.
5. The procedures for assessing the conformity of appliances with the essential requirements are based on the modular approach set out in Council Decision 93/465/EEC (summary 1.13). Assessment of the conformity of materials is the responsibility of:
— bodies designated by the Member States in accordance with common assessment criteria and notified to the Commission and the other Member States, or
— the manufacturers themselves.
6. Before being placed on the market appliances must bear the EC conformity marking, which:
— indicates conformity with the abovementioned Directives;
— takes the form of the distinctive 'EC' letters;
— is affixed by the manufacturer or his representative established in the Community.
7. Where appliances are also covered by other Directives providing for the EC marking, the presence of the marking on the appliances indicates that they meet the requirements of these Directives.
8. Other marks may also be affixed to appliances, provided there is no risk of confusion with the conformity marking.
9. A safeguard clause setting up a Community procedure and requiring any Member State which has introduced a measure to:

— withdraw from the market,
— ban the placing on the market,
— or restrict the free movement of an appliance which is accompanied by one of the means of attestation provided for in the Directives and which bears the EC marking,
must immediately notify that measure to the Commission.
10. Transitional period from 1 January 1995 (date on which Directive 93/68/EEC enters into force) to 1 January 1997, during which time the manufacturer has the option of:
— placing on the market a product which meets the requirements of the Directives and bears the EC marking, whereby the free movement of the product is ensured even if a more restrictive national regulation is still in force; or
— placing on the market a product which does not meet the requirements of the Directives and does not bear the EC marking. The product must in this case meet the requirements of a law in force on 31 December 1996.
11. Sanctions adopted by the Member States should they find that the EC marking has been affixed unduly.

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

— Directive 89/336/EEC: 1.7.1991
— Directive 92/31/EEC: 1.8.1992
— Directive 93/68/EEC: 1.7.1994

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

— Directive 89/336/EEC: 1.1.1992
— Directive 92/31/EEC: 1.8.1992
— Directive 93/68/EEC: 1.1.1995

(6) References

Amended opinion	Official Journal L 139, 23.5.1989
	Official Journal L 144, 27.5.1989
	Official Journal L 126, 12.5.1992
	Official Journal L 220, 30.8.1993

(7) Follow-up work

(8) Commission implementing measures

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

A Commission communication forming part of the implementation of Directive 89/336/EEC was published on 24 November 1992 (Official Journal C 306, 24.11.1992).
The communication publishes, for information purposes, a list of the bodies in Denmark, Germany, Italy and the United Kingdom notified in pursuance of Directive 89/336/EEC.

1. THE NEW APPROACH IN HARMONIZATION

1.8. Non-automatic weighing instruments

(1) Objective

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

(2) Community measures

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

Council Directive 93/68/EEC of 22 July 1993 amending Directive 90/384/EEC, as well as Directives 87/404/EEC, 88/378/EEC, 89/106/EEC, 89/336/EEC, 89/392/EEC, 89/686/EEC, 90/385/EEC, 90/396/EEC, 91/263/EEC, 92/42/EEC and 73/23/EEC.

(3) Contents

1. Definitions of 'weighing instrument' and 'non-automatic weighing instrument'.
2. The Directives apply 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 marking (see summary 1.13 regarding the EC marking of conformity).
3. Member States must ensure that only those instruments complying with the provisions of the Directives 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 Directives. 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 marking has been affixed to instruments not conforming to the relevant essential requirements.
5. Instruments for which compliance with the essential requirements is mandatory must undergo an EC type-examination, followed by either an EC declaration of production conformity or EC verification. Instruments which do not employ electronic devices and in which the load-measuring device does not use a spring to balance the load do not need to undergo an EC type-examination. If manufacturers so wish, these procedures may also be applied to instruments for which

compliance with the essential requirements is not mandatory. Instruments normally designed for specific applications and for which 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 an EC type-examination, type conformity declaration, EC verification, EC unit verification, technical documentation relating to the project, minimum criteria to be applied in designating the bodies notifed, EC conformity marking and other inscriptions on instruments.

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

— Directive 90/384/EEC: 1.7.1992
— Directive 93/68/EEC: 1.7.1994

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

— Directive 90/384/EEC: 1.1.1993
— Directive 93/68/EEC: 1.1.1995

(6) References

Official Journal L 189, 20.7.1990
Official Journal L 220, 30.8.1993

(7) Follow-up work

(8) Commission implementing measures

— Commission communications in application of Article 9(1) of Council Directive 90/384/EEC on non-automatic weighing instruments:
— Official Journal C 74, 16.3.1993;
— Official Journal C 126, 7.5.1993;
— Official Journal C 244, 8.9.1993.
These communications publish a list of notified bodies and tasks in respect of which they have been notified.

— Commission communications pursuant to Article 5(2) of Council Directive 90/384/EEC on non-automatic weighing instruments:
Official Journal C 104, 15.4.1993;
Official Journal C 153, 4.6.1994.
These communications concern the publication of the titles and references of harmonized standards pursuant to Directive 90/384/EEC.

1. THE NEW APPROACH IN HARMONIZATION

1.9. Active implantable medical equipment

(1) Objective	To harmonize and improve the standard of safety to be met by active implantable electromedical devices used in human medicine.
(2) Community measures	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical equipment. Council Directive 93/68/EEC of 22 July 1993 amending Directive 90/385/EEC, as well as Directives 87/404/EEC, 88/378/EEC, 89/106/EEC, 89/336/EEC, 89/392/EEC, 89/686/EEC, 90/384/EEC, 90/396/EEC, 91/263/EEC, 92/42/EEC and 73/23/EEC.
(3) Contents	1. Definitions of 'medical device', 'active implantable medical device', 'made-to-measure device', 'device intended for clinical investigations', 'destination', 'placing in service'. 2. Member States must not impede the placing on the market, the free movement and the implantation of devices which meet the essential safety requirements specified in the annex and which bear the EC marking (see summary 1.13 regarding the EC conformity marking). Marketing and implantation of devices without the EC marking will be permitted where the device is intended for clinical evaluation or is a prototype intended for research purposes. 3. Obligation on Member States to publish national standards implementing the relevant harmonized standards. Member States must presume that devices complying with the abovementioned harmonized standards comply with the Directives' essential safety requirements. Provisions for those devices and national standards considered not to meet the essential health and safety requirements; consultation with a standing committee and withdrawal of a product from the market or of a standard. Requirement that, as soon as he becomes aware of any such situation as a result of applying technical/monitoring procedures, the manufacturer shall inform the competent authorities of any incident leading to the death or a deterioration in the state of health of the patient. 4. Devices will be subject to a conformity assessment procedure. Member States must designate bodies responsible for such procedures. 5. Annexes containing essential safety requirements for devices, EC type-examination, EC verification, EC declaration of conformity to type, declaration on special-purpose devices, clinical assessment, minimum criteria governing the appointment of the bodies to be notified, copy of the EC conformity marking.
(4) Deadline for implementation of the legislation in the Member States	— Directive 90/385/EEC: 1.7.1992 — Directive 93/68/EEC: 1.7.1994
(5) Date of entry into force (if different from the above)	— Directive 90/385/EEC: 1.1.1993 — Directive 93/68/EEC: 1.1.1995

(6) References	Official Journal L 189, 20.7.1990 Official Journal L 220, 30.8.1993
(7) Follow-up work	
(8) Commission implementing measures	Publication for information of the list of notified bodies within the meaning of Article 11 of Council Directive 90/385/EEC (Official Journal C 209, 3.8.1993).

1. THE NEW APPROACH IN HARMONIZATION

1.10. Medical devices

(1) Objective

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

(2) Community measures

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

(3) Contents

1. This Directive applies to medical devices and accessories, excluding devices used for *in-vitro* diagnosis and the active implantable devices covered by Directive 90/385/EEC (summary 1.9), the medicines covered by Directive 65/65/EEC, the cosmetic products covered by Directive 76/768/EEC, human blood and plasma and human organs and tissues.
2. It contains definitions of the terms: 'medical device', 'accessory', 'custom-made device', 'device intended for clinical investigation', 'device intended for *in-vitro* diagnoses', 'manufacturer', 'intended purpose', marketing', 'placing in service'.
3. The Member States will take all necessary steps to ensure that devices may be placed on the market and put into service only if they in no way compromise the safety and health of patients, users and other persons when properly installed, maintained and used in accordance with their intended purpose.
4. Such devices must meet the essential design and construction requirements set out in Annex 1, particularly with regard to the choice of materials used and the incompatibility with biological tissues and cells, in order to minimize the contamination risk to persons involved in the transport, storage and use of the devices and to patients.
5. The Member States will presume that devices which conform with the national standards implementing the relevant existing harmonized standards comply with the essential requirements. The Member States must publish the references of the national standards implementing the abovementioned harmonized standards.
6. The Member States may create no obstacles to the placing on the market or the putting into service of devices bearing the EC marking (see summary 1.13 regarding the EC marking of conformity). Similarly, they may create no obstacles to devices which do not bear the EC mark but are intended for clinical investigation and use by authorized persons or to custom-made devices meeting the conditions laid down in this Directive.
7. All devices placed on the market, other than custom-made devices or devices intended for clinical investigations, must bear the EC marking of conformity.
8. Any Member State which ascertains that devices complying with the Directive could compromise the health and/or safety of patients, users or other persons must take all appropriate measures to withdraw such devices from the market and must inform the Commission of any such interim measures.
9. Exact reasons must be given for all decisions to refuse or restrict the placing on the market or the putting into service of a device or the carrying out of clinical investigations or to withdraw devices from the market. Such decisions must be notified to the party concerned who

	must be informed of the remedies available and of the time-limits for them. 10. The Directive refers to the Committee on 'Standards and Technical Regulations' and establishes a Committee on 'Medical Devices' to assist the Commission.
(4) Deadline for implementation of the legislation in the Member States	1.7.1994
(5) Date of entry into force (if different from the above)	1.1.1995
(6) References	Official Journal L 169, 12.7.1993
(7) Follow-up work	
(8) Commission implementing measures	

1. THE NEW APPROACH IN HARMONIZATION

1.11. Gas appliances

(1) Objective

To ensure a single Community market in appliances burning gaseous fuels by laying down the essential safety requirements and type-approval rules.

(2) Community measures

Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to gas appliances.

Council Directive 93/68/EEC of 22 July 1993 amending Directive 90/396/EEC, as well as Directives 87/404/EEC, 88/378/EEC, 89/106/EEC, 89/336/EEC, 89/392/EEC, 89/686/EEC, 90/384/EEC, 90/385/EEC, 91/263/EEC, 92/42/EEC and 73/23/EEC.

(3) Contents

1. These Directives apply to:
— appliances burning gaseous fuels and used for cooking, heating, hot water production, refrigeration, lighting and washing, hereinafter referred to as 'appliances'; burners using air under pressure and heating units fitted with such burners are treated as appliances;
— safety and control devices and subassemblies other than burners using air under pressure and heating units fitted with such burners, hereinafter referred to as 'equipment'.
2. Appliances designed specifically for use in an industrial process are excluded from the scope of the Directive.
3. Definitions of 'gaseous fuel' and of 'appliance under normal conditions of use'.
4. Member States must ensure that the appliances specified are only placed on the market or brought into service on condition that they do not jeopardize the safety of persons, domestic animals or property.
5. The appliances and equipment must satisfy the essential requirements stipulated in Annex I.
6. Member States must not prohibit, restrict or impede the placing on the market or the putting into service of appliances which satisfy the essential requirements set out in point 5 above.
7. If a Member State finds that, under normal conditions of use, an appliance fitted with an EC marking (see summary 1.13 regarding the EC marking of conformity) poses a risk to the safety of persons, domestic animals or property, it shall take all the steps necessary to have the appliance withdrawn or to prohibit or restrict the placing on the market of such an appliance. The Member States shall forthwith notify the Commission of these measures.
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 marking, etc.

(4) Deadline for implementation of the legislation in the Member States	— Directive 90/396/EEC: 1.7.1991 — Directive 93/68/EEC: 1.7.1994	
(5) Date of entry into force (if different from the above)	— Directive 90/396/EEC: 1.1.1992 — Directive 93/68/EEC: 1.1.1995	
(6) References		Official Journal L 196, 26.7.1990 Official Journal L 220, 30.8.1993
(7) Follow-up work		
(8) Commission implementing measures	Commission communication as part of the implementation of Council Directive 90/396/EEC relating to appliances burning gaseous fuels (Official Journal C 78, 19.3.1993). This communication publishes the list of identified bodies responsible for implementing the conformity certification procedures referred to in Annex II to Directive 90/396/EEC.	

1. THE NEW APPROACH IN HARMONIZATION

1.12. Personal protective equipment

(1) Objective

To ensure the free movement of personal protective equipment (PPE) within the Community market by completely harmonizing the essential safety requirements to which it must conform.

(2) Community measures

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

Council Directive 93/68/EEC of 22 July 1993 amending Directive 89/686/EEC, as well as Directives 87/404/EEC, 88/378/EEC, 89/106/EEC, 89/336/EEC, 89/392/EEC, 90/384/EEC, 90/385/EEC, 90/396/EEC, 91/263/EEC, 92/42/EEC and 73/23/EEC.

Council Directive 93/95/EEC of 29 October 1993 amending Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment (PPE).

(3) Contents

1. The Directives apply to all PPE:
— any device or appliance designed to be worn or held by an individual for protection against one or more safety and health hazards;
— intended for professional and private use (sport, leisure, domestic use).
Except PPE covered by Directives with the same objectives and PPE specifically referred to in Annex I.
2. These Directives run parallel to the Directive dealing with the choice and use of PPE at the workplace.
3. They define the objectives or 'essential requirements' which PPE must satisfy at the time of manufacture and before it is placed on the market:
— the general requirements applicable to all PPE;
— the additional requirements specific to certain types of PPE;
— and also the additional requirements specific to particular risks.
4. Harmonized European standards are drawn up on the basis of essential requirements by European standardization bodies. These standards, which are not compulsory, are published in the *Official Journal of the European Communities* and transposed in the form of national standards with identical contents.
5. Any PPE manufactured in conformity with the harmonized standards is deemed to satisfy the essential requirements.
6. Procedures for the testing of PPE for conformity with the essential requirements are based on the modular approach set out in Council Decision 93/495/EEC (see summary 1.13).
7. Conformity assessment of PPE is carried out:
— either by bodies designated by the Member States in accordance with minimum assessment criteria and communicated to the Commission and the other Member States;
— or by the manufacturers themselves.
8. PPE providing protection against minimal risks requires only a simple declaration of conformity from the manufacturer.

	9. Before being placed on the market, the PPE must bear the EC conformity marking which: — indicates its conformity with the provisions of these Directives; — consists of: — the distinctive 'EC' initials; — the last two figures of the year in which the marking is affixed, unless otherwise stated; — is affixed by the manufacturer or his authorized representative in the Community. 10. Where a notified body is involved in the production control phase, its identification number is included in the CE marking. 11. Where PPE is the subject of other Directives which require the CE marking, affixation of the marking also indicates that the PPE satisfies the requirements of these Directives. 12. Any other mark may be affixed on the PPE, unless it risks being confused with the conformity markings. 13. Penalties adopted by the Member States in cases where the latter establish that the CE marking has been affixed unduly. 14. Transitional period until 30 June 1995 during which the Member States shall authorize the placing on the market and/or putting into service of PPE which conform to the regulations in force on their territory before 30 June 1992.
(4) Deadline for implementation of the legislation in the Member States	— Directive 89/686/EEC: 31.12.1991 — Directive 93/68/EEC: 1.7.1994 — Directive 93/95/EEC: 29.1.1994
(5) Date of entry into force (if different from the above)	— Directive 89/686/EEC: 1.7.1992 — Directive 93/68/EEC: 1.1.1995
(6) References	Official Journal L 399, 30.12.1989 Official Journal L 220, 30.8.1993 Official Journal L 276, 9.11.1993
(7) Follow-up work	
(8) Commission implementing measures	Commission Communications as part of the implementation of Directive 89/686/EEC: — Official Journal C 44, 19.2.1992; — Official Journal C 345, 23.12.1993. Their purpose is the publication of titles and references of European harmonized standards complying with one or more of the essential requirements of Directive 89/686/EEC.

1. THE NEW APPROACH IN HARMONIZATION

1.13. EEC conformity marking

(1) Objective

To establish harmonized procedures for the assessment of the conformity of industrial products with the levels of protection imposed by the technical harmonization Directives and define common rules for the affixing and use of the EC marking.

(2) Community measures

Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the EC conformity marking, which are intended to be used in the technical harmonization Directives.

(3) Contents

1. This decision repeals Decision 90/683/EEC (Official Journal L 380, 31.12.1990).
2. The decision:
— establishes a range of procedures for assessing the conformity of industrial products to the objectives or 'essential requirements' laid down by the technical harmonization Directives, particularly with regard to safety, public health or consumer protection;
— lays down rules for affixing the EC conformity marking provided for in the technical harmonization Directives concerning the design, manufacture, placing on the market, entry into service or use of industrial products.
3. Assessment of the conformity of industrial products is carried out by bodies designated by the Member States in accordance with the Community procedure for the notification of bodies. The list of such bodies is published in the *Official Journal of the European Communities*.
4. Conformity assessment is generally carried out in two stages which relate to the design phase of products and to their production phase.
5. The decision provides for eight assessment procedures or modules which cover these two phases in a variety of ways:
— internal production control;
— EC type-examination;
— conformity to type;
— production quality assurance;
— product quality assurance;
— product verification;
— unit verification;
— full quality assurance.
6. Additional modules, or variations in the use of these modules, are authorized when the specific circumstances of a particular sector or Directive so warrant.
7. Where the assessment procedure(s) used show(s) that the individual product or a representative example of production satisfies the requirements of the specific Directive that applies to them, the manufacturer or his agent established within the Community must affix the EC marking to each product and draw up a written declaration of conformity.

	8. The EC conformity marking: — has a single form: it consists of the EC mark and of the identification number of the notified body involved in the production control phase; — is affixed to the product itself, to its packaging or to the accompanying document; — enables the product in question to be placed on the Community market, and to circulate freely and be used there. 9. Where an industrial product is subject to other Directives covering other aspects which also provide for the affixing of the EC marking, the latter shall indicate conformity to all the Directives concerned. 10. Any other mark, such as those attesting to conformity with national or European standards, may be affixed to industrial products, unless it is likely to be confused with the EC marking. 11. Member States impose sanctions on manufacturers or their representatives where they find that the EC marking has been improperly affixed. 12. The Commission reports periodically on the functioning of this decision.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	22.7.1993
(6) References	Official Journal L 220, 30.8.1993
(7) Follow-up work	
(8) Commission implementing measures	

1. THE NEW APPROACH IN HARMONIZATION

1.14. Hydraulically and oil-electrically operated lifts

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

1. THE NEW APPROACH IN HARMONIZATION

1.15. Lifts

(1) Objective	To apply uniform rules for all lifts.
(2) Proposal	Proposal for a Council Directive on the approximation of the laws of the Member States regarding lifts.
(3) Contents	1. The proposal for a Directive applies to lifts permanently serving buildings and constructions and the safety components used in such lifts. It does not apply *inter alia* to lifts designed for military purposes, mine lifts or stage lifts. 2. Lifts and safety components must undergo one of the conformity assessment procedures provided for in the Directive, leading to the issue of a declaration of conformity. 3. Lifts and their safety components must satisfy the essential health and safety requirements in respect of their design and construction. These essential requirements cover all the hazards to which lift users may be exposed. The risks incurred by maintenance personnel are covered by Council Directive 89/392/EEC (summary 1.4). 4. Lifts and safety components which satisfy the essential health and safety requirements receive the EC marking of conformity. 5. Lifts bearing the EC marking may be placed on the market in all Member States. However, lifts and their safety components which are liable to endanger the safety of persons may be prohibited from sale or withdrawn from the market. 6. Council Directives 84/528/EEC and 84/529/EEC (Official Journal L 300, 19.11.1984) will be repealed 48 months following adoption of the proposal for a Directive.
(4) Opinion of the European Parliament	First reading: Parliament approved the Commission's proposal subject to certain technical amendments concerning the definition of lifts and procedures for evaluating their conformity to the essential health and safety requirements laid down by the text.
(5) Current status of the proposal	Cooperation procedure The Commission presented the proposal for a Directive on 14 February 1992. First reading: On 29 October 1992 Parliament approved the Commission proposal subject to amendments. The Commission has accepted some of the amendments. The Commission presented an amended proposal on 9 June 1993. On 16 June 1994 the Council adopted its common position. The common position is currently before Parliament for a second reading.
(6) References	Commission proposal COM(92) 35 final — Official Journal C 62, 11.3.1992 Amended proposal COM(93) 240 final — Official Journal C 180, 2.7.1993

European Parliament opinion First reading	Official Journal C 305, 23.11.1992
Economic and Social Committee opinion	Official Journal C 287, 4.11.1992

1. THE NEW APPROACH IN HARMONIZATION

1.16. Electrical equipment for use in potentially explosive atmospheres

(1) Objective	To add new means of protection available for specific equipment which has become available as a result of technical progress.
(2) Community measures	Council Directive 90/487/EEC of 17 September 1990 amending Directive 79/196/EEC on the approximation of the laws of the Member States concerning electrical equipment for use in potentially explosive atmospheres employing certain types of protection.
(3) Contents	1. The means of protection provided for in Directive 79/196/EEC are extended to include encapsulation 'm' and electrical systems with intrinsic safety 'i'. 2. Six new European standards are added to the references to harmonized European standards in Annex I to Directive 79/196/EEC.
(4) Deadline for implementation of the legislation in the Member States	1.7.1992
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 270, 2.10.1990
(7) Follow-up work	The Directive will be cancelled on 1 July 1996 — see summary 1.17. On 15 June 1994 the Commission adopted Directive 94/26/EC adapting to technical progress Council Directive 79/196/EEC on the approximation of the laws of the Member States concerning electrical equipment for use in potentially explosive atmospheres employing certain types of protection (Official Journal L 157, 24.6.1994). This Directive adapts the contents of the harmonized standards referred to in Annex I to Directive 79/196/EEC to which the electrical equipment must conform in the light of the present state of technical progress.
(8) Commission implementing measures	

1. THE NEW APPROACH IN HARMONIZATION

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

(1) Objective

To ensure the free movement of equipment and protective systems intended for use in explosive atmospheres by harmonizing the national provisions.

(2) Community measures

European Parliament and Council Directive 94/9/EC of 23 March 1994 on the forthcoming legislation for Member States on protective devices and systems for use in potentially explosive atmospheres.

(3) Contents

1. The Directive applies to electrical and non-electrical protective devices and systems (surface and mining equipment) used in potentially explosive atmospheres and to items of equipment for use outside potentially explosive atmospheres but which impinge upon devices that are present in any such atmospheres.
2. The Directive does not apply to:
— medical equipment;
— protective devices and systems used on premises where potentially explosive or chemically unstable substances are stored;
— on seagoing ships and mobile offshore units;
— on certain means of transport.
3. Protective devices and systems must meet the essential safety and health requirements. These are divided up into three categories:
— common requirements concerning protective devices and systems;
— additional requirements applying to devices which can trigger an explosion;
— additional requirements for protective systems.
4. The procedures for obtaining the EC conformity marking (summary 1.13) depend upon the device and level of safety provided. The Directive sets out in detail the procedures to be followed with regard to the various categories of protective devices and systems used in potentially explosive atmospheres. These devices are typified by a protection-level scale which determines the type of procedure to be followed.
5. Certain procedures for the assessment and checking of protective devices and systems are carried out by a notified body; a list of these will be published in the *Official Journal of European Communities* together with their identification numbers and the tasks for which they have been notified. Moreover, procedures ranging from unit verification to internal production control by manufacturers are laid down for well-defined conformity categories.
6. The EC conformity marking must be affixed to equipment in a visible manner, together with the identification number of the notified body where the latter is involved in the production control stage. Any other marking may be affixed to equipment provided that the visibility and legibility of the EC marking are not thereby reduced.
7. Equipment and protective systems complying with the Directive and bearing the EC conformity marking are deemed to be able to move freely throughout the European market. However, they may be withdrawn from the market if they adversely affect human or animal health or property.

	8. Transitional period until 30 June 2003 during which Member States will allow the placing on the market and bringing into service of equipment conforming to the provisions in force on their territory on 23 March 1994. 9. With effect from 1 July 2003 this Directive repeals Council Directives 76/177/EEC (Official Journal L 24, 31.1.1976), 79/196/EEC (Official Journal L 43, 20.2.1979), as last amended by Council Directive 90/487/EEC (summary 1.16), and Council Directive 82/130/EEC (Official Journal L 59, 2.3.1982).
(4) Deadline for implementation of the legislation in the Member States	1.9.1995
(5) Date of entry into force (if different from the above)	1.3.1996
(6) References	Official Journal L 100, 19.4.1994
(7) Follow-up work	
(8) Commission implementing measures	

1. THE NEW APPROACH IN HARMONIZATION

1.18. Low-voltage electrical equipment

(1) Objective

To ensure freedom of movement and the placing on the Community market of electrical equipment by harmonizing all the safety requirements that it has to meet.

(2) Community measures

Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits.

Council Directive 93/68/EEC of 22 July 1993 amending Directive 73/23/EEC as well as Directives 87/404/EEC, 88/378/EEC, 89/106/EEC, 89/336/EEC, 89/392/EEC, 89/686/EEC, 90/384/EEC, 90/385/EEC, 90/396/EEC, 91/263/EEC, 92/42/EEC.

(3) Contents

1. These Directives establish the objectives or 'essential requirements' relating to safety applicable to electrical equipment intended:
— for use with a voltage rating of between 50 and 1 000 volts for alternating current and between 75 and 1 500 volts for direct current;
— for trade within the Community;
excluding certain equipment and phenomena.
2. Harmonized European standards are drawn up on the basis of the essential requirements by European standardization bodies. These standards, which are not compulsory, are published in the Official Journal of the European Communities.
3. All electrical equipment which is manufactured in accordance with the relevant harmonized standards is presumed to meet the essential requirements of the Directive.
4. The assessment procedure consists of internal production control (see summary 1.13).
5. Before being placed on the market, the electrical equipment must have affixed to it the EC conformity marking which:
— attests to its conformity to the provisions of these Directives;
— consists of a single design, the initials EC;
— is affixed by the manufacturer or his authorized representative established within the Community.
6. Where the electrical equipment is subject to other Directives which also provide for the affixing of the EC marking, the latter shall indicate that the equipment in question is also presumed to conform to the provisions of those Directives.
7. Any other marking may be affixed to the electrical equipment unless it is likely to be confused with the conformity marking.
8. Procedures and penalties established by the Member States where they find that the CE marking has been improperly affixed.
9. Transitional period from 1 January 1995 (date of entry into force of Directive 93/68/EEC) to 1 January 1997 during which Member States allow the placing on the market and the bringing into service of electrical equipment which conforms to the regulations in force on their territory before 1 January 1995.

(4) Deadline for implementation of the legislation in the Member States	— Directive 73/23/EEC: 21.8.1974, except for derogations — Directive 93/68/EEC: 1.7.1994	
(5) Date of entry into force (if different from the above)	Directive 93/68/EEC: 1.1.1995	
(6) References		Official Journal L 77, 26.3.1973 Official Journal L 220, 30.8.1993
(7) Follow-up work		
(8) Commission implementing measures	Commission communications within the framework of Council Directive 73/23/EEC on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits: Official Journal C 319, 26.11.1993 Official Journal C 169, 22.6.1994 These communications publish the list of standards drawn up by common agreement between the bodies notified by the Member States.	

1. THE NEW APPROACH IN HARMONIZATION

1.19. Recreational craft

(1) Objective

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

(2) Community measures

European Parliament and Council Directive 94/25/EC of 16 June 1994 on the approximation of the laws, Regulations and administrative provisions of the Member States relating to recreational craft.

(3) Contents

1. The Directive applies to all craft intended to be used for sporting and recreational purposes with a hull length of between 2.5 and 24 m and to the items and equipment set out in the annex. The craft must meet the essential requirements, with regard to health and safety and the protection of the environment and consumers, set out in the annex.
2. The Member States must take all necessary action to ensure that recreational craft can only be placed on the market or put into service for their intended purpose if they do not constitute a threat to the health and safety of persons, goods and the environment. They may not prohibit, restrict or impede the marketing or use in their territory of recreational craft which fulfill the provisions of the Directive, including the conformity procedues for the various types of craft, and which bear the 'EC' conformity marking.
3. The Member States assume that recreational craft fulfill the essential requirements of the Directive if they comply with the relevant national standards adopted in accordance with the harmonized Community standards. Any Member State which believes that the harmonized standards do not fully satisfy the essential requirements of the proposed Directive must refer the matter to the Standing Committee set up under Council Directive 83/189/EEC (summary 1.1), stating its reasons. The Commission has the same right.
4. Before recreational craft are produced and marketed, they must, depending on their hull length and production characteristics, undergo one of the procedures (given in the annex) for assessment of their conformity with the provisions of the Directive.
5. The 'EC' marking shown in the annex is to be affixed either by the manufacturer or by his authorized representative established in the Community. It signifies that the craft, its components and equipment comply with the Directive's essential requirements and with the assessment procedures it lays down. Other marks may be affixed to the craft, its components and equipment provided they do not impair the visibility and legibility of the 'EC' marking.
6. Where the products concerned are covered by other Directives relating to other aspects and requiring the 'EC' marking to be affixed, the marking signifies that these products also satisfy the provisions of those other Directives.
7. Transitional arrangements enable recreational craft, their components and equipment to be placed on the market and put into service if they have been manufactured in accordance with the national rules in force when this Directive is adopted.

(4) Deadline for implementation of the legislation in the Member States	16.12.1995	
(5) Date of entry into force (if different from the above)	16.6.1996	
(6) References		Official Journal L 164, 30.6.1994
(7) Follow-up work		
(8) Commission implementing measures		

1. THE NEW APPROACH IN HARMONIZATION

1.20. Pressure equipment

(1) Objective

To ensure the free movement of pressure equipment within the Community market by harmonizing the national safety and health protection requirements to which they are subject.

(2) Proposal

Proposal for a Council Directive on the approximation of the laws of the Member States concerning pressure equipment.

(3) Contents

1. This proposal for a Directive concerns pressure equipment subject to a pressure greater than 0.5 bar (or less than −0.5 bar). Pressure equipment intended for the transport of dangerous goods is not covered by the proposal.
2. The proposal determines the objectives or 'essential requirements' which the abovementioned equipment must satisfy at the time of manufacture and before they are placed on the market; these requirements replace the corresponding national provisions.
3. Council Directive 76/767/EEC (Offical Journal L 262, 27.9.1976) shall be repealed as from 1 July 1996, except as regards the application of Directives 84/525/EEC, 84/526/EEC and 84/527/EEC.
4. Harmonized European standards are drawn up on the basis of essential requirements by European standardization bodies. These standards, which are not compulsory, are published in the *Official Journal of the European Communities*.
5. Procedures for the testing of pressure equipment for conformity with the essential requirements are based on the modular approach set out in Council Decision 93/465/EEC (see summary 1.13). Conformity assessment is carried out by bodies designated by the Member States in accordance with minimum assessment criteria and communicated to the Commission and the other Member States.
6. The assessment procedures depend on the risk inherent in the pressure equipment. Each category of pressure eqiuipment is covered by an appropriate procedure or offers the choice between various equally stringent procedures.
7. The manufacturer shall be solely responsible for establishing the conformity of equipment presenting minor risks.
8. Member States may authorize users to perform certain defined tasks in the assessment of conformity under this proposal for a Directive.
9. Before being placed on the market, pressure equipment must bear the EC conformity marking which:
— shall consist of:
  — the distinctive 'EC' initials;
  — the identification number of the body involved in the production control phase;
— indicates its conformity with the provisions of this proposal and of the other relevant Directives concerning affixation of the EC marking;
— shall not be affixed on equipment presenting a minor pressure risk.
10. Any other mark may be affixed on this equipment unless it risks being confused with the EC marking.

11. Penalties adopted by the Member States in cases where the latter or notified bodies establish that the EC marking has been affixed unduly.
12. Transitional period until 1 July 1999 during which the Member States shall authorize the placing on the market and/or putting into service of pressure equipment which complies with the regulations in force on their territory at the date of adoption of this Directive.

(4) Opinion of the European Parliament

(5) Current status of the proposal

Co-decision procedure

The Commission presented the proposal on 15 July 1993.

First reading: On 19 April 1994 Parliament approved the Commission proposal subject to amendments. The Commission has accepted some of the amendments.

The Commission presented an amended proposal on 30 June 1994.

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

(6) References

Commission proposal	
COM(93) 319 final	Official Journal C 246, 9.9.1993
Amended proposal	
COM(94) 278 final	Not yet published
European Parliament opinion	
First reading	Not yet published
Economic and Social Committee opinion	Not yet published

1. THE NEW APPROACH IN HARMONIZATION

1.21. New hot-water boilers

(1) Objective

To ensure freedom of movement for new hot-water boilers in the internal market through the total harmonization of the essential efficiency requirements that they must meet.

(2) Community measures

Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels.

Council Directive 93/68/EEC of 22 July 1993 amending Directive 92/42/EEC as well as Directives 87/404/EEC, 88/378/EEC, 89/106/EEC, 89/336/EEC, 89/392/EEC, 89/686/EEC, 90/384/EEC, 90/385/EEC, 90/396/EEC, 91/263/EEC and 73/23/EEC.

(3) Contents

1. These Directives come under the SAVE Programme concerning the promotion of energy efficiency in the Community.
2. They determine the objectives or 'essential requirements' to be met, during manufacture and before being placed on the market, by new hot-water boilers fired with liquid or gaseous fuels with a rated output of no less than 4 kW and no more than 400 kW:
— standard boilers;
— low-temperature boilers;
— gas condensing boilers.
3. Harmonized European standards are drawn up on the basis of the essential requirements by the European standardization bodies. These standards, which are not compulsory, are published in the *Official Journal of the European Communities* and transposed in the form of national standards with identical characteristics.
4. Any boiler manufactured in accordance with the relevant harmonized standards is presumed to conform to the essential requirements.
5. The procedures for assessing the conformity of new boilers to the essential requirements are based on the modular aproach set out in Council Decision 93/465/EEC (summary 1.13). The assessment of the conformity of the boilers is carried out:
— either by bodies designated by the Member States in accordance with the minimum assessment criteria and notified to the Commission and the other Member States;
— or by the manufacturers themselves.
6. The EC conformity marking must be affixed to boilers before they are placed on the market. This marking:
— symbolizes their conformity to the provisions of these Directives;
— has a single form, the initials 'EC';
— is affixed by the manufacturer or his agent established within the Community.
7. Where a boiler is subject to other Directives providing for the affixing of the EC marking, the latter indicates that the boiler is also presumed to conform to the provisions of those other Directives.
8. Any other mark may be affixed to boilers unless they are likely to be confused with the conformity markings.
9. Standardized additional specific markings are:
— the last two digits of the year in which the EC marking was affixed;
— and, solely in the case of boilers whose efficiency is superior to the requirements for standard boilers, the energy performance label.

	10. Penalties imposed by the Member States where they find that the EC marking has been affixed unduly. 11. Commission report on the functioning of EC marking procedures. 12. Transitional period from 1 January 1994 to 1 January 1998 during which Member States may permit the placing on the market and putting into service of boilers conforming to the rules in force on their territory before 21 May 1992.
(4) Deadline for implementation of the legislation in the Member States	— Directive 92/42/EEC: 31.12.1992 — Directive 93/68/EEC: 1.7.1994
(5) Date of entry into force (if different from the above)	— Directive 92/42/EEC: 1.1.1994 — Directive 93/68/EEC: 1.1.1995
(6) References	Official Journal L 167, 22.6.1992 Official Journal L 220, 30.8.1993
(7) Follow-up work	
(8) Commission implementing measures	

1. THE NEW APPROACH IN HARMONIZATION

1.22. Precious metals

(1) Objective

To ensure the free movement of articles of precious metal in the internal market by harmonizing national laws on consumer protection and fair trading.

(2) Proposal

Proposal for a Council Directive on articles of precious metal.

(3) Contents

1. The articles covered by the proposed Directive are:
— those made of gold, platinum, palladium and silver, and the same coated with other precious metals, where such articles are intended for the Community consumer;
— semi-finished articles of precious metal or those coated with precious metals intended for use in the manufacture of the abovementioned articles.
2. The proposal for a Directive:
— establishes the objectives or 'essential requirements' (e.g. marking) to be met by the abovementioned articles during manufacture and before they are placed on the market;
— lays down the rules relating to the marking of such articles and to certification procedure.
3. Harmonized European standards were drawn up on the basis of the essential requirements by the European standardization bodies. These standards, which are not compulsory, are published in the *Official Journal of the European Communities*.
4. The procedures for attesting the conformity of articles of precious metal to the essential requirements are based on the modular approach set out in Council Decision 93/465/EEC (summary 1.13). Conformity is assessed by the bodies designated by the Member States in accordance with the minimum assessment criteria and notified to the Commission and to the other Member States.
5. Before being placed on the market, articles of precious metal must be struck with:
— a fineness mark indicating that they meet the requirements of this proposal; these articles need not, therefore, bear the EC mark. This mark covers the specific surrounds used for each precious metal to identify the metal used;
— a sponsor's mark, registered by the Member States and accompanied by a small letter 'e', which makes it possible to identify the applicant, the notified body chosen by the applicant, the conformity procedure applied and the date of registration.
6. Where marking is technically difficult, it is replaced by an EC certificate of conformity issued by the manufacturer or by his authorized representative. It indicates the standard of fineness of the precious metal or metals concerned.
7. Any traditional mark may be struck on an article provided that it does not lead to confusion with a fineness mark or sponsor's mark or the letter 'e'.
8. Penalties imposed by the Member States where they or the notified bodies find that a fineness mark has been affixed improperly or that an EC certificate of conformity has been issued improperly.

(4) Opinion of the European Parliament		
(5) Current status of the proposal	Co-decision procedure The Commission presented the proposal on 14 October 1993. First reading: On 19 April 1994 Parliament approved the Commission proposal subject to amendments. The Commission has accepted some of the amendments. An amended proposal incorporating the amendments proposed by Parliament and accepted by the Commission is awaited.	
(6) References	Commission proposal COM(93) 322 final	Official Journal C 318, 25.11.1993
	European Parliament opinion First reading	Not yet published
	Economic and Social Committee opinion	Official Journal C 148, 30.5.1994

2. MOTOR VEHICLES

Current position and outlook

As part of its general programme for the removal of technical barriers to trade drawn up in 1969 the Community has taken steps to introduce a full EC type-approval procedure for passenger cars. Since 1970 this procedure has been covered by several Directives laying down the administrative conditions attached to the approval of cars, buses and lorries and to the approval of their components. In addition Directive 70/156/EEC introduces a list of components and characteristics of those vehicles covered, or to be covered, by separate Directives which will put forward optional harmonization of the technical requirements to apply to them (summary 2.13). The optional nature of these provisions was deleted by Directive 92/53/EEC, which amends Directive 70/156/EEC and thus henceforth makes the 45 rules listed mandatory for manufacturers from 1 January 1996. The vehicle roadworthiness tests have been adapted in order to meet these type-approval criteria (summary 2.14).

The introduction of a Community type-approval procedure for motor vehicles is thus a basic issue and benefits both vehicle manufacturers and consumers: it simplifies type-approval, enables a certificate of conformity that is recognized throughout the Community to be issued and helps to remove barriers to vehicle registration. Indeed, since 1 January 1993 all manufacturers, whether established or not within the Community, may sell a type of vehicle in any Member State provided that vehicle complies with the 45 technical Directives. From 1 January 1996 new vehicles purchased within the Community may be registered in the Member State of residence of the purchaser since the vehicle will, by definition, meet Community standards. Vehicles having received EC type-approval before that date may be registered throughout the Community.

It was precisely this approach which the Community opted for in 1992 in order to achieve full harmonization of the technical regulations applying to two- or three-wheel motor vehicles (summaries 2.1 to 2.12). The framework Directive covering such vehicles lists 47 mandatory technical requirements.

For the purpose of environmental protection, exhaust gas limit values have been laid down for motor vehicles. These values are regularly lowered and adapted to technical progress (summaries 2.25 to 2.28).

2. MOTOR VEHICLES

2.1. EEC type-approval: two- or three-wheeled motor vehicles: type-approval

(1) Objective

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

(2) Community measures

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

(3) Contents

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

In addition, any technical entity and any component produced in conformity with the approved type must include, if the relevant specific regulation so provides, a component type-approval mark which meets the requirements set out in the annex.

8. The manufacturer of a vehicle and the producer of a technical entity or component are to be responsible for the manufacture of each vehicle or the production of each technical entity or component in conformity with the type which has been type-approved or component type-approved.

9. If a Member State confirms that vehicles, technical entities or components constitute a road safety hazard even though they are of a type which has been type-approved or component type-approved, it may ban the sale, placing in service or use in its territory for a maximum period of six months. It must immediately inform the Commission and the other Member States thereof.

10. Member States may not prohibit the marketing, sale, bringing into service or use of new vehicles and new technical entities or new components conforming to the provisions of the Directive. Only vehicles, technical entities and components complying with the Directive may be marketed, sold and used in the Member States.

11. Member States may introduce or continue to apply in their national legislation a second category of mopeds having a maximum design speed of 25 km/h, to the extent that this does not involve modifications to the vehicles beyond what is necessary to ensure effective limitation of their maximum speed. However, three years after the date of entry into force of the Regulation, the Council is to decide, on a proposal from the Commission, whether this possibility should be maintained or removed.

12. Member States which have special provisions regarding the presence of pedals on mopeds may, however, continue to apply their national legislation for a maximum period of three years from the date of entry into force of the Directive.

13. A committee is set up for the adaptation to technical progress of the Regulations on two- or three-wheeled vehicles. It is composed of representatives of the Member States and is chaired by a representative of the Commission. The committee is to draw up its own rules of procedure.

14. Annexes containing the list of the components and characteristics of the vehicles conforming to the Directive, a model of the information document, a model of the type-approval form, a model of the certificate of conformity accompanying each vehicle in the series of the type that has been approved, and accompanying each technical entity or component not fitted as original equipment to the series of the type that has been component type-approved, a model of the type-approval mark, and provisions relating to checking the conformity of production.

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

1.1.1994

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

(6) References

Official Journal L 225, 10.8.1992

(7) Follow-up work	On 1 December 1993 the Commission submitted a proposal for a Directive on certain components or characteristics of two- or three-wheeled motor vehicles (COM(93) 449 final — Official Journal C 177, 29.6.1994). The objective of this proposal is to harmonize the technical requirements applicable to certain components or characteristics of two- or three-wheeled motor vehicles of all types, as defined in Directive 92/61/EEC. It also includes provisions establishing the equivalence between certain provisions of the proposal and the relevant ECE/UNO Regulations. Finally, the proposal contains provisions paving the way for a reduction in the limit values for pollutants and the sound level of two- or three-wheeled motor vehicles in the near future.
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.2. EEC type-approval: two- or three-wheeled motor vehicles: rear registration-plate mount

(1) Objective

To lay down technical requirements applying to the rear registration-plate mount for two- or three-wheeled motor vehicles.

(2) Community measures

Council Directive 93/94/EEC of 29 October 1993 on the rear registration-plate mount for two- or three-wheeled motor vehicles.

(3) Contents

1. This Directive forms part of the type-approval procedure for two- or three-wheeled motor vehicles covered by Council Directive 92/61/EEC (summary 2.1).
2. The vehicles covered by the Directive are as follows:
— mopeds: two- or three-wheeled vehicles powered by an engine having a cylinder capacity not exceeding 50 cm^3 and having a maximum design speed not exceeding 45 km/h;
— motorcycles: two-wheeled vehicles with or without sidecar powered by an engine having a cylinder capacity of more than 50 cm^3 and/or having a maximum design speed of more than 45 km/h;
— tricycles: vehicles with three symmetrical wheels and an engine having a cylinder capacity of more than 50 cm^3 and/or a maximum design speed of more than 45 km/h;
— quadricycles: four-wheeled vehicles powered by an engine with a cylinder capacity not exceeding 50 cm^3, a maximum design speed of 45 km/h and an unladen mass not exceeding 350 kg are considered to be mopeds, while other quadricycles are classified as tricycles.
3. Laying-down of the dimensions of the registration-plate location:
— mopeds: 90 mm wide and 165 mm high;
— motorcycles and tricycles: 205 mm wide and 165 mm high.
4. Requirements concerning the angle of inclination and height of the plate mount, and the optimum visibility conditions applying to the plate to be attached.
5. Procedure for the adaptation of the requirements to technical progress.
6. Procedure for granting component type-approval:
— the application for component type-approval is lodged with the competent authority within a Member State by the manufacturer or assembler;
— the competent authority component type-approves the rear registration-plate mount if this meets the technical requirements of this proposal and coincides with the data provided by the manufacturer;
— to that end that same authority fills out the component type-approval certificate annexed to the Directive.
7. The requirements relating to the rear registration-plate mount form part of a body of 47 characteristics provided for by Council framework Directive 92/61/EEC, all of which must be produced at one and the same time by manufacturers if two- or three-wheeled motor vehicles are to be able to be type-approved and placed on the Community market.

(4) Deadline for implementation of the legislation in the Member States	1.5.1995	
(5) Date of entry into force (if different from the above)	1.11.1995	
(6) References		Official Journal L 311, 14.12.1993
(7) Follow-up work		
(8) Commission implementing measures		

2. MOTOR VEHICLES

2.3. EEC type-approval: two- or three-wheeled motor vehicles: statutory inscriptions

(1) Objective

To harmonize the national laws and set up a component type-approval procedure concerning statutory inscriptions to be affixed to two- or three-wheeled motor vehicles.

(2) Community measures

Council Directive 93/34/EEC of 14 June 1993 on statutory inscriptions to be affixed to two- or three-wheeled motor vehicles.

(3) Contents

1. This Directive forms part of the type-approval procedure for two- or three-wheeled motor vehicles covered by Council Directive 92/61/EEC (summary 2.1).
2. The vehicles covered by the Directive are as follows:
- mopeds: two- or three-wheeled vehicles powered by an engine having a cylinder capacity not exceeding 50 cm^3 and having a maximum design speed not exceeding 45 km/h;
- motorcycles: two-wheeled vehicles with or without sidecar powered by an engine having a cylinder capacity of more than 50 cm^3 and/or having a maximum design speed of more than 45 km/h;
- tricycles: vehicles with three symmetrical wheels and an engine having a cylinder capacity of more than 50 cm^3 and/or a maximum design speed of more than 45 km/h;
- quadricycles: four-wheeled vehicles powered by an engine with a cylinder capacity not exceeding 50 cm^3, a maximum design speed of 45 km/h and an unladen mass not exceeding 350 kg are considered to be mopeds, while other quadricylces are classified as tricycles.

3. All vehicles shall bear a plate and the following indelible inscriptions, listed in order:
- manufacturer's name;
- type-approval mark:
  - the vehicle approval number;
  - the lower-case letter 'e', followed by the number or symbol identifying the Member State having granted approval;
  - a digital or alphabetical code identifying the vehicle;
- the vehicle identification number (VIN) comprising:
  - a three-character code (letters or digits) intended to designate a geographical area, a country within a geographical area and a specific manufacturer;
  - six characters (letters or digits) intended to identify the general characteristics of the vehicle (type, variant and version);
  - eight characters, the last four of which have to be digital in order, together with the two other parts to enable a specific vehicle to be identified;
- the make and the silencer-type references, except in the case of mopeds and motorcyles;
- the sound level when stationary.

4. The plate and inscriptions are affixed by the manufacturer or his authorized representative at a point such that it may be easily accessible on a part which normally is not likely to be replaced during use.

	5. The manufacturer may affix additional information below or to one side of the mandatory markings, outside a clearly-marked rectangle which contains the information required. 6. Size and type of authorized characters (Latin letters and Arabic numerals) and an example of the manufacturer's data plate for information purposes. 7. Procedure for the adaptation of the requirements to technical progress. 8. Procedures for the granting of component type-approval: — the application for component type-approval is lodged by the manufacturer or assembler with the competent authority within a Member State; — the competent authority component type-approves the statutory inscriptions if these meet the technical requirements of this proposal and are in line with the information provided by the manufacturer; — this same authority shall, to this end, fill out the component type-approval certificate annexed to the Directive. 9. The requirements concerning statutory inscriptions form part of a body of 47 characteristics provided for by Council framework Directive 92/61/EEC, all of which must be produced at one and the same time by manufacturers if two- or three-wheeled motor vehicles are to be able to be type-approved and placed on the Community market. 10. However, Member States may, on a non-discriminatory basis, retain specific essential requirements in order to implement road-traffic rules, provided that those specific requirements concern vehicle use and do not involve any design changes which are likely to impede their type-approval within the European Community.
(4) Deadline for implementation of the legislation in the Member States	14.12.1994
(5) Date of entry into force (if different from the above)	14.6.1995, except for derogations.
(6) References	Official Journal L 188, 29.7.1993
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.4. EEC type-approval: two- or three-wheeled motor vehicles: maximum dimensions, masses and loads

(1) Objective

To harmonize the masses and dimensions of two- or three-wheeled motor vehicles.

(2) Community measures

Council Directive 93/93/EEC of 29 October 1993 on the masses and dimensions of two- or three-wheeled motor vehicles.

(3) Contents

1. This Directive forms part of the procedure for the type-approval of two- or three-wheeled motor vehicles covered by Council Directive 92/61/EEC (summary 2.1).
2. The vehicles covered by the Directive are as follows:
— mopeds: two- or three-wheeled vehicles powered by an engine having a capacity not exceeding 50 cm^3 and having a maximum design speed of not more than 45 km/h;
— motorcycles: two-wheeled vehicles with or without sidecar powered by an engine having a cylinder capacity of more than 50 cm^3 and/or having a maximum design speed of more than 45 km/h;
— tricycles: vehicles with three symmetrical wheels that are powered by an engine having a cylinder capacity of more than 50 cm^3 and/or having a maximum design speed of more than 45 km/h;
— quadricycles: four-wheeled vehicles powered by an engine having a cylinder capacity not exceeding 50 km^3 and having a maximum speed of 45 km/h, the unladen mass of which does not exceed 350 kg are considered to be mopeds, while other quadricycles are classified as tricycles.
3. Establishment of maximum authorized dimensions, masses and loads:
— dimensions: length 4 m, width 2 m and height 2.50 m;
— masses:
  — two-wheeled vehicles: technically permissible mass declared by manufacturer;
  — three-wheeled vehicles: 1 000 kg;
  — the towable mass of two- or three-wheeled vehicles shall not exceed 50 % of the mass of the vehicle in running order;
— loads: the maximum load to be borne by three-wheeled mopeds is 800 kg and that of tricycles 1 500 kg.
4. Laying down the conditions for checking the masses and dimensions of the vehicles concerned.
5. Procedure for the adaptation of the requirements to technical progress.
6. Procedure for the granting of component type-approval:
— the application for component type-approval is lodged with the competent authority within a Member State by the manufacturer or assembler;
— the competent authority component type-approves the masses and dimensions of the vehicles concerned if these meet the technical requirements of this Directive and are in line with the information provided by their manufacturer;
— to that end that same authority fills out the component type-approval certificate annexed to this Directive.

	7. The requirements concerning masses and dimensions form part of a body of 47 characteristics required by Council framework Directive 92/61/EEC, all of which must be supplied by manufacturers at one and the same time if two- or three-wheeled motor vehicles are to be able to be type-approved and placed on the Community market.
(4) Deadline for implementation of the legislation in the Member States	1.5.1995
(5) Date of entry into force (if different from the above)	1.11.1995
(6) References	Official Journal L 311, 14.12.1993
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.5. EEC type-approval: two- or three-wheeled motor vehicles: controls, tell-tales and indicators

(1) Objective

To harmonize the laws of the Member States with regard to controls, tell-tales and indicators of motor vehicles.

(2) Community measures

Council Directive 93/29/EEC of 14 June 1993 on the identification of controls, tell-tales and indicators for two- or three-wheeled motor vehicles.

(3) Contents

1. This Directive comes under the type-approval procedure for two- or three-wheeled motor vehicles which was the subject of Council Directive 92/61/EEC (summary 2.1).
2. The vehicles covered by the Directive are as follows:
— mopeds: two- or three-wheeled vehicles with or without sidecar powered by an engine having a cylinder capacity not exceeding 50 cm^3 and having a maximum design speed not exceeding 45 km/h;
— motorcycles: two-wheeled vehicles with or without sidecar powered by an engine having a cylinder capacity of more than 50 cm^3 and/or having a maximum design speed of more than 45 km/h;
— tricycles: vehicles with three symmetrical wheels and an engine having a cylinder capacity of more than 50 cm^3 and/or a maximum design speed of more than 45 km/h;
— quadricycles: four-wheeled vehicles powered by an engine with a cylinder capacity not exceeding 50 cm^3, a maximum design speed of 45 km/h and an unladen mass not exceeding 350 kg are considered to be mopeds, while other quadricycles are classified as tricycles.
3. Recognition of equivalence between requirements of the Directive and those of Regulation No 60 of the United Nations Economic Commission for Europe (ECE/UN).
4. Requirements concerning colour of tell-tales, geometric visibility of lights, installation and structure of model base for the symbols.
5. Procedure for adapting requirements to technical progress or to amendments of the ECE/UN Regulation.
6. Procedure for granting type-approval:
— the application for type-approval is submitted by the manufacturer to the competent authority of a Member State;
— the competent authority grants type-approval in respect of controls, tell-tales and indicators if the latter fulfils the technical requirements of this proposal and match the data supplied by the manufacturer;
— the competent authority fills in to this effect the type-approval certificate to be found attached to the proposal.
7. The requirements relating to controls, tell-tales and indicators form part of a set of 47 characteristics provided for by Council framework Directive 92/61/EEC which must be observed as a whole by manufacturers so that two- or three-wheeled motor vehicles may be type-approved and placed on the Community market.

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

14.12.1994

(5) Date of entry into force (if different from the above)	14.6.1995, except for derogations.
(6) References	Official Journal L 188, 29.7.1993
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.6. EEC type-approval: two- or three-wheeled motor vehicles: braking devices

(1) Objective

To harmonize the laws of the Member States and establish a type-approval procedure with regard to the braking of two- or three-wheeled motor vehicles.

(2) Community measures

Council Directive 93/14/EEC of 5 April 1993 on the braking of two- or three-wheeled motor vehicles.

(3) Contents

1. This Directive comes under the type-approval procedure for two- or three-wheeled motor vehicles which was the subject of Council Directive 92/61/EEC (summary 2.1).
2. The vehicles covered by the Directive are as follows:
— mopeds: two- or three-wheeled vehicles with or without sidecar powered by an engine having a cylinder capacity not exceeding 50 cm^3 and having a maximum design speed not exceeding 45 km/h;
— motorcycles: two-wheeled vehicles with or without sidecar powered by an engine having a cylinder capacity of more than 50 cm^3 and/or having a maximum design speed of more than 45 km/h;
— tricycles: vehicles with three symmetrical wheels and an engine having a cylinder capacity of more than 50 cm^3 and/or a maximum design speed of more than 45 km/h;
— quadricycles: four-wheeled vehicles powered by an engine with a cylinder capacity not exceeding 50 cm^3, a maximum design speed of 45 km/h and an unladen mass not exceeding 350 kg are considered to be mopeds, while other quadricycles are classified as tricycles.
3. Recognition of equivalence between requirements of the Directive and those of Regulation No 78 of the United Nations Economic Commission for Europe (ECE/UN).
4. Specifications concerning the design, construction and assembly of braking devices, and braking tests and performances based on braking distance.
5. Characteristics of braking devices for various types of vehicles:
— two-wheeled moped or motocycle without sidecar: two service braking devices with independent controls and transmissions, one acting at least on the front wheel and the other at least on the rear wheel;
— motorcycle with sidecar: same provisions as for motorcycles without sidecar; if abovementioned device does not produce the required performance, a supplementary brake on the wheel of the sidecar is required;
— tricycles: service braking device which operates on all the wheels, emergency braking device which may be the parking brake and a parking braking device acting on the wheel(s) of at least one axle.
6. Specific requirements relating to the performance of braking systems equipped with anti-lock devices fitted to two-wheeled mopeds, two-wheeled motorcycles and tricycles.
7. Procedure for adapting requirements to technical progress or to amendments of the ECE/UN Regulation.

	8. Procedure for granting type-approval: — the application for type-approval is submitted by the manufacturer to the competent authority of a Member State; — the competent authority grants type-approval in respect of braking devices if the latter fulfil the technical requirements of this Directive and match the data supplied by the manufacturer; — the competent authority fills in to this effect the type-approval certificate to be found attached to the Directive. 9. The requirements relating to braking devices form part of a set of 47 characteristics provided for by Council framework Directive 92/61/EEC which must all be observed by manufacturers so that two- or three-wheeled motor vehicles may be type-approved and placed on the Community market.
(4) Deadline for implementation of the legislation in the Member States	5.11.1994
(5) Date of entry into force (if different from the above)	5.4.1995
(6) References	Official Journal L 121, 15.5.1993
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.7. EEC type-approval: two- or three-wheeled motor vehicles: maximum design speed

(1) Objective

To harmonize national laws and establish a type-approval procedure with regard to maximum design speed (measurement method), maximum torque (measurement method) and maximum net engine power (permissible limit value and measurement method) of two- or three-wheeled motor vehicles.

(2) Proposal

Proposal for a Council Directive on the maximum design speed, maximum torque and maximum net engine power of two- or three-wheeled motor vehicles.

(3) Contents

1. This proposal forms part of the type-approval procedure for two- or three-wheeled motor vehicles covered by Council Directive 92/61/EEC (summary 2.1).
2. The vehicles covered by the proposal are divided into the following types:
— mopeds: two- or three-wheeled vehicles fitted with an engine having a cylinder capacity not exceeding 50 cm^3 and a maximum design speed of not more than 45 km/h;
— motorcycles: two-wheeled vehicles with or without sidecar, fitted with an engine having a cylinder capacity of more than 50 cm^3 and/or having a maximum design speed of more than 45 km/h;
— tricycles: vehicles with three symetrically arranged wheels fitted with an engine having a cylinder capacity of more than 50 cm^3 and/or a maximum design speed of more than 45 km/h;
— quadricycles: four-wheeled vehicles whose engine cylinder capacity does not exceed 50 cm^3, whose maximum design speed is not more than 45 km/h and whose unladen mass is less than 350 kg are considered to be mopeds, while other quadricycles are classed as tricycles.
3. Requirements relating to the method of measuring maximum design speed and covering test conditions and procedure and the maximum speed of the vehicle.
4. Requirements relating to the maximum permissible power and methods of measuring maximum torque and maximum net engine power:
— the net power output of the vehicles concerned must not exceed 74 kW;
— specific requirements concerning spark-ignition engines for mopeds, motorcycles and tricycles and relating to:
  — accuracy of torque and power measurements under full load;
  — the measurement test and the test report;
  — the correction factors for torque and power;
  — the maximum torque and maximum net power measurement tolerances.
5. Procedure for adapting requirements to technical progress.
6. Procedure for granting type-approval:
— the application for type-approval is submitted by the manufacturer to the competent authority of a Member State;

— the competent authority grants type-approval in respect of the maximum design speed, the maximum torque and the maximum net power if these conform to the technical requirements of this proposal and to the data provided by the manufacturer;
— to this end, it fills in the type-approval certificate contained in the annex to the proposal.

7. The requirements relating to the maximum design speed, the maximum torque and the maximum net power form part of a list of 47 characteristics set out in Council Directive 92/61/EEC all of which have to be complied with for two- or three-wheeled motor vehicles to be approved and marketed in the Community.

(4) Opinion of the European Parliament

First reading: Parliament adopted the Commission's proposal subject to one amendment.

Second reading: Parliament announced its intention of rejecting the common position adopted by the Council. Parliament opposed the 74 kW limit on the maximum engine power of two- or three-wheeled motor vehicles and wished to delete all reference to such a limit. It also disagreed with the committee procedure.

(5) Current status of the proposal

Co-decision procedure

The Commission presented the proposal on 26 February 1992.

First reading: On 11 February 1993 Parliament approved the Commission proposal subject to an amendment. The Commission has not accepted the amendment.

On 28 June 1993 the Council adopted its common position.

Second reading: On 9 February 1994 Parliament announced its intention of rejecting the common position.

On 1 March 1994 the Council convened the Conciliation Committee to clarify its common position.

On 4 May 1994, Parliament approved the Council's common position subject to amendments. The Commission has accepted part of one of the amendments.

A Commission opinion amending the proposal and incorporating the amendment it accepted is awaited.

(6) References

Commission proposal	
COM(91) 497 final	Official Journal C 93, 13.4.1992
European Parliament opinion	
First reading	Official Journal C 305, 23.11.1992
Second reading	Not yet published
Economic and Social Committee opinion	Official Journal C 313, 30.11.1992

2. MOTOR VEHICLES

2.8. EEC type-approval: two- or three-wheeled motor vehicles: audible warning device

(1) Objective

To harmonize national laws on audible warning devices for two- or three-wheeled motor vehicles.

(2) Community measures

Council Directive 93/30/EEC of 14 June 1993 on audible warning devices for two- or three-wheeled motor vehicles.

(3) Contents

1. This proposal forms part of the approval procedure for two- or three-wheeled motor vehicles as covered by the Council framework Directive 92/61/EEC (summary 2.1).
2. The vehicles covered by the proposal are divided into:
— mopeds: two- or three-wheeled vehicles fitted with an engine having a cylinder capacity not exceeding 50 cm^3 and a maximum design speed of not more than 45 km/h;
— motorcycles: two-wheeled vehicles with or without sidecar, fitted with an engine having a cylinder capacity of more than 50 cm^3 and/or having a maximum design speed of more than 45 km/h;
— tricycles: vehicles with three symetrically arranged wheels fitted with an engine having a cylinder capacity of more than 50 cm^3 and/or a maximum design speed of more than 45 km/h;
— quadricycles: vehicles with four wheels whose engine cylinder capacity does not exceed 50 cm^3, whose maximum design speed is not more than 45 km/h and whose unladen mass is less than 350 kg are considered to be mopeds; other quadricycles are classed as tricycles.
3. Recognition of equivalence between the provisions of the proposal for a Directive and those of Regulation No 28 of the United Nations Economic Commission for Europe (UN/ECE).
4. Requirements relating to the design of audible warning devices:
— maximum A-weighted sound level:
  — 115 dB(A) for audible warning devices intended mainly for mopeds, motorcycles and tricycles developing a power of not more than 7 kW;
  — 118 dB(A) for audible warning devices intended mainly for motorcycles and tricycles developing a power of more than 7 kW;
— durability test:
  — 10 000 times in the case of warning devices intended mainly for mopeds, motorcycles and tricycles developing a power not exceeding 7 kW;
  — 50 000 times in the case of warning devices intended mainly for motorcycles and tricycles developing a power of more than 7 kW.
5. Procedure for adapting the provisions to technical progress or to amendments to the UN/ECE Regulation.
6. Procedure for granting type-approval:
— the application for type-approval is submitted by the manufacturer to the competent authority of a Member State;
— the competent authority grants type-approval for audible warning devices if they conform to the technical requirements of this proposal and to the data provided by the manufacturer;

	— to this end it fills in the type-approval certificate contained in the annex to the proposal. 7. The requirements relating to audible warning devices form part of a list of 47 characteristics set out in Council framework Directive 92/61/EEC all of which must be complied with by manufacturers for two- or three-wheeled motor vehicles to be approved and marketed in the Community.
(4) Deadline for implementation of the legislation in the Member States	14.12.1994
(5) Date of entry into force (if different from the above)	14.6.1995, except for derogations.
(6) References	Official Journal L 188, 29.7.1993
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.9. EEC type-approval: two- or three-wheeled motor vehicles: lighting and light-signalling devices

(1) Objective

To harmonize the laws of the Member States and establish a type-approval procedure with regard to lighting and light-signalling devices on two- or three-wheeled motor vehicles.

(2) Community measures

Council Directive 93/92/EEC of 29 October 1993 on the installation of lighting and light-signalling devices on two- or three-wheeled motor vehicles.

(3) Contents

1. This Directive comes under the type-approval procedure for two- or three-wheeled motor vehicles which was the subject of Council framework Directive 92/61/EEC (summary 2.1).
2. The vehicles covered by the Directive are as follows:
— mopeds: two- or three-wheeled vehicles powered by an engine having a cylinder capacity not exceeding 50 cm^3 and having a maximum design speed not exceeding 45 km/h;
— motorcycles: two-wheeled vehicles with or without sidecar powered by an engine having a cylinder capacity of more than 50 cm^3 and/or having a maximum design speed of more than 45 km/h;
— tricycles: vehicles with three symmetrical wheels and an engine having a cylinder capacity of more than 50 cm^3 and/or a maximum design speed of more than 45 km/h;
— quadricycles: four-wheeled vehicles powered by an engine with a cylinder capacity not exceeding 50 cm^3, a maximum design speed of 45 km/h and an unladen mass not exceeding 350 kg are considered to be mopeds, while other quadricycles are classified as tricycles.
3. Requirements relating to numbers, installation diagrams, geometrical visibility, alignment, incorporation with other devices and telltales for each lighting and light-signalling device according to the type of vehicle.
4. List of colours of the various lights.
5. Procedure for adapting requirements to technical progress.
6. Procedure for granting type-approval:
— the application for type-approval is submitted by the manufacturer to the competent authority of a Member State;
— the competent authority grants type-approval in respect of the lighting and light-signalling devices if they fulfil the technical requirements of this Directive and match the data supplied by the manufacturer;
— the competent authority fills in to this effect the type-approval certificate to be found attached to the Directive.
7. The requirements relating to the installation of lighting and light-signalling devices form part of a set of 47 characteristics provided for by Council framework Directive 92/61/EEC which must all be observed by manufacturers so that two- or three-wheeled motor vehicles may be type-approved and placed on the Community market.

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

1.5.1995

(5) Date of entry into force (if different from the above)	1.11.1995
(6) References	Official Journal L 311, 14.12.1993
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.10. EEC type-approval: two- or three-wheeled motor vehicles: restraint devices for passengers

(1) Objective

To harmonize the laws of the Member States and establish a type-approval procedure with regard to restraint devices for passengers on two-wheeled motor vehicles.

(2) Community measures

Council Directive 93/32/EEC of 14 June 1993 on restraint devices for passengers on two-wheeled motor vehicles.

(3) Contents

1. This proposal comes under the type-approval procedure for two- or three-wheeled motor vehicles which was the subject of Council Directive 92/61/EEC (summary 2.1).
2. The vehicles covered by the proposal are as follows:
— mopeds: two-wheeled vehicles powered by an engine having a cylinder capacity not exceeding 50 cm^3 and having a maximum design speed not exceeding 45 km/h;
— motorcycles: two-wheeled vehicles with or without sidecar powered by an engine having a cylinder capacity of more than 50 cm^3 and/or having a maximum design speed of more than 45 km/h.
3. General requirements concerning the design and fitting of restraint systems:
— the restraint system must take the form of a belt or handgrip(s);
— the belt and its attachment must be able to withstand, without snapping or suffering permanent deformation, a vertical traction force of 2 000 N applied statically to the centre of the surface of the strap at a maximum pressure of 2 MPa;
— the handgrip must be able to withstand, without snapping or suffering permanent deformation, a vertical traction force of 2 000 N applied statically to the centre of the surface of the handgrip at a maximum pressure of 2 MPa; if two handgrips are used, each must be able to withstand, without snapping or suffering permanent deformation, a vertical traction force of 1 000 N applied statically to the centre of the surface of the handgrip at a maximum pressure of 1 MPa;
4. Procedure for adapting requirements to technical progress.
5. Procedure for granting type-approval:
— the application for type-approval is submitted by the manufacturer to the competent authority of a Member State;
— the competent authority grants type-approval in respect of the restraint system if the latter fulfils the technical requirements of this proposal and matches the data supplied by the manufacturer;
— the competent authority fills in to this effect the type-approval certificate to be found attached to the proposal.
6. The requirements relating to passenger restraint systems form part of a set of 47 characteristics provided for by Council Directive 92/61/EEC which must all be observed by manufacturers so that two- or three-wheeled motor vehicles may be type-approved and placed on the Community market.

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

14.12.1994

(5) Date of entry into force (if different from the above)	14.6.1995, except for derogations.
(6) References	Official Journal L 188, 29.7.1993
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.11. EEC type-approval: two- or three-wheeled motor vehicles: anti-theft devices

(1) Objective

To harmonize anti-theft devices for two- or three-wheeled motor vehicles.

(2) Community measures

Council Directive 93/33/EEC of 14 June 1993 on protective devices intended to prevent the unauthorized use of two- or three-wheeled motor vehicles.

(3) Contents

1. This Directive forms part of the approval procedure for two- or three-wheeled motor vehicles as provided for in Council Directive 92/61/EEC (summary 2.1).
2. The vehicles covered by the Directive are divided into:
— mopeds: two- or three-wheeled vehicles fitted with an engine having a cyclinder capacity not exceeding 50 cm^3 and a maximum design speed of not more than 45 km/h;
— motorcycles: two-wheeled vehicles with or without sidecar, fitted with an engine having a cylinder capacity of more than 50 cm^3 and/or having a maximum design speed of more than 45 km/h;
— tricycles: vehicles with three symmetrically arranged wheels fitted with an engine having a cylinder capacity of more than 50 cm^3 and/or a maximum design speed of more than 45 km/h;
— quadricycles: four-wheeled vehicles whose engine cylinder capacity does not exceed 50 cm^3, whose maximum design speed is not more than 45 km/h and whose unladen mass is less than 350 kg are considered to be mopeds; other quadricycles are classed as tricycles.
3. Recognition of equivalence between the provisions of the Directive and those of United Nations Economic Commission for Europe (UN/ECE) Regulation No 62.
4. The protective device may:
— act solely and positively on the steering (type 1);
— act positively on the steering at the same time as the device which switches off the engine of the vehicle (type 2);
— when preloaded, act on the steering at the same time as the device which switches off the engine of the vehicle (type 3);
— act positively on the transmission (type 4).
5. General requirements relating to the design and operation of anti-theft devices:
— all two- or three-wheeled motor vehicles, with the exception of mopeds, must be fitted with an anti-theft device which meets the requirements contained in this Directive; if an anti-theft device is fitted to a moped, it must meet the requirements contained in this Directive;
— it must be necessary to disable the protective device in order to point, drive or move the vehicle straight ahead;
— the key can only be removed when the catch is fully engaged or withdrawn;
— the protective device must form part of the vehicle's original equipment;

	— the key locking system must incorporate at least 1 000 different combinations or a quantity equivalent to the number of vehicles built annually if that number is lower than 1 000; — the key and lock code must not be visible; — the protective device must be such that, when the vehicle is set in motion and the engine is turning, there is no likelihood of accidental jamming or deterioration of the steering device or transmission. 6. Requirements specific to the type of protective device. 7. Conditions governing the testing of protective devices. 8. Procedure for adapting the provisions of this Directive to technical progress or to amendments to the United Nations Economic Commission for Europe Regulation. 9. Procedure for granting component type-approval: — the application for component type-approval is submitted by the manufacturer to the competent authority within a Member State; — the competent authority grants component type-approval for the protective devices if these conform to the technical requirements of this Directive and to the data provided by the manufacturer; — to this end this authority fills in the component type-approval certificate contained in the annex to the Directive. 10. The requirements relating to protective devices form part of a list of 47 characteristics set out in Council framework Directive 92/61/EEC, all of which have to be complied with by manufacturers for two- or three-wheeled motor vehicles to be approved and marketed within the Community.
(4) Deadline for implementation of the legislation in the Member States	14.12.1994
(5) Date of entry into force (if different from the above)	14.6.1995, except for derogations.
(6) References	Official Journal L 188, 29.7.1993
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.12. EEC type-approval: two- or three-wheeled motor vehicles: stands for two-wheeled vehicles

(1) Objective

To harmonize the national laws and to set up a component type-approval procedure in respect of stands for two-wheeled motor vehicles.

(2) Community measures

Council Directive 93/31/EEC of 14 June 1993 on stands for two-wheeled motor vehicles.

(3) Contents

1. This Directive forms part of the approval procedure for two- or three-wheeled motor vehicles covered by Council Directive 92/61/EEC (summary 2.1).
2. The vehicles covered by the Directive are as follows:
— mopeds: two- or three-wheeled vehicles powered by an engine having a capacity not exceeding 50 cm^3 and having a maximum design speed of not more than 45 km/h;
— motorcycles: two-wheeled vehicles with or without sidecar powered by an engine having a cylinder capacity of more than 50 cm^3 and/or having a maximum design speed of more than 45 km/h;
3. General requirements concerning the design and fitting of stands:
— all two-wheeled vehicles shall be provided with at least one stand;
— the stand is to be either a prop stand or a centre stand, or both;
— the stand is to be equipped with a steadying system which holds it in its closed or retracted position;
— in addition the vehicles concerned may be equipped with a warning light which, when the ignition is switched on, lights up and remains lit until the stand is in the closed or retracted position.
4. Individual specifications depending upon the type of stand.
5. Stand test conditions and explanatory diagrams.
6. Procedure for the adaptation of the requirements to technical progress.
7. Procedure for the granting of component type-approval:
— the application for component type-approval is lodged with the competent authority within a Member State by the manufacturer or assembler;
— the competent authority component type-approves the stand if this meets the requirements of this Directive and is in line with the information supplied by its manufacturer;
— to that end that same authority fills out the component type-approval certicate annexed to this Directive.
8. The requirements concerning the stand form part of a body of 47 characteristics required by Council framework Directive 92/61/EEC, which must be supplied at one and the same time if two-wheeled vehicles are to be able to be type approved and placed on the Community market.

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

14.12.1994

(5) Date of entry into force (if different from the above)	14.6.1995, except for derogations.
(6) References	Official Journal L 188, 29.7.1993
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.13. EEC type-approval: motor vehicles and their trailers: component type-approval

(1) Objective

To harmonize the laws of the Member States and implement a procedure for the Community type-approval of motor vehicles and their trailers.

(2) Community measures

Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers.

As amended by the following measures:
Council Directive 78/315/EEC of 21 December 1977;
Council Directive 78/547/EEC of 12 June 1978;
Council Directive 80/1267/EEC of 16 December 1980;
Council Directives 87/358/EEC and 87/403/EEC of 25 June 1987;
Council Directive 92/53/EEC of 18 June 1992.

(3) Contents

1. These Directives apply to the type-approval of category-M_1 vehicles, powered by an internal combustion engine, and their trailers, whether produced in a single or in several stages, and to the type-approval of the systems, components and separate technical units intended for such vehicles and their trailers.
2. They do not apply to the type-approval of solo vehicles and quadricycles within the meaning of Council Directive 92/61/EEC (summary 2.1).
3. Type-approval procedure for each type of vehicle, system, component or separate technical unit:
- application for type-approval:
  - lodged by the manufacturer with the authorities responsible for type-approval within a single Member State;
  - accompanied by a manufacturer's information package and type-approval certificate under each of the separate Directives applying, in compliance with the present Directives;
  - contains individual specifications for multi-stage type approvals;
- type-approval procedure:
  - type-approval is granted by each Member State if the type at issue conforms to the information contained in the manufacturer's information package and meets the technical requirements of the separate Directives;
  - each Member State shall, to this end, complete a type-approval certificate and its annexes concerning the results of tests and shall send this to the applicant;
  - type-approval may be refused if there is likely to be a road safety hazard;
  - a reciprocal information system is set up between the type-approval authorities in each Member State;
- amendments to type-approvals:
  - the application for the amendment or extension of a type-approval is submitted solely to the Member State originally having granted type-approval;
  - the changes to be made to the document differ depending on whether it relates to a vehicle, system, component or separate

technical unit;
  — further tests and inspections after a type-approval document has been amended are authorized if the Member State considers it necessary; the type-approval certificate and its annexes are thus not prepared until these new checks have been conducted:
— certificate of conformity:
  — drawn up by the manufacturer on the basis of the type-approval certificate and in conformity with the annexes to the Directive;
  — contains detailed information on the aspects it has been possible to add or alter and on any potential restrictions on the use of the components and separate technical units;
  — for registration or taxation purposes Member States may require that further information be added to the certificate of conformity.

4. Registration and marketing:
— a valid certificate of conformity is required:
  — for the marketing, placing in service and registration of the vehicles concerned;
  — for the marketing and placing in service of components and separate technical units intended for vehicles covered by the Directives;
— however, a Member State may:
  — refuse to permit the permanent registration or entry into service of incomplete vehicles as long as they remain incomplete:
  — under certain conditions refuse to register and/or prohibit the sale of, placing in service on its territory of vehicles, components and separate technical units if these seriously impair road safety, even if accompanied by a valid certificate of conformity, or have been marked in an adequate manner.

These exceptions do not apply to vehicles:
— that are intended for the armed forces, civil defence, fire-fighting services and other law-enforcement agencies;
— that are not covered by these Directives or are either entirely or partly exempted therefrom.

5. The following vehicles may, under certain conditions, be exempted from compliance with one or several separate Directives:
— vehicles produced in small production runs;
— end-of-series vehicles;
— vehicles, components or separate technical units designed in accordance with techniques or principles that are essentially incompatible with one or several of the requirements of separate Directives (for, at the most, 24 months).

6. Procedure for the recognition of equivalence between the provisions of the Directives and those of international or non-member country Regulations under bilateral or multilateral agreements between the Community and non-member countries.

7. Procedures governing conformity of production.

8. Non-conformity with the type that has been approved is established:
— by the Member State having conducted type-approval, or by any other Member State;
— in relation to the type-approval certificate and/or file; and
— after the existence has been established of discrepancies that have not been authorized by the type-approving States in pursuance of the Directives.

It is for the type-approving State to take the steps needed in order to restore conformity.

	9. Procedure for the adaptation of the annexes to technical progress. 10. Each Member State shall inform the Commission and the other Member States of the references for the authorities responsible for type-approval and roadworthiness testing. 11. Annexes concerning the type-approval procedure, certificate of conformity, multi-stage type-approval and exemptions.
(4) Deadline for implementation of the legislation in the Member States	— Directive 70/156/EEC: 6.8.1971 — Directive 78/315/EEC: 21.6.1979 — Directive 78/547/EEC: 12.12.1979 — Directive 80/1267/EEC: 16.6.1982 — Directive 87/358/EEC: 1.10.1988 — Directive 87/403/EEC: 1.10.1988 — Directive 92/53/EEC: 31.12.1992
(5) Date of entry into force (if different from the above)	Directive 92/53/EEC: 1.1.1993 unless otherwise specified
(6) References	Official Journal L 42, 23.2.1970 Official Journal L 81, 28.3.1978 Official Journal L 168, 26.6.1978 Official Journal L 375, 31.12.1980 Official Journal L 192, 11.7.1987 Official Journal L 220, 8.8.1987 Official Journal L 225, 10.8.1992
(7) Follow-up work	On 14 May 1992 the Commission put forward a proposal for a Council Directive on the approximation of the laws of the Member States relating to the behaviour, in fire, of the materials used for the interior fittings of certain categories of motor vehicle (COM(92) 201 final — Official Journal C 154, 19.6.1992). This proposal is intended to supplement framework Directive 70/156/EEC by harmonizing the technical standards on the behaviour in fire of the materials used in the structure of the interior fittings of public service vehicles.
(8) Commission implementing measures	Commission Directive of 29 September 1993 adapting to technical progress the Council Directive 70/156/EEC on the type-approval of motor vehicles and their trailers. The Directive is intended to provide all of the Member States with scope for granting exemptions from one or several separate Directives to end-of-run vehicles, regardless of category.

2. MOTOR VEHICLES

2.14. EEC type-approval: motor vehicles and their trailers: roadworthiness tests

(1) Objective

To harmonize the frequency of roadworthiness tests for motor vehicles and the compulsory list of items to be tested.

(2) Community measures

Council Directive 77/143/EEC of 29 December 1976 on the approximation of the laws of the Member States relating to roadworthiness tests for motor vehicles and their trailers.

Amended by the following measures:
Council Directive 88/449/EEC of 26 July 1988;
Council Directive 91/225/EEC of 27 March 1991;
Council Directive 91/328/EEC of 21 June 1991;
Council Directives 92/54/EEC and 92/55/EEC of 22 June 1992;
Commission Directive 94/23/EC of 8 June 1994.

(3) Contents

1. These Directives concern:
— buses;
— coaches;
— heavy goods vehicles;
— trailers and semi-trailers over 3.5 tonnes;
— taxis;
— ambulances;
— light commercial vehicles not exceeding 3.5 tonnes (light goods vehicles);
— private cars with no more than eight seats, excluding the driver's seat.

2. The Member States may exclude from the scope of these Directives:
— vehicles belonging to the armed forces and forces of law and order;
— certain vehicles used in exceptional conditions.

3. The Directives provide for periodic roadworthiness tests on the above vehicles to be carried out by the Member States or by the bodies responsible for testing in the Member States.

4. Roadworthiness tests particularly concern:
— braking systems;
— steering and steering wheel;
— visibility;
— lamps, reflectors and electrical equipment;
— axles, wheels, tyres and suspension;
— chassis and chassis attachments;
— nuisance, including exhaust emissions;
— vehicle identification.

5. The interval between tests depends on the type of vehicle concerned:
— light commercial vehicles and private cars are to be tested four years after they are first used and at two-year intervals thereafter;
— other vehicles are to be tested one year after they are first used and annually thereafter.

6. The Member States may depart from the Directives with regard to:
— the interval between tests;
— the number of items to be tested;
— the compulsory nature of tests;
— the categories of vehicles tested.

7. The Member States are responsible for issuing proof that vehicles they have tested comply with these Directives and recognizing proof issued by other Member States.
8. Adoption of specific Directives relating to different tests and the procedure for adapting their standards and methods to technical progress.

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

— Directive 77/143/EEC: 28.12.1977
— Directive 88/449/EEC: 1.1.1993, unless otherwise specified
— Directive 91/225/EEC: 31.12.1991
— Directive 91/328/EEC: 30.6.1993, unless otherwise specified
— Directive 92/54/EEC: 21.6.1993
— Directive 92/55/EEC: 21.6.1993
1.1.1994: private cars;
1.1.1998: private cars where there is no periodic roadworthiness test comparable to that provided for in the Directive;
1.1.1993: light commercial vehicles;
1.1.1995: light commercial vehicles where there is no roadworthiness test for vehicles in that category.
— Directive 94/23/EC: 1.1.1997

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

Directive 94/23/EC: 4.7.1994

(6) References

Official Journal L 47, 18.2.1977
Official Journal L 222, 12.8.1988
Official Journal L 103, 23.4.1991
Official Journal L 178, 6.7.1991
Official Journal L 225, 10.8.1992
Official Journal L 147, 14.6.1994

(7) Follow-up work

(8) Commission implementing measures

2. MOTOR VEHICLES

2.15. EEC type-approval: motor vehicles and their trailers: mechanical coupling devices

(1) Objective	To facilitate the interchangeability of motor vehicles and trailers within the territory of the Community and to harmonize the technical requirements for mechanical coupling devices.
(2) Community measures	European Parliament and Council Directive 94/20/EC of 30 May 1994 relating to the mechanical coupling devices of motor vehicles and their trailers and their attachment to these vehicles.
(3) Contents	1. This Directive contributes towards implementation of the EEC type-approval procedure provided for by Council Directive 70/156/EEC on the approximation of the laws of Member States relating to the type-approval of motor vehicles and their trailers (summary 2.13). 2. The Directive defines 'vehicle' and 'mechanical coupling type'. 3. With effect from 1 October 1995 Member States may prohibit the first entry into service of vehicles of which the mechanical coupling devices fail to comply with the provisions of this Directive. Conversely, Member States may not refuse EEC type-approval or national type-approval for a vehicle or prohibit the sale, registration or use of a vehicle on grounds relating to its coupling device, if the device satisfies the requirements laid down in the Directive. The same applies to component type-approval and to the sale or use of a mechanical coupling device. 4. A procedure for adaptation to technical progress is also included.
(4) Deadline for implementation of the legislation in the Member States	
(5) Date of entry into force (if different from the above)	
(6) References	Not yet published.
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.16. EEC type-approval: motor vehicles and their trailers: lateral protection for goods vehicles

(1) Objective	To harmonize the requirements to be met by vehicles as regards the side-guards of motor vehicles and their trailers.
(2) Community measures	Council Directive 89/297/EEC of 13 April 1989 on the approximation of the laws of the Member States relating to the lateral protection (side-guards) of certain motor vehicles and their trailers.
(3) Contents	1. The Directive applies to big and heavy goods vehicles and their trailers (categories N_2, N_3, O_3 and O_4 as defined in Council Directive 70/156/EEC (summary 2.13) on type-approval of motor vehicles and their trailers) intended for road use with or without bodywork and having a maximum design speed above 25 km/h. It does not apply to buses as their normal bodywork fulfils the requirements. 2. No Member State may refuse for reasons connected with lateral protection to grant type-approval to vehicles which meet the requirements set out in the annex or prevent their sale, registration and use. Any modifications to parts or characteristics referred to in the annex shall be transmitted to the Member State which carried out the EEC type-approval. The Member State may then decide whether to hold fresh tests on the modified type. 3. Annexes containing technical requirements for lateral protection and application form for EEC type-approval. Appendix containing model of annex to type-approval certificate with information on lateral protection. 4. Consultation of a standing committee by the Commission before adapting the annex to technical progress.
(4) Deadline for implementation of the legislation in the Member States	30.10.1989
(5) Date of entry into force (if different from the above)	1.6.1990 and 1.5.1991
(6) References	Official Journal L 124, 5.5.1989
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.17. Weights and dimensions: cars

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

2. MOTOR VEHICLES

2.18. Weights and dimensions: motor vehicles and their trailers

(1) Objective

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

(2) Proposal

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

(3) Contents

1. The Directive applies to the masses, dimensions and technical requirements for all vehicles, except those in category M_1, which are intended to be type-approved, according to their design characteristics.
2. Applications for EEC type-approval of motor vehicles and their trailers must be submitted by the manufacturer or his agent.
3. An EEC type-approval certificate is issued on presentation of three documents relating, in particular, to the description of the vehicle and after checks and tests have been carried out by the testing body.
4. Member States may not refuse EEC type-approval or national type-approval of a vehicle type, or refuse or prohibit the sale, registration, entry into service or use of a vehicle on grounds relating to its masses and dimensions if these satisfy the requirements of this Directive.
5. From 1 October 1993 Member States may no longer issue the document provided for in Council Directive 70/156/EEC (summary 2.13) in respect of a type of vehicle of which the masses and dimensions do not meet the requirements of the Directive. Similarly, they may refuse to grant national type-approval in respect of a type of vehicle of which the masses and dimensions do not meet the requirements of the Directive.

(4) Opinion of the European Parliament

First reading: Parliament approved the Commission proposal subject to amendments concerning its scope and the technical specifications of motor vehicles and their trailers.

(5) Current status of the proposal

Co-decision procedure

The Commission presented the proposal on 17 July 1991.

First reading: On 12 February 1992 Parliament approved the Commission proposal subject to amendments. The Commission has accepted some of the amendments.

An amended proposal incorporating the amendments proposed by Parliament and accepted by the Commission is awaited.

(6) References

Commission proposal COM(91) 239 final	Official Journal C 230, 4.9.1991
European Parliament opinion	Official Journal C 67, 16.3.1992
Economic and Social Committee opinion	Official Journal C 49, 24.2.1992.

2. MOTOR VEHICLES

2.19. Interior fittings

(1) Objective

To harmonize the laws of the Member States in respect of the interior fittings of motor vehicles.

(2) Community measures

Council Directive 74/297/EEC of 4 June 1974 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (behaviour of steering device under impact).

Amended by the following measure:
Council Directive 91/662/EEC of 6 December 1991.

(3) Contents

1. These Directives apply to the behaviour of the steering device fitted to category M_1 motor vehicles and category N_1 vehicles the maximum permissible weight of which is less than 1 500 kg in respect of driver protection in the event of a head-on collision.
2. Component type-approval procedure for each type of vehicle and steering control:
- — application for EC approval:
  - — lodged by the manufacturer or his authorized representative with the authorities respnsible for approval within a Member State;
  - — accompanied by the information requested in line with Annex I to the present Directive;
- — approval procedure:
  - — provision is made for three types of test which concern either the type of vehicle or the type of steering control:
    these are the impact test against a barrier, the impact test against a test block and the headform test;
  - — where the type of vehicle or steering control meets the requirements of the tests an EEC approval certificate and its annex are issued by the Member State authority that is responsible for approval.

3. Implementation of the Directive:
- — 1 October 1992: manufacturers voluntarily meeting the safety standards may obtain EEC approval;
- — 1 October 1995: mandatory application of the safety standards for:
  - — component type-approval of the steering device fitted to forward-control category M_1 vehicles and to all motor vehicles the maximum permissible weight of which does not exceed 1 500 kg;
  - — the placing on the market of steering controls intended to be fitted to one or several types of vehicle;
- — 1 October 1996, mandatory application of safety standards concerning:
  - — the steering device for normal-control category M_1 motor vehicles;
  - — the steering control for all types of vehicle.

These provisions shall only apply from 1 October 1997 to:
- — category M_1 vehicles;
- — category N_1 vehicles the maximum permissible weight of which does not exceed 1 500 kg.

4. Procedure for the adaptation of the Directive to technical progress.

(4) Deadline for implementation of the legislation in the Member States	— Directive 74/297/EEC: 4.12.1975 — Directive 91/662/EEC: 1.10.1992
(5) Date of entry into force (if different from the above)	Directive 91/662/EEC: 1.10.1996, unless otherwise specified.
(6) References	Official Journal L 165, 20.6.1974 Official Journal L 366, 31.12.1991
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.20. Tyres: motor vehicles and their trailers

(1) Objective	To harmonize the national type-approval for tyres and their fitting to motor vehicles and their trailers.
(2) Community measures	Council Directive 92/23/EEC of 31 March 1992 on tyres for motor vehicles and their trailers.
(3) Contents	1. The Directive applies to original and replacement tyres fitted to motor vehicles in category M_1 and trailers in Council Directive 70/156/EEC (summary 2.13). 2. It concerns the technical requirements for the construction and testing of tyres for passenger cars and trailers and requirements relating to the fitting of the tyres to the vehicle.
(4) Deadline for implementation of the legislation in the Member States	1.7.1992
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 129, 14.5.1992
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.21. Tyres: tyre pressure gauges for motor vehicles

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

2. MOTOR VEHICLES

2.22. 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.
(2) Community measures	Council Directive 92/22/EEC of 31 March 1992 concerning safety glass and glazing materials for motor vehicles and their trailers.
(3) Contents	1. The proposal for a Council Directive aims at laying down requirements for the type-approval of the different types of glass and requirements for EEC type-approval of particular vehicles with regard to the installation of the various glazing materials. 2. The proposal also lays down the materials permitted for use in windscreens and for glass other than windscreens.
(4) Deadline for implementation of the legislation in the Member States	1.7.1992
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 129, 14.5.1992
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.23. Motorcycle noise

(1) Objective

To harmonize national Regulations on the sound level and exhaust system of motorcycles.

(2) Community measures

Council Directive 78/1015/EEC of 23 November 1978 on the approximation of the laws of the Member States on the permissible sound level and exhaust system of motorcycles.

Amended by the following measures:
Council Directive 87/56/EEC of 18 December 1986;
Council Directive 89/235/EEC of 13 March 1989.

(3) Contents

1. The Directives apply to motorcycles, i.e. two-wheeled vehicles, with or without a sidecar, fitted with an engine intended for use on the road and having a maximum design speed of more than 50 km/h.
2. The Directives establish common limits for the sound level of motorcycles and technical requirements relating to exhaust systems (construction, materials and durability).
3. The Directives lay down two procedures:
— national type-approval based on harmonized requirements, to be adopted by Member States in addition to or instead of national type-approval according to national requirements;
— EEC type-approval.
4. National type-approval procedure for each type of motorcycle:
— the application for type-approval must be made by the manufacturer to the competent authorities in a single Member State;
— the application must contain the information required by the existing Directives;
— various type-approval tests must be provided for according to the different categories of motorcycle;
— where the type of motorcycle fulfils the test requirements, a national type-approval certificate shall be issued by the competent authority of the Member State in question;
— a system for the mutual exchange of information shall be established between the different national competent authorities;
— each Member State must apply mutual recognition to national type-approval granted by other Member States;
— any lack of national type-approval does not entitle the Member State concerned to adopt discriminatory measures against motorcycles manufactured in compliance with harmonized rather than national requirements;
— applications for amending or extending type-approval may only be made to the Member State which granted the original type-approval;
— further tests and inspections following amendments to a type-approval file shall be authorized if the Member State considers them necessary.
5. EEC type-approval procedure for exhaust systems (silencers), replacement exhaust systems or components thereof as separate technical units:
— the procedure must be identical to the national type-approval procedure;

	— the type-approval application must comply with Annex II of the Directives; — the Member State responsible for tests shall issue an EEC type-approval certificate.
(4) Deadline for implementation of the legislation in the Member States	— Directive 78/1015/EEC: 30.9.1980, unless otherwise specified — Directive 87/56/EEC: 30.9.1988, unless otherwise specified — Directive 89/235/EEC: 30.9.1989, unless otherwise specified
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 349, 13.12.1978 Official Journal L 24, 27.1.1987 Official Journal L 98, 11.4.1989
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.24. Motor vehicle noise

(1) Objective

To implement Community Regulations relating to vehicle noise based on complete harmonization.

(2) Community measures

Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles.

Amended by the following measures:
Commission Directive 73/350/EEC of 7 November 1973;
Council Directive 77/212/EEC of 8 March 1977;
Commission Directive 81/334/EEC of 13 April 1981;
Commission Directive 84/372/EEC of 3 July 1984;
Council Directive 84/424/EEC of 3 September 1984;
Council Directive 87/354/EEC of 25 June 1987;
Commission Directive 89/491/EEC of 17 July 1989;
Council Directive 92/97/EEC of 10 November 1992.

(3) Contents

1. The Directives apply to any motor vehicle intended for use on the road, with or without bodywork, having at least four wheels and a maximum design speed exceeding 25 km/h, with the exception of vehicles which run on rails, agricultural tractors and machinery and public works vehicles.
2. The Directives lay down limits for the noise level of the mechanical parts and exhaust systems of the vehicles concerned. The limits range from 74 dB(A) for motor cars to 80 dB(A) for high-powered goods vehicles.
3. Permissible values are drawn up for specific categories of vehicles:
— cars;
— public transport vehicles;
— goods vehicles.
4. Member States are required to publish noise level values for type-approval by 1 October 1994.
5. Hence Member States may not, for reasons relating to the permissible sound level and exhaust system:
— refuse or prohibit the sale, registration, placing on the market or use of vehicles which comply with the provisions of the Directive;
— prohibit the placing on the market of an exhaust system or technical unit if they correspond to a type in respect of which type-approval has been granted.
6. Tax incentives granted by Member States to encourage new limits to be met in advance may be authorized if they are:
— non-discriminatory;
— for a limited period;
— of an amount which is significantly lower than the cost of the equipment fitted;
— applied to vehicles fitted with equipment which enables future European standards to be met in advance.
7. Type-approval procedure for each type of vehicle, exhaust system and technical unit (silencer and replacement exhaust system):
— the application for EEC type-approval shall be submitted by the manufacturer or his authorized representative;

— it shall contain the information required by the existing Directives;
— different type-approval tests shall be provided for;
— where the type of vehicle, exhaust system or technical unit meets the test requirements, an EEC type-approval certificate shall be issued by the competent authority of the Member State in question.

8. Provisions for a second stage in the reduction of motor vehicle noise: the Council will undertake by 1 October 1995, on a proposal from the Commission by 31 March 1994, to lay down criteria and methods for limiting the noise arising from contact between tyres and the road surface.

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

— Directive 70/157/EEC: 6.7.1970
— Directive 73/350/EEC: 29.2.1974
— Directive 77/212/EEC: 31.3.1977
— Directive 81/334/EEC: 31.12.1981
— Directive 84/372/EEC: 5.7.1984
— Directive 84/424/EEC: 31.12.1984
— Directive 87/354/EEC: 31.12.1987
— Directive 89/491/EEC: 1.1.1990
— Directive 92/97/EEC: 30.6.1993

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

— Directive 73/350/EEC: 1.10.1975, unless otherwise specified
— Directive 77/212/EEC: 1.10.1982, unless otherwise specified
— Directive 81/334/EEC: 1.1.1985, unless otherwise specified
— Directive 84/424/EEC: 1.10.1989, unless otherwise specified
— Directive 92/97/EEC: 1.10.1996
1.10.1993: manufacturers complying voluntarily with limits may obtain EEC type-approval;
1.10.1995: compulsory application of limits for type-approval of new types of vehicles;
1.10.1996: compulsory application of limits for all types of vehicles, including those type-approved previously.

(6) References

Official Journal L 42, 23.2.1970
Official Journal L 321, 22.11.1973
Official Journal L 66, 12.3.1977
Official Journal L 131, 18.5.1981
Official Journal L 196, 26.7.1984
Official Journal L 238, 6.9.1984
Official Journal L 192, 11.7.1987
Official Journal L 238, 15.8.1989
Official Journal L 371, 19.12.1992

(7) Follow-up work

(8) Commission implementing measures

2. MOTOR VEHICLES

2.25. Air pollution: passenger cars: petrol engines, diesel engines

(1) Objective

To establish limit values for emissions from petrol-engined and diesel-engined passenger cars.

(2) Community measures

Council Directive 70/220/EEC of 20 March 1970 on the approximation of the laws of the Member States relating to measures to be taken against air pollution by emissions from motor vehicles.

Amended by the following measures:
Council Directive 74/290/EEC of 28 May 1974;
Commission Directive 77/102/EEC of 30 November 1976;
Commission Directive 78/665/EEC of 14 July 1978;
Council Directive 83/351/EEC of 16 June 1983;
Council Directive 88/76/EEC of 3 December 1987;
Council Directive 88/436/EEC of 16 June 1988;
Commission Directive 89/491/EEC of 17 July 1989;
Council Directive 89/458/EEC of 18 July 1989;
Council Directive 91/441/EEC of 26 June 1991;
Council Directive 93/59/EEC of 28 June 1993;
Council Directive 94/12/EC of 23 March 1994.

(3) Contents

1. The Directives cover motor vehicles with positive-ignition and compression-ignition engines:
— intended for use on public roads;
— with or without body;
— with at least four wheels;
— with a maximum authorized mass not exceeding 3 500 kg and a maximum design speed of at least 50 km/h;
— except for agricultural vehicles and machines and civil engineering equipment.

2. The Directives apply to tailpipe emissions, evaporative emissions, emissions of crankcase gases and the durability of anti-pollution devices for all motor vehicles equipped with positive-ignition engines and to the tailpipe emissions from vehicles of categories M_1 and N_1 equipped with compression-ignition engines, with the exception of those vehicles of category N_1 for which type-approval has been granted pursuant to Directive 88/77/EEC (summary 2.26).

3. The Directives lay down differing limit values for emissions, by petrol and diesel cars:
— of carbon monoxide;
— of unburnt hydrocarbons;
— of nitrogen oxides from petrol and diesel engines;
— and, specifically for diesel engines, limit values for particulate pollutants;
Depending on the category of vehicle, the reductions range from 25 to 50%.

4. Tax incentives granted by Member States to encourage advance compliance with new limit values are permitted on condition that they are:
— non discriminatory;
— for a limited period only;
— worth less than the cost of the devices installed;

— apply to vehicles equipped with technology enabling the future European standards to be met in advance.

5. Procedure for type-approval of vehicles:

— the application for EEC type-approval with regard to tailpipe emissions, evaporative emissions and the durability of anti-pollution devices is submitted by the vehicle manufacturer or by his authorized representative;

— it must contain the information required pursuant to the Directives;

— there are five types of type-approval tests depending on the category to which the vehicles belong. They concern:
  — average tailpipe emissions after a cold start;
  — carbon monoxide emissions;
  — crankcase gas emissions;
  — evaporative emissions;
  — durability of anti-pollution devices;

— if the vehicle type meets the test requirements, an EEC type-approval certificate is issued by the competent body of the Member State which is responsible for the type-approval.

6. Further reduction of limit values: the Council undertakes to lay down before 30 June 1996, on the basis of a proposal presented by the Commission no later than 31 December 1994, more stringent standards which will become applicable from the year 2000. These new limit values will serve as a basis for calculating tax incentives.

7. The new full European test cycle provided for by Directive 91/441/EEC is the procedure used to establish conformity with the limit values.

8. Clause concerning manufacturers whose world-wide annual production is less than 10 000 units, allowing them to obtain EEC type-approval on the basis of the US emission standards or of the 'Master document' prepared by the international meeting in Stockholm on air pollution by motor vehicles, as an alternative to the European standards laid down by the above Directives.

9. Annexes on EEC type-approval, the information document and the tests (conditions, test procedure, analyses).

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

— Directive 70/220/EEC: 29.6.1970
— Directive 74/290/EEC: 30.9.1974
— Directive 77/102/EEC: 31.12.1976
— Directive 78/665/EEC: 31.12.1978
— Directive 83/351/EEC: 30.11.1983
— Directive 88/76/EEC: 30.6.1988
— Directive 88/436/EEC: 1.10.1988
— Directive 89/491/EEC: 1.1.1990
— Directive 89/458/EEC: 31.12.1989
— Directive 91/441/EEC: 31.12.1991
— Directive 93/59/EEC: 30.9.1993
— Directive 94/12/EC: 1.7.1994

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

— Directive 70/220/EEC: 1.10.1971
— Directive 74/290/EEC: 1.10.1976
— Directive 77/102/EEC: 1.10.1980
— Directive 78/665/EEC: 1.10.1981
— Directive 83/351/EEC: 1.10.1986
— Directive 88/76/EEC: 1.10.1990
— Directive 88/436/EEC: 1.10.1990

— Directive 89/458/EEC: 31.12.1992
— Directive 91/441/EEC: 1.1.1992: manufacturers conforming voluntarily to the limit values can obtain EEC type-approval;
1.7.1992: mandatory application of the limit values for type-approval of new vehicle types;
31.12.1992: mandatory application of the limit values to all vehicle types, including those approved previously.
— Directive 93/59/EEC: 1.10.1993: new type-approvals;
1.10.1994: all new vehicles.
— Directive 94/12/EC: 1.10.1996: new type-approvals;
1.10.1997: all new vehicles.

(6) References

Official Journal L 76, 6.4.1970
Official Journal L 159, 15.6.1974
Official Journal L 32, 3.2.1977
Official Journal L 223, 14.8.1978
Official Journal L 197, 20.7.1983
Official Journal L 36, 9.2.1988
Official Journal L 214, 6.8.1988
Official Journal L 238, 15.8.1989
Official Journal L 226, 3.8.1989
Official Journal L 242, 30.8.1991
Official Journal L 186, 28.7.1993
Official Journal L 100, 19.4.1994

(7) Follow-up work

(8) Commission implementing measures

2. MOTOR VEHICLES

2.26. Air pollution: emission of gaseous pollutants from diesel engines

(1) Objective	To approximate the technical requirements for diesel engines within the Community to combat air pollution.
(2) Community measures	Council Directive 88/77/EEC of 3 December 1987 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous pollutants from diesel engines for use in vehicles.
(3) Contents	1. For the purpose of this Directive a vehicle is any vehicle propelled by a diesel engine intended for use on the road, with or without bodywork, having at least four wheels and a maximum design speed exceeding 25 km/h, with the exception of vehicles which run on rails, agricultural tractors and machines, and public works vehicles. 2. From 1 July 1988 no Member State may, on grounds relating to the gaseous pollutants emitted from an engine, refuse to grant EEC or national type-approval or prohibit the entry into service, use, sale or registration of vehicles equipped with engines which satisfy the requirements of the Directive. From 1 October 1990 Member States may prohibit the entry into service, use, registration and sale of new vehicles equipped with engines which fail to satisfy the requirements of the Directive. 3. If an engine which has received type-approval is modified, the Member State which granted type-approval must decide whether fresh tests need to be performed and take appropriate action. If the tests reveal failure to comply with the Directive, the modifications will not be approved. 4. The amendments necessary to adapt the requirements of the annexes to technical progress will be adopted in accordance with the procedure laid down in Directive 70/156/EEC (summary 2.13). 5. The technical annexes include detailed information on the type-approval and testing procedures (with specifications of the limits for emissions of gaseous pollutants).
(4) Deadline for implementation of the legislation in the Member States	1.7.1988
(5) Date of entry into force (if different from the above)	30.9.1990 for the particular types of vehicle and diesel engines specified in the annex.
(6) References	Official Journal L 36, 9.2.1988
(7) Follow-up work	See summary 2.27.
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.27. Air pollution: emissions from diesel engines: new standards

(1) Objective

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

(2) Community measures

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

(3) Contents

1. After 1 January 1992 Member States may not:
— refuse to grant EEC type-approval, or to issue the document provided for by Article 10 of Council Directive 70/156/EEC (summary 2.13) or to grant national type-approval for a type of vehicle with a diesel engine, or
— prohibit the registration, sale, entry into service or use of new vehicles of that type, or
— refuse to grant EEC type-approval or national type-approval for a type of diesel engine, or
— prohibit the sale or use of new diesel engines,
if they satisfy the requirements contained in Council Directive 88/77/EEC (summary 2.26).
2. After 1 July 1992 Member States:
— may no longer grant EEC type-approval or issue the document provided for by Article 10 of Directive 70/156/EEC, and;
— must refuse to grant national type-approval for types of diesel engine and types of vehicle with a diesel engine,
where emissions do not comply with limits laid down in line A of the table in Annex I of Directive 88/77/EEC.
3. After 1 October 1995 Member States:
— may no longer grant EEC type-approval or issue the document provided for by Article 10 of Directive 70/156/EEC, and
— must refuse to grant national type-approval for types of diesel engine and types of vehicle with a diesel engine,
where emissions do not comply with limits laid down in line B of the table in Annex I of Directive 88/77/EEC.
4. Until 30 September 1993 points 2 and 3 shall not apply to types of vehicle with a diesel engine if that engine is accompanied by a type-approval certificate issued before 1 July 1992 in accordance with the provisions of Directive 88/77/EEC and of Annex VIII of this Directive.
5. After 1 October 1993 Member States shall prohibit the registration, sale, entry into service and use of new vehicles with a diesel engine and shall prohibit the sale and use of new diesel engines where emissions do not comply with limits laid down in line A of the table of Annex I of Directive 88/77/EEC.
6. After 1 October 1996 Member States shall prohibit the registration, sale, entry into service and use of new vehicles with a diesel engine and shall prohibit the sale and use of new diesel engines where emissions do not comply with limits laid down in line B of the table of Annex I of Directive 88/77/EEC.

	7. By the end of 1991 the Commission will be presenting a new proposal for making an improved diesel fuel available in the Member States with a maximium authorized sulphur content of 0.05%. 8. Member States may make provision for tax incentives for the vehicles covered by this Directive. Such incentives must: — apply to all domestic car production and to imported vehicles which are marketed in a Member State and are fitted with equipment allowing the European standards to be met in 1996 to be satisfied; — cease on the date set for the compulsory entry into force of the emission values for new vehicles; — be of a value, for each type of vehicle, lower than the actual cost of the equipment fitted to meet the values set and of its fitting to the vehicle. 9. Before the end of 1993 the Commission will be reporting on the progress made regarding: — the availability of techniques for controlling air-polluting emissions from diesel engines, particularly those of less than 85 kW; — a new statistical method for the monitoring of production conformity to be adopted in accordance with the provisions of Directive 88/77/EEC. If necessary, it will submit a proposal for revising upwards the limit values for particulate emissions. The Council shall take a decision on the basis of that proposal not later than 30 September 1994. 10. Before the end of 1996, in the light of the technical progress achieved, the Commission shall submit a revision of the limit values for polluting emissions combined with a revision of the test procedure. The new limit values shall not be applicable before 1 October 1999 as regards new type-approvals. 11. Annexes containing amendments to the Annexes of Directive 88/77/EEC concerning scope, definitions and abbreviations, application for EEC type-approval, requirements and tests and production conformity; information document; test procedure; technical characteristics of reference fuel prescribed for approval tests and to verify conformity of production; analytical and sampling systems; EEC type-approval certificate.
(4) Deadline for implementation of the legislation in the Member States	1.1.1992
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 295, 25.10.1991
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.28. Air pollution: sulphur content of certain liquid fuels

(1) Objective	To limit the sulphur content of gasoils and kerosenes.
(2) Community measures	Council Directive 93/12/EEC of 22 March 1993 relating to the sulphur content of gasoil.
(3) Contents	1. The Directive shall not apply to gasoils intended for processing or to those contained in the fuel tanks of motor vehicles crossing a frontier between a third country and a Member State. 2. During the first stage, a single limit value of 0.2% in weight shall be fixed for the sulphur content of all gasoils as from 1 October 1994. This provision shall apply to all gasoils falling under CN Code 2710 00 69, and to any petroleum product which, by reason of its distillation limits, falls into the category of middle distillates (including kerosenes). For diesel fuels, a limit value of 0.05% by weight shall apply as from 1 October 1996. Member States shall take all necessary steps to ensure the gradual availability of this product. 3. In the event of difficulties in the supply of crude oil or petroleum products, the Member State concerned is required to inform the Commission thereof. The Commission may authorize a higher limit for sulphur content for a period not exceeding six months. 4. By way of derogation, the Greek Government will be allowed to authorize the marketing of bunker gasoils with a sulphur content of more than 0.2% in weight until 30 September 1999.
(4) Deadline for implementation of the legislation in the Member States	1.10.1994
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 74, 27.3.1993
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.29. Spray-suppression devices

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

2. MOTOR VEHICLES

2.30. Road vehicles: weights and dimensions

(1) Objective

To harmonize Member States' rules on the weights and dimensions of certain commercial road vehicles with a view to permitting the improved use of such vehicles in traffic between Member States.

(2) Community measures

Council Directive 85/3/EEC of 19 December 1984 on the weights, dimensions and certain other technical characteristics of certain road vehicles.

Amended by the following measures:
Council Directive 86/360/EEC of 24 July 1986;
Council Directive 86/364/EEC of 24 July 1986;
Council Directive 88/218/EEC of 11 April 1988;
Council Directive 89/338/EEC of 27 April 1989;
Council Directive 89/460/EEC of 18 July 1989;
Council Directive 89/461/EEC of 18 July 1989;
Council Directive 91/60/EEC of 4 February 1991;
Council Directive 92/7/EEC of 10 February 1992.

(3) Contents

1. These Directives apply to:
— the dimensions of vehicles with at least four wheels and a maximum speed in excess of 25 km/h, intended to be used on the road for:
  — either the carriage of goods where their maximum laden weight is greater than 3.5 tonnes (motor vehicle coupled to a trailer, motor vehicle coupled to a semi-trailer, or thick-walled refrigerated vehicle),
  — or passenger transport where they have more than nine seats (bus or articulated bus);
— the weights and certain other characteristics of the above vehicles.

2. The Directives lay down the maximum authorized weights and dimensions of the vehicles concerned.

3. Any vehicle:
— registered or put into circulation in a Member State,
— used in international traffic, and
— complying with the limit values specified in the Directive

may be used on the territory of the other Member States.

4. Specific provisions apply to vehicles with five or six axles, articulated vehicles and road trains:
— vehicles with five or six axles:
  — first put into circulation on or after 1 January 1990,
  — satisfying the above three criteria,
  — and complying with the requirements of the fourteen Directives listed in Annex II

may circulate freely;
— articulated vehicles:
  — put into circulation before 1 January 1991,
  — not complying with certain of the Directive's provisions
  — and no longer than 15.5 m

may also circulate freely;

— road trains:
  — put into circulation before 31 December 1991,
  — not complying with certain of the Directive's provisions,
  — and no longer than 18 m

may circulate freely until 31 December 1998.

5. Exemptions from the Directives:

— Member States:
  — are free to adopt provisions that differ from the Directives with regard to vehicles registered or put into circulation on their territory;
  — are entitled to require such vehicles to meet their national requirements;
— Any Member State authorizing weights and dimensions in excess of those laid down in the Directives may limit their application to vehicles registered or put into circulation on its territory when used in domestic traffic in that Member State;
— Member States may limit the weight and dimensions of vehicles on certain roads or civil engineering structures, irrespective of their State of registration.

6. Certain provisions of points 3, 5 and 6 relating to vehicles of various types do not apply in Ireland or the United Kingdom until 31 December 1998.

7. Proof of a vehicle's compliance with the Directive:

— The Member States must adopt one of the following measures regarding proof of a vehicle's compliance with these Directives:
  — a manufacturer's plate supplemented by a plate bearing the vehicle's dimensions in accordance with Council Directive 76/114/EEC (Official Journal L 24, 30.1.1976);
  — a single plate containing the information of both the above-mentioned plates;
  — a single document issued by the competent authorities of the Member State in which the vehicle is registered or put into circulation and containing the same information as the plates.
— Member States must recognize proof issued by another Member State;
— The Member State in which a vehicle is registered is responsible for making any subsequent amendments to proof of compliance.

8. The annexes lay down the maximum weights and dimensions of the vehicles concerned and list the specific Directives with which vehicles of a given type must comply.

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

— Directive 85/3/EEC: 1.7.1986, unless otherwise specified
— Directive 86/360/EEC: 1.7.1986, unless otherwise specified
— Directive 86/364/EEC: 28.7.1987
— Directive 88/218/EEC: 2.1.1989
— Directive 89/338/EEC: 1.7.1989, unless otherwise specified
— Directive 89/460/EEC: Not communicated
— Directive 89/461/EEC: 31.12.1990
— Directive 91/60/EEC: 30.9.1991
— Directive 92/7/EEC: 31.12.1992

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

(6) References

Official Journal L 2, 3.1.1985
Official Journal L 217, 5.8.1986
Official Journal L 221, 7.8.1986
Official Journal L 98, 15.4.1988
Official Journal L 142, 25.5.1989
Official Journal L 226, 3.8.1989
Official Journal L 37, 9.2.1991
Official Journal L 57, 2.3.1992

(7) Follow-up work

(8) Commission implementing measures

2. MOTOR VEHICLES

2.31. Speed-limitation devices for heavy vehicles and coaches

(1) Objective	To limit the maximum speed of heavy vehicles used to carry goods or passengers on the Community's roads.
(2) Community measures	Council Directive 92/24/EEC of 31 March 1992 relating to speed-limitation devices of certain categories of motor vehicles.
(3) Contents	1. This Directive applies to EEC type-approved speed-limitation devices and their installation in motor vehicles. 2. An application for EEC type-approval of a speed-limitation device must be submitted by the manufacturer of the vehicle or the manufacturer of the device. 3. The speed-limitation device must be so designed, constructed and assembled as to resist the corrosion and ageing phenomena to which it may be exposed. 4. It must be impossible to raise or override the limitation threshold whilst a vehicle is in use. 5. The holder of an approval must ensure conformity of production. In particular, he must guarantee the existence of procedures allowing effective quality control of the speed limitation device. 6. EEC type-approval may be withdrawn where production does not comply with the requirements. 7. Member States may not refuse type-approval or national type-approval for a vehicle, or refuse or prohibit the sale, registration, entry into service or use of a vehicle on grounds relating to its equipment with a speed-limitation device, if the latter conforms to the requirements of this Directive. Similarly, Member States may not refuse EEC or national type-approval for a speed-limiting device, or prohibit the sale or use of a speed-limiting device. 8. From 1 January 1994 Member States may no longer issue the document provided for in the third indent of Article 10(1) of Directive 70/156/EEC (summary 2.13) in respect of a type of vehicle of which the speed-limitation devices do not meet the requirements of the Directive. Similarly, from 1 October 1994 they can refuse to grant national type-approval in respect of a type of vehicle of which the speed-limitation devices do not comply with the provisions of this Directive.
(4) Deadline for implementation of the legislation in the Member States	1.1.1993
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 129, 14.5.1992
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.32. Speed-limitation devices for motor vehicles

(1) Objective	To limit the maximum speed of commercial vehicles operating on Community roads.
(2) Community measures	Council Directive 92/6/EEC of 10 February 1992 relating to the installation and use of speed-limitation devices in certain categories of motor vehicles in the Community.
(3) Contents	1. The Directive applies to category M_3 vehicles of over 10 tonnes and category N_3 vehicles. 2. As in Council Directive 70/156/EEC (summary 2.13), the following definitions apply: — Category M_3: vehicles used for the carriage of passengers, comprising of more than eight seats in addition to the driver's seat and having a maximum weight exceeding 5 tonnes; — Category N_3: vehicles used for the carriage of goods and having a maximum weight exceeding 12 tonnes. 3. Category M_3 and category N_3 motor vehicles referred to in point 1 and registered in any Member State after 1 January 1988 may use the public highway as long as they are fitted with a device which limits vehicle speed to a maximum of 100 km/h and 85 km/h respectively. 4. The Directive does not apply to motor vehicles: — of the armed forces, civil protection forces, the fire brigades or the forces responsible for maintaining public order; — which, because of their design, cannot exceed 80 km/h if they are category N_3 vehicles, or 100 km/h if they are category M_3 vehicles and weigh over 10 tonnes; — used solely in urban areas to provide public services.
(4) Deadline for implementation of the legislation in the Member States	1.10.1993
(5) Date of entry into force (if different from the above)	— 1.1.1994: for new vehicles; — 1.1.1995: for vehicles registered after 1 January 1988.
(6) References	Official Journal L 57, 2.3.1992
(7) Follow-up work	
(8) Commission implementing measures	

2. MOTOR VEHICLES

2.33. External projections on cabs of commercial vehicles

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

3. TRACTORS AND AGRICULTURAL MACHINERY

Current position and outlook

The existence of differing national technical regulations and standards is a major problem in the manufacture of agricultural machinery. Production lines cannot be rationalized, thus preventing manufacturers from taking advantage of economies of scale. A further problem is the absence of Community-wide type-approval procedures. Individual Member States thus require national testing and certification of components and the tractor itself: a costly and wasteful process.

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

Since 1 January 1990 manufacturers have been able to obtain EEC type-approval from the inspection authorities and on this basis issue certificates of conformity for each of the tractors produced. The type-approval and certificate are recognized throughout the Community. However, since the system is optional manufacturers may continue to apply for national type-approval. They do so where they feel that the Community requirements, above all in respect of safety, are too stringent.

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

3. TRACTORS AND AGRICULTURAL MACHINERY

3.1. EEC type-approval: components and characteristics

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

3. TRACTORS AND AGRICULTURAL MACHINERY

3.2. EEC type-approval

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

3. TRACTORS AND AGRICULTURAL MACHINERY

3.3. Front-mounted protection structures

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

4. FOODSTUFFS

Current position and outlook

The creation of the single market for foodstuffs is the result of a lengthy legislative process which began in the early 1960s with the adoption of the first Directives on food additives and is about to be completed with the adoption of new Directives in this area (summaries 4.5 to 4.8).

Initially, the Community had followed a dual approach: a horizontal approach covering a range of foodstuffs (e.g. the additives that they could contain and the general rules on labelling for all foodstuffs) and a vertical approach aimed at regulating the manufacture and marketing of specific products (e.g. chocolate, preserves and fruit juices).

The vertical approach was, however, a very cumbersome and ineffective process, often requiring years of negotiations for each product under consideration. It was therefore decided in 1985 to opt for a 'new approach' which is both more rational and more flexible and which redefines the method of harmonization and also simplifies the procedure for applying that method.

The new approach redefines the method of harmonization because it replaces vertical harmonization with horizontal harmonization. The Community now no longer legislates on specific products but draws up rules which will determine the requirements common to all foodstuffs. The measures that it proposes seek to ensure that foodstuffs meet the essential requirements, namely protection of public health, consumer protection, fair trading and public controls on foodstuffs.

By redefining those matters requiring regulations at Community level, it has been possible to speed up harmonization and greatly reduce the amount of work involved.

The new approach also simplifies the harmonization procedure. The Council now only adopts framework Directives laying down the essential health and safety requirements, leaving it to the Commission to adopt measures giving the details and technical specifications. For example, in the matter of materials coming into contact with foodstuffs, the Council has adopted a framework Directive on such materials, while the Commission has adopted a series of specific Directives on regenerated-cellulose film, plastics, vinylchloride monomer, etc. (summaries 4.19 to 4.25).

This 'new approach in harmonization' applies not only to foodstuffs but has proved necessary in a number of sectors where vertical harmonization was too slow and unwieldy to achieve genuine freedom of movement for goods within the Community.

In the foodstuffs sector, this approach was furthered by the publication of interpretative communications in 1985, 1989 and 1991.

Current Community legislation in this area clearly reflects the new approach adopted by the Community.

Legislation on individual products, the result of vertical harmonization, still applies since the Community is completing work begun in this area and continues to propose amendments where these prove necessary although it has given up this approach in sectors not covered by common legislation (summaries 4.50 to 4.60).

Most legislation on foodstuffs, however, stems from the new approach and therefore concerns aspects which are common to all foodstuffs, such as additives, labelling, materials coming into contact with them, etc.

4. FOODSTUFFS

4.1. General provisions: Standing Committee for Foodstuffs

(1) Objective	To set up a Standing Committee for Foodstuffs.
(2) Community measures	Council Decision 69/414/EEC of 13 November 1969 setting up a Standing Committee for Foodstuffs.
(3) Contents	1. This Decision institutes a Standing Committee for Foodstuffs, reporting to the Commission, for the purpose of ensuring close cooperation between the Member States and the Commission and of enabling the latter to consult experts. 2. The Committee consists of representatives of the Member States and is chaired by a representative of the Commission. 3. The Committee is consulted when measures adopted by the Council in the field of foodstuffs so specify. At the initiative of its Chairman or at the request of one of its members the Committee may also consider any other question relating to foodstuffs. 4. The Committee shall adopt its own rules of procedure.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	13.11.1969
(6) References	Official Journal L 291, 19.11.1969
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.2. General provisions: Scientific Committee for Food

(1) Objective	To establish a Scientific Committee for Food.
(2) Community measures	Commission Decision 74/234/EEC of 16 April 1974 relating to the institution of a Scientific Committee for Food. Amended by the following measure: Commission Decision 86/241/EEC of 25 April 1986.
(3) Contents	1. The following text contains a consolidation of existing Decisions relating to the institution of a Scientific Committee for Food. 2. These Decisions institute a Scientific Committee for Food, reporting to the Commission, for the purpose of ensuring close cooperation between the Member States and the Commission and of enabling the latter to consult experts. The Committee may be consulted by the Commission on any problem relating to the protection of the health and safety of persons arising from the consumption of food (such as the composition of food, the use of food additives, the presence of contaminants, etc.). It may also, on its own initiative, draw the attention of the Commission to any such problem. 3. The Decisions lay down the rules governing the membership of the Committee, and its rules of procedure and functioning. 4. The members of the Committee are obliged to treat matters discussed in the Committee as confidential.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	Not communicated.
(6) References	Official Journal L 136, 20.5.1974 Official Journal L 163, 19.6.1986
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.3. General provisions: Advisory Committee for Foodstuffs

(1) Objective	To establish a new Statute of the Advisory Committee for Foodstuffs.
(2) Community measures	Commission Decision 80/1073/EEC of 24 October 1980 establishing a new Statute of the Advisory Committee for Foodstuffs.
(3) Contents	1. Commission Decision 80/1073/EEC of 24 October 1980 repeals Commission Decision 75/420/EEC. 2. The Decision institutes an Advisory Committee for Foodstuffs, attached to the Commission, for the purpose of ensuring close cooperation between the Member States and the Commission and of enabling the latter to consult experts. The Committee may be consulted by the Commission on any matter related to the harmonization of foodstuffs legislation. It may also, on its own initiative, draw the attention of the Commission to any such matter even if its opinion has not been specifically sought. 3. The Decision lays down the rules governing the membership of the Committee and the appointment of its members. It consists of 10 permanent members and 20 experts divided into five economic groups representing agriculture (COPA and Cogeca), commerce (the most representative organizations), consumers (CCC), industry (UNICE) and workers (ESC). The Commission has adopted the practice of consulting these socio-economic organizations; it is not legally required to do so as is the case with the Standing Committee for Foodstuffs (summary 4.1). 4. The Decision lays down the Committee's rules of procedure and the role of the Commission. 5. Those taking part in the meetings of the Committee are obliged to treat all matters discussed in the Committee as confidential.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	26.11.1980
(6) References	Official Journal L 318, 26.11.1980
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.4. General provisions: assistance and cooperation with scientific examination

(1) Objective	To permit cooperation between the administrations of the Member States and the Commission to give necessary assistance for scientific examinations
(2) Community measures	Council Directive 93/5/EEC of 25 February 1993 on assistance and cooperation to the Commission by the Member States in the scientific examination of questions relating to food.
(3) Contents	1. The Directive applies when a Council act requires the opinion of the Scientific Committee for Food and when problems relating to the protection of the health and safety of persons arise from the consumption of food (summary 4.2). 2. The Member States are required to designate the authorities or bodies which will be responsible for cooperation with the Commission and for the distribution of work to appropriate institutes within Member States as regards such main tasks as drawing up risk assessment protocols in relation to foods and methods of nutritional evaluation. They must notify the Commission accordingly. 3. The Member States are required to take the necessary measures, including financial measures, to enable their competent authorities and bodies to cooperate with the Commission and lend it the scientific assistance it needs in such fields as medicine, toxicology, biology, microbiology, biotechnology, novel foods and processes, methods of analysis, risk assessment techniques, physics and chemistry. 4. The Commission is authorized to open negotiations with a view to concluding agreements with third countries guaranteeing their participation in certain forms of cooperation laid down in the Directive, including the establishment of work programmes and definition of the rules for the administrative management of such cooperation.
(4) Deadline for implementation of the legislation in the Member States	1.6.1993
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 52, 4.3.1993
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.5. Additives: authorized food additives

(1) Objective	To establish a common list of additives for use in foodstuffs intended for human consumption.
(2) Community measures	Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives for use in foodstuffs intended for human consumption.
(3) Contents	1. The scope of the Directive covers food additives used as ingredients during the manufacture or preparation of food and which are part of the finished product and listed in one of the categories in Annex I (a 'food additive' being any substance not normally consumed as a food itself, the intentional addition of which results in its becoming an ingredient). 2. The only substances which may be used as food additives are those included in the approved lists and then only under the conditions of use mentioned in those lists (e.g. preservatives, emulsifiers, sweeteners, raising agents). 3. The Council will draw up: — a list of substances the use of which is authorized to the exclusion of all others; — a list of foodstuffs to which these substances may be added and the conditions under which they may be added, and restrictions which may be imposed in respect of technological purposes; — rules concerning substances used as solvents including purity criteria where necessary. 4. A special procedure permitting the Commission to legislate after consulting the Standing Committee on Foodstuffs will apply to: — the drawing up of purity criteria; — where necessary, the methods of analysis needed to verify that the criteria of purity are satisfied; — where necessary, the procedure for taking samples and the methods for the qualitative and quantitative analysis of food additives in and on foodstuffs; — other rules necessary to ensure compliance with the rule that only listed additives may be used. 5. Provisions for action by Member States on listed additives even if the additives which are considered for specific reasons to carry a health risk comply with the Directive. 6. Conditions for provisional authorization by a Member State for the marketing and use of unlisted additives belonging to the categories listed in Annex 1 to the Directive in the light of scientific and technical progress, e.g. maximum limit of two years' circulation. 7. Information requirements on labelling and packaging of additives for sale to both the consumer and the manufacturer.
(4) Deadline for implementation of the legislation in the Member States	28.6.1990

(5) Date of entry into force (if different from the above)	— 28.12.1990: permit trade in products which meet the requirements of the Directive; — 28.12.1991: prohibit trade in products which do not meet the requirements of the Directive.
(6) References	Official Journal L 40, 11.2.1989
(7) Follow-up work	See summaries 4.6 to 4.8.
	On 16 June 1994 the Council adopted a Directive amending Directive 89/107/CEE on the approximation of the laws of the Member States concerning food additives intended for human consumption. Member States are authorized to prohibit the use of certain additives in foodstuffs produced using traditional methods on their territories, provided the prohibition existed on 1 January 1992 and that the free movement of goods is not affected. However, Member States are required to permit on their territory the production of non-traditional products in conformity with the Directives on additives.
(8) Commission implementing measures	

4. FOODSTUFFS

4.6. Additives: colouring

(1) Objective	To lay down the list and maximum quantities of colours authorized for use in foodstuffs.
(2) Community measures	European Parliament and Council Directive 94/XXX/EC of 16 June 1994 on colours intended for use in foodstuffs.
(3) Contents	1. The Directive applies to the colours used in authorized foodstuffs as listed in Annex I thereto, such as E 100 (curcumin) and E 102 (tartrazine). 2. The Directive does not apply to: — foodstuffs, flavourings and their components, incorporated during the manufacturing of compound foodstuffs, such as paprika and saffron; — colours used for the colouring of eggshells and for stamping meat and the inedible external parts of foodstuffs. 3. The Directive prohibits the use of colours in certain foodstuffs, including mineral water and whole milk. 4. Exceptions are allowed to the ban mentioned in paragraph 3 for certain foodstuffs, such as wholemeal bread, beer and smoked and cured fish, to which specific colours may be added.
(4) Deadline for implementation of the legislation in the Member States	
(5) Date of entry into force (if different from the above)	
(6) References	Not yet published.
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.7. 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) Community measures	European Parliament and Council Directive 94/XXX/EC of 16 June 1994 on sweeteners intended for use in foodstuffs.
(3) Contents	1. This Directive is a specific Directive forming part of the comprehensive Directive 89/107/EEC (summary 4.5). 2. The Directive applies to food additives used to impart a sweet taste to foodstuffs or as table-top sweeteners. It does not apply to foodstuffs with sweetening properties such as honey. 3. The sweeteners which may be placed on the market for sale to consumers or for use in the production of foodstuffs and the maximum doses for the use of such additives in foodstuffs are specified in the annex. The doses specified refer to ready-to-eat foodstuffs only. 4. Member States are required to establish a system of regular surveys to monitor sweetener consumption. On the basis of this information, the conditions of use of sweeteners as laid down in the Directive may, if necessary, be amended.
(4) Deadline for implementation of the legislation in the Member States	
(5) Date of entry into force (if different from the above)	
(6) References	Not yet published.
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.8. Additives: additives other than colouring and sweeteners

(1) Objective

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

(2) Proposal

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

(3) Contents

1. The Directive is a specific Directive forming part of the comprehensive Directive 89/107/EEC (summary 4.5).
2. The Directive lists in annexes the substances which may be used as food additives other than colouring and sweeteners.
3. The presence of a food additive is permitted in a compound foodstuff to the extent that the food additive is permitted in the separate ingredients that make up the compound foodstuff. Its presence is also permitted in a foodstuff which is intended to be used solely in the preparation of another foodstuff provided the compound foodstuff conforms to the provisions of the Directive.
4. The maximum levels indicated in the annexes refer to foodstuffs as marketed.
5. Within five years of the adoption of the Directive, the Commission will review the conditions of use and propose modifications where necessary.

(4) Opinion of the European Parliament

First reading: Parliament approved the Commission's proposal subject to certain amendments. These amendments concern customer information on the presence of additives in the final product, how these additives are used in certain basic foodstuffs, the role of the Scientific Committee on Foodstuffs for Human Consumption and procedures for adaptation of the Directive.

(5) Current status of the proposal

Co-decision procedure

The Commission presented the proposal on 1 July 1992.

First reading: On 26 May 1993 Parliament approved the Commission proposal subject to amendments. The Commission has accepted some of the amendments.

The Commission presented an amended proposal on 22 June 1993.

On 10 March 1994 the Council adopted its common position, which is now before Parliament for a second reading.

(6) References

Commission proposal COM(92) 255 final	Official Journal C 206, 13.8.1992
Amended proposal COM(93) 290 final	Official Journal C 189, 13.7.1993
European Parliament opinion First reading	Official Journal C 176, 28.6.1993
Economic and Social Committee opinion	Official Journal C 108, 19.4.1993

4. FOODSTUFFS

4.9. Additives: verification of purity criteria for certain additives

(1) Objective	To lay down Community methods of analysis for verifying that certain additives used in foodstuffs satisfy criteria of purity.
(2) Community measures	First Commission Directive 81/712/EEC of 28 July 1981 laying down Community methods of analysis for verifying that certain additives used in foodstuffs satisfy criteria of purity.
(3) Contents	1. This Directive establishes the analytical methods necessary to verify the general or specific purity criteria for certain additives used in foodstuffs. 2. Annex I specifies the area of application and Annex II specifies the methods to be used.
(4) Deadline for implementation of the legislation in the Member States	20.2.1983
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 257, 10.9.1981
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.10. Additives: flavourings

(1) Objective

To harmonize the laws on flavourings authorized for use in foodstuffs in order to facilitate the free movement of foodstuffs in the Community whilst protecting health.

(2) Community measures

Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production.

Amended by the following measure:
Commission Directive 91/71/EEC of 16 January 1991.

(3) Contents

1. The following text contains a consolidation of existing Directives in this field.
2. The Directive applies to flavourings used to impart odour and/or taste to food. It also applies to flavourings and foodstuffs imported into the Community. It does not apply to flavourings and foodstuffs intended for export out of the Community.
3. The Member States must take the necessary measures to ensure that flavourings may not be marketed or used unless they comply with the conditions laid down in the Directive, such as the purity criteria and the rules on the maximum contents of dangerous or undesirable substances.
4. Provision is also made for the adoption of specific Directives applicable to certain groups of flavourings, e.g. chemically synthesized flavouring substances.
5. The Commission, in collaboration with the Standing Committee on Foodstuffs, will adopt a list of authorized substances or matters and the methods of analysis required to monitor compliance with the approved composition and other applicable criteria (summary 4.1).
6. Procedures to be followed if a Member State finds that one of the substances listed in the annex to the Directive or a flavouring poses a danger to human health, even though it complies with the Directive, are laid down.
7. Labelling requirements are imposed for flavourings not for sale to the final consumer, for example an indication of the name and address of the manufacturer or packer and a sales description indicating the substances used.
8. Labelling requirements are also imposed for flavourings intended for sale to the final consumer, for example an indication of the minimum shelf life, of the batch number and of the conditions for storage and use.
9. These mandatory details must be easily visible, clearly legible, indelible and written in a language understood by purchasers.

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

— Directive 88/388/EEC: 22.12.1989
— Directive 91/71/EEC: 30.6.1992: authorization to market flavourings complying with the Directive;
1.1.1994: prohibition of the marketing of flavourings which do not comply with the Directive.

(5) Date of entry into force (if different from the above)	Directive 88/388/EEC:	22.6.1990:	authorization to market and use flavourings complying with the Directive;
		22.6.1991:	prohibition of the marketing and use of flavourings which do not comply with the Directive.
(6) References			Official Journal L 184, 15.7.1988 Official Journal L 42, 15.2.1991
(7) Follow-up work	On 1 December 1993 the Commission presented a proposal for a European Parliament and Council Regulation laying down a Community procedure for flavouring substances used in foodstuffs (COM(93) 609 final). This proposal for a Regulation establishes a Community procedure for drawing up a list of flavouring substances for use in foodstuffs. The list will be drawn up in stages, following consultation of the Scientific Committee for Food, in order to ensure a high level of protection of public health. On 5 May 1994 Parliament adopted, in first reading, the Commission's proposal subject to certain amendments. The Commission presented an amended proposal on 3 June 1994 (COM(94) 236 final, Official Journal C 171, 24.6.1994).		
(8) Commission implementing measures			

4. FOODSTUFFS

4.11. Additives: inventory of the source materials and substances used in the preparation of flavourings

(1) Objective	To charge the Commission with the task of drawing up an inventory of source materials and substances used in the preparation of flavourings.
(2) Community measures	Council Decision 88/389/EEC of 22 June 1988 on the establishment, by the Commission, of an inventory of the source materials and substances used in the preparation of flavourings.
(3) Contents	1. This Decision instructs the Commission to establish, within two years and after consultation with Member States, an inventory of the various source materials and substances that may be used in the preparation of flavourings. This concerns, for example, flavouring sources made of foodstuffs, flavouring substances synthesized or isolated chemically, source materials used to produce smoked flavours, etc. 2. The Commission is also required to update this inventory.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	Not communicated.
(6) References	Official Journal L 184, 15.7.1988
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.12. Additives: preservatives

(1) Objective

To harmonize the legislation concerning the preservatives authorized in food in order to ease the free movement of food within the Community while ensuring consumer protection.

(2) Community measures

Council Directive 64/54/EEC of 5 November 1963 on the approximation of the laws of the Member States relating to preservatives which may be used in foods intended for human consumption.

Amended by the following measures:
Council Directive 65/569/EEC of 23 December 1965;
Council Directive 66/722/EEC of 14 December 1966;
Council Directive 67/427/EEC of 27 June 1967;
Council Directive 68/420/EEC of 20 December 1968;
Council Directive 70/359/EEC of 13 July 1970;
Council Directive 71/160/EEC of 30 March 1971;
Council Directive 72/2/EEC of 20 December 1971;
Council Directive 72/444/EEC of 26 December 1972;
Council Directive 74/62/EEC of 17 December 1973;
Council Directive 74/394/EEC of 22 July 1974;
Council Directive 76/462/EEC of 4 May 1976;
Council Directive 76/629/EEC of 20 July 1976;
Council Directive 78/145/EEC of 30 January 1978;
Council Directive 79/40/EEC of 18 December 1978;
Council Directive 81/214/EEC of 16 March 1981;
Council Directive 83/585/EEC of 25 November 1983;
Council Directive 83/636/EEC of 13 December 1983;
Council Directive 84/86/EEC of 6 February 1984;
Council Directive 84/223/EEC of 10 April 1984;
Council Directive 84/261/EEC of 7 May 1984;
Council Directive 84/458/EEC of 18 September 1984;
Council Directive 85/7/EEC of 19 December 1984;
Council Directive 85/172/EEC of 28 February 1985;
Council Directive 85/585/EEC of 20 December 1985.

(3) Contents

1. The following text contains a consolidation of existing Directives in the field of preservatives.
2. These Directives define which preservatives may be used to treat foodstuffs and lay down their conditions of use. They also concern preservatives and foods imported into the Community. They do not apply to preservatives and foods intended to be exported from the Community.
3. Procedures to be followed when a Member State establishes that, while complying with the Directives, one of the preservatives is a hazard to human health.
4. List of the general purity criteria to be met by authorized preservatives that are intended for use in foodstuffs, and description of the procedure to be followed in order to lay down specific purity criteria.
5. Labelling requirements. These cover, for example, the name and address of the manufacturer or of the vendor concerned, the number and description of the preservatives.

(4) Deadline for implementation of the legislation in the Member States	Directive 64/54/EEC: 6.11.1964 Directive 65/569/EEC: not communicated Directive 66/722/EEC: not communicated Directive 67/427/EEC: 1.7.1968 Directive 68/420/EEC: not communicated Directive 70/359/EEC: not communicated Directive 71/160/EEC: 1.10.1971 Directive 72/2/EEC: not communicated Directive 72/444/EEC: 30.12.1972 Directive 74/62/EEC: 1.1.1974 Directive 74/394/EEC: 1.1.1974 Directive 76/462/EEC: 5.5.1977 Directive 76/629/EEC: 1.7.1976 Directive 78/145/EEC: 1.1.1978 Directive 79/40/EEC: 1.1.1979 Directive 81/214/EEC: 1.7.1981 Directive 83/585/EEC: 1.7.1982 Directive 83/636/EEC: not communicated Directive 84/86/EEC: not communicated Directive 84/223/EEC: not communicated Directive 84/261/EEC: 14.5.1984 Directive 84/458/EEC: 16.9.1984 Directive 85/7/EEC: not communicated Directive 85/172/EEC: not communicated Directive 85/585/EEC: 31.12.1986
(5) Date of entry into force (if different from the above)	Directive 64/54/EEC: 6.11.1965 Directive 65/569/EEC: 24.12.1965 Directive 66/722/EEC: 16.12.1966 Directive 68/420/EEC: 20.12.1968 Directive 70/359/EEC: 16.7.1970 Directive 72/2/EEC: 21.12.1971 Directive 83/636/EEC: 21.12.1983 Directive 84/86/EEC: 9.2.1984 Directive 84/223/EEC: 13.4.1984 Directive 85/7/EEC: 27.12.1984 Directive 85/172/EEC: 4.3.1985
(6) References	Official Journal 12, 27.1.1964 Official Journal 222, 28.12.1965 Official Journal 233, 20.12.1966 Official Journal 148, 11.7.1967 Official Journal L 309, 24.12.1968 Official Journal L 157, 18.7.1970 Official Journal L 87, 17.4.1971 Official Journal L 2, 4.1.1972 Official Journal L 298, 31.12.1972 Official Journal L 38, 11.2.1974 Official Journal L 208, 30.7.1974 Official Journal L 126, 14.5.1976 Official Journal L 223, 16.8.1976 Official Journal L 44, 15.2.1978 Official Journal L 13, 19.1.1979 Official Journal L 101, 11.4.1981 Official Journal L 335, 30.11.1983 Official Journal L 357, 21.12.1983

Official Journal L 40, 11.2.1984
Official Journal L 104, 17.4.1984
Official Journal L 129, 15.5.1984
Official Journal L 256, 26.7.1984
Official Journal L 2, 3.1.1985
Official Journal L 65, 6.3.1985
Official Journal L 372, 31.12.1985

(7) Follow-up work

(8) Commission implementing measures

4. FOODSTUFFS

4.13. Additives: specific purity criteria for preservatives

(1) Objective	To list the specific purity criteria which preservatives must meet.
(2) Community measures	Council Directive 65/66/EEC of 26 January 1965 laying down specific criteria of purity for preservatives authorized for use in foodstuffs intended for human consumption. Amended by the following measures: Council Directive 67/428/EEC of 27 June 1967; Council Directive 76/463/EEC of 4 May 1976; Council Directive 86/604/EEC of 8 December 1986.
(3) Contents	1. The following text contains a consolidation of existing Directives on specific purity criteria for preservatives. 2. These Directives list the specific purity criteria which preservatives must meet.
(4) Deadline for implementation of the legislation in the Member States	— Directive 65/66/EEC: 1.6.1966 — Directive 67/428/EEC: 1.7.1968 — Directive 76/463/EEC: 5.5.1977 — Directive 86/604/EEC: 1.1.1988
(5) Date of entry into force (if different from the above)	Directive 76/463/EEC: 5.5.1978
(6) References	Official Journal 22, 9.2.1965 Official Journal 148, 11.7.1967 Official Journal L 126, 14.5.1976 Official Journal L 352, 13.12.1986
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

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

(1) Objective

To harmonize the laws on emulsifiers, stabilizers, thickeners and gelling agents authorized in foodstuffs in order to facilitate the free movement of foodstuffs in the Community whilst protecting health.

(2) Community measures

Council Directive 74/329/EEC of 18 June 1974 on the approximation of the laws of the Member States relating to emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs.

Amended by the following measures:
Council Directive 78/612/EEC of 29 June 1978;
Council Directive 80/597/EEC of 29 May 1980;
Council Directive 85/6/EEC of 19 December 1984;
Council Directive 85/7/EEC of 19 December 1984;
Council Directive 86/102/EEC of 24 March 1986;
Council Directive 89/393/EEC of 14 June 1989.

(3) Contents

1. The following text contains a consolidation of existing Directives in the field of emulsifiers, stabilizers, thickeners and gelling agents.
2. These Directives stipulate which emulsifiers, stabilizers, thickeners and gelling agents may be used for processing foodstuffs, and under which conditions. They also apply to emulsifiers, stabilizers, thickeners, gelling agents and foodstuffs imported into the Community. They do not apply to emulsifiers, stabilizers, thickeners, gelling agents and foodstuffs intended for export out of the Community.
3. Procedures to be followed if a Member State finds that a substance complying with the provisions of the Directives nevertheless poses a hazard to human health are laid down.
4. The general purity criteria to be satisfied by substances authorized for use in foodstuffs are listed and the procedure for establishing the specific purity criteria is laid down.
5. Labelling requirements are imposed, for example, an indication of the name and address of the manufacturer or seller responsible and of the number and designation of the substances.

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

— Directive 74/329/EEC: 20.6.1975
— Directive 78/612/EEC: 5.7.1979
— Directive 80/597/EEC: 3.6.1981
— Directive 85/6/EEC: not communicated
— Directive 85/7/EEC: not communicated
— Directive 86/102/EEC: 26.3.1987
— Directive 89/393/EEC: not communicated

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

— Directive 74/329/EEC: 20.6.1976
— Directive 78/612/EEC: 5.7.1980
— Directive 80/597/EEC: 3.6.1982
— Directive 85/6/EEC: 21.12.1984
— Directive 85/7/EEC: 27.12.1984
— Directive 86/102/EEC: 26.3.1988
— Directive 89/393/EEC: 1.1.1989

(6) References

Official Journal L 189, 12.7.1974
Official Journal L 197, 22.7.1978
Official Journal L 155, 23.6.1980

Official Journal L 2, 3.1.1985
Official Journal L 2, 3.1.1985
Official Journal L 88, 3.4.1986
Official Journal L 186, 30.6.1989

(7) Follow-up work

(8) Commission implementing measures

4. FOODSTUFFS

4.15. Additives: specific purity criteria for emulsifiers, stabilizers, thickeners and gelling agents

(1) Objective	To draw up a list of specific purity criteria to be met by emulsifiers, stabilizers, thickeners and gelling agents.
(2) Community measures	Council Directive 78/663/EEC of 25 July 1978 laying down specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs. Amended by the following measures: Council Directive 82/504/EEC of 12 July 1982; Commission Directive 90/612/EEC of 26 October 1990; Commission Directive 92/4/EEC of 10 February 1992.
(3) Contents	1. The following text contains a consolidation of existing Directives in the field of specific criteria of purity for emulsifiers, stabilizers, thickeners and gelling agents. 2. These Directives set out lists of specific purity criteria to be met by emulsifiers, stabilizers, thickeners and gelling agents.
(4) Deadline for implementation of the legislation in the Member States	— Directive 78/663/EEC: 31.2.1980 — Directive 82/504/EEC: 1.1.1984 — Directive 90/612/EEC: 12.11.1991 — Directive 92/4/EEC: 1.6.1993
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 223, 14.8.1978 Official Journal L 230, 5.8.1982 Official Journal L 326, 24.11.1990 Official Journal L 55, 29.2.1992
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.16. Additives: colouring matters

(1) Objective

To harmonize the laws concerning colouring matters in order to promote the free movement of foodstuffs within the Community while ensuring health protection.

(2) Community measures

Council Directive 62/2645/EEC of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorized for use in foodstuffs intended for human consumption.

Amended by the following measures:
Council Directive 65/469/EEC of 25 October 1965;
Council Directive 67/653/EEC of 24 October 1967;
Council Directive 68/419/EEC of 20 December 1968;
Council Directive 70/358/EEC of 13 July 1970;
Council Directive 76/399/EEC of 6 April 1976;
Council Directive 78/144/EEC of 30 January 1978;
Council Directive 81/20/EEC of 20 January 1981;
Council Directive 85/7/EEC of 19 December 1984.

(3) Contents

1. The following text contains a consolidation of existing Directives concerning colouring matters.
2. These Directives lay down lists of colouring matters which may be used to treat foodstuffs, together with their conditions of use. They also apply to colouring matters imported into the Community. They do not concern colouring matters intended to be exported from the Community.
3. Procedures to be followed where a Member State establishes that, although it complies with the Directives, one of the colouring matters constitutes a danger to human health.
4. Breakdown of the general and specific purity criteria to be met by the authorized colouring matters.
5. Labelling requirements. At issue here are, for example, the name and address of the responsible manufacturer or vendor, the number of the colouring matter and the statement 'Colouring matter for foodstuffs'.

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

— Directive 62/2645/EEC: 26.10.1963
— Directive 65/469/EEC: 31.12.1966
— Directive 67/653/EEC: 1.1.1968
— Directive 68/419/EEC: not communicated
— Directive 70/358/EEC: not communicated
— Directive 76/399/EEC: not communicated
— Directive 78/144/EEC: 1.2.1979
— Directive 81/20/EEC: 1.7.1981
— Directive 85/7/EEC: not communicated

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

— Directive 62/2645/EEC: 26.10.1964
— Directive 68/419/EEC: 21.12.1968
— Directive 70/358/EEC: 16.7.1970
— Directive 76/399/EEC: 9.4.1976
— Directive 85/7/EEC: 27.12.1984

(6) References

Official Journal 115, 11.11.1962
Official Journal 178, 26.10.1965
Official Journal 263, 30.10.1967
Official Journal L 309, 24.12.1968
Official Journal L 157, 18.7.1970
Official Journal L 108, 26.4.1976
Official Journal L 44, 15.2.1978
Official Journal L 43, 14.2.1981
Official Journal L 2, 3.1.1985

(7) Follow-up work

(8) Commission implementing measures

4. FOODSTUFFS

4.17. Additives: antioxidants

(1) Objective

To harmonize legislation relating to antioxidants so as to facilitate the free movement of foodstuffs in the Community and while ensuring health protection.

(2) Community measures

Council Directive 70/357/EEC of 13 July 1970 on the approximation of the laws of the Member States concerning the antioxidants authorized for use in foodstuffs intended for human consumption.

Amended by the following measures:
Council Directive 74/412/EEC of 1 August 1974;
Council Directive 78/143/EEC of 30 January 1978;
Council Directive 81/962/EEC of 24 November 1981;
Council Directive 85/7/EEC of 19 December 1984;
Council Directive 87/55/EEC of 18 December 1986.

(3) Contents

1. The following text contains a consolidation of existing Directives on antioxidants.
2. These Directives lay down lists of substances having an antioxidant effect which can be used in the treatment of foodstuffs, and the conditions in which they may be used. They apply to antioxidants imported into the Community and not to antioxidants intended for export to third countries.
3. Procedures to be followed when a Member State establishes that a substance having an antioxidant effect may endanger human health even though it complies with the provisions of the Directives.
4. Listing of the general criteria of purity which the authorized substances intended for use in foodstuffs must satisfy and adoption of the procedure for laying down specific criteria of purity.
5. Labelling requirements. These include, for example, the name and address of the manufacturer and/or seller responsible and the numbers and names of the substances used.

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

— Council Directive 70/357/EEC: 13.7.1971
— Council Directive 74/412/EEC: not communicated
— Council Directive 78/143/EEC: 1.2.1979
— Council Directive 81/962/EEC: 1.12.1982
— Council Directive 85/7/EEC: not communicated
— Council Directive 87/55/EEC: not communicated

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

— Directive 70/357/EEC: 13.7.1972
— Directive 74/412/EEC: 5.8.1974
— Directive 85/7/EEC: 27.12.1984
— Directive 87/55/EEC: 24.12.1986

(6) References

Official Journal L 157, 18.7.1970
Official Journal L 221, 12.8.1974
Official Journal L 44, 15.2.1978
Official Journal L 354, 9.12.1981

Official Journal L 2, 3.1.1985
Official Journal L 24, 24.1.1987

(7) Follow-up work

(8) Commission implementing measures

4. FOODSTUFFS

4.18. Additives: specific purity criteria for antioxidants

(1) Objective	To list the specific purity criteria which substances with antioxidant effects must meet.
(2) Community measures	Council Directive 78/664/EEC of 25 July 1978 laying down specific criteria of purity for antioxidants which may be used in foodstuffs intended for human consumption. Amended by the following measure: Council Directive 82/712/EEC of 18 October 1982.
(3) Contents	1. The following text contains a consolidation of existing Directives on specific purity criteria for antioxidants. 2. These Directives list the specific purity criteria which substances with antioxidant effects must meet.
(4) Deadline for implementation of the legislation in the Member States	— Directive 78/664/EEC: 1.2.1980 — Directive 82/712/EEC: 30.6.1984
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 223, 14.8.1978 Official Journal L 297, 23.10.1982
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.19. Materials and articles in contact with foodstuffs: materials in contact with foodstuffs

(1) Objective	To lay down common rules for the composition of materials and articles intended to come into contact with foodstuffs.
(2) Community measures	Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs.
(3) Contents	1. The Directive applies to materials and articles intended to come into contact with foodstuffs. Covering or coating substances, such as the substances covering cheese rinds, prepared meat products or fruit, which may be consumed together with the food, do not belong to this category. 2. Materials and articles must be manufactured so that they do not transfer their constituents to food in quantities which could: — endanger human health, or — bring about an unacceptable change in the composition of the foodstuffs or a deterioration in their organoleptic properties. 3. Specific Directives will be adopted for plastics, regenerated cellulose film, elastomers and rubber, paper and board, ceramics, glass, metals and alloys, wood, including cork, textile products and paraffin wax or microcrystalline wax. The Directives may include a list of the authorized substances, special conditions of use, purity standards, etc. 4. The Commission will adopt these specific Directives in accordance with the procedure laid down, after consulting with the Standing Committee on Foodstuffs. 5. When a Member State establishes that the use of a material endangers human health although it complies with the relevant specific Directive, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. The Commission will examine as soon as possible the grounds of this decision and will take appropriate action. 6. Requirements for marketing materials and articles coming into contact with foodstuffs, e.g. they must bear an indication such as the words 'for food use'; they must bear the name and address of the manufacturer or a trade mark. This information must be easily visible, clearly legible and indelible.
(4) Deadline for implementation of the legislation in the Member States	10.7.1990
(5) Date of entry into force (if different from the above)	Member States shall, where appropriate, amend their laws, Regulations and administrative provisions so as to: — 10.7.1990: permit trade in and the use of materials and articles complying with this Directive — 10.1.1992: prohibit trade in and the use of materials and articles which do not comply with this Directive

(6) References	Official Journal L 40, 11.2.1989
(7) Follow-up work	
(8) Commission implementing measures	Directive 80/590/EEC — Official Journal L 151, 19.6.1980 Commission Directive of 9 June 1980 determining the symbol that may accompany materials and articles intended to come into contact with foodstuffs. This Directive was adopted pursuant to Directive 76/893/EEC which has been repealed and replaced by Directive 89/109/EEC. It establishes in the annex the symbol which may accompany materials and articles intended to come into contact with foodstuffs. The use of this symbol must be authorized by the Member States.

4. FOODSTUFFS

4.20. Materials and articles in contact with foodstuffs: vinyl chloride monomer

(1) Objective	To harmonize the legislation relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs.
(2) Community measures	Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs.
(3) Contents	1. This Directive is a specific Directive under framework Directive 76/893/EEC which was repealed and replaced by Directive 89/109/EEC (summary 4.19). 2. Materials and articles which are intended to come into contact with foodstuffs can transfer vinyl chloride monomer to these articles in quantities liable to endanger human health. 3. The Directive specifies that such materials and articles must not contain vinyl chloride monomer in a quantity exceeding 1 mg/kg of finished product and must not pass on to foodstuffs more than 0.01 mg/kg of vinyl chloride monomer. These limits are checked using Community methods of analysis (see point 8). 4. The Council shall re-examine this Directive on the basis of Commission reports on the implementation of the Directive.
(4) Deadline for implementation of the legislation in the Member States	26.11.1979
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 44, 15.2.1978
(7) Follow-up work	
(8) Commission implementing measures	— Directive 80/766/EEC — Official Journal L 213, 16.8.1980 Commission Directive of 8 July 1980 laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs. This Directive lays down the Community method of analysis for the determination of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs. This method meets the criteria laid down in the annex to Directive 78/142/EEC. — Directive 81/432/EEC — Official Journal L 167, 24.6.1981 Commission Directive of 29 April 1981 laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs.

This Directive lays down the Community method of analysis for determining the quantity of vinyl chloride released by materials and articles into foodstuffs.

4. FOODSTUFFS

4.21. Materials and articles in contact with foodstuffs: testing migration of constituents of plastic materials and articles

(1) Objective

To lay down the basic rules necessary for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.

(2) Community measures

Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.

Amended by the following measure:
Council Directive 93/8/EEC of 15 March 1993.

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

Directive 82/711/EEC and 93/8/EEC
1. The following text contains a consolidation of existing Directives relating to testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.
2. Directive 82/711/EEC is a specific Directive under Directive 76/893/EEC which is repealed and replaced by Directive 89/109/EEC (summary 4.19).
3. The overall and specific migration levels of constituents of materials and articles into or onto foodstuffs or food simulants must not exceed the limits laid down in Directive 90/128/EEC (summary 4.23) or in any other relevant specific Directive.
4. Verification of compliance of migration into foodstuffs shall be carried out under the most extreme conditions of time and temperature forseeable in actual use. For food simulants verification shall be carried out using conventional migration tests, the basic rules for which are described in Directive 93/8/EEC.
5. The Directives lay down the procedure to be followed in cases where a Member States ascertains that, for a given plastic material or article, the basic rules for migration tests are inappropriate.

Directive 85/572/EEC
1. This Directive is a Council measure implementing Directive 82/711/EEC.
2. The annex lays down the list of authorized simulants and the concentration of those simulants. Thus, prior legislation on plastic packaging is implemented while taking account of the technical progress achieved in migration testing.

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

— Directive 82/711/EEC: 1.1.1991: authorization to market products complying with the Directive;
1.1.1993: ban on the marketing of products complying with the Directive.
— Directive 93/8/EEC: 1.4.1994
— Directive 85/572/EEC: see Directive 82/711/EEC

(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 297, 23.10.1982 Official Journal L 90, 14.4.1993 Official Journal L 372, 31.12.1985
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.22. Materials and articles in contact with foodstuffs: ceramics

(1) Objective	To harmonize the laws relating to ceramic articles intended to come into contact with foodstuffs.
(2) Community measures	Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.
(3) Contents	1. This Directive is a specific Directive coming under framework Directive 76/893/EEC, which is hereby repealed and replaced by Directive 89/109/EEC (summary 4.19). 2. Ceramic articles are capable of transferring lead and cadmium. These substances pose a threat to human health. 3. In order to prevent this risk, the Directive imposes a ceiling on the quantities of lead and cadmium allowed to pass into foodstuffs. 4. These limits must be checked by means of a test, the basic rules of which are set out in the annex to this Directive and in conjunction with a method of analysis also described in the same annex. 5. The Directive lays down the procedures to be followed for the updating and application of the Directive.
(4) Deadline for implementation of the legislation in the Member States	— 18.10.1987: marketing authorization for products complying with the Directive — 18.10.1989: ban on the marketing of products not complying with the Directive
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 277, 20.10.1984
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.23. Materials and articles in contact with foodstuffs: plastics materials

(1) Objective

To harmonize the legislation relating to plastics materials and articles intended to come into contact with foodstuffs.

(2) Community measures

Commission Directive 90/128/EEC of 23 February 1990 relating to plastics materials and articles intended to come into contact with foodstuffs.

Amended by the following measures:
Commission Directive 92/39/EEC of 14 May 1992;
Commission Directive 93/9/EEC of 15 March 1993.

(3) Contents

1. The following text contains a consolidation of existing Directives relating to plastics materials and articles intended to come into contact with foodstuffs.
2. Directive 90/128/EEC is a specific Directive under framework Directive 89/109/EEC (summary 4.19).
3. Plastics materials and articles can transfer constituents to foodstuffs in quantities which could endanger human health.
4. To prevent that risk the Directive stipulates that the migration limit for constituents of plastics materials and articles shall be 10 milligrams per square decimetre of surface area of the material or article. In certain circumstances this limit is set at 60 milligrams of the constituents released per kilogram of foodstuff.
5. Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in Directives 82/711/EEC and 85/572/EEC (summary 4.21) and the further provisions set out in the annexes to Directive 90/128/EEC.
6. The Directives specify which monomers and other starting substances may be used for the manufacture of plastics materials and articles intended to come into contact with foodstuffs and the conditions in which they may be used.
7. At the marketing stages other than the retail stages, the plastics materials and articles which are intended to be placed in contact with foodstuffs must be accompanied by a written declaration certifying that they comply with the provisions of Directive 89/109/EEC. This requirement does not apply to plastics materials and articles which by their nature are clearly intended to come into contact with foodstuffs.

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

— Directive 90/128/EEC: 31.12.1990
— Directive 92/39/EEC: 31.12.1992
— Directive 93/9/EEC: 1.4.1994

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

— Directive 90/128/EEC: 1.1.1991: authorization to market products complying with the Directive;
1.1.1993: ban on the marketing of products not complying with the Directive.

	— Directive 92/39/EEC:	31.3.1994:	authorization to market and use products complying with the Directive;
		1.4.1995:	ban on the marketing and use of products not complying with the Directive.
	— Directive 93/9/EEC:	1.4.1994:	authorization to market and use products complying with the Directive;
		1.4.1996:	ban on the marketing and use of products not complying with the Directive.
(6) References			Official Journal L 75, 21.3.1990 Official Journal L 168, 23.6.1992 Official Journal L 90, 14.4.1993
(7) Follow-up work			
(8) Commission implementing measures			

4. FOODSTUFFS

4.24. Materials and articles in contact with foodstuffs: regenerated cellulose film

(1) Objective	To harmonize the laws relating to materials and articles of regenerated cellulose film intended to come into contact with foodstuffs.
(2) Community measures	Commission Directive 93/10/EEC of 15 March 1993 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs. Commission Directive 93/111/EC of 10 December 1993 amending Directive 93/10/EEC relating to materials and articles made of regnerated cellulose film intended to come into contact with foodstuffs.
(3) Contents	1. Directive 93/10/EEC is a reworked version of Directive 83/229/EEC, as last amended by Directive 92/15/EEC. It is also a specific Directive coming under framework Directive 89/109/EEC (summary 4.19). Directive 93/111/EC amends only the date from which the trade in and use of products not complying with Directive 93/10/EEC are prohibited. 2. Regenerated cellulose film is a film obtained from refined cellulose derived from wood or cotton that have not been recycled. Appropriate substances can be added to the body or surface of the material for technological reasons. 3. The materials and articles are capable of transferring regenerated cellulose film to foodstuffs in quantities likely to pose a threat to human health. 4. Directive 93/10/EEC sets out in the annex a list of substances that can be used in the manufacture of regenerated cellulose films and also the conditions governing their use. 5. The printed side of the regenerated cellulose films must not be allowed to come into contact with foodstuffs. 6. For marketing purposes (with the exception of retail sales), materials and articles of regenerated cellulose film that are intended to come into contact with foodstuffs must be accompanied by a written declaration certifying that they comply with Directive 89/109/EEC. This provision does not apply to materials and articles which, by their very nature, are clearly intended to come into contact with foodstuffs. 7. Where special conditions of use are indicated, the materials and articles of regenerated cellulose film should be labelled accordingly.
(4) Deadline for implementation of the legislation in the Member States	1.1.1994
(5) Date of entry into force (if different from the above)	— Directive 93/10/EEC: 1.1.1994: licence to use regenerated cellulose film intended to come into contact with foodstuffs complying with this Directive; 1.1.1994: ban on the marketing and use of regenerated cellulose film intended to come into contact with foodstuffs not

		complying either with this Directive or with Directive 83/229/EEC;
	1.1.1995:	ban on the marketing and use of regenerated cellulose film intended to come into contact with foodstuffs not complying with this Directive but complying with Directive 83/229/EEC.
— Directive 93/111/EC:	1.1.1994:	ban on the marketing and use of regenerated cellulose film intended to come into contact with foodstuffs and not complying either with this Directive or with Directive 83/229/EEC.
(6) References		Official Journal L 93, 17.4.1993 Official Journal L 310, 14.12.1993
(7) Follow-up work		
(8) Commission implementing measures		

4. FOODSTUFFS

4.25. Materials and articles in contact with foodstuffs: release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers

(1) Objective	To harmonize the laws concerning the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers.
(2) Community measures	Commission Directive 93/11/EEC of 15 March 1993 concerning the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers.
(3) Contents	1. This Directive is a specific Directive coming under framework Directive 89/109/EEC (summary 4.19). 2. Elastomer or rubber teats and soothers are capable of releasing N-nitrosamines and also substances that are likely to be transformed into N-nitrosamines (so-called nitrosatable substances) which, by virtue of their toxicity, pose a threat to human health. 3. Accordingly, the migration of substances must not exceed the following limits: — 0.01 mg of the total quantity of N-nitrosamines released per kg (parts of elastomer or rubber teats and soothers) — 0.1 mg of the total quantity of N-nitrosatable substances (parts of elastomer or rubber teats and soothers). 4. These limits must be checked by means of a test, subject to the conditions set out in the annex to this Directive. The analytical method to be employed is also laid down in this annex, albeit only on a provisional basis. The task of defining a detailed analytical method will be undertaken as soon as additional results relating to the performance of this and alternative methods become available.
(4) Deadline for implementation of the legislation in the Member States	1.1.1994
(5) Date of entry into force (if different from the above)	— 1.4.1994: marketing authorization and licence to use teats and soothers complying with the Directive; — 1.4.1995: ban on the marketing and use of teats and soothers not complying with the Directive.
(6) References	Official Journal L 93, 17.4.1993 Amended opinion Official Journal L 164, 7.7.1993
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.26. Labelling: labelling, presentation and advertising

(1) Objective

To harmonize the legislation on the labelling of foodstuffs so as to ensure that they can move freely and that consumers are informed and protected.

(2) Community measures

Council Directive 79/112/EEC of 18 December 1978 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.

Amended by the following measures:
Council Directive 85/7/EEC of 19 December 1984;
Council Directive 86/197/EEC of 26 May 1986;
Council Directive 89/395/EEC of 14 June 1989;
Commission Directive 91/72/EEC of 16 January 1991;
Commission Directive 93/102/EC of 16 November 1993.

(3) Contents

1. The following text contains a consolidation of existing Directives on the labelling, presentation and advertising of foodstuffs.
2. The scope of these Directives includes both foodstuffs intended for supply to restaurants, hospitals and other similar mass caterers and foodstuffs intended for sale to the ultimate consumer. The Directives do not apply to products intended for export outside the Community.
3. The labelling, presentation and advertising of foodstuffs and the relevant detailed procedures must not be such as to mislead the consumer or to attribute to a foodstuff (except for natural mineral waters and foodstuffs intended for special diets, which are covered by specific Community provisions) properties for the prevention, treatment or cure of a human illness.
4. The labelling of foodstuffs must contain the following particulars:
— the name under which the product is sold;
— the list of ingredients;
— the net quantity (for prepackaged foodstuffs);
— the date of minimum durability (or the use-by date in the case of highly perishable foodstuffs);
— special conditions for keeping or use;
— name or business name and address of the manufacturer or packager or of a vendor established in the Community;
— place of origin or provenance where the omission of such information might mislead the consumer;
— instructions for use, where appropriate;
— indication of the acquired alcoholic strength for beverages containing more than 1.2 % alcohol by volume.
5. The conditions in which these compulsory indications must appear on the packaging of the foodstuffs and the exemptions laid down in the Directives.
6. Member States may maintain national provisions which require the name of the manufacturing or packaging establishment to be shown in the case of nationally-produced foodstuffs.
7. Specific Community provisions, applicable to particular foodstuffs, may derogate from or supplement foodstuffs labelling requirements, provided that they do not affect the information to the purchaser.

8. The marketing of foodstuffs which comply with the Directives can only be prohibited in the case of non-harmonized national provisions which are justified on particular grounds, such as the protection of public health or the protection of industrial or commercial property, etc.

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

— Directive 79/112/EEC: 22.12.1980: authorizes trade in products conforming to the Directive;
22.12.1982: prohibits trade in products not conforming to the Directive.
— Directive 85/7/EEC: not communicated
— Directive 86/197/EEC: 1.5.1988: authorizes trade in products conforming to the Directive;
1.5.1989: prohibits trade in products not conforming to the Directive.
— Directive 89/395/EEC: 20.12.1990: authorizes trade in products conforming to the Directive;
20.6.1992: prohibits trade in products not conforming to the Directive.
— Directive 91/72/EEC: 30.6.1992: authorizes trade in products conforming to the Directive;
1.1.1994: prohibits trade in products not conforming to the Directive.
— Directive 93/102/EC: 1.1.1995: authorizes trade in products conforming to the Directive;
30.6.1996: prohibits trade in products not conforming to the Directive.

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

Directive 85/7/EEC: 27.12.1984
Directive 93/102/EC: 28.11.1993

(6) References

Official Journal L 33, 8.2.1979
Official Journal L 2, 3.1.1985
Official Journal L 144, 29.5.1985
Official Journal L 186, 30.6.1989
Official Journal L 42, 15.2.1991
Official Journal L 291, 25.11.1993

(7) Follow-up work

A consolidated version of Directive 79/112/EEC was put forward by the Commission in December 1989 (SEC(89) 2151).
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.
Examination of this proposal is still outstanding.

On 9 April 1992 the Commission put forward a new proposal for a Council Directive amending Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (COM(91) 536, Official Journal C 122, 14.5.1992).
The aim of the proposal is to fill a gap as regards the labelling of foodstuffs containing a single ingredient and to re-examine the labelling of alcoholic beverages. It also provides for compulsory indication of the quantity of certain ingredients (composition of foodstuffs) and supplements the provisions concerning the name under

which a product is sold ('mutual recognition as between Member States').
On 12 April 1994 the Commission presented an amended proposal (COM(94) 24 final, Official Journal C 118, 29.4.1994).

On 10 November 1993 the Commission adopted an interpretative communication concerning the use of languages in the marketing of foodstuffs in the light of the judgment in the Peeters case (COM(93) 532 final, Official Journal C 345, 23.12.1993).
In this communication the Commission points out that the labelling of foodstuffs for sale to the ultimate consumer must be in an easily understood language, which generally means the official language(s) of the country of marketing. However, foreign terms or expressions easily understood by the purchaser must be allowed.

On 2 May 1994 the Commission submitted a proposal for a Council Directive concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Directive 79/112/EEC (COM(94) 160 final. Since Directive 79/112/EEC makes provision for making other particulars compulsory (in addition to those specified in Directive 79/112/EEC), the Commission proposes that, in order to ensure better information for consumers, it should be specified on the packaging that certain products are packaged using packaging gases.

(8) Commission implementing measures

— Directive 83/463/EEC — Official Journal L 255, 15.9.1983
Commission Directive of 22 July 1983 introducing temporary measures for the designation of certain ingredients in the labelling of foodstuffs for sale to the ultimate consumer. This Directive establishes a temporary numbering system for the ingredients of foodstuffs which have not yet been allocated an EEC number, pending the implementation of Community provisions introducing new EEC numbers.

— Directive 87/250/EEC — Official Journal L 113, 30.4.1987
Commission Directive of 15 April 1987 on the indication of alcoholic strength by volume in the labelling of alcoholic beverages for sale to the ultimate consumer. This Directive makes it obligatory to indicate the alcoholic strength by volume in the labelling of certain alcoholic beverages intended for the ultimate consumer. It also gives the tolerances allowed in respect of the indications of the alcoholic strength by volume.

4. FOODSTUFFS

4.27. Labelling: identification of foodstuffs by lot

(1) Objective

To define a common system for identifying the lot to which a foodstuff belongs after production or packaging, in order to ensure its free movement and enable the consumer to be properly informed.

(2) Community measures

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

Amended by the following measures:
Council Directive 91/238/EEC of 22 April 1991;
Council Directive 92/11/EEC of 3 March 1992.

(3) Contents

1. The following text contains a consolidation of existing Directives on indications or marks identifying the lot to which a foodstuff belongs.
2. The term 'lot' means a batch of sales units of a foodstuff produced, manufactured or packaged under the same conditions.
3. The indication of the lot must appear on all foodstuffs before they can be put on sale.
4. Certain exceptions are provided for, because of technical problems concerning the indication of the lot (for example, with regard to certain agricultural products).
5. The lot is determined by the producer, manufacturer or packager of the foodstuff in question, or the first seller within the Community.
6. The indication is preceded by the letter 'L', except where it can be distinguished clearly from other labelling indications. In all cases, it must be clearly visible, clearly legible and indelible.
7. 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.
8. The Directives apply without prejudice to the indications laid down by specific Community provisions. The Commission will publish and keep up to date a list of the provisions in question.

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

— Directive 89/396/EEC: 20.6.1990: permit trade in products which meet the requirements of the Directive;
1.7.1992: prohibit trade in products which do not meet the requirements of the Directive.
— Directive 91/238/EEC: not communicated
— Directive 92/11/EEC: not communicated

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

(6) References	Official Journal L 186, 30.6.1989 Official Journal L 107, 27.4.1991 Official Journal L 65, 11.3.1992
(7) Follow-up work	
(8) Commission implementing measures	On 25 July 1991 the Commission presented a Communication on the implementation of Directive 89/396/EEC (COM(91) 297/II final — Official Journal C 219, 22.8.1991).

4. FOODSTUFFS

4.28. Labelling: nutrition labelling rules

(1) Objective

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

(2) Community measures

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

(3) Contents

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

Until 1 October 1995 the voluntary inclusion in the nutrition labelling of one or more of the nutrients, sugar, saturated fatty acids, dietary fibre or sodium does not bring into play the obligation referred to in Article 4(1) and (2) to mention all of these nutrients.
7. The declared energy value and amount of nutrients shall be given in figures using specific units of measurement. The information shall be expressed per 100g or per 100ml per package. Information on vitamins and minerals must, in addition, be expressed as a percentage of the recommended daily allowance (RDA), which may also be given in graphic form.
8. All of the above information shall be grouped together in a clearly visible place and shall be in legible, indelible characters and in a language easily understood by the purchaser. Member States shall not introduce nutrition labelling specifications that are more detailed than those contained in this Directive.
9. With regard to foodstuffs which are not prepackaged when sold to the ultimate consumer and mass caterers and foodstuffs which are packaged at the places of immediate sale, the scope of the information referred to in point 6 and the manner in which it is provided may be laid down in national provisions until Community measures are

possibly adopted in accordance with the procedure provided for in this Directive.
10. Any measure which may have an effect on public health shall be adopted after consulting the Scientific Committee for Food.

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

— 1.4.1992: permit trade in products which meet the requirements of the Directive
— 1.10.1993: prohibit trade in products which do not meet the requirements of the Directive

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

(6) References

Official Journal L 276, 6.10.1990

(7) Follow-up work

(8) Commission implementing measures

4. FOODSTUFFS

4.29. Labelling: spirit drinks

(1) Objective	To lay down common rules for describing alcoholic drinks. This will facilitate the free movement of these products within the Community.
(2) Community measures	Council Regulation (EEC) No 1576/89 of 30 May 1989 laying down general rules on the definition, description and presentation of spirit drinks. Council Regulation (EEC) No 3280/92 of 9 November 1992 amending Regulation (EEC) No 1576/89 laying down general rules on the definition, description and presentation of spirit drinks.
(3) Contents	1. Definitions of generic terms including 'gin', 'rum', 'whisky' and of general terms including 'spirit drink', 'sweetening', 'mixing', 'blending', etc. Spirit drinks marketed for human consumption may not be described by associating words such as 'style', 'type' or 'flavour'. 2. Restrictions on the sale of spirit drinks, e.g. whisky sold in the Community must have a minimum alcoholic strength per volume of 40 %. 3. Addition of substances to the products. Water may be added, provided it meets the quality requirements of water intended for human consumption. Except in a few cases, only natural aromatic substances and preparations may be used as flavourings. 4. Rules concerning the labelling and presentation of these products, with particular reference to origin and method of manufacture, e.g. the alcoholic strength must be expressed to the nearest half per cent, and the name under which the drinks are sold may be supplemented by the term 'blend' where the product has undergone this procedure. 5. From 1 January 1993 containers with a closing device covered by lead-based capsules or foil may not be used for these products. 6. Annexes setting out the characteristics of ethyl alcohol of agricultural origin and geographical designations for different categories of products.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	— Regulation (EEC) No 1576/89: 15.12.1989 15.6.1989: for Articles 13 to 16 — Regulation (EEC) No 3280/92: 16.11.1992.
(6) References	Official Journal L 160, 12.6.1989 Official Journal L 327, 13.11.1992
(7) Follow-up work	
(8) Commission implementing measures	— Regulation (EEC) No 3773/89 (Official Journal L 365, 15.12.1989) Commission Regulation of 14 December 1989 laying down transitional measures relating to spirit drinks. This Regulation has been amended by the following measures: Regulation (EEC) No 1759/90 — Official Journal L 162, 28.6.1990 Regulation (EEC) No 3207/90 — Official Journal L 307, 7.11.1990

— Regulation (EEC) No 1014/90 (Official Journal L 105, 25.4.1990) Commission Regulation of 24 April 1990 laying down detailed implementing rules on the definition, description and presentation of spirit drinks. This Regulation has been amended by the following measures:
Regulation (EEC) No 1180/91 — Official Journal L 115, 8.5.1991
Regulation (EEC) No 1781/91 — Official Journal L 160, 25.6.1991
Regulation (EEC) No 3458/92 — Official Journal L 350, 1.12.1992

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

Regulation (EC) No 1267/94 — Official Journal L 138, 2.6.1994
Commission Regulation of 1 June 1994 applying the agreements between the European Union and third countries on the mutual recognition of certain spirit drinks.
This Regulation lays down in the Annex thereto the list of product descriptions that may be used only for products produced in accordance with the legislation of the third countries concerned (this covers in particular 'Tennessee Whisky' and 'Bourbon Whisky' originating in the United States of America).

4. FOODSTUFFS

4.30. Labelling: provisions applicable to aromatized drinks

(1) Objective

To facilitate the free movement of aromatized drinks in the Community while preserving product quality standards and consumer information.

(2) Community measures

Council Regulation (EEC) No 1601/91 of 10 June 1991 laying down general rules on the definition, description and presentation of aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails.

Council Regulation (EEC) No 3279/92 of 9 November 1992 amending Regulation (EEC) No 1601/91 laying down general rules on the definition, description and presentation of aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails.

(3) Contents

Regulation (EEC) No 1601/91

1. The Regulation distinguishes between three categories of drinks according to their wine content, their alcoholic strength, and whether they contain added alcohol. The three categories are: aromatized wines, aromatized wine-based drinks and aromatized wine-product cocktails.
2. The use of water in the preparation of these drinks is authorized provided that the quality of the water conforms to Council Directives 80/777/EEC (summary 4.58) and 80/778/EEC (summary 4.59). Council Directive 89/107/EEC (summary 4.5) also applies to additives used in aromatized drinks, while the oenological processes and practices to be used are those laid down in Council Regulation (EEC) No 822/87.
3. The ethyl alcohol used to dilute or dissolve authorized additives must be of agricultural origin and its use must be limited to a strict minimum.
4. The designations of aromatized drinks laid down in the Regulation are mandatory and reserved exclusively for these drinks. Since the reputation of certain drinks is closely linked with their traditional place of origin, it is compulsory to indicate the place of origin in cases where the drink does not originate in the region where it is traditionally produced. For example, the name 'Sangria' must be followed by the name of the country in which it is produced if not Spain or Portugal.
5. Aromatized drinks which do not comply with the Regulation may not be marketed using terms such as 'style', 'type', 'flavour' or similar indications associating them with one of the designations laid down in the Regulation.
6. The labelling of aromatized drinks is subject to the general rules laid down in Council Directive 79/112/EEC (summary 4.26). However, because of the special characteristics of such drinks, additional provisions have been included in this Regulation.
7. Member States are responsible for ensuring that the provisions of this Regulation are complied with and must appoint one or more monitoring agencies. The Member States and the Commission must communicate to each other the data necessary for implementing this Regulation.

	8. Aromatized drinks exported to third countries must comply with this Regulation. Regulation (EEC) No 3279/92 1. Amendment of the definitions of 'Sangria' and 'Kalte Ente'. 2. The Regulation prohibits, from 1 January 1993, the sale and placing on the market of the products concerned in bottles fitted with closing devices covered by lead-based capsules or foil.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	— Regulation (EEC) No 1601/91: 14.6.1991, except for derogations — Regulation (EEC) No 3279/92: 16.11.1992
(6) References	Official Journal L 149, 14.6.1991 Official Journal L 327, 13.11.1992
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.31. Foodstuffs with a particular nutritional purpose: certificates of specific character

(1) Objective

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

(2) Community measures

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

(3) Contents

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

	7. Member States must introduce stringent inspection arrangements to ensure that foodstuffs carrying a reference to their registered specific character comply with the product specification. 8. A third country may, on the initiative of its producers, apply for a Community certificate of specific character for a foodstuff offering equivalent guarantees to those laid down in the Regulation. The Commission has authority to initiate negotiations with a view to concluding international agreements. 9. Member States are to take the necessary measures to ensure legal protection against abusive or fallacious use or imitation of registered trade descriptions. Registered names are protected against all practices constituting unfair competition. 10. The Commission is to be assisted by a regulatory committee (of an advisory nature) composed of the representatives of the Member States.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	24.7.1993
(6) References	Official Journal L 208, 24.7.1992
(7) Follow-up work	
(8) Commission implementing measures	Regulation (EEC) No 1848/93 — Official Journal L 168, 10.7.1993 Commission Regulation of 9 July 1993 laying down detailed rules for the application of Council Regulation (EEC) No 2082/92 on certificates of specific character for agricultural products and foodstuffs.

4. FOODSTUFFS

4.32. Foodstuffs with a particular nutritional purpose: geographical indications and designations of origin

(1) Objective

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

(2) Community measures

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

(3) Contents

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

6. A third country may apply for the registration of a designation in its territory by following a similar procedure.
7. The Commission has authority to negotiate agreements with third countries for the reciprocal protection of designations.
8. Registered PGIs and PDOs are legally protected against any misuse or false or misleading indication.
9. The Commission is assisted by a regulatory committee composed of the representatives of the Member States and chaired by the representative of the Commission.
10. Within six months of the entry into force of the Regulation, Member States are to inform the Commission which of their legally protected names or, in those Member States where there is no protection system, which of their names established by usage they wish to register pursuant to the Regulation.
11. Member States may maintain national protection of the names communicated until such time as a Decision on registration has been taken.

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

Not required.

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

24.7.1993

(6) References

Official Journal L 208, 24.7.1992

(7) Follow-up work

(8) Commission implementing measures

— Regulation (EEC) No 2037/93 — Official Journal L 185, 28.7.1993
Commission Regulation of 27 July 1993 laying down detailed rules of application of Council Regulation (EEC) No 2081/92 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs.
This Regulation establishes a system for informing consumers when the name of an agricultural product or a foodstuff is registered at Community level as a protected designation of origin or a protected geographical indication.

— Communication to traders involved with designations of origin and geographical indications for agricultural products and foodstuffs concerning the simplified procedure for Community registration as laid down in Article 17 of Council Regulation (EEC) No 2081/92.
The aim of the communication is to provide information to traders affected by the simplified procedure on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, with a view to registering at Community level the designations which already exist in the Member States.

4. FOODSTUFFS

4.33. Foodstuffs with a particular nutritional purpose: Scientific Committee for designations of origin, geographical indications and certificates of specific character

(1) Objective	To set up a Scientific Committee for designations of origin, geographical indications and certificates of specific character.
(2) Community measures	Commission Decision 93/53/EEC of 21 December 1992 setting up a Scientific Committee for designations of origin, geographical indications and certificates of specific character.
(3) Contents	1. This Decision sets up a Scientific Committee in order to assist the Commission in the field of designations of origin, geographical indications and certificates of specific character. 2. At the request of the Commission this Committee examines all of the technical problems involved in the recording of names of agricultural products and foodstuffs and of disputes between the Member States. More particularly this concerns: — the factors involved in defining a geographical description and a designation of origin (and in particular any well-known and famous features); — generic character; — assessment of traditional character; — assessment of the criteria applying to the fairness of commercial transactions and the risk of consumer confusion where there is conflict between the designation of origin or geographical indication and makes, homonyms or existing products that are legally placed on the market. 3. The Decision lays down the rules governing the composition of the Committee, the duration of its remit and the appointment of its members. 4. The Committee's working rules and the Commission's role are defined in this Decision. The Committee only has a quorum if all of its members are present. These are elected by a simple majority. 5. The members of the Committee are required to maintain the confidentiality of the matters dealt with.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	Not communicated.
(6) References	Official Journal L 13, 21.1.1993
(7) Follow-up work	On 14 June 1994 the Commission adopted a Decision amending Decision 93/53/EEC setting up a Scientific Committee for designation of origin, geographical indications and certificates of specific character.

This Decision relaxes the conditions for the delivery of an opinion by enabling the Committee to conduct its business validly when at least five of its members are present.

(8) Commission implementing measures

4. FOODSTUFFS

4.34. Foodstuffs for particular nutritional uses: foodstuffs intended for particular nutritional uses

(1) Objective

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

(2) Community measures

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

(3) Contents

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

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

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

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

(6) References

Official Journal L 186, 30.6.1989

(7) Follow-up work

On 28 March 1994, the Commission presented a proposal for a European Parliament and Council Directive on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (COM(94) 97 final, Official Journal C 108, 16.4.1994). This proposal is designed to amend Annex I to Directive 89/398/EEC by shortening the list of categories of foodstuffs for which specific Directives are to be adopted.

(8) Commission implementing measures

A list of competent authorities of the Member States in line with Article 9 of Council Directive 89/398/EEC on the approximation of the laws of Member States relating to foodstuffs intended for particular nutritional uses (Official Journal C 168, 19.6.1993).

4. FOODSTUFFS

4.35. Foodstuffs for particular nutritional uses: infant formulas

(1) Objective	To establish rules on the composition, labelling, advertising and marketing of infant formulas and follow-on formulas.
(2) Community measures	Commission Directive 91/321/EEC of 14 May 1991 on infant formulas and follow-on formulas. Council Directive 92/52/EEC of 18 June 1992 on infant formulas and follow-on forumulas intended for export to third countries. The Council has also adopted a Resolution on the marketing of breast-milk substitutes by Community manufacturers in developing countries.
(3) Contents	1. Directive 91/321/EEC is a specific Directive deriving from Directive 89/398/EEC (summary 4.34). 2. It lays down rules for the marketing of infant formulas and follow-on formulas intended for use by infants in good health in the Community. It also provides for Member States to give effect to the principles and aims of the International Code of Marketing of Breast-milk Substitutes. 3. These marketing rules include the stipulation of authorized food ingredients, compositional criteria, substances which may be used in the manufacture of the formulas concerned, sales names, compulsory label information additional to that required under Council Directive 79/112/EEC on the labelling of foodstuffs (summary 4.26), etc. 4. Advertising of infant formulas is restricted to publications specializing in baby care and scientific publications. Member States are required to ensure that objective and consistent information is provided on the feeding of infants and young children. 5. Council Directive 92/52/EEC applies certain provisions of Commission Directive 91/321/EEC to the same products exported to third countries.
(4) Deadline for implementation of the legislation in the Member States	— Directive 91/321/EEC: 1.12.1992: authorization to market products conforming to the Directive; 1.6.1994: ban on the marketing of products not conforming to the Directive. — Directive 92/52/EEC: 1.6.1994: ban on imports of products not conforming to the Directive.
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 175, 4.7.1991 Official Journal L 179, 1.7.1992
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.36. Control of foodstuffs: sampling and analysis methods

(1) Objective	To allow the Commission to adopt Community methods for the sampling and analysis of foodstuffs where necessary.
(2) Community measures	Council Directive 85/591/EEC of 20 December 1985 on the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption.
(3) Contents	1. Methods of sampling and analysis must be adopted by the Commission and, where appropriate, the Council when necessary. Account must be taken of: — the need to ensure that Community law is uniformly applied; — the existence of barriers to intra-Community trade. 2. Member States may use other tested and scientifically valid methods provided that this does not hinder the free movement of products recognized as complying with the rules by virtue of Community methods. 3. Use of measures adopted in accordance with the Directive and believed to be inappropriate may be temporarily suspended by a Member State in its territory pending appropriate action by the Commission.
(4) Deadline for implementation of the legislation in the Member States	23.12.1987
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 372, 31.12.1985
(7) Follow-up work	
(8) Commission implementing measures	Directive 87/524/EEC — Official Journal L 306, 28.10.1987 Commission Directive of 6 October 1987 laying down Community methods of sampling for chemical analysis for the monitoring of preserved milk products. The Directive lays down Community methods of sampling for chemical analysis relating to the control of certain partly or wholly dehydrated preserved milk products.

4. FOODSTUFFS

4.37. Control of foodstuffs: official inspection of foodstuffs

(1) Objective	To provide for official inspections of food in order to protect the health and economic interests of consumers.
(2) Community measures	Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs.
(3) Contents	1. The Directive lays down general principles governing the official inspection of foodstuffs, namely the inspection of foodstuffs, food additives, vitamins, mineral salts, trace elements and materials coming into contact with foodstuffs to ensure that they comply with provisions designed to prevent risks to public health, ensure fair trading and protect consumer interests. 2. Procedures concerning the carrying out of inspections both on a regular basis and in those instances when non-compliance is suspected. 3. Items subject to inspection include raw materials, semi-finished products, finished products, cleaning and maintenance products used in connection with the production of foodstuffs, etc. 4. Analysis of samples is entrusted to official laboratories. 5. Inspectors must have the right to carry out their inspections. They are bound by professional secrecy. Within one year of the adoption of the Directive by the Council, the Commission must present a report on: — training provision for food inspectors; — quality standards for laboratories involved in inspection and sampling; — the possibility of establishing a Community inspection service, including opportunities for all institutions and persons involved in the inspections to exchange information. 6. Member States must draw up forward programmes laying down the nature and frequency of inspections and must inform the Commission annually of the implementation thereof. On the basis of this information the Commission must draw up a recommendation for a coordinated inspection programme.
(4) Deadline for implementation of the legislation in the Member States	20.6.1990
(5) Date of entry into force (if different from the above)	20.6.1991
(6) References	Official Journal L 186, 30.6.1989
(7) Follow-up work	The Commission presented additional measures concerning the control of foodstuffs (summary 4.38).
(8) Commission implementing measures	— On 13 September 1990 the Commission adopted a communication to the Council and to the European Parliament regarding the uniform application of Directive 89/397/EEC (COM(90) 392 final). The Commission notes that the professional function of a 'food inspector' in the various Member States is not clearly defined. It

considers it essential to define areas in which personnel responsible for official food control must have received training to an appropriate professional level. It accepts the need for additional training. It considers that a system of quality standards should be introduced for all those laboratories which have been entrusted by the competent authorities with the control of foodstuffs. The Commission is proposing the recognition of equivalent analysis methods. Finally, the Commission believes that there are a number of arguments in favour of establishing a Community inspection service entrusted with the uniform application of Community law.

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

— Recommendation 92/540/EEC — Official Journal L 350, 1.12.1992
Commission Recommendation of 9 November 1992 relating to a coordinated programme for the official inspection of foodstuffs for 1993. To be certain that the requirements concerning health protection are complied with, to guarantee fair trading and to protect the interests of consumers, the Commission recommends to the Member States that they take samples of and check parameters in relation to the following products: adulteration of orange juice, nitrates, and nitrites in infant formulas containing vegetables, checking the weight of deep frozen seafood, microbiological analysis of ice-cream and of prepared dishes.

— Recommendation 94/175/EC — Official Journal L 80, 24.3.1994
Commission Recommendation of 11 March 1994 relating to a coordinated programme for the official inspection of foodstuffs for 1994. In this recommendation the Member States are invited to take samples of and check parameters in relation to the following products in 1994:
— aflatoxin B I in products which might contain it (in particular food products for children);
— listeria in meat-based pâtés for retail sale;
— fraud relating to deep frozen fish-based products;
— fraud relating to goat's and ewe's cheese.

4. FOODSTUFFS

4.38. Control of foodstuffs: additional measures concerning the control of foodstuffs

(1) Objective	To supplement the general principles for the inspection of foodstuffs and allow uniform application by the Member States of Council Directive 89/397/EEC on the official control of foodstuffs.
(2) Community measures	Council Directive 93/99/EEC of 29 October 1993 regarding additional measures concerning the control of foodstuffs.
(3) Contents	1. This Directive supplements Council Directive 89/397/EEC (summary 4.37). 2. Officials must have adequate training and experience in areas such as chemistry, (veterinary) medicine, microbiology, food hygiene, food processing and law. 3. To ensure the reliability of the results of official analyses and to facilitate mutual recognition of the results obtained by the inspection authorities: — the laboratories authorized to carry out the inspections must comply with the general criteria for the operation of testing laboratories laid down in European standard EN 45001 and with certain OECD principles of good laboratory practice; — the methods of analysis used by the laboratories must comply with the criteria laid down concerning specificity, detection limit, sensitivity, accuracy, etc. 4. The authorities responsible for the evaluation of the laboratories must meet the general criteria applicable to the official laboratory accreditation bodies set out in European Standard EN 45003. 5. Officials designated by the Commission will cooperate with the competent authorities of the Member States in the control and evaluation of the equivalence and efficiency of the official control systems of the Member States. The Commission will send the Member States regular reports on the work of its specific staff. 6. The competent authorities are required to collaborate with one another and with the Commission in the administrative area, particularly by exchanges of information aimed at ensuring the implementation of the legal provisions and quality standards applicable to foodstuffs.
(4) Deadline for implementation of the legislation in the Member States	— 1.5.1995 — 1.11.1998: Article 3
(5) Date of entry into force (if different from the above)	

(6) References

(7) Follow-up work

(8) Commission implementing measures

Official Journal L 290, 24.11.1993

4. FOODSTUFFS

4.39. Control of foodstuffs: hygiene of foodstuffs

(1) Objective	To improve food hygiene standards in the Community.
(2) Community measures	Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs.
(3) Contents	1. This Directive supplements Council Directive 89/397/EEC on the official control of foodstuffs (summary 4.37). 2. Unless a derogation applies, food businesses are required to comply with the rules governing the hygiene for foodstuffs, as set out in the annex, during the preparation, processing, manufacture, packaging, storage, transport, distribution, handling, sale and supply of foodstuffs. They must also use HACCPs. 3. Application of the EN 29 000 series of European standards (ISO 9 000 series on quality and quality assurance systems) is recommended, wherever appropriate, as a means of ensuring compliance with general food hygiene regulations and the guides to good practice. 4. Member States will encourage the sectors concerned to draw up guides to good hygiene practices to which businesses will be able to refer on a voluntary basis. These guides will serve as a reference for observing good hygiene practice. 5. Subject to certain conditions, Member States will be allowed to maintain, amend or introduce national hygiene provisions which are more specific than those laid down in this Directive.
(4) Deadline for implementation of the legislation in the Member States	14.12.1994
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 175, 19.7.1993
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.40. Contamination: maximum level of radioactive contamination

(1) Objective	To lay down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency.
(2) Community measures	Council Regulation (Euratom) No 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency. Amended by the following measure: Council Regulation (Euratom) No 2218/89 of 18 July 1989.
(3) Contents	1. The following text contains a consolidation of existing Regulations governing the admissibility for consumption of foodstuffs and of feedingstuffs which have been subjected to radioactive contamination. 2. The Regulations set out the procedure to be followed for determining the maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs which may be placed on the market following a nuclear accident or any other case of radiological emergency. 3. Where the Commission has received information about the existence of an accident or any other case of radiological emergency during which the maximum permitted levels are likely to be reached or have been reached, it shall adopt a Regulation rendering applicable those maximum levels. The period of validity of such a Regulation shall be as short as possible and shall not exceed three months. The Commission shall submit to the Council a proposal for a Regulation to adapt or confirm the provisions of the abovementioned Regulation within one month of its adoption. When so doing it shall take account of the opinion of experts, the basic standards laid down in accordance with the Treaty and the principle that all exposures shall be kept as low as reasonably achievable in order to protect public health. The period of validity of this second Regulation is also limited; the period may be revised at the request of a Member State or on the initiative of the Commission. 4. The maximum permitted levels laid down in the Regulations may be revised or supplemented in the light of expert opinion. 5. Foodstuffs and feedingstuffs not in compliance with the maximum permitted levels shall not be placed on the market.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	— Regulation (Euratom) No 3954/87: 2.1.1988 — Regulation (Euratom) No 2218/89: 25.7.1989
(6) References	Official Journal L 371, 30.12.1987 Official Journal L 211, 22.7.1989

(7) Follow-up work

(8) Commission implementing measures

Regulation (Euratom) No 944/89/EEC — Official Journal L 101, 13.4.1989
Commission Regulation of 12 April 1989 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency. This Regulation establishes the list of minor foodstuffs, i.e. those which are consumed least. For these foodstuffs the maximum permitted levels are considerably higher (ten times higher than those under the heading 'Other foodstuffs except minor foodstuffs' in Regulation (Euratom) No 3954/87).

4. FOODSTUFFS

4.41. Contamination: conditions governing imports following Chernobyl

(1) Objective	To lay down the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station.
(2) Community measures	Council Regulation (EEC) No 737/90 of 22 March 1990 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station.
(3) Contents	1. This Regulation continues on from Regulation (EEC) No 3955/87 (amended by Regulation (EEC) No 4003/89) which was only applicable up to 31 March 1990. 2. It lays down the maximum permitted levels of radioactive contamination with which agricultural products must comply in order to be released for sale on the Community market. The accumulated maximum radioactive level in terms of caesium-134 and -137 must not exceed 600 Bq/kg. For certain products the maximum radioactive level is set much lower; in the case of milk and foodstuffs intended for the special feeding of infants, for example, the maximum permitted level is only 370 Bq/kg. 3. Member States must check compliance with the maximum permitted levels, taking into account contamination levels in the country of origin. 4. Procedure to be followed in the event of failure to comply with the maximum permitted levels when laying down arrangements for applying the Regulation and when amending the list of products concerned. 5. This Regulation enters into force on 1 April 1990 and expires on 31 March 1995 unless the Council decides otherwise before that date.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	1.4.1990
(6) References	Official Journal L 82, 29.3.1990
(7) Follow-up work	
(8) Commission implementing measures	Regulation (EEC) No 1518/93 — Official Journal L 150, 22.6.1993 Commission Regulation of 21 June 1993 establishing a list of products excluded from the application of Council Regulation (EEC) No 737/90 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station. This Regulation repeals Regulation (EEC) No 598/92 and establishes a new list of products excluded from the scope of Regulation (EEC) No 737/90. This is the third list adopted under the procedure laid down in Article 7 of Regulation (EEC) No 737/90.

4. FOODSTUFFS

4.42. Contamination: conditions of export following a nuclear accident

(1) Objective	To prevent the export to third countries of products in which the level of contamination exceeds the maximum levels permitted in the Community following a nuclear accident or any other case of radiological emergency.
(2) Community measures	Council Regulation (EEC) No 2219/89 of 18 July 1989 on the special conditions for exporting foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency.
(3) Contents	1. Foodstuffs and feedingstuffs in which the level of contamination exceeds the relevant maximum levels applicable on the internal market pursuant to Regulation (Euratom) No 3954/87 (summary 4.40) may not be exported. 2. Member States shall carry out checks to ensure that these maximum permitted levels are observed. 3. Each Member State must communicate to the Commission the fullest information on the application of this Regulation. The Commission shall forward this information to the other Member States. 4. Procedure to be followed for laying down the rules of application.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	21.7.1989
(6) References	Official Journal L 211, 22.7.1989
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.43. Contamination: early exchange of information in the event of a radiological emergency

(1) Objective	To establish Community arrangements for the early exchange of information in the event of a radiological emergency.
(2) Community measures	Council Decision 87/600/EEC of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency.
(3) Contents	1. This Decision requires Member States to notify and provide information to the Commmission and to the Member States affected or liable to be affected whenever a Member State decides to take measures of a widespread nature in order to protect the general public in the event of a radiological emergency. 2. Such information must include the nature and time of the event, its exact location and the nature of the facility or activity involved, the cause, the foreseeable development and the protective measures taken or planned. This information must subsequently be supplemented by any further relevant information. 3. Upon receipt of this information, Member States are required to inform the Commission of the measures taken and Recommendations issued or envisaged and, at appropriate intervals, of the levels of radioactivity measured by their monitoring facilities in foodstuffs, feedingstuffs, drinking water and the environment. The Commission must then forward that information, plus information it receives from non-Community countries, to the competent authorities of all the other Member States. 4. The point of contact and the Commission service designated to forward this information shall be available on a 24-hour basis. 5. The information may be used without restrictions except when it is provided in confidence by the notifying Member State.
(4) Deadline for implementation of the legislation in the Member States	17.3.1988
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 371, 30.12.1987
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.44. Contamination: contaminants in food

(1) Objective	To establish a procedure for assessing the permissible toxicity levels for contaminants in foodstuffs, considering all possible sources.
(2) Community measures	Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food.
(3) Contents	1. No foodstuffs containing a toxicologically unacceptable amount of a contaminant may be marketed. Contaminants, i.e. any substance unintentionally added to food and present therein in the form of a residue from production, manufacture, processing, preparation, treatment, packing, packaging, transport or storage or as a result of environmental contamination, must be kept at the lowest possible levels. 2. The Regulation does not apply to contaminants covered by more specific legislation. 3. The maximum tolerances for specific contaminants will be established by the Standing Committee on Foodstuffs, after consultation with the Scientific Committee for Food. 4. Draft technical standards and Regulations on the maximum tolerances for contaminants must be notified to the Commission which can consult the Member States through the Standing Committee for Foodstuffs. 5. Member States may not prohibit trade in foods which comply with this Regulation for any reason related to the aspects covered by the provisions of this Regulation. 6. The Regulation includes a safeguard clause: Member States may temporarily suspend or restrict marketing on their territory of any foodstuff suspected of containing contaminants which would endanger human health.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	1.3.1993
(6) References	Official Journal L 37, 13.2.1993
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.45. Contamination: extraction solvents

(1) Objective

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

(2) Community measures

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

Amended by the following measure:
Council Directive 92/115/EEC of 17 December 1992.

(3) Contents

1. The following text contains a consolidation of existing Directives in the field of extraction solvents.
2. The Directives apply to extraction solvents used in the production of foodstuffs or food ingredients including those imported into the Community. They do not apply to extraction solvents used for the production of additives, vitamins and other nutritional additives not listed in the annex to the Directive nor to extraction solvents exported from the Community. Member States must, however, ensure that the use of these additives does not result in dangerous levels of extraction solvent residue in foodstuffs.
3. Definitions of 'solvent' and 'extraction solvent'.
4. Member States shall authorize the use of extraction solvents listed in the annex to these Directives. They shall not authorize any others.
5. 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.
6. 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.
7. Purity criteria for extraction solvents, e.g. they shall not contain a toxicologically dangerous amount of any substance.
8. If a Member State believes an authorized solvent to be dangerous to human health the Member State may temporarily suspend authorization of the solvent. The Commission shall then examine the grounds given by the Member State.
9. Labelling requirements including the name of the substance, indication that the material is of suitably good quality, the business name of the manufacturer or packager, etc.
10. Annex containing list of authorized extraction solvents and conditions of use.

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

— Directive 88/344/EEC: 13.6.1991
— Directive 92/115/EEC: 1.7.1993: authorization of the sale of goods conforming to this Directive;
1.1.1993: ban on the sale of goods not conforming to this Directive.

(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 157, 24.6.1988 Official Journal L 409, 31.12.1992
(7) Follow-up work	On 14 December 1993 the Commission presented a proposal for a Directive of the European Parliament and the Council amending for the second time Council Directive 88/344/EEC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (COM(93) 659 final). This proposal seeks to re-introduce cyclohexane, deleted from the annex to Directive 88/344/EEC by Directive 92/115/EEC, pursuant to some specific information from the Scientific Committee for Food. First reading: Parliament approved the Commission's proposal without amendment. The Council adopted a common position on 10 March 1994.
(8) Commission implementing measures	

4. FOODSTUFFS

4.46. Manufacturing and processing methods: quick-frozen food

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

4. FOODSTUFFS

4.47. Manufacturing and processing methods: foodstuffs treated with ionizing radiation

(1) Objective

To harmonize Member State provisions concerning the irradiation of foodstuffs.

(2) Proposal

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

(3) Contents

1. The Directive applies to the processing and marketing of foodstuffs and food ingredients treated with ionizing radiation. It does not apply to foodstuffs exposed to ionizing radiation emitted by measuring or inspection devices up to a specified limit, nor to foodstuffs prepared under medical supervision for patients requiring sterile diets.
2. Irradiated foodstuffs may only be marketed if they comply with the Directive and Member States may not prohibit, restrict or obstruct the marketing of foodstuffs which have been irradiated in conformity with the Directive.
3. Annex 1 of the Directive lists foodstuffs authorized for irradiation treatment and the maximum radiation doses. Permitted radiation sources are listed in Annex 2, and Annex 3 specifies how the overall absorbed dose is to be calculated. Provision is made for amending these annexes.
4. Foodstuffs may not be re-irradiated. However, the full needed dose for a specific technological function may be given as the sum of fractionated doses. Irradiation may be used in conjunction with other processes. A procedure is established for exceptions to these provisions.
5. Member States are to ensure that irradiated foodstuffs are only marketed if their packaging or containers bear specific information. Where products are intended for sale to the final consumer, the information requirements of Council Directive 79/112/EEC on the labelling, presentation and advertising of foodstuffs have to be complied with (summary 4.26). Foodstuffs not intended for sale to the ultimate consumer must bear information such as the fact that the product has been irradiated and the name and address of the irradiation unit.
6. Provisions for the establishment of regulatory authorities in the Member States to control the irradiation of foodstuffs. The Directive specifies the authorities' responsibilities, the information they must send to the Commission and the standards of good practice which they must ensure are followed.
7. Units for the irradiation of foodstuffs will have to be approved by the designated authorities and be subject to control and inspection. Units must keep a record for each source of ionizing radiation containing specified information, e.g. the nature and quantity of foodstuffs irradiated and data for the control of the irradiation process. These records must be preserved for five years. Detailed rules concerning these records will be adopted.
8. Irradiated foodstuffs may not be imported from third countries unless they comply with the provisions of the Directive. Documents accompanying the foodstuffs must provide the name and address of the

irradiation unit and the necessary records. It must be confirmed that irradiation has been officially supervised ensuring that the irradiation conditions are equivalent to those required by the Directive. The Commission may make arrangements with third countries regarding mutual notification of irradiation plants and Community inspection in third countries.

9. Appropriate materials shall be used for the packaging of foodstuffs to be irradiated.

10. The Commission, after consultation of the Standing Committee on Foodstuffs and certain other standing committees where appropriate, is empowered to:

— amend the annexes to take account of scientific and technological developments;

— adopt detailed rules for the records to be kept by approved irradiation units;

— take appropriate measures should a Member State conclude that the irradiation of a foodstuff is harmful to human health, although conforming to the Directive.

(4) Opinion of the European Parliament

First reading: Parliament approved the Commission's proposal subject to amendments concerning, in particular, the list of products for which ionizing radiation is authorized and public access to the scientific data relating to evaluation.

(5) Current status of the proposal

Cooperation procedure

The Commission presented the proposal on 2 December 1988.

First reading: On 11 October 1989 Parliament approved the Commission proposal subject to amendments. The Commission has accepted some of the amendments.

The Commission presented an amended proposal on 15 November 1989.

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

(6) References

Commission proposal COM(88) 654 final	Official Journal C 336, 31.12.1988
Amended proposal COM(89) 100 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

4.48. Manufacturing and processing methods: organically grown agricultural products and foodstuffs

(1) Objective

To set up a harmonized framework for the labelling, production and control of agricultural products and foodstuffs bearing, or intended to bear, indications referring to organic production methods.

(2) Community measures

Council Regulation (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs.

Amended by the following measures:
Council Regulation (EEC) No 2083/92 of 14 July 1992;
Council Regulation (EC) No 1468/94 of 20 June 1994.

(3) Contents

1. The Regulations apply to agricultural products for which the rules of production are laid down in Annex I, and to the foodstuffs in which such products are incorporated.
2. Definitions of terms 'labelling', 'production', 'preparation', etc.
3. The Regulations lay down rules for the labelling of organically-produced agricultural products marketed without further processing and foodstuffs derived therefrom.
4. The Regulations also lay down rules of production containing, in particular, very strict provisions regarding the use of fertilizers and plant-protection products.
5. Implementation of a system of notification and a system of regular inspection for producers, carried out by private bodies approved and supervised by the Member State or by a public body.
6. The Regulation also provides for a system to ensure that products imported from third countries have been produced and marketed in conditions of production and inspection equivalent to those applicable to Community products. These third countries will be entered in a list to be drawn up by a Commission Decision. Until 31 December 1995, the marketing of products imported from third countries not included in the list shall be authorized provided that the importer supplies the competent authority of the importing Member State with sufficient proof that the products in question have been obtained under production standards equivalent to those laid down in the Regulations and have been subject to inspections equivalent to those laid down in the Regulations.
7. Member States may not ban or restrict the marketing of products produced in accordance with the Regulations.
8. Annexes containing the principles of organic production on farms, the list of products to be used for fertilization, soil improvement or combating parasites and disease, the minimum inspection requirements and precautionary measures under the regular inspection scheme, the information to be notified, the text (in the different languages) of the indication that products are covered by the regular inspection scheme and the list of authorized non-agricultural ingredients, of substances authorized for use during preparation and of agricultural ingredients.

(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	— Regulation (EEC) No 2092/91: 22.7.1991 — Regulation (EEC) No 2083/92: 24.7.1992, with exceptions — Regulation (EC) No 1468/94: 1.7.1994
(6) References	Official Journal L 198, 22.7.1991 Official Journal L 208, 24.7.1992 Official Journal L 159, 28.6.1994
(7) Follow-up work	
(8) Commission implementing measures	— Regulation (EEC) No 94/92 — Official Journal L 11, 17.1.1992 Commission Regulation of 14 January 1992 laying down detailed rules for implementing the arrangements for imports from third countries provided for in Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs. Products imported from third countries may be marketed only if they originate in a third country included on the list laid down in this Regulation. The Regulation also specifies the detailed rules for scrutiny of an application by a third country to be included in the list. — Regulation (EEC) No 1535/92 — Official Journal L 162, 16.6.1992 Commission Regulation of 15 June 1992 amending Annexes I and III to Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs. — Regulation (EEC) No 3457/92 — Official Journal L 350, 1.12.1992 Commission Regulation of 30 November 1992 laying down detailed rules concerning the inspection certificate for imports from third countries into the Community provided for in Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs. — Regulation (EEC) No 3713/92 — Official Journal L 378, 23.12.1992 Commission Regulation of 22 December 1992 deferring the date of application of Article 11(1) of Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs, with regard to imports from certain third countries. This Regulation, as amended by Commission Regulation (EEC) No 1593/93 of 24 June 1993 (Official Journal L 153, 25.6.1993) and by Commission Regulation (EC) No 688/94 of 28 March 1994 (Official Journal L 84, 29.3.1994) defers the date of application of Article 11(1) of Regulation (EEC) No 2092/91 to 28 February 1995 for products imported from Argentina, Austria, Australia, Israel, Sweden and Switzerland. — Regulation (EEC) No 207/93 — Official Journal L 25, 2.2.1993 Commission Regulation of 29 January 1993 defining the content of Annex VI to Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs and laying down detailed rules for implementing the provisions of Article 5(4) thereof.

— Regulation (EEC) No 2608/93 — Official Journal L 239, 24.9.1993
Commission Regulation of 23 September 1993 amending Annexes I, II and III to Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs.

— List of bodies or public authorities in charge of the inspection provided for in Article 15 of Regulation (EEC) No 2092/91 (Official Journal C 284, 21.10.1993).

— Regulation (EC) No 468/94 — Official Journal L 59, 3.3.1994
Commission Regulation of 2 March 1994 amending Annex VI to Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs.

4. FOODSTUFFS

4.49. Manufacturing and processing methods: novel foods and novel food ingredients

(1) Objective

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

(2) Proposal

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

(3) Contents

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

(4) Opinion of the European Parliament

First reading: Parliament approved the Commission's proposal subject to certain amendments concerning, in particular, the definition of the scope of the Regulation, the procedure to be followed prior to the placing of new foods on the market, and the labelling of genetically modified foods.

(5) Current status of the proposal

Co-decision procedure

The Commission presented the proposal on 7 July 1992.

First reading: On 27 October 1993 Parliament approved the Commission proposal subject to amendments. The Commission has accepted some of the amendments.

The Commission presented an amended proposal on 1 December 1993.

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

(6) References

Commission proposal COM(92) 295 final/II	Official Journal C 190, 29.7.1992
Amended proposal COM(93) 631 final	Official Journal C 16, 19.1.1994
European Parliament opinion First reading	Official Journal C 315, 22.11.1993
Economic and Social Committee opinion	Official Journal C 108, 19.4.1993

4. FOODSTUFFS

4.50. Product legislation: erucic acid

(1) Objective	To fix the maximum level of erucic acid authorized in oils and fats intended for human consumption and in foodstuffs containing added oils or fats.
(2) Community measures	Council Directive 76/621/EEC of 20 July 1976 relating to the fixing of the maximum level of erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils or fats.
(3) Contents	1. The Directive fixes an upper limit for the erucic acid level in the products to which it applies: this level, calculated on the total level of fatty acids in the fat component, must not exceed 5%. 2. The preventive and protective character of these rules is reinforced by the existence of a safeguard clause to which the Member States may have recourse. If a Member State thinks that the erucic acid level laid down in this Directive poses a threat to human health, it may suspend application of the Community provisions and inform the Commission and other Member States accordingly. The Commission then puts the matter before the Standing Committee on Foodstuffs and, in accordance with the usual procedure, submits a proposal for measures to be taken to amend the Directive. 3. Methods of sampling and analysis to enable the erucic acid level to be determined in fats and foodstuffs to which they have been added are also adopted according to the procedure of the Standing Committee on Foodstuffs.
(4) Deadline for implementation of the legislation in the Member States	1.1.1977
(5) Date of entry into force (if different from the above)	1.7.1977
(6) References	Official Journal L 202, 28.7.1978
(7) Follow-up work	
(8) Commission implementing measures	Directive 80/891/EEC — Official Journal L 254, 27.9.1980 Commission Directive of 25 July 1980 relating to the Community method of analysis for determining the erucic acid content in oils and fats intended to be used as such for human consumption and foodstuffs containing added oils or fats. The Directive lays down the Community method of analysis for determining the erucic acid content of oils and fats which come under Directive 76/621/EEC.

4. FOODSTUFFS

4.51. Product legislation: cocoa and chocolate

(1) Objective

To harmonize national laws on cocoa and chocolate products so as to facilitate their movement within the Community.

(2) Community measures

Council Directive 73/241/EEC of 24 July 1973 on the approximation of the laws of the Member States relating to cocoa and chocolate products intended for human consumption.

Amended by the following measures:
Council Directive 74/411/EEC of 1 August 1974;
Council Directive 74/644/EEC of 19 December 1974;
Council Directive 75/155/EEC of 4 March 1975;
Council Directive 76/628/EEC of 20 July 1976;
Council Directive 78/842/EEC of 10 October 1978;
Council Directive 80/608/EEC of 30 June 1980;
Council Directive 85/7/EEC of 19 December 1984;
Council Directive 89/344/EEC of 3 May 1989.

(3) Contents

1. The following text contains a consolidation of existing Directives in the field of cocoa and chocolate.
2. The Directives deal with five sets of problems to ensure the free movement of cocoa and chocolate products: the definitions of those products, their composition, manufacturing specifications, packaging and labelling.
3. Cocoa and chocolate products may not be marketed in the Community unless they conform to the definitions and rules laid down in the Directives.
4. The names set out in the Directives are reserved for the products defined therein and must be used in trade to designate them. Nonetheless, exceptions may be made to this principle to take account of established custom.
5. Trade in products conforming to the definitions and rules laid down in the Directives must not be impeded by the application of national non-harmonized provisions governing the composition, manufacturing specifications, packaging or labelling of these products in particular or of foodstuffs in general, except where such provisions are justified on the grounds of protection of public health, repression of frauds, protection of industrial and commercial property, indications of source, applications of origin and repression of unfair competition.

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

— Directive 73/241/EEC: 1.8.1974
— Directive 74/411/EEC: not communicated
— Directive 74/644/EEC: not communicated
— Directive 75/155/EEC: 1.7.1975
— Directive 76/628/EEC: 29.7.1977
— Directive 78/609/EEC: 5.7.1979
— Directive 78/842/EEC: not communicated
— Directive 80/608/EEC: 21.6.1979
— Directive 85/7/EEC: not communicated
— Directive 89/344/EEC: 1.1.1988

(5) Date of entry into force (if different from the above)	— Directive 73/241/EEC: 1.8.1975 — Directive 74/411/EEC: 2.8.1974 — Directive 74/644/EEC: 20.12.1974 — Directive 76/628/EEC: 29.7.1978: authorization to market products conforming to the Directive; 29.7.1983: ban on the marketing of products not conforming to the Directive. — Directive 78/609/EEC: 5.7.1980: authorization to market products conforming to the Directive; 5.7.1981: ban on the marketing of products not conforming to the Directive. — Directive 78/842/EEC: 13.10.1978 — Directive 85/7/EEC: 27.12.1984
(6) References	Official Journal L 228, 16.8.1973 Official Journal L 221, 12.8.1974 Official Journal L 349, 28.12.1974 Official Journal L 64, 11.3.1975 Official Journal L 223, 16.8.1976 Official Journal L 197, 22.7.1978 Official Journal L 291, 17.10.1978 Official Journal L 170, 3.7.1980 Official Journal L 2, 3.1.1985 Official Journal L 142, 25.5.1989
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.52. Product legislation: sugar

(1) Objective	To harmonize the laws on sugars intended for human consumption and facilitate their movement within the Community.
(2) Community measures	Council Directive 73/437/EEC of 11 December 1973 on the approximation of the laws of the Member States concerning sugars intended for human consumption.
(3) Contents	1. Directive 73/437/EEC defines ten varieties of sugar and lays down their compositional characteristics and rules for their packaging and labelling. 2. Products conforming to these definitions and characteristics must be marketed under their given name. Non-conforming products must carry a name clealy distinguishable from the names defined in the Directive, which are reserved for the products concerned. 3. Trade in products conforming to the definitions and rules of the Directive may not be impeded by the application of national non-harmonized provisions governing the composition, manufacturing specifications, packaging or labelling of these products in particular or of foodstuffs in general, except where such provisions are justified on the grounds of protection of public health, repression of frauds, protection of industrial and commercial property, indications of source, applications of origin and the repression of unfair competition.
(4) Deadline for implementation of the legislation in the Member States	13.12.1974
(5) Date of entry into force (if different from the above)	13.12.1975
(6) References	Official Journal L 356, 27.12.1973
(7) Follow-up work	
(8) Commission implementing measures	Directive 79/796/EEC — Official Journal L 239, 22.9.1979 Commission Directive of 26 July 1979 laying down Community methods for testing certain sugars intended for human consumption. This Directive lays down Community analytical methods which must be used to test certain sugars intended for human consumption, as laid down by Directive 73/437/EEC.

4. FOODSTUFFS

4.53. Product legislation: honey

(1) Objective	To harmonize the laws relating to honey so as to facilitate its movement within the Community.
(2) Community measures	Council Directive 74/409/EEC of 22 July 1974 on the harmonization of the laws of the Member States relating to honey.
(3) Contents	1. Directive 74/409/EEC gives a general definition of honey and indicates the main varieties, along with their names, which may be marketed in the Community. It also establishes general and specific compositional characteristics and indicates the principal labelling requirements. 2. The names stipulated in the Directive are recognized and protected throughout the Community and may be used only in conformity with the definitions and rules laid down in the Directive. The name 'honey' must be used in trade to designate any product which conforms to those rules and definitions. Compound foodstuffs which contain another product in addition to honey, even in small quantities, are not entitled to the names reserved under the Directive. 3. Subject to the usual exceptions, trade in products which conform to the Directive may not be impeded by the application of national provisions governing the composition, manufacturing specifications, packaging and labelling of these products or of foodstuffs in general.
(4) Deadline for implementation of the legislation in the Member States	23.7.1975
(5) Date of entry into force (if different from the above)	23.7.1976
(6) References	Official Journal L 221, 12.8.1974
(7) Follow-up work	
(8) Commission implementing measures	

4. FOODSTUFFS

4.54. Product legislation: fruit juices and similar products

(1) Objective	To harmonize the laws relating to fruit juices so as to facilitate their movement in the Community.
(2) Community measures	Council Directive 93/77/EEC of 21 September 1993 relating to fruit juices and certain similar products.
(3) Contents	1. The Directive consolidates Council Directive 75/726/EEC on the approximation of the legislation of the Member States concerning fruit juices and certain similar products and is amended by Council Directives 79/168/EEC, 81/487/EEC and 89/394/EEC. 2. Community legislation defines four types of product intended for direct consumption: fruit juice (including reconstituted juice), concentrated fruit juice, fruit nectar and dried fruit juice. It lays down manufacturing specifications and labelling rules for these products. 3. The names corresponding to these definitions are reserved names. They must be used for the products concerned and are applied regardless of the product's destination. This is important, especially with regard to compound foodstuffs obtained, *inter alia*, from fruit juices (fruit jellies and soft drinks): the words 'with fruit juice' may appear in the name of such foodstuffs only if the ingredient used conforms to the definition of fruit juice.
(4) Deadline for implementation of the legislation in the Member States	Not communicated.
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 244, 30.9.1993
(7) Follow-up work	
(8) Commission implementing measures	Directive 93/45/EEC — Official Journal L 159, 1.7.1993 Commission Directive of 17 June 1993 concerning the manufacture of nectars without the addition of sugars or honey. This Directive authorizes the use of certain fruits, individually or mixed together, to manufacture nectars without the addition of sugars or honey where their naturally high sugar content so warrants.

4. FOODSTUFFS

4.55. Product legislation: fruit jams, jellies, marmalades and chestnut purée

(1) Objective

To harmonize the laws relating to fruit jams, jellies, marmalades and chestnut purée so as to facilitate the free movement of foodstuffs within the Community.

(2) Community measures

Council Directive 79/693/EEC of 24 July 1979 on the approximation of the laws of the Member States relating to fruit jams, jellies, marmalades and chestnut purée.

Amended by the following measures:
Council Directive 80/1276/EEC of 22 December 1980;
Council Directive 88/593/EEC of 18 November 1988.

(3) Contents

1. The following text contains a consolidation of existing Directives in the field of fruit jams, jellies, marmalades and chestnut purée.
2. The Directives define the products to which they apply and reserve the names corresponding to products which conform to the definitions and rules they lay down.
3. They list and define the raw materials which may be used in the manufacture of the products concerned, the additives which may be added to those products and the maximum sulphur dioxide content. Very precise rules are laid down for the labelling of the products concerned.
4. Member States are required to permit the marketing of products which conform to the provisions of the Directives, subject to the usual derogations.

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

— Directive 79/693/EEC: 27.7.1981: authorization to market products conforming to the Directive;
27.7.1982: ban on the marketing of products not conforming to the Directive.
— Directive 80/1276/EEC: not communicated
— Directive 88/593/EEC: 31.12.1989: authorization to market products conforming to the Directive;
1.1.1991: ban on the marketing of products not conforming to the Directive.

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

Directive 80/1276/EEC: 1.1.1981

(6) References

Official Journal L 205, 13.8.1979
Official Journal L 375, 31.12.1980
Official Journal L 318, 25.11.1988

(7) Follow-up work

(8) Commission implementing measures

In December 1990 the Commission presented a Communication on the approximation of the laws of the Member States relating to fruit jams, jellies, marmalades and chestnut purée (COM(90) 508 final).
The Communication informed the Council and the European Parliament that the current state of the market, characterized by a growing number of products with low energy values, did not lend itself to the drafting of a proposal on the use of Community names for jams as provided for in Directive 79/693/EEC.

4. FOODSTUFFS

4.56. Product legislation: preserved milk

(1) Objective

To harmonize national laws relating to preserved milk so as to facilitate its movement within the Community.

(2) Community measures

Council Directive 76/118/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to certain partly or wholly dehydrated preserved milk for human consumption.

Amended by the following measures:
Council Directive 78/630/EEC of 19 June 1978;
Council Directive 83/635/EEC of 13 December 1983.

(3) Contents

1. The following text contains a consolidation of existing Directives in the field of preserved milk.
2. With a view to ensuring the free movement of preserved milk, while at the same time laying down manufacturing specifications to meet consumer requirements, the Directives define certain preserved milks and lay down common rules on composition and manufacturing specifications and on the packaging and labelling of these products.
3. The preserved milk defined in the Directives may not be marketed unless it conforms to the definitions and rules laid down therein. Products which do not conform are therefore banned in the Community. As regards the labelling rules, as amended, this ban took effect on 1 January 1987.
4. The names listed in the Directives are reserved for the products defined therein and must be used in the marketing of those products. Several other names, listed in the Directives, may be reserved by the Member States concerned and used in their territory; the transitional nature of this derogation was removed.

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

— Directive 76/118/EEC: 22.12.1976
— Directive 78/630/EEC: not communicated
— Directive 83/635/EEC: 1.1.1986: authorization to market products conforming to the Directive;
1.1.1987: ban on the marketing of products not conforming to the Directive.

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

— Directive 76/118/EEC: 22.12.1977
— Directive 78/630/EEC: 22.6.1978

(6) References

Official Journal L 24, 30.1.1976
Official Journal L 206, 29.7.1978
Official Journal L 357, 21.12.1983

(7) Follow-up work

(8) Commission implementing measures

Directive 79/1067/EEC — Official Journal L 327, 24.12.1979
Commission Directive of 13 November 1979 laying down Community methods of analysis for testing certain partly or wholly dehydrated preserved milk for human consumption.
This Directive lays down Community methods of analysis which must be followed when testing certain partly or wholly dehydrated preserved milk intended for human consumption, as provided for in Directive 76/118/EEC.

4. FOODSTUFFS

4.57. Product legislation: edible caseins and caseinates

(1) Objective	To harmonize national laws relating to caseins and caseinates so as to facilitate their movement within the Community.
(2) Community measures	Council Directive 83/417/EEC of 25 July 1983 on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption.
(3) Contents	1. Directive 83/417/EEC defines the lactoproteins to which it applies and reserves the names corresponding to those definitions. These names must be used in trade to designate products conforming to the rules of the Directive. The products defined by the Directive may not be placed on the market unless they conform to the definitions and rules laid down in the Directive. Products which are not covered by the Directive must be named and labelled in such a way that the buyer is not misled as to their nature, quality or use. 2. The compositional characteristics and processing specifications of caseins and caseinates are laid down and included in the definition of the products concerned. 3. Directive 83/147/EEC lays down rules on labelling complementary to those of Directive 79/122/EEC. 4. The Directive contains the usual safeguard clause and the clause on the free movement of products conforming to the Directive. 5. The Directive provides that the Council, where necessary, will adopt purity criteria for the technological adjuvants which may be used and that the Commission, through the Standing Committee for Foodstuffs procedure, will determine the methods of analysis necessary for checking the purity criteria and the sampling procedures. The methods of analysis necessary for checking the composition of caseins and caseinates were covered in Commission Directive 85/503/EEC, adopted according to that procedure. The same procedure was used in the adoption of Directive 86/424/EEC laying down methods of sampling for chemical analysis of edible caseins and caseinates.
(4) Deadline for implementation of the legislation in the Member States	— 2.8.1985: authorization to market products conforming to the Directive — 2.8.1986: ban on the marketing of products not conforming to the Directive
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 237, 26.8.1983
(7) Follow-up work	
(8) Commission implementing measures	— Directive 85/503/EEC — Official Journal L 308, 20.11.1985 Commission Directive of 25 October 1985 on methods of analysis for edible caseins and caseinates. This Directive lays down Community methods of analysis which must be followed when testing edible caseins and caseinates, as provided for by Directive 83/417/EEC.

— Directive 86/424/EEC — Official Journal L 243, 28.8.1986
Commission Directive of 15 July 1986 laying down methods of sampling for chemical analysis of edible caseins and caseinates.
This Directive establishes sampling procedures, as provided for by Directive 83/417/EEC.

4. FOODSTUFFS

4.58. Product legislation: natural mineral waters

(1) Objective

To harmonize the laws of the Member States relating to the exploitation and marketing of natural mineral waters so as to facilitate their movement within the Community.

(2) Community measures

Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters.

Amended by the following measures:
Council Directive 80/1276/EEC of 22 December 1980;
Council Directive 85/7/EEC of 19 December 1984.

(3) Contents

1. The following text contains a consolidation of existing Directives in the field of natural mineral waters.
2. The Directives concern water extracted from the ground of a Member State and recognized as natural mineral water by the responsible authority. They also concern water extracted from the ground of third countries, imported into the Community and recognized as natural mineral water by the responsible authority of a Member State, provided that the authority empowered to that effect in the country of extraction has certified that the water complies with the provisions of the Directives.
3. The Directives define the characteristics of natural mineral waters, the treatments and additions which may be made to them and the conditions of exploitation of springs.
4. Member States which recognize a mineral water as such must justify that decision, which is published, and inform the Commission thereof. The list of recognized mineral waters is published in the *Official Journal of the European Communities*.
5. The Directives lay down very precise rules on the labelling and packaging of natural mineral waters.
6. Only waters complying with the provisions of the Directives may be marketed as natural mineral waters. Trade in such waters may not be impeded by the application of non-harmonized national provisions governing the properties, composition, conditions of exploitation, packaging, labelling or advertising of natural mineral waters or of foodstuffs in general, subject to the usual derogations.

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

— Directive 80/777/EEC: 17.7.1982: authorization to market products conforming to the Directive;
17.7.1984: ban on the marketing of products not conforming to the Directive.
— Directive 80/1276/EEC: not communicated
— Directive 85/7/EEC: not communicated

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

— Directive 80/1276/EEC: 31.12.1980
— Directive 85/7/EEC: 27.12.1984

(6) References

Official Journal L 229, 30.8.1980
Official Journal L 375, 31.12.1980
Official Journal L 2, 3.1.1985

(7) Follow-up work

(8) Commission implementing measures

4. FOODSTUFFS

4.59. Product legislation: quality of water for human consumption

(1) Objective

To harmonize the laws of the Member States relating to the quality of water intended for human consumption so as to facilitate its movement within the Community.

(2) Community measures

Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption.

Amended by the following measures:
Council Directive 81/858/EEC of 19 October 1981;
Council Directive 91/692/EEC of 23 December 1991.

(3) Contents

1. The following text contains a consolidation of existing Directives on the quality of water intended for human consumption.
2. The Directives lay down quality requirements for water intended for human consumption. They apply to all such water, whether intended for direct consumption or used in a foodstuffs business or affecting the wholesomeness of final foodstuffs. They do not apply to natural mineral water (summary 4.58) or to recognized medicinal waters or waters defined as such by the competent national authorities.
3. The marketing of water conforming to the Directive may be prohibited or impeded only by national provisions justified by the existence of a health risk.
4. Member States may make provision for derogations from Community legislation, e.g. to take account of natural situations or exceptional meteorological conditions.
5. Member States must ensure that application of the Directive's provisions does not lead to any deterioration in the present quality of water intended for human consumption or an increase in the pollution of waters used for the production of drinking water.
6. Every three years Member States must send the Commission a sectoral report giving information on the implementation of the Directives.
7. Procedures for updating and applying the Directives.

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

— Directive 80/778/EEC: 17.7.1982
— Directive 81/858/EEC: not communicated
— Directive 91/692/EEC: 1.1.1993: Articles 2 and 3
1.1.1994: Article 4
1.1.1995: Article 5

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

— Directive 80/778/EEC: 17.7.1985
— Directive 81/858/EEC: 1.1.1981

(6) References

Official Journal L 229, 30.8.1980
Official Journal L 319, 7.11.1981
Official Journal L 377, 31.12.1991

(7) Follow-up work

(8) Commission implementing measures

4. FOODSTUFFS

4.60. Product legislation: coffee and chicory extracts

(1) Objective

To harmonize laws on coffee and chicory extracts so as to facilitate their movement within the Community.

(2) Community measures

Council Directive 77/436/EEC of 27 June 1977 on the approximation of the laws of the Member States relating to coffee and chicory extracts.

Amended by the following measures:
Council Directive 85/7/EEC of 19 December 1984;
Council Directive 85/573/EEC of 19 December 1985.

(3) Contents

1. The following text contains a consolidation of existing Directives in the field of coffee and chicory extracts.
2. The Directives lay down rules on the compositional characteristics of extracts of coffee and chicory, substances liable to be used in their manufacture, and their packaging and labelling. They also indicate the conditions in which certain names may be used for certain of these products.
3. Coffee extracts and chicory extracts, blends of coffee extracts and chicory extracts and extacts of blends of roasted coffee and roasted chicory may be marketed only if such products conform to the definitions and rules laid down in the Directives. The names laid down by the Directives are reserved for the products defined therein and must be used to designate them in trade.
4. Trade in products conforming to the definitions and rules of the Directives may not be impeded, except with the usual reservations, by the application of non-harmonized national provisions governing the composition, manufacturing specifications, packaging and labelling of those particular products or of foodstuffs in general.

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

— Directive 77/436/EEC: 28.6.1978
— Directive 85/7/EEC: 27.12.1984

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

— Directive 77/436/EEC: 28.6.1979: authorization to market products conforming to the Directive;
28.6.1980: ban on the marketing of products not conforming to the Directive.
— Directive 85/573/EEC: 1.1.1987: authorization to market products conforming to the Directive;
1.7.1988: ban on the marketing of products not conforming to the Directive.

(6) References

Official Journal L 172, 12.7.1977
Official Journal L 2, 3.1.1985
Official Journal L 372, 31.12.1985

(7) Follow-up work

(8) Commission implementing measures	Directive 79/1066/EEC — Official Journal L 327, 24.12.1979 Commission Directive of 13 November 1979 laying down Community methods of analysis for testing coffee and chicory extracts. The Directive lays down Community methods of analysis to be followed for testing coffee and chicory extracts.

5. PHARMACEUTICAL PRODUCTS

Current position and outlook

Since 1993 the technical requirements for the testing and manufacture of medicines for human and veterinary use and the rules on the labelling, advertising, wholesale distribution and prescription sales of medicines and on the transparency of the national measures on pricing and refunds have been totally harmonized.

The Community's strategy has revolved around two chief ideas.

Firstly, efforts have concentrated on consolidation and completion of the existing legislation by extending its scope, delegating the power to adopt technical amendments, making the national price control and refund schemes more transparent, acceding to the European Pharmacopoeia, harmonizing the conditions for administering medicines to patients and providing patients with fuller information on medicinal products.

Secondly, the reform of the marketing licensing system for medicinal products in the Community has been implemented. In 1993 the Council adopted one Regulation and three Directives concerning the future marketing licensing system and the establishment of the European Agency for the Evaluation of Medicinal Products.

Consequently, from 1995 onwards firms will have the choice between central authorization of new medicinal products which will be mandatory for biotechnology and decentralized mutual recognition of national authorizations granted in the past for existing medicinal products. A European Agency for the Evaluation of Medicinal Products will be set up in London to coordinate these new procedures (summary 5.20).

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

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

5. PHARMACEUTICAL PRODUCTS

5.1. Marketing authorization: general conditions: basic Directive

(1) Objective

To harmonize the marketing conditions for medicinal products.

(2) Community measures

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products.

Amended by the following measures:
Council Directive 66/454/EEC of 28 July 1966;
Council Directive 75/319/EEC of 20 May 1975;
Council Directive 83/570/EEC of 26 October 1983;
Council Directive 87/21/EEC of 22 December 1986;
Council Directive 89/341/EEC of 3 May 1989;
Council Directive 89/342/EEC of 3 May 1989;
Council Directive 89/343/EEC of 3 May 1989;
Council Directive 92/27/EEC of 31 March 1992;
Council Directive 92/73/EEC of 22 September 1992;
Council Directive 93/39/EEC of 14 June 1993.

(3) Contents

1. The following text contains a consolidation of existing Directives concerning the marketing of medicinal products.
2. The provisions apply to proprietary medicinal products for human use intended to be placed on the market and to industrially manufacture medicinal products the marketing of which has been authorized in one Member State.
However, they do not apply to:
— medicinal products prepared according to prescription, i.e. prepared in a pharmacy from a prescription intended for a specific patient;
— medicinal products prepared in accordance with an official formula, i.e. prepared in a pharmacy in accordance with the instructions in a pharmacopoeia and intended to be given direct to the patients by the pharmacy;
— medicinal products intended for research and development trials;
— intermediate products intended for subsequent processing by an authorized manufacturer.
3. No medicinal product may be placed on the market of a Member State without prior authorization from the competent authority of the Member State concerned. The application for authorization must be lodged with the competent authority of the Member State concerned and accompanied by a series of very specific items of information such as a description of the method of preparation, the therapeutic indications, contra-indications, secondary effects, etc.
4. When the competent authority authorizes the marketing of a medicnal product, it will inform the person responsible for marketing that it approves the summary of the characteristics of the product. It will then send the European Agency for the Evaluation of Medicinal Products a copy of the authorization accompanied by the summary of the characteristics of the product. It will also draw up an evaluation report regarding the results of the analytical, pharmaco-toxicological and clinical tests carried out on the medicinal product in question. This report will be regularly updated.

5. A marketing authorization will be refused if it appears that the medicinal product is harmful under normal conditions of use, that it has no or very little therapeutic effect or that it does not have the stated composition in terms of quality and quantity. Authorization will also be refused if the information requested is incomplete or not given.
6. The competent authorities of the Member States may refuse to grant marketing authorization for a medicinal product for contraceptive purposes if their legislation prohibits the marketing of medicinal products used essentially for such purposes.
7. The authorization must be granted within 210 days of the application being lodged.
8. If a Member State ascertains that an authorization application made after 1 January 1995 is being examined by another Member State, it will await the evaluation report drawn up by this Member State pursuant to point 4 above. It will then recognize the decision of the other Member State within 90 days of receipt of the evaluation report or, if it believes that authorization of the medicinal product in question could pose a risk to public health, it will apply the procedures provided for in Articles 10 to 14 of Council Directive 75/319/EEC (summary 5.2).
9. As of 1 January 1998, if a Member State learns that the marketing of a medicinal product has been authorized by another Member State, it shall request from the latter the evaluation report referred to in point 4 above. It will then recognize the decision of the other Member State within 90 days or, if it believes that authorization of the medicinal product in question could pose a risk to public health, it will apply the procedures provided for in Articles 10 to 14 of Council Directive 75/319/EEC (summary 5.2).
10. The authorization is valid for a period of five years renewable by five-yearly periods.
11. The marketing authorization may be suspended or withdrawn on the same grounds as those invoked for refusal to grant marketing authorization.

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

— Directive 65/65/EEC: 31.12.1966
— Directive 66/454/EEC: 29.7.1966
— Directive 75/319/EEC: 21.11.1976
— Directive 83/570/EEC: 31.10.1985
— Directive 87/21/EEC: 1.7.1987
1.1.1992: Spain, Portugal and Greece
— Directive 89/341/EEC: 1.1.1992
— Directive 89/342/EEC: 1.1.1992
— Directive 89/343/EEC: 1.1.1992
— Directive 92/27/EEC: 1.1.1993
— Directive 92/73/EEC: 31.12.1993
— Directive 93/39/EEC: 1.1.1995
1.1.1998 for Article 1(7)

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

Directive 65/65/EEC: 3.2.1970

(6) References

Official Journal L 22, 9.2.1965
Official Journal L 144, 5.8.1966
Official Journal L 147, 9.6.1975
Official Journal L 332, 28.11.1983
Official Journal L 15, 17.1.1987
Official Journal L 142, 25.5.1989

	Official Journal L 142, 25.5.1989 Official Journal L 142, 25.5.1989 Official Journal L 113, 30.4.1992 Official Journal L 297, 13.10.1992 Official Journal L 214, 24.8.1993
(7) Follow-up work	
(8) Commission implementing measures	Directive 91/356/EEC — Official Journal L 193, 17.7.1991 Commission Directive of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.

5. PHARMACEUTICAL PRODUCTS

5.2. Marketing authorization: additional conditions

(1) Objective

To pursue the approximation begun by Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products with a view to achieving completely free movement of proprietary medicinal products within the European Community.

(2) Community measures

Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.

Amended by the following measures:
Council Directive 78/420/EEC of 2 May 1978;
Council Directive 83/570/EEC of 26 October 1983;
Council Directive 89/341/EEC of 3 May 1989;
Council Directive 89/342/EEC of 3 May 1989;
Council Directive 89/343/EEC of 3 May 1989;
Council Directive 89/381/EEC of 14 June 1989;
Council Directive 92/27/EEC of 31 March 1992;
Council Directive 92/73/EEC of 22 September 1992;
Council Directive 93/39/EEC of 14 June 1993.

(3) Contents

1. The following text contains a consolidation of existing Directives on the marketing of proprietary medicinal products.
2. The Directives apply to medicinal products for human use.
3. Medicinal products may not be placed on the market of a Member State without authorization from the competent authority of that Member State (see Directive 65/65/EEC — summary 5.1).
4. Applications for authorization must be accompanied by various documents and particulars, including the manufacturer's control methods (sterility tests, stability tests, etc.) and the results of physico-chemical, biological or microbiological, pharmacological and toxicological tests and clinical trials. Member States must make sure that this information is accompanied by reports from experts possessing the necessary technical or professional qualifications when it is submitted to the competent authorities.
5. Authorization will not be granted unless the conditions set out above are complied with.
6. Member States must verify that manufacturers and importers of medicinal products coming from non-member countries are able to comply with the provisions of Directive 65/65/EEC.
7. A Committee for Proprietary Medicinal Products has been set up to facilitate the adoption of a common position by the Member States with regard to decisions on the issuing of marketing authorizations and to promote thereby the free movement of medicinal products. This Committee comes under the European Agency for the Evaluation of Medicinal Products (summary 5.20).
8. The Committee acts:
— to make it easier to obtain product authorization in other Member States when authorization has already been obtained for the same product in one Member State (A);

— where a Member State considers that it is unable to grant a marketing authorization (B);
— where one or more Member States have granted authorization while one or more other Member States have refused it (C);
— to give its opinion before a Member State takes a decision to grant, suspend or revoke an authorization (D).

9. Where the Committee acts, it deliberates and delivers a reasoned opinion on the matter within 90 days. In situations C and D, this deadline may be extended by 90 days.

10. An appeal may be made against the Committee's decision. The Committee has 60 days in which to adopt a definitive position.

11. The Commission draws up a draft decision on the application within 30 days. This draft is sent to the Member States and to the applicant. After the Standing Committee on Medicinal Products for Human Use has issued its opinion (summary 1.5.2.3), the Commission adopts a final decision which is addressed to the Member States concerned and to the person responsible for marketing the product. The Member States implement the decision within 30 days.

12. Medicinal products may not be manufactured without authorization, even if they are intended for export. Authorization is also required for imports from non-member countries into a Member State.

13. Authorization must, in principle, be granted within 90 days from the date on which the competent authority receives the application.

14. The competent authority of the Member State concerned ensures, through repeated inspections, that the legal prescriptions regarding the medicinal products are being complied with.

15. Proprietary medicinal products are withdrawn from the market where:
— they prove to be harmful under normal conditions of use;
— they are lacking in therapeutic efficacy;
— their qualitative and quantitative composition is not as declared;
— the controls on the finished product have not been carried out.

16. The competent authority may limit the prohibition to supply the product, or its withdrawal from the market, to those batches which are the subject of dispute.

17. The Member States establish a system of pharmacovigilance to ensure the adoption of the relevant regulations concerning medicinal products authorized in the Community with due regard for information gathered on the undesirable effects of medicinal products under normal conditions of use. This information is gathered by a person responsible for pharmacovigilance under the person responsible for marketing.

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

— Directive 75/319/EEC: 21.11.1976
— Directive 78/420/EEC: 3.5.1978
— Directive 83/570/EEC: 31.10.1985
— Directive 89/341/EEC: 1.1.1992
— Directive 89/342/EEC: 1.1.1992
— Directive 89/343/EEC: 1.1.1992
— Directive 89/381/EEC: 1.1.1992
— Directive 92/27/EEC: 1.1.1993
— Directive 92/73/EEC: 31.12.1993
— Directive 93/39/EEC: 1.1.1995
1.1.1998 for Article 1(7)

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

— Directive 89/341/EEC: 31.12.1992: extension to existing medicinal products
— Directive 89/342/EEC: 31.12.1992: extension to immunological medicinal products
— Directive 89/343/EEC: 31.12.1992: extension to radiopharmaceuticals
— Directive 89/381/EEC: 31.12.1992: extension to existing medicinal products derived from human blood or human plasma
— Directive 92/27/EEC: 1.1.1994: ban on medicinal products with non-conforming labels or leaflets.

(6) References

Official Journal L 147, 9.6.1975
Official Journal L 123, 11.5.1978
Official Journal L 332, 28.11.1983
Official Journal L 142, 25.5.1989
Official Journal L 142, 25.5.1989
Official Journal L 142, 25.5.1989
Official Journal L 181, 28.6.1989
Official Journal L 113, 30.4.1992
Official Journal L 297, 13.10.1992
Official Journal L 214, 24.8.1993

(7) Follow-up work

(8) Commission implementing measures

— Directive 91/356/EEC — Official Journal L 193, 17.7.1991
Commission Directive of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.
This Directive supplements Article 19a of Directive 75/319/EEC and deals mainly with personnel, premises and equipment, documentation, production, quality control, complaints and product recall and self-inspection.

— Directive 91/507/EEC — Official Journal L 270, 26.9.1991
Commission Directive of 19 July 1991 modifying the Annex to Council Directive 75/319/EEC on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products.

5. PHARMACEUTICAL PRODUCTS

5.3. Marketing authorization: additional conditions: testing of medicinal products

(1) Objective	To adopt a new procedure to introduce technical updates into the legislation on the testing of medicinal products so as to make it more effective.
(2) Community measures	Council Directive 75/318/EEC of 20 May 1975 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. Amended by the following measures: Council Directive 83/570/EEC of 26 October 1983; Council Directive 87/19/EEC of 22 December 1986; Council Directive 89/341/EEC of 3 May 1989; Commission Directive 91/507/EEC of 19 July 1991. Council Directive 93/39/EEC of 14 June 1993;
(3) Contents	1. The following text contains a consolidation of existing Directives in the field of the testing of medicinal products. 2. Article 4 of Directive 65/65/EEC (see summary 5.1) requires that various documents and particulars accompany all applications for authorization to market a medicinal product. These documents and particulars are described in detail in the annex to the consolidated text. 3. The annex contains the following headings: — administrative data; — summary of product characteristics; — expert reports; — chemical, pharmaceutical and biological testing of medicinal products; — toxicological and pharmacological tests; — clinical documentation. 4. The Directives also empower the Commission to adapt the existing testing legislation to technical progress. 5. They set up a 'Standing Committee for Medicinal Products for Human Use' 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 before making any amendments. Matters are referred to the Council only where the Commission disagrees with the Committee.
(4) Deadline for implementation of the legislation in the Member States	— Directive 75/318/EEC: 21.11.1976 — Directive 83/570/EEC: 31.10.1985 — Directive 87/19/EEC: 1.7.1987 — Directive 89/341/EEC: 1.1.1992 — Directive 91/507/EEC: 1.1.1992 — Directive 93/39/EEC: 1.1.1995 1.1.1998 for Article 1(7)
(5) Date of entry into force (if different from the above)	Directive 89/341/EEC: 31.12.1992: extension to existing medicinal products

(6) References

Official Journal L 147, 9.6.1975
Official Journal L 332, 28.11.1983
Official Journal L 15, 17.1.1987
Official Journal L 142, 25.5.1989
Official Journal L 270, 26.9.1991
Official Journal L 214, 24.8.1993

(7) Follow-up work

(8) Commission implementing measures

5. PHARMACEUTICAL PRODUCTS

5.4. Marketing authorization: standards for testing

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

5. PHARMACEUTICAL PRODUCTS

5.5. Distribution and use of medicinal products: wholesale distribution of medicinal products

(1) Objective	To guarantee optimum conditions for the preservation, transport and handling of medicinal products.
(2) Community measures	Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human consumption.
(3) Contents	1. The Directive sets out to guarantee control of the entire distribution chain, from leaving the factory to being sold to the public. 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. 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. 4. 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 once 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 market ordered by the authorities. 5. The procedure for granting 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. 6. If need be, the Commission will publish guidelines on good distribution practice and, where appropriate, will consult for this purpose the Pharmaceutical Committee.
(4) Deadline for implementation of the legislation in the Member States	1.1.1993
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 113, 30.4.1992
(7) Follow-up work	
(8) Commission implementing measures	Guidelines on good distribution practice for medicinal products for human use (Official Journal C 63, 1.3.1994). On 29 January 1994, in accordance with Article 10 of Directive 92/25/EEC, the Commission adopted guidelines on good distribution

practice for medicinal products for human use setting out the rules to be followed by wholesalers to ensure that they do not impair the quality of such products in the course of their distribution and that they can participate effectively in identifying and recalling defective or counterfeit products introduced into the distribution network.

5. PHARMACEUTICAL PRODUCTS

5.6. Distribution and use of medicinal products: classification for the supply of medicinal products

(1) Objective	To harmonize conditions for the supply of medicinal products sold over the counter or on prescription.
(2) Community measures	Council Directive 92/26/EEC of 31 March 1992 concerning the classification for the supply of medicinal products for human use.
(3) Contents	1. The conditions for the supply of medicinal products for human use need to be harmonized to ensure the free movement of those products within the Community. 2. The Directive therefore lays down that, when a marketing authorization is granted, the competent authorities must specify the classification of the medicinal product into: — a medicinal product subject to medical prescription; — a medicinal product not subject to medical prescription. 3. The first category may be divided into subcategories: — medicinal products on renewable or non-renewable medical prescription; — medicinal products subject to special medical prescription; — medicinal products on restricted medical prescription, reserved for use in certain specialized areas. 4. The Directive describes the conditions which place medicinal products in one or another category. 5. The competent authorities must draw up a list each year of the medicinal products subject on their territory to medical prescription. This list must be communicated each year to the Commission and the other Member States.
(4) Deadline for implementation of the legislation in the Member States	1.1.1993
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 113, 30.4.1992
(7) Follow-up work	
(8) Commission implementing measures	

5. PHARMACEUTICAL PRODUCTS

5.7. Distribution and use of medicinal products: advertising of medicinal products for human use

(1) Objective

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

(2) Community measures

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

(3) Contents

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

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

5. PHARMACEUTICAL PRODUCTS

5.8. Distribution and use of medicinal products: prices: pricing and health insurance

(1) Objective	To obtain an overall picture of national pricing agreements and to try to remove the existing disparities between Member States in order to move closer the goal of a common market in medicinal products.
(2) Community measures	Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems.
(3) Contents	1. The Directive lays down certain requirements which Member States must follow when they legislate on the prices of medicinal products. 2. If the marketing of a medicinal product is permitted only after a Member State has approved the price of the product, certain rules must be followed: — the Member State must take the decision within 90 days; — in the event of refusal, the grounds of the decision must be given; — at least once a year, the Member State must publish a list of the medicinal products the price of which has been fixed during the relevant period, together with the prices which may be charged for such products. 3. The same rules apply if an increase in the price of a medicinal product is permitted only after prior approval has been obtained from the competent authorities of the Member State. 4. In the event of a price freeze imposed on all medicinal products by the competent authorities of a Member State, that Member State must ascertain, at least once a year, whether the macroeconomic conditions justify that the freeze be continued unchanged. In exceptional cases a derogation from a price freeze may be requested. 5. Where a Member State adopts a system of direct or indirect controls on the profits of persons responsible for placing medicinal products on the market, the Member State concerned must communicate certain information to the Commission. 6. Member States must follow certain rules if they decide that health insurance will only cover listed medicinal products. 7. Certain specific provisions must be complied with if a Member State decides to exclude certain medicinal products from the coverage of its national health insurance system. 8. A Committee is set up to examine any question relating to the application of the Directive.
(4) Deadline for implementation of the legislation in the Member States	31.12.1989
(5) Date of entry into force (if different from the above)	

(6) References

Official Journal L 40, 11.2.1989

(7) Follow-up work

(8) Commission implementing measures

5. PHARMACEUTICAL PRODUCTS

5.9. Distribution and use of medicinal products: pricing: price control and reimbursements

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

5. PHARMACEUTICAL PRODUCTS

5.10. Medicinal products for human use: Pharmaceutical Committee

(1) Objective	To set up a Pharmaceutical Committee to deal with problems arising in the field of proprietary medicinal products.
(2) Community measures	Council Decision 75/320/EEC of 20 May 1975 setting up a Pharmaceutical Committee.
(3) Contents	1. The Decision sets up a Pharmaceutical Committee composed of representatives from the Member States and chaired by a Commission representative. 2. The Committee's task is to examine any questions relating to proprietary medicinal products and, in particular, the preparation of proposals for Directives and amendments to Directive 65/65/EEC (summary 5.1).
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	Not communicated.
(6) References	Official Journal L 147, 9.6.1975
(7) Follow-up work	
(8) Commission implementing measures	

5. PHARMACEUTICAL PRODUCTS

5.11. Marketing authorization: general conditions

(1) Objective

To pursue the approximation begun by Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products with a view to achieving completely free movement of veterinary medicinal products within the European Community.

(2) Community measures

Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products.

Amended by the following measures:
Council Directive 90/676/EEC of 13 December 1990;
Council Directive 90/677/EEC of 13 December 1990;
Council Directive 92/74/EEC of 22 September 1992;
Council Directive 93/40/EEC of 14 June 1993.

(3) Contents

1. The following text contains a consolidation of existing Directives in the field of veterinary medicinal products.
2. The provisions of those Directives apply to:
— veterinary medicinal products offered for sale, *inter alia*, in the form of proprietary medicinal products, ready-made veterinary medicinal products or premixes for medicated feedingstuffs;
— veterinary medicinal products used in order to produce active or passive immunity;
— immunological veterinary medicinal products;
— homeopathic veterinary medicinal products.
3. They do not apply to:
— medicated feedingstuffs;
— veterinary medicinal products based on radioactive isotopes.
4. No veterinary medicinal product may be placed on the market of a Member State wtihout prior authorization from the competent authority of that Member State or without a marketing authorization having been issued in accordance with Council Regulation (EEC) No 2309/93 (summary 5.20). Applications for authorization must be accompanied by various documents and particulars, including the manufacturer's control methods (sterility tests, stability tests, etc.) and the results of physico-chemical, biological or microbiological, pharmacological and toxicological tests and clinical trials. Member States must make sure that this information is compiled by experts with the necessary technical or professional qualifications before it is submitted to the competent authorities.
5. Competent authorities will not authorize the marketing of a veterinary medicinal product intended to be administered to animals whose flesh or products are intended for human consumption unless the maximum residue limits for the active principle contained in the medicinal product have been set in accordance with Council Regulation (EEC) No 2377/90 (summary 5.13).
6. When the competent authority of a Member State issues a marketing authorization, it will send a copy of the same to the European Agency

for the Evaluation of Medicinal Products (summary 5.20). It will also draw up an evaluation report on the case dealing with the results of the analytical, pharmaco-toxicological and clinical tests carried out on the veterinary medicinal product in question. This report will be regularly updated.

7. Authorizations must, in principle, be granted within 210 days from the date of presentation.

8. If a Member State ascertains that an authorization application made after 1 January 1995 is being actively examined by another Member State, it will await the result of this examination and the evaluation report. It will then recognize the decision of the other Member State within 90 days of receipt of the evaluation report unless it believes that authorization of the medicinal product in question could pose a risk to human or animal health.

9. As of 1 January 1998, if a Member State is informed that another Member State has authorized the marketing of a veterinary medicinal product, it shall request from it the evaluation report and shall within 90 days either extend its recognition to or withhold it from the authorization decision of the other Member State.

10. Marketing authorization will be refused and veterinary medicinal products withdrawn if it becomes apparent that:

— the medicinal product is harmful under the conditions of use stated at the time of application;
— the medicinal product does not have any therapeutic effect or has insufficient effect on the species of animal for which the treatment was intended;
— the withdrawal period recommended by the applicant is inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer;
— the information requested is incomplete or missing.

11. Authorization is valid for five years and renewable for five-year periods.

12. A Committee for Veterinary Medicinal Products has been set up in order to facilitate the adoption of a common position by the Member States with regard to marketing authorizations and to promote thereby the free movement of veterinary medicinal products.

13. The Committee acts:

— to make it easier to obtain product authorization in other Member States when authorization has already been obtained for the same product in one Member State;
— where a Member State considers that it is unable to grant a marketing authorization;
— where one or more Member States have granted authorization while one or more other Member States have refused it;
— to give its opinion before a Member State takes a decision to grant, suspend or revoke an authorization.

14. Medicinal products may not be manufactured without authorization, even if they are intended for export. Authorization is also required for imports from non-member countries into a Member State.

15. The competent authority of the Member State concerned ensures, through repeated inspections, that the legal prescriptions regarding the medicinal products are being complied with.

16. The Directives lay down in detail the information which must be given on the packaging and leaflets of medicinal products.

(4) Deadline for implementation of the legislation in the Member States	— Directive 81/851/EEC: 9.10.1983 — Directive 90/676/EEC: 1.1.1992 — Directive 90/677/EEC: 1.1.1992 — Directive 92/74/EEC: 31.12.1993 — Directive 93/40/EEC: 1.1.1995 1.1.1998 for Article 1(7)	
(5) Date of entry into force (if different from the above)	— Directive 90/676/EEC: 1.1.1996:	entry into force for existing veterinary medicinal products
	— Directive 90/677/EEC: 1.1.1997:	entry into force for existing immunological veterinary medicinal products
(6) References		Official Journal L 317, 6.11.1981 Official Journal L 373, 31.12.1990 Official Journal L 373, 31.12.1990 Official Journal L 297, 13.10.1992 Official Journal L 214, 24.8.1993
(7) Follow-up work		
(8) Commission implementing measures	Directive 91/412/EEC — Official Journal L 228, 17.8.1991 Commission Directive of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products. This Directive supplements Article 27a of Directive 81/851/CEE and deals mainly with the guidelines for good manufacturing practice concerning personnel, premises and equipment, documentation, production, quality control, work contracted out, complaints and product recall and self-inspection.	

5. PHARMACEUTICAL PRODUCTS

5.12. Marketing authorization: additional conditions

(1) Objective

To adopt a new procedure for introducing technical updates into legislation on the testing of veterinary medicinal products so as to make it more effective.

(2) Community measures

Council Directive 81/852/EEC of 28 September 1981 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.

Amended by the following measures:
Council Directive 87/20/EEC of 22 December 1986;
Commission Directive 92/18/EEC of 20 March 1992;
Council Directive 93/40/EEC of 14 June 1993.

(3) Contents

1. The following text contains a consolidation of existing Directives on the testing of veterinary medicinal products.
2. Directive 81/851/EEC (summary 5.11) requires that various documents and particulars accompany all applications for authorization to market a veterinary medicinal product. These documents and particulars are described in detail in the annex to the consolidated text.
3. The annex contains the following headings:
— requirements relating to veterinary medicinal products other than immunological veterinary medicinal products, e.g:
  — administrative data;
  — summary of product characteristics;
  — expert reports;
  — analytical tests;
  — safety and residues testing;
  — pre-clinical and clinical testing.
— requirements for immunological veterinary medicinal products e.g:
  — administrative data;
  — summary of product characteristics;
  — expert reports;
  — analytical tests;
  — safety testing;
  — efficacy trials.
4. The Directives also empower the Commission to adapt the current testing legislation to technical progress.
5. They set up a 'Standing Committee for Veterinary Medicinal Products' on the adaptation to technical progress of the Directives on the removal of technical barriers to trade in the veterinary medicinal products sector which the Commission must consult before making any amendments. Matters are referred to the Council only where the Commission disagrees with the Committee.

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

— Directive 81/852/EEC: 9.10.1983
— Directive 87/20/EEC: 1.7.1987
— Directive 92/18/EEC: 1.4.1993
— Directive 93/40/EEC: 1.1.1995
1.1.1998 for Article 1(7)

(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 317, 6.11.1981 Official Journal L 15, 17.1.1987 Official Journal L 97, 10.4.1992 Official Journal L 214, 24.8.1993
(7) Follow-up work	
(8) Commission implementing measures	

5. PHARMACEUTICAL PRODUCTS

5.13. Technical aspects: animal feedingstuffs: veterinary medicinal product residues

(1) Objective

To establish maximum residue limits for veterinary medicinal products for all pharmacologically active substances used in the Community in veterinary medicinal products administered to food-producing animals.

(2) Community measures

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

Amended by the following measures:
Commission Regulation (EEC) No 675/92 of 18 March 1992;
Commission Regulation (EEC) No 762/92 of 27 March 1992;
Commission Regulation (EEC) No 3093/92 of 27 October 1992;
Commission Regulation (EEC) No 895/93 of 16 April 1993;
Council Regulation (EEC) No 2901/93 of 18 October 1993;
Commission Regulation (EC) No 3425/93 of 14 December 1993;
Commission Regulation (EC) No 3426/93 of 14 December 1993.

(3) Contents

1. The following text contains a consolidation of existing Regulations in the field of veterinary medicinal product residues.
2. Definitions of the following terms:
— residues of veterinary medicinal products: all pharmacologically active substances which remain in foodstuffs obtained from animals to which the veterinary medicinal product has been administered;
— maximum residue limit: the maximum concentration of residue resulting from the use of a veterinary medicinal product which may be accepted by the Community to be legally permitted in or on a food.
3. The Regulations classify pharmacologically active substances used in veterinary medicinal products in four categories:
— those for which maximum residue limits have been established (Annex I);
— those for which it is not necessary for the protection of public health to establish a maximum residue limit (Annex II);
— those for which provisional maximum residue limits may be established (Annex III);
— those for which no maximum residue limits can be established because, at whatever limit, they constitute a hazard to the health of the consumer (Annex IV);
4. The Regulations describe in detail the procedures to be followed in the following situations:
— to obtain the inclusion in one of the four annexes:
  — of a new pharmacologically active substance;
  — of pharmacologically active substances the use of which in veterinary medicinal products is authorized on the date of entry into force of the Regulation;
— to amend the Annexes at the request of a Member State in the light of new information, in order to protect human or animal health.
5. Following amendment of the annexes, the Commission must publish a summary of the assessment of the safety of the substances concerned.

6. The Member States may not prohibit or impede the putting into circulation within their territories of foodstuffs of animal origin originating in other Member States on the grounds that they contain residues of veterinary medicinal products if the quantity of residue does not exceed the maximum residue limit provided for in Annexes I or III, or if the substance concerned is listed in Annex II.

7. Without exception, with effect from 1 January 1997 the administration to food-producing animals of veterinary medicinal products containing substances not listed in Annexes I, II or III will be prohibited in the Community.

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

Not required.

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

— Regulation (EEC) No 2377/90: 1.1.1992
— Regulation (EEC) No 675/92: 19.5.1992
— Regulation (EEC) No 762/92: 28.3.1992
— Regulation (EEC) No 3093/92: 28.12.1992
— Regulation (EEC) No 895/93: 17.6.1993
— Regulation (EEC) No 2901/93: 23.10.1993
— Regulation (EC) No 3425/93: 15.2.1994
— Regulation (EC) No 3426/93: 15.2.1994

(6) References

Official Journal L 224, 18.8.1990
Official Journal L 73, 19.3.1992
Official Journal L 83, 28.3.1992
Official Journal L 311, 28.10.1992
Official Journal L 93, 17.4.1993
Official Journal L 264, 23.10.1993
Official Journal L 312, 15.12.1993
Official Journal L 312, 15.12.1993

(7) Follow-up work

(8) Commission implementing measures

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

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

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

— Regulation (EEC) No 895/93 — Official Journal L 93, 17.4.1993
Commission Regulation of 16 April 1993 amending Annexes I, II and III to Council Regulation (EEC) No 2377/90 laying down a Community

procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

— The Commission has published a communication adopted pursuant to Article 7(2) of Council Regulation (EEC) No 2377/90 (Official Journal C 263, 29.9.1993).
In this communication it gives notice of the timetable provided for in that Article.

— Regulation (EC) No 955/94 — Official Journal L 108, 29.4.1994
Commission Regulation of 28 April 1994 amending Annexes I and II to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

— Regulation (EC) No 1430/94 — Official Journal L 156, 23.6.1994
Commission Regulation of 22 June 1994 amending Annexes I, II, III and IV to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

5. PHARMACEUTICAL PRODUCTS

5.14. Technical aspects: preparation and marketing of medicated feedingstuffs

(1) Objective	To prevent distortions in competition in the keeping and rearing of farm animals and to safeguard public health from any dangers arising from the use of medicated feedingstuffs for animals intended for food production.
(2) Community measures	Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community.
(3) Contents	1. The Directive provides that only authorized medicated pre-mixes may be used to manufacture medicated feedingstuffs and that precise instructions must be given for the utilization of such feedingstuffs. 2. Producers must have adequate premises and staff whose knowledge of and qualifications in mixing technology are adequate. 3. Producers shall also be responsible for the quality of the products placed on the market. 4. Medicated feedingstuffs may be placed on the market only in sealed packaging labelled in accordance with the Community provisions in force. 5. Medicated feedingstuffs may be supplied to stockfarmers only on presentation of a prescription from a veterinarian subject to certain specific conditions. 6. Where medicated feedingstuffs are administered to animals intended for human consumption, treated animals must not be slaughtered before the end of the legally stipulated withdrawal period. 7. In order to permit effective controls, those concerned must keep a register, or retain documents for a certain period. 8. The safeguard measures laid down by Directive 89/662/EEC and the rules on veterinary checks laid down in that Directive shall apply to trade in medicated pre-mixes.
(4) Deadline for implementation of the legislation in the Member States	— 31.12.1992: Article 11(2) — 1.10.1991: all other provisions
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 92, 7.4.1990
(7) Follow-up work	
(8) Commission implementing measures	

5. PHARMACEUTICAL PRODUCTS

5.15. Medicinal products for veterinary and human use: colouring matters for medicinal products

(1) Objective

To harmonize the use of colouring agents in medicinal products.

(2) Community measures

Council Directive 78/25/EEC of 12 December 1977 on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products.

Amended by the following measures:
Council Directive 81/464/EEC of 24 June 1981.

(3) Contents

1. The following text contains a consolidation of existing Directives on the colouring of medicinal products.
2. The colouring matters which may be added to medicinal products are listed in Annex 1 Sections 1 and 2 to the Directive of 23 October 1962 (Official Journal 115, 11.11.1962). This Directive deals only with colouring matters whose use is authorized in food for human consumption. However, the Council has permitted the use in the preparation of medicinal products of colouring agents used in foodstuffs. Hence the reference to the Directive of 23 October 1962.
3. However, no distinction is drawn between colouring matters which colour the mass and the surface of medicinal products and those which only colour the surface.
4. Where a colouring matter is deleted from the Directive of 23 October 1962 but the marketing of foodstuffs containing this colouring matter is permitted to continue for a limited period, this provision also applies to medicinal products. This limited period of use may, however, be amended for medicinal products according to a procedure laid down in the Directive.
5. The Directive sets up a committee made up of representatives from the Member States and chaired by a representative from the Commission.

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

— Directive 78/25/EEC: 15.6.1979
— Directive 81/464/EEC: 1.10.1981

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

(6) References

Official Journal L 11, 14.1.1978
Official Journal L 183, 4.7.1981

(7) Follow-up work

(8) Commission implementing measures

5. PHARMACEUTICAL PRODUCTS

5.16. Medicinal products for veterinary and human use: supplementary protection certificate for medicinal products

(1) Objective	The introduction at Community level of a supplementary protection certificate for medicinal products in order to reduce the disparity and lack of protection in this area.
(2) Community measures	Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.
(3) Contents	1. The Regulation is intended to remedy the current lack of protection for pharmaceutical research offered at national level by the patents system. 2. Under the current system the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research. 3. Under the Regulation, holders of both a patent and a certificate must be granted a maximum of 15 years' protection from the time the medicinal product in question first receives marketing authorization. 4. The certificate may not be granted for a period of more than five years. 5. Certificate applications may be made for any product which is protected by a patent on the territory of a Member State and which has received marketing authorization as a medicinal product in accordance with Directive 65/65/EEC (summary 5.1) or Directive 81/851/EEC (summary 5.11). 6. The Regulation sets out the conditions for applying for a certificate, the cases in which applications will be accepted or rejected, the conditions for the expiry, invalidity and publication of the certificate and for appeals against decisions taken under the Regulation. 7. A transitional period is laid down to enable the Community pharmaceutical industry catch up to some extent with its main competitors, which have been enjoying greater legal protection for several years.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	2.1.1993

(6) References

Official Journal L 182, 2.7.1992

(7) Follow-up work

(8) Commission implementing measures

5. PHARMACEUTICAL PRODUCTS

5.17. Medicinal products for veterinary and human use: contained use of genetically modified micro-organisms

(1) Objective	To lay down common measures for the contained use of genetically modified micro-organisms for the purposes of protecting human health and the environment.
(2) Community measures	Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms.
(3) Contents	1. Member States are required to regulate the contained use of genetically modified micro-organisms in order to minimize their potential negative effects on human health and the environment, as micro-organisms released in the environment of one Member State in the course of their contained use may spread into other Member States. 2. The Directive classifies genetically modified micro-organisms into two groups according to the level of hazard. 3. In order to minimize the risk to human health and the environment, the user must adhere to certain principles of safety and health. In addition, before undertaking for the first time in a particular installation the contained use of genetically modified micro-organisms, the user must submit to the authorities a notification enabling them to ensure that the proposed installation can be used for this activity without danger. 4. The notification will contain different information depending on the level of risk involved. 5. Member States may, if they wish, make provision for consulting groups or the public on any aspect of the proposed contained use. 6. Member States must ensure that an emergency response plan is drawn up to ensure an effective response in the event of an accident and that the persons likely to be affected by an accident are informed about all matters relating to their safety. 7. In the event of an accident the user must immediately inform the competent authority and communicate all the information necessary in order to assess its impact and to adopt the appropriate measures. In addition, the Member State must inform the Commission and any other Member State liable to be affected by the accident. 8. The Commission shall set up a register of the accidents which have occurred, including an analysis of their causes, the experience gained and the measures taken to avoid similar accidents. 9. To enable the contained use of genetically modified micro-organisms to be monitored throughout the Community, Member States have to provide the Commission with certain information. 10. The Commission is assisted by a committee which deals with matters relating to the implementation of the Directive and its adaptation to technical progress.
(4) Deadline for implementation of the legislation in the Member States	23.10.1991

(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 117, 8.5.1990
(7) Follow-up work	
(8) Commission implementing measures	Decision 91/448/EEC — Official Journal L 239, 28.8.1991 Commission Decision of 29 July 1991 concerning the guidelines for classification referred to in Article 4 of Directive 90/219/EEC.

5. PHARMACEUTICAL PRODUCTS

5.18. Medicinal products for veterinary and human use: deliberate release into the environment of genetically modified organisms

(1) Objective

To harmonize the legislation governing the deliberate release into the environment of genetically modified organisms in order to protect human health and the environment.

(2) Community measures

Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms.

(3) Contents

1. Member States are required to regulate the deliberate release into the environment of genetically modified organisms in order to minimize their potential negative effects on human health and the environment, since living organisms released in the environment for experimental purposes or as commercial products may cross national frontiers and affect other Member States by virtue of their irreversible effects on the environment.
2. Any person wishing to undertake a deliberate release of a genetically modified organism (GMO) must submit a notification to the competent authority of the Member State within whose territory the release is to take place. This notification shall include a technical dossier of information including a full risk assessment, appropriate safety and emergency response measures and, in the case of products, precise instructions and conditions for use, plus a proposal for labelling and packaging.
3. The notifier may proceed with the release only when he has obtained the consent of the competent authorities, who are required to respond within 90 days.
4. The public may be consulted, if the Member State considers it necessary, with regard to a proposed deliberate release for experimental purposes.
5. Each Member State must send the Commission a summary of each notification received within 30 days of its receipt. The Commission must forward these summaries to the other Member States for information and, where appropriate, for comment.
6. The procedure for dealing with an application to place on the market products containing GMOs is similar (notification followed by consent, at Community level, issued by the competent authorities of the Member State, but on behalf of all the Member States). The other Member States are allowed a period of 60 days in which to lodge objections. In the event of a disagreement the Commission takes a decision in accordance with the procedure laid down in Article 21 (committee voting by qualified majority). As soon as the notifier receives the consent the product may be placed on the market and may be used throughout the Community.
7. Where a product containing a GMO or a combination of GMOs is placed on the market and has been duly authorized pursuant to this Directive, a Member State may not, on grounds relating to matters covered by this Directive, prohibit, restrict or impede the deliberate release of this product on its territory, if the conditions set out in the written consent have been adhered to. There is a procedure for dealing with cases of hazards to human health or the environment.

8. The Commission is assisted by a committee which deals with matters relating to the implementation of the Directive and its adaptation to technical progress.

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

23.10.1991

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

(6) References

Official Journal L 117, 8.5.1990

(7) Follow-up work

On 4 November 1991 the Council adopted Decision 91/596/EEC concerning the summary notification information format referred to in Article 9 of Directive 90/220/EEC (Official Journal L 322, 23.11.1991). This Decision was amended by Commission Decision 94/211/EC (see point 8).

(8) Commission implementing measures

— Decision 91/274/EEC — Official Journal L 135, 30.5.1991
Commission Decision of 21 May 1991 on a list of Community legislation referred to in Article 10 of Directive 90/220/EEC.

— Decision 92/146/EEC — Official Journal L 60, 5.3.1992
Commission Decision of 11 February 1992 concerning the summary notification information format referred to in Article 12 of Directive 90/220/EEC.

— Commission Decision of 18 December 1992 concerning the placing on the market of products containing GMOs pursuant to Article 13 of Directive 90/220/EEC.

— Decision 93/572/EEC — Official Journal L 276, 9.11.1993
Commission Decision of 19 October 1993 concerning the placing on the market of products containing GMOs pursuant to Article 13 of Directive 90/220/EEC.

— Decision 93/584/EEC — Offical Journal L 279, 12.11.1993
Commission Decision of 22 October 1993 establishing the criteria for simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC.
This text applies only to genetically modified plants, which is the group of GMOs with which most of the experience has been acquired to date.

— Directive 94/15/EC — Official Journal L 103, 22.4.1994
Commission Directive of 15 April 1994 adapting to technical progress for the first time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms.

— Decision 94/211/EC — Official Journal L 105, 26.4.1994
Commission Decision of 15 April 1994 amending Council Decision 91/596/EEC concerning the summary notification information format referred to in Article 9 of Council Directive 90/220/EEC.
This decision replaces the Annex to Decision 91/596/EEC.

5. PHARMACEUTICAL PRODUCTS

5.19. Medicinal products for veterinary and human use: protection of animals used for experimental purposes

(1) Objective	To reduce to a minimum the number of animals used for experimental purposes, ensure they are given proper care and avoid needless suffering.
(2) Community measures	Council Directive 86/609/EEC of 24 November 1986 on the approximation of the laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes.
(3) Contents	1. The Directive is intended to protect animals used for experimental purposes by approximating the laws of the Member States in this field. 2. No experiments may be conducted on animals belonging to endangered species. 3. Animals must be accommodated in the best possible conditions and a competent person must take care to prevent any pain or avoidable suffering, distress or lasting harm. 4. Each Member State designates the authority responsible for ensuring that the Directive is properly implemented. 5. Experiments may only be conducted with authorization and only if there is no other scientific method not entailing the use of animals. 6. In general, all experiments must be conducted under anaesthesia or analgesics. 7. At the end of any experiment a veterinarian must decide whether an animal is to be kept alive or killed humanely. 8. Persons planning to conduct an experiment causing severe pain to an animal must notify the competent authority and wait for its authorization. 9. Persons conducting experiments must have received appropriate training. 10. Breeding establishments must be approved by the competent authority and must record the movements of all their animals. 11. Animals must be marked as soon as possible. 12. User establishments must be registered with the authority and must comply with a number of conditions set out in the Directive. 13. In order to avoid unnecessary duplication of experiments for the purposes of satisfying national or Community health and safety legislation, Member States must recognize the validity of data generated by experiments carried out in the territory of another Member State.
(4) Deadline for implementation of the legislation in the Member States	24.11.1989
(5) Date of entry into force (if different from the above)	

(6) References

Official Journal L 358, 18.12.1986

(7) Follow-up work

(8) Commission implementing measures

5. PHARMACEUTICAL PRODUCTS

5.20. Medicinal products for veterinary and human use: European Agency for the Evaluation of Medicinal Products

(1) Objective

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

(2) Community measures

Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

(3) Contents

1. No medicinal product derived from biotechnology and no culture medium used in veterinary medicine can be marketed in the Community unless an authorization has been issued by the Community in accordance with the provisions of this Regulation. The person responsible for marketing a medicinal product may apply for a marketing authorization to be issued by the Community. Such an authorization can be obtained by submitting an application to the European Agency for the Evaluation of Medicinal Products.
2. The Regulation distinguishes between medicinal products for human use and those for veterinary use.
3. With regard to medicinal products for human use, 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 such products.
4. Following a written request by the Committee, Member States are required to forward the information needed in order to verify that the manufacturer of a medicinal product from a third country is competent to manufacture the medicinal product in question. Authorization of a medicinal product will be refused, if:
— after verification of the information and documentation submitted, it emerges that the quality, safety or efficacy of the medicinal product has not been adequately demonstrated;
— the information and documentation supplied by the applicant are not correct, or the labelling or package insert proposed by the applicant do not comply with the provisions of Council Directive 92/27/EEC (Official Journal L 113, 30.4.1992).
5. Applicants have 15 days in which to appeal against this decision.
6. Marketing authorizations are granted by the Commission through the regulatory committee procedure. When an authorization is granted, an announcement to this effect is published, for information purposes, in the *Official Journal of the European Communities*. Authorizations remain valid for five years and are renewable for five-year periods.
7. Marketing authorizations granted in accordance with this Regulation apply throughout the Community.
8. Medicinal products authorized by the Community pursuant to this Regulation are covered by the 10-year protection period provided for under Council Directive 65/65/EEC (summary 5.1).

9. 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.
10. The authorities responsible for supervision must check that the person responsible for marketing the medicinal product complies with the requirements of Directive 75/319/EEC.
11. The Regulation sets up a European Agency for the Evaluation of Medicinal Products. The Agency will collaborate with the World Health Organization on international drug monitoring and send it information on activities in the Community which could affect public health protection in third countries.
12. The opinion of the Agency on medicinal products intended for veterinary use is delivered by the Committee on Veterinary Medicinal Products.
13. The procedure for veterinary medicinal products is virtually identical to the procedure for medicinal products for human use and is described in detail in the Regulation.
14. The Agency has legal personality and exercises the widest possible legal powers recognized under the law in all the Member States.
15. The Agency's head-office is in London.

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

Not required.

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

1.1.1995: Titles I, II, III and V
For the other provisions, the day following the day on which the competent authorities decide on the seat of the Agency.

(6) References

Official Journal L 214, 24.8.1993

(7) Follow-up work

On 27 May 1994 the Commission submitted a proposal for a Council Regulation (EC) on fees payable to the European Agency for the Evaluation of Medicinal Products (COM(94) 167 final).
In order to enable the Agency to be self-financing, the Regulation lays down rules for the charging of fees for issuing and maintaining Community marketing authorizations.

(8) Commission implementing measures

5. PHARMACEUTICAL PRODUCTS

5.21. Medicinal products for veterinary and human use: European Pharmacopoeia

(1) Objective	To harmonize national laws on the manufacture, movement and distribution of medicinal products in Europe by creating a European Pharmacopoeia.
(2) Community measures	Council Decision 94/358/EC of 16 June 1994 accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia.
(3) Contents	1. On 22 July 1964, Belgium, France, Germany, Italy, Luxembourg, the Netherlands, Switzerland and the United Kingdom signed a Convention on the elaboration of a European Pharmacopoeia. 2. The objectives are to harmonize specifications for medicinal substances which are of general interest to the peoples of Europe and to hasten the drawing-up of specifications for the growing number of new medicinal substances appearing on the market. 3. These objectives are attained by creating a European Pharmacopoeia made up of monographs which become official standards applicable in the territories of the Contracting States. 4. On 16 November 1989 a Protocol to the Convention was signed which enabled the European Community to accede to the Convention. The Protocol entered into force on 1 November 1992. 5. A total of 19 European countries are now party to the Convention: — the 12 Member States of the European Community; — six EFTA countries; — Cyprus. 6. The European Pharmacopoeia is drawn up by two bodies: — the European Pharmacopoeia Commission is responsible for preparing and adopting technical decisions on the monographs. It consists of eminent scientists appointed by each of the Contracting Parties for their competence; — the Public Health Committee of the Council of Europe administratively oversees the Commission's activities and, in particular, lays down the date for implementation of the monographs, although it may not alter any of their technical content.
(4) Deadline for implementation of the legislation in the Member States	Not required.
(5) Date of entry into force (if different from the above)	Not communicated.

(6) References

(7) Follow-up work

(8) Commission implementing measures

Official Journal L 158, 25.6.1994

5. PHARMACEUTICAL PRODUCTS

5.22. Medicinal products for veterinary and human use: good laboratory practice: tests

(1) Objective	To avoid repetition of tests caused by divergent laboratory practices between Member States and to protect animals by limiting the number of animal experiments by means of mutual recognition of results obtained on the basis of uniform methods.
(2) Community measures	Council Directive 87/18/EEC of 18 December 1986 on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.
(3) Contents	1. The Directive requires Member States to take all measures necessary to ensure that laboratories carrying out non-clinical tests on pharmaceutical products in accordance with Council Directives 75/318/EEC (summary 5.3) and 81/852/EEC (summary 5.12) comply with the principles of good laboratory practice specified in Annex 2 to the OECD Decision of 12 May 1981 on the mutual acceptance of data for the evaluation of chemical products. 2. These measures include inspections and study checks in accordance with OECD Recommendations.
(4) Deadline for implementation of the legislation in the Member States	30.6.1988
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 15, 17.1.1987
(7) Follow-up work	
(8) Commission implementing measures	

5. PHARMACEUTICAL PRODUCTS

5.23. Medicinal products for veterinary and human use: good laboratory practice: inspection and verification

(1) Objective	To harmonize national laws on the inspection and verification of good laboratory practice.
(2) Community measures	Council Directive 88/320/EEC of 9 June 1988 on the inspection and verification of good laboratory practice. Amended by the following measure: Commission Directive 90/18/EEC of 18 December 1989.
(3) Contents	1. The following text contains a consolidation of existing Directives in the field of good laboratory practice. 2. The Directives lay down a system for checking laboratories which claim to use good laboratory practice (GLP) in the conduct of tests on chemicals. 3. They are concerned only with the inspection and verification of the organizational processes and the conditions under which laboratory studies are planned, performed, recorded and reported for the non-clinical testing, carried out in accordance with the rules and Regulations, of all chemicals in order to assess the effects of such products on man, animals and the environment. 4. Each Member State designates the authorities responsible for the inspection of laboratories within its territory. 5. Each year the Member States must send the Commission and a Committee set up by the Directives a report containing a list of laboratories inspected and the date and conclusion of the inspections. 6. If an inspection is favourable, the Member State will vouch for the laboratory's compliance with GLP and this decision is binding on the other Member States. 7. If a Member State finds that a laboratory claiming GLP compliance does not in fact comply with GLP it must inform the Commission, which informs the other Member States. 8. The Directives lay down the procedure to be followed in the situation referred to at 7 above. 9. The Directives give a detailed description, in the annexes, of the rules to be followed when establishing national GLP compliance monitoring programmes so that these programmes may be internationally acceptable.
(4) Deadline for implementation of the legislation in the Member States	— Directive 88/320/EEC: 1.1.1989 — Directive 90/18/EEC: 1.7.1990
(5) Date of entry into force (if different from the above)	

(6) References

Official Journal L 145, 11.6.1988
Official Journal L 11, 13.1.1990

(7) Follow-up work

(8) Commission implementing measures

5. PHARMACEUTICAL PRODUCTS

5.24. Medicinal products for veterinary and human use: high-technology medicinal products: placing on the market

(1) Objective

To harmonize the laws of the Member States relating to the placing on the market of high-technology medicinal products.

(2) Community measures

Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology.

Council Directive 93/41/EEC of 14 June 1993 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 is repealed with effect from 1 January 1995 by Council Directive 93/41/EEC.
2. The Community coordination measures in respect of high-technology medicinal products have been incorporated and developed in the new legislative measures relating to authorization to place medicinal products on the Community market, namely Council Regulation (EEC) No 2309/93 (summary 5.20) and Council Directives 93/39/EEC (summaries 5.1 to 5.3) and 93/40/EEC (summary 5.11 and 5.12).
3. Directive 93/39/EEC seeks to harmonize the decisions taken in the various Member States with regard to medicinal products, by:
— providing that a Member State ought in principle to recognize a marketing authorization which has been granted by another Member State (with the exception of those medicinal products which are subject to the centralized Community authorization procedure established by Regulation (EEC) No 2309/93) unless there are serious grounds for supposing that the authorization of the medicinal product concerned may present a risk to public health. In the event of a disagreement between the Member States, a scientific evaluation of the matter must be undertaken by the Committee for Proprietary Medicinal Products attached to the European Agency for the Evaluation of Medicinal Products, leading to a single decision on the area of disagreement which is binding on the Member States concerned;
— requesting the Member States to suspend the examination of an application for authorization to place on the market a medicinal product which is currently under active consideration by another Member State and subsequently to recognize the decision reached by that State;
— improving cooperation and exchange of information between Member States relating to the supervision of medicinal products.
4. Directive 93/40/EEC clarifies Directive 93/39/EEC further by introducing the following provisions:
— in the event of a disagreement between Member States, a scientific evaluation must be undertaken by the Committee for Veterinary Medicinal Products;
— in order to improve the protection of public health, it specifies that foodstuffs for human consumption may not be taken from animals

	which have been used in clinical trials of veterinary medicinal products unless the standards laid down in Regulation (EEC) No 2377/90 (summary 5.13) have been met.
(4) Deadline for implementation of the legislation in the Member States	Directive 87/22/EEC: 1.7.1987 Directive 93/41/EEC: 1.1.1995
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 15, 17.1.1987 Official Journal L 214, 24.8.1993
(7) Follow-up work	
(8) Commission implementing measures	

6. CHEMICAL PRODUCTS

Current position and outlook

Free movement of chemical products throughout the Community cannot be guaranteed unless measures to harmonize dangerous substances and preparations limit the placing on the market and the use of certain substances and preparations and lay down requirements in respect of the classification, packaging and labelling of products and substances.

In the area of classification, packaging and labelling, 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 relevant measures undertaken by the Community have to be seen as part of a continuing process which already has a long history. For example, the Community first adopted a Directive on the classification, packaging and labelling of dangerous substances in 1967.

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

The Community has undertaken the following measures:

— restrictions on the marketing and use of certain dangerous substances and preparations (summaries 6.1 to 6.10).
On the basis of the Directives amending Directive 76/769/EEC, the Council and, in certain cases, the Commission prohibit or restrict the placing on the market of dangerous substances or preparations. This procedure has been used to ban products such as cadmium or Ugilec 121 and Ugilec 141 and to limit the use of PCBs and asbestos. In such matters the Commission has a duty to ensure that the level of regulation is consistent with the protection requirements in each Member State. Since that requirement has not been fulfilled, on 2 December 1992 the Commission decided to confirm German legislation imposing a total ban on PCBs under Article 100a(4). In May 1994 the Court of Justice annulled this decision by the Commission on the grounds that no adequate reasons had been given for it. On the other hand, the Court made no comment on the substance of the decision. The Commission therefore proposes to adopt a fresh Decision along the same lines but giving fuller reasons for it;

— classification, packaging and labelling of dangerous substances (summary 6.11); the general Directive on the classification, packaging and labelling of dangerous preparations, which replaced the earlier Directives, has been in force for over three years. The preparatory work to include in it the assessment of environmental hazards has started, and an amending proposal will be sent to the Council by the first half of 1995.
The Commission has made a start on implementing the Directive with regard to certain categories of packaging and the exchange of information between administrations;

— classification, packaging and labelling of dangerous substances; a proposal for a Directive to consolidate Directive 67/548/EEC was submitted by the Commission in December 1993;

— the placing of biocidal products on the market (summary 6.12);

— marketing of fertilizers (summaries 6.13 to 6.15).

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

6. CHEMICAL PRODUCTS

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

(1) Objective	To restrict the marketing and use of PCBs and PCTs (polychlorinated biphenyls and polychlorinated terphenyls).
(2) Community measures	Council Directive 85/467/EEC of 1 October 1985 amending for the sixth time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (PCBs/PCTs).
(3) Contents	1. Prohibition of the use of PCBs and PCTs except under certain conditions: — closed-system electrical equipment transformers, resistors and inductors; — large condensers (with a total weight equal to or over 1 kg); — in certain small condensers; — heat-transmitting fluids in closed-circuit heat-transfer installations; — hydraulic fluids for underground mining equipment. These uses of PCBs and PCTs will come to an end on 30 June 1986. 2. New labelling requirements: Member States may prescribe that equipment and plants containing PCBs and PCTs must display instructions concerning their disposal, maintenance and use.
(4) Deadline for implementation of the legislation in the Member States	30.6.1986
(5) Date of entry into force (if different from the above)	4.10.1985
(6) References	Official Journal L 269, 11.10.1985
(7) Follow-up work	On 9 September 1991 the Commission presented a proposal for a Council Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations (SEC(91) 1608 final/2). This proposal relates to the legislative consolidation of the field. It replaces the various Directives now being consolidated, including Directive 85/467/EEC. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made.
(8) Commission implementing measures	

6. CHEMICAL PRODUCTS

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

(1) Objective	To prohibit certain uses of asbestos in order to ensure adequate public health protection throughout the Community.
(2) Community measures	Council Directive 85/610/EEC of 20 December 1985 amending for the seventh time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (asbestos).
(3) Contents	Prohibition of the marketing and use of asbestos for: — toys; — materials and preparations applied by spraying; — products in powder form; — items for smoking; — filters and insulation devices for use in catalytic heaters using liquified gas; — paints and varnishes.
(4) Deadline for implementation of the legislation in the Member States	31.12.1987
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 375, 31.12.1985
(7) Follow-up work	On 9 September 1991 the Commission presented a proposal for a Council Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations (SEC(91) 1608 final/2). This proposal relates to the legislative consolidation of the field. It replaces the various Directives now being consolidated, including Directive 85/610/EEC. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made.
(8) Commission implementing measures	

6. CHEMICAL PRODUCTS

6.3. Marketing and use of dangerous substances: eighth amendment

(1) Objective	To add to the existing list new dangerous substances and/or preparations covered by the restrictions on marketing and/or use.
(2) Community measures	Council Directive 89/677/EEC of 21 December 1989 amending for the eighth time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.
(3) Contents	This amendment concerns restrictions on the marketing and use of 11 chemical substances or families of substances, in particular: — five carcinogenic substances the marketing of which is strictly regulated; — lead sulphates and lead carbonates which may not be used as constituents of paints; — mercury compounds, arsenic compounds and organostannic compounds which may no longer be used as constituents of preparations used to prevent the fouling of the hulls of boats or of any totally or partly submerged appliances or equipment.
(4) Deadline for implementation of the legislation in the Member States	21.6.1991
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 398, 30.12.1989
(7) Follow-up work	On 9 September 1991 the Commission presented a proposal for a Council Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations (SEC(91) 1608 final/2). This proposal relates to the legislative consolidation of the field. It replaces the various Directives now being consolidated, including Directive 89/677/EEC. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made.
(8) Commission implementing measures	

6. CHEMICAL PRODUCTS

6.4. Marketing and use of dangerous substances: Committee procedure

(1) Objective	To provide the Community with means of adapting to technical progress the Community legislation on the marketing and use of dangerous substances.
(2) Community measures	Council Directive 89/678/EEC of 21 December 1989 amending for the eighth time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.
(3) Contents	This amendment concerns the manner in which decisions on the adaptation of the Directive's annexes to technical progress are to be taken.
(4) Deadline for implementation of the legislation in the Member States	Not communicated.
(5) Date of entry into force (if different from the above)	4.1.1990
(6) References	Official Journal L 398, 30.12.1989
(7) Follow-up work	On 9 September 1991 the Commission presented a proposal for a Council Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations (SEC(91) 1608 final/2). This proposal relates to consolidation of the legislation in this field. It replaces the various Directives now being consolidated, including Directive 89/678/EEC. It maintains the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made.
(8) Commission implementing measures	

6. CHEMICAL PRODUCTS

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

(1) Objective	To strictly regulate the marketing of pentachlorophenol and its compounds with a view to ensuring adequate protection of public health in the whole of the Community.
(2) Community measures	Council Directive 91/173/EEC of 21 March 1991 amending for the ninth time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.
(3) Contents	Prohibition of the use of pentachlorophenol and its compounds in concentrations equal to or greater than 0.1% by mass in substances or preparations intended for use in industrial installations: — for the treatment of wood; — for the impregnation of heavy-duty textiles; — as a synthesizing and/or processing agent.
(4) Deadline for implementation of the legislation in the Member States	31.12.1991
(5) Date of entry into force (if different from the above)	1.7.1992
(6) References	Official Journal L 85, 5.4.1991
(7) Follow-up work	On 9 September 1991 the Commission presented a proposal for a Council Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations (SEC(91) 1608 final/2). This proposal relates to the legislative consolidation of the field. It replaces the various Directives now being consolidated, including Directive 91/173/EEC. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made.
(8) Commission implementing measures	

6. CHEMICAL PRODUCTS

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

(1) Objective	To prohibit certain uses of cadmium with a view to protecting the environment and human health.
(2) Community measures	Council Directive 91/338/EEC of 18 June 1991 amending for the 10th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.
(3) Contents	1. Ban on the use of cadmium and its compounds in three areas of application: pigments, stabilizers and plating. 2. A general derogation clause is provided to cover reasons of safety and reliability and situations where the use of cadmium may be essential. 3. The Council will reassess the situation within three years of the date of adoption of the Directive.
(4) Deadline for implementation of the legislation in the Member States	31.12.1992
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 186, 12.7.1991
(7) Follow-up work	On 9 September 1991 the Commission presented a proposal for a Council Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations (SEC(91) 1608 final/2). This proposal relates to the legislative consolidation of the field. It replaces the various Directives now being consolidated, including Directive 91/338/EEC. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made.
(8) Commission implementing measures	

6. CHEMICAL PRODUCTS

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

(1) Objective	To lay down rules on the marketing and use of certain dangerous substances and preparations with a view to protection of the environment and human health.
(2) Community measures	Council Directive 91/339/EEC of 18 June 1991 amending for the 11th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.
(3) Contents	1. A ban on the use of Ugilec 141 except in, or for the maintenance of, plant and machinery already in service until such plant and machinery is disposed of or reaches the end of its service life. 2. A ban on the use of Ugilec 121 and DBBT.
(4) Deadline for implementation of the legislation in the Member States	18.6.1992
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 186, 12.7.1991
(7) Follow-up work	On 9 September 1991 the Commission presented a proposal for a Council Directive relating to restrictions on the marketing and use of certain dangerous substances and preparations (SEC(91) 1608 final/2). This proposal relates to consolidation of the legislation in this field. It replaces the various Directives now being consolidated, including Directive 91/339/EEC. It maintains the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made.
(8) Commission implementing measures	

6. CHEMICAL PRODUCTS

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

(1) Objective	To update the placing on the market of polybromobiphenyl ethers for the purposes of protecting human health and the environment.
(2) Proposal	Proposal for a Council Directive amending Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.
(3) Contents	A ban on the use of polybromobiphenyl ether and its compounds in concentrations by mass equal to or greater than 0.1%, with an exemption for a period of five years from the adoption of this Directive for decabromobiphenyl ether, octabromobiphenyl ether and pentabromobiphnenyl ether, which must not be present in concentrations greater than those specified above.
(4) Opinion of the European Parliament	Not yet delivered.
(5) Current status of the proposal	Cooperation procedure The Commission presented the proposal for a Directive on 28 January 1991. The proposal has been sent to the European Parliament for its opinion.
(6) References	Commission proposal COM(91) 7 final — Official Journal C 46, 22.2.1991 Economic and Social Committee opinion — Official Journal C 191, 22.7.1991

6. CHEMICAL PRODUCTS

6.9. Marketing and use of dangerous substances: creosote, chlorinated solvents, CMT substances and preparations, nickel and flammable substances — 13th and 15th amendments

(1) Objective	To regulate the marketing and use by the general public of dangerous preparations in order to ensure protection of the environment and health.
(2) Proposal	Proposal for a Council Directive amending for the 13th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. Proposal for a Council Directive amending for the 15th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.
(3) Contents	Proposal for a Council Directive amending for the 13th time Directive 76/769/EEC The Directive amends the Annex to Council Directive 76/769/EEC (Official Journal L 762, 27.9.1976) which established an ad hoc system to restrict the marketing and use of dangerous substances and preparations, such as creosote and wood treated with creosote, any substance classified as carcinogenic, mutagenic and teratogenic and preparations containing such substances, plus certain chlorinated solvents. Proposal for a Council Directive amending for the 15th time Council Directive 76/769/EEC The Directive amends Annex I to Council Directive 76/769/EEC by listing flammable substances whose use is prohibited.
(4) Opinion of the European Parliament	Proposal for a Council Directive amending for the 13th time Directive 76/769/EEC First reading: Parliament approved the Commission's proposal subject to certain amendments. The Commission accepted some of these amendments. They were of a technical nature. Proposal for a Council Directive amending for the 15th time Directive 76/769/EEC First reading: Parliament approved the Commission's proposal without amendment.
(5) Current status of the proposal	Co-decision procedure 13th amendment The Commission presented the proposal for a Directive on 1 June 1992. First reading: On 19 January 1994 Parliament approved the Commission proposal subject to amendments. The Commission has accepted some of the amendments. The Commission presented an amended proposal on 29 March 1994.

On 16 June 1994 the Council adopted a common position.
The common position is now before Parliament for a second reading.

15th amendment
The Commission presented the proposal for a Directive on 18 October 1993.
First reading: On 15 December 1993 Parliament approved the Commission proposal without amendments.
On 27 June 1994 the Council adopted its common position.
The common position is now before Parliament for a second reading.

(6) References

Commission proposal	
COM(92) 195 final	Official Journal C 157, 24.6.1992
Amended proposal COM(94) 95 final	Official Journal C 157, 8.6.1994
European Parliament opinion	
First reading	Not yet published
Economic and Social Committee opinion	Official Journal C 332, 16.12.1992
Commission proposal	
COM(93) 499 final	Official Journal C 306, 12.11.1993
European Parliament opinion	
First reading	Not yet published
Economic and Social Committee opinion	Official Journal C 133, 16.5.1994

6. CHEMICAL PRODUCTS

6.10. Marketing and use of dangerous substances: creosote, chlorinated solvents, CMT substances and preparations, nickel and flammable substances — 14th amendment

(1) Objective	To regulate the marketing and use by the general public of dangerous preparations in order to ensure protection of the environment and health.
(2) Community measures	Council Directive XXX/EEC of 14 June 1994 amending for the 14th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.
(3) Contents	The Directive amends Annex I to Council Directive 76/769/EEC in order to restrict the use of nickel in jewellery and personal items coming into contact with the skin.
(4) Deadline for implementation of the legislation in the Member States	
(5) Date of entry into force (if different from the above)	
(6) References	Not yet published.
(7) Follow-up work	
(8) Commission implementing measures	

6. CHEMICAL PRODUCTS

6.11. Classification, packaging and labelling of dangerous preparations

(1) Objective

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

(2) Community measures

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

(3) Contents

1. The Directive applies to dangerous preparations as defined in Article 1(2) 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 for aerosols.
3. Provisions relating to the marketing of dangerous preparations.
4. Provision for the assessment of the health hazards of a product, i.e. those considered to be toxic, harmful, corrosive, irritant, carcinogenic, mutagenic, teratogenic, and as having special effects on health.
5. Packaging requirements, e.g. containers of dangerous preparations sold to the public must not have a shape and/or graphic design likely to attract children. They must be strong and resistant and have a suitable fastening system.
6. Labelling requirements including clear and indelible marking of the package with:
— the trade name of the preparation,
— the chemical name of the substance, etc.
Also, provision for the labelling of a product which has not yet been fully tested.
7. Manufacturers or those responsible for placing the preparation on the market shall hold the data used for the classification and labelling of the preparation at the disposal of the authorities of the Member States. Member States will appoint bodies responsible for receiving and ensuring the confidentiality of this information.
8. Member States shall set up a system of specific information (in safety data-sheet form) relating to dangerous products. This will primarily be used by industry to ensure health and safety at work.
9. Member States may temporarily suspend or make subject to special conditions the sale of a dangerous preparation on their territory. They may do so if it constitutes a hazard by reason of its classification, packaging or labelling. The Member State must immediately notify the Commission and other Member States of such action.
10. Member States may not prohibit, restrain or hinder the marketing of goods which comply with this Directive.
11. Annexes containing concentration limits of dangerous substances and special provisions on the labelling of certain preparations.
12. Directive 92/32/EEC amends Directive 88/379/EEC in the way it classifies preparations by category.

(4) Deadline for implementation of the legislation in the Member States	7.6.1991	
(5) Date of entry into force (if different from the above)		
(6) References	Amended opinion	Official Journal L 187, 16.7.1988 Official Journal L 110, 1.5.1991
(7) Follow-up work		
(8) Commission implementing measures	— Directive 89/178/EEC — Official Journal L 64, 8.3.1989 Commission Directive of 22 February 1989 adapting to technical progress Council Directive 88/379 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations. — Directive 90/35/EEC — Official Journal L 19, 24.1.1990 Commission Directive of 19 December 1989 defining in accordance with Article 6 of Directive 88/379/EEC the categories of preparations the packaging of which must be fitted with child-resistant fastenings and/or carry a tactile warning of danger. Date of entry into force: 10.6.1991. — Directive 91/155/EEC — Official Journal L 76, 22.3.1991 Commission Directive of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC. This Directive sets up a more detailed information system for industrial users. Date of entry into force: 8.6.1991. The Directive has been amended by Commission Directive 93/112/EC (Official Journal L 314, 16.12.1993). — Publication by the Commission (Official Journal L 180A, 8.7.1991) of a guide to the labelling of dangerous substances and preparations. — Directive 91/442/EEC — Official Journal L 238, 27.8.1991 Commission Directive of 23 July 1991 on dangerous preparations the packaging of which must be fitted with child-resistant fastenings. This Directive describes certain dangerous preparations as being likely to present a danger for children even if they do not fall into the categories of danger defined by Directive 90/35/EEC. The packaging must, therefore, be fitted with child-resistant fastenings. — Directive 93/18/EEC — Official Journal L 104, 29.4.1993 Commission Directive of 5 April 1993 adapting for the third time to technical progress Council Directive 88/379/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations. The Annexes to the Directive replace Annexes I and II to Directive 88/379/EEC and lay down particular provisions concerning the labelling	

of preparations which, although they contain one or more dangerous substances, are not necessarily classified as dangerous in Directive 88/379/EEC. The Member States have until 1 July 1994 to conform to the Directive.

6. CHEMICAL PRODUCTS

6.12. Biocidal products

(1) Objective

To ensure the free movement of biocidal products and of goods treated with such products, without any risks for man and the environment.

(2) Proposal

Proposal for a Council Directive concerning the placing of biocidal products on the market.

(3) Contents

1. The Directive supplements Directive 91/414/EEC concerning the placing of plant protection products on the market (Official Journal L 230, 19.8.1991). It follows a comparable approach: establishment of an approved list of active substances at Community level accompanied, at Member State level, by the granting and mutual recognition of authorizations.
2. Definition and scope: 'biocidal products' are non-agricultural pesticides such as insecticides, disinfectants, wood or other preservatives and industrial biocides.
3. The Directive establishes an approved Community list of active substances which may be used in biocidal products to combat harmful organisms.
4. A procedure is laid down for authorization to market biocidal products containing the active substances on the approved list. Such authorization may be granted, modified or cancelled by the Member States on the basis of the common requirements laid down by the Directive and of the common principles to be drafted by the Commission in the light of the opinion of the Standing Committee on Biocidal Products consisting of representatives of the Member States chaired by a representative of the Commission.
5. The principle of mutual recognition of authorizations granted by the Member States is established, accompanied by a safeguard clause.
6. A procedure is also provided for temporary authorization (for three years) by the Member States for the placing on their markets of biocidal products containing an active substance not yet on the approved list but complying with the conditions. This time limit is extended to 10 years for biocidal products not yet on the approved list but already on the market.
7. A 10-year programme will be started for systematic evaluation of active substances on the market which should be included on the approved list.
8. The Member States are also given the possibility of using an unauthorized biocidal product or active substance for research and development purposes, subject to strict conditions.
9. Harmonized rules are established on information exchange and confidentiality.
10. The rules laid down in Directives 88/379/EEC and 78/631/EEC (summary 6.11) and a few additional rules laid down in the Directive apply to the classification, packaging and labelling of biocidal products.
11. A safety data sheet system is established to keep users of biocidal products informed.
12. Rules are laid down on advertising of biocidal products.

	13. An obligation is placed on the Member States to make suitable arrangements for official monitoring of biocidal products to establish whether they comply with the requirements of the Directive.
(4) Opinion of the European Parliament	Not yet delivered.
(5) Current status of the proposal	Cooperation procedure The Commission presented the proposal for a Directive on 27 July 1993. The proposal has been sent to the European Parliament and the Economic and Social Committee for their opinions.
(6) References	Commission proposal COM(93) 351 final — Official Journal C 239, 3.9.1993

6. CHEMICAL PRODUCTS

6.13. Marketing of fertilizers: liquid fertilizers

(1) Objective	To extend the laws on the marketing of fertilizers to include liquid fertilizers.
(2) Community measures	Council Directive 88/183/EEC of 22 March 1988 amending Directive 76/116/EEC in respect of fluid fertilizers.
(3) Contents	1. Marketing requirements for liquid fertilizers. Only fertilizers listed in this Directive may be designated EEC fertilizers. Fluid fertilizers may only be marketed if directions for their correct storage and prevention of accidents are provided. 2. An annex containing a list of fluid fertilizers.
(4) Deadline for implementation of the legislation in the Member States	25.3.1989
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 83, 29.3.1988
(7) Follow-up work	On 5 December 1991 a consolidated version of Directive 76/116/EEC was presented by the Commission (SEC(91) 1858 final). It relates to the legislative consolidation of the field and will replace the various Directives now being consolidated. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made.
(8) Commission implementing measures	

6. CHEMICAL PRODUCTS

6.14. Marketing of fertilizers: solid and fluid fertilizers

(1) Objective	To extend the existing legislation on fertilizers to include their calcium, magnesium, sodium and sulphur content or to market them as EEC fertilizers.
(2) Community measures	Council Directive 89/284/EEC of 13 April 1989 supplementing and amending Directive 76/116/EEC in respect of the calcium, magnesium, sodium and sulphur content of fertilizers.
(3) Contents	1. A declaration of the magnesium, sodium and sulphur content of fertilizers may be made, provided that these elements are present in quantities at least equal to the minimum values laid down. 2. A declaration of calcium content considered to be a nutrient need only be made for calcium sulphate and calcium chloride solution fertilizers. 3. Fertilizers complying with the Directive may be marked 'EEC fertilizer'. 4. Required marking for identification purposes includes: — 'EEC fertilizer', — the designation of the type of fertilizer and the guaranteed nutrient content. 5. List of fertilizers containing calcium, magnesium and sulphur as principal nutrients.
(4) Deadline for implementation of the legislation in the Member States	17.4.1990
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 111, 22.4.1989
(7) Follow-up work	On 5 December 1991 a consolidated version of Directive 89/284/EEC was adopted by the Commission (SEC(91) 1858 final). It relates to the legislative consolidation of the field and will replace the various Directives now being consolidated. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made.
(8) Commission implementing measures	

6. CHEMICAL PRODUCTS

6.15. Marketing of fertilizers: trace elements

(1) Objective	To extend existing Community legislation on fertilizers (summaries 6.13 and 6.14) to include specific nutrients in fertilizers.
(2) Community measures	Council Directive 89/530/EEC of 18 September 1989 supplementing and amending Council Directive 76/116/EEC (Official Journal L 24, 30.1.1976) on the approximation of the laws of the Member States in respect of the trace elements boron, cobalt, copper, iron, manganese, molybdenum and zinc contained in fertilizers.
(3) Contents	1. Solid or fluid fertilizers complying with the existing Directive and containing one or more of the trace elements boron, cobalt, copper, iron, manganese, molybdenum and zinc may be marked 'EEC fertilizer', provided they meet the technical requirements detailed in the annex. A mixture of at least two of these trace elements may be termed 'EEC fertilizer'. These fertilizers must be packaged. 2. The content of the trace elements must be declared when they are present above a specified minimum and when they satisfy the requirements of Directive 76/116/EEC on fertilizers. 3. Compulsory markings for the identification of fertilizers, e.g. the words 'EEC fertilizer'; trace elements must be listed in alphabetical order of chemical symbol. 4. A Member State may authorize further information on labels within its territory; this would contain suitable dose rates and conditions of use for a fertilizer applied to a particular crop and soil condition. 5. Tolerance allowances for declared trace element content.
(4) Deadline for implementation of the legislation in the Member States	18.3.1991
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 281, 30.9.1989
(7) Follow-up work	On 5 December 1991 a consolidated version of Directive 89/530/EEC was adopted by the Commission (SEC(91) 1858 final). It relates to the legislative consolidation of the field and will replace the various Directives now being consolidated. It respects the substance of the consolidated texts and simply groups them together, the formal changes required by the consolidation being the only ones made.
(8) Commission implementing measures	

7. CONSTRUCTION

Current position and outlook

The construction sector raises problems of three kinds:

— obstacles to the free movement of construction machinery and equipment;

— divergent legislation on construction works including buildings and relating to the safety of their occupants;

— obstacles to the free movement of construction products.

To remedy these hindrances to establishment and functioning of the internal market, the Commission has harmonized the relevant technical specifications and provisions. Specifically:

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

— safety measures in hotels (summary 7.2): Given that many hotels are older buildings and because of the number of persons at risk, a minimum level of safety needs to be guaranteed. A recommendation on this subject has been sent to the Member States;

— construction products: The Directive on the free movement of construction products (summary 7.3), based on the new approach to technical harmonization, aims at laying down essential requirements relating mainly to safety and health.
These requirements — as applying to construction works — are detailed, and translated into product criteria, in interpretative documents. In order to be able to be marketed bearing EC labelling, construction products must meet the relevant harmonized technical specificiations which are to be drawn up by the European standardization bodies (standards) or by the European technical approval body (European technical approvals). In addition the attestation of conformity procedure must be complied with.

7. CONSTRUCTION

7.1. Tower cranes: sound levels

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

7. CONSTRUCTION

7.2. Fire safety in hotels

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

7. CONSTRUCTION

7.3. Construction products

(1) Objective

To harmonize national legislation with respect to the health and safety requirements applicable to construction products.

(2) Community measures

Council Directive 89/106/EEC of 21 December 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to construction products.

Council Directive 93/68/EEC of 22 July 1993 amending Directive 89/106/EEC, as well as Directives 87/404/EEC, 88/378/EEC, 89/336/EEC, 89/686/EEC, 89/392/EEC, 90/384/EEC, 90/385/EEC, 90/396/EEC, 91/263/EEC, 92/42/EEC and 73/23/EEC.

(3) Contents

Directive 89/106/EEC

1. The Directive applies to construction products, which are defined as any products produced with a view to their incorporation in a permanent manner in construction works.
2. Products may only be placed on the market if they are fit for their intended use. They must be such that works in which they are incorporated satisfy the essential requirements with regard to mechanical strength and stability, safety in case of fire, hygiene, health and the environment, safety in use, protection against noise and energy economy and heat retention for an economically reasonable working life.
3. Harmonized European standards for construction products shall be established by the European standardization bodies after consulting the Standing Committee on Construction (which was set up by the Directive).
4. A system of European technical approval is designed to assess the suitability of new products in terms of whether they satisfy the essential requirements set out in point 2 above if a harmonized standard cannot or cannot yet be prepared.
5. Where neither a European standard nor guidelines for European technical approval yet exist, construction products may continue to be assessed and marketed in accordance with national requirements.
6. Products which bear the EC mark shall be assumed to conform to requirements. Procedures for inspecting for conformity shall be laid down in accordance with the relevant decisions by the Standing Committee.
7. Products conforming to standards, but which are thought to pose a safety threat, may be temporarily withdrawn from the market.
8. Annexes containing detailed information on the essential requirements, European technical approval, attestation of conformity with technical specifications, certification bodies, inspection bodies and testing laboratories.

Directive 93/68/EEC

The aim of this Directive is to state and clarify the amendments to Directive 89/106/EEC resulting from uniform provisions on the EC marking.

(4) Deadline for implementation of the legislation in the Member States	— Directive 89/106/EEC: 27.6.1991 — Directive 93/68/EEC: 1.7.1994
(5) Date of entry into force (if different from the above)	Directive 93/68/EEC: 1.1.1995
(6) References	Official Journal L 40, 11.2.1989 Official Journal L 220, 30.8.1993
(7) Follow-up work	Interpretative documents drawn up by technical committees were unanimously approved by the Standing Committee on Construction on 31 January 1994 (Official Journal C 62, 28.2.1994).
(8) Commission implementing measures	Decision 94/23/EC — Official Journal L 17, 20.1.1994 Commission Decision of 17 January 1994 on common procedural rules for European technical approval (ETA). The Decision defines the common procedural rules which must be complied with when submitting an application for European technical approval and in the preparation, granting, withdrawal, modification and extension of such approval.

8. OTHER AREAS

Current position and outlook

This heading covers various fields.

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

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

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

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

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

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

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

8. OTHER AREAS

8.1. Noise: household appliances

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

8. OTHER AREAS

8.2. Noise: lawnmowers

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

8. OTHER AREAS

8.3. Noise: emissions from construction plant

(1) Objective	To harmonize national legislation on the control of noise emitted from construction equipment to ensure adequate environmental and health protection.
(2) Community measures	Council Directive 86/662/EEC of 22 December 1986 on the limitation of noise emitted by hydraulic excavators, rope-operated excavators, dozers, loaders and excavator-loaders.
(3) Contents	1. The Directive applies to the sound-power level of noise emitted into the environment, and the sound-pressure level of noise emitted at the operator's position of earth-moving machines used to perform work on civil-engineering and building sites. The four particular types of earth-moving machines are defined in detail. 2. The permitted sound-power level is between 106 dB(A)/1pW and 118 dB(A)/1pW according to the net installed power in kW of the machinery. All machines that comply will be issued with an EC type-examination certificate. 3. Member States must ensure that the marketing and use of earth-moving machines that do not comply with the Directive are prohibited. 4. Member States may limit the use of these machines in certain areas. 5. Six annexes containing technical information.
(4) Deadline for implementation of the legislation in the Member States	30.12.1988. The level of noise fixed by the Commission must be respected six years after the entry into force of the Directive.
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 384, 31.12.1986
(7) Follow-up work	On 12 May 1993 the Commission presented a proposal for a Directive amending Council Directive 86/662/EEC on the limitation of noise emitted by earth-moving machinery (COM(93) 154 final — Official Journal C 157, 9.6.1993). This proposal lays down new permissible sound-power levels on the basis of a new test method, conditions for the extension of EC type-examination certificates and the period of validity thereof. On 24 March 1994 the Council adopted a common position.
(8) Commission implementing measures	Directive 89/514/EEC — Official Journal L 253, 30.8.1989 Commission Directive of 2 August 1989 adapting to technical progress Council Directive 86/662/EEC on the limitation of noise emitted by hydraulic excavators, rope-operated excavators, dozers, loaders and excavator-loaders.

8. OTHER AREAS

8.4. Good laboratory practice (GLP)

(1) Objective	To set up a harmonized system for the verification of studies and for inspections of laboratories, ensuring that the latter comply with good laboratory practice (GLP) in order to allow for mutual recognition of tests carried out in these laboratories.
(2) Community measures	Council Directive 88/320/EEC of 9 June 1988 on the inspection and verification of good laboratory practice (GLP).
(3) Contents	1. The Directive applies to the inspection and verification of the conditions under which non-clinical tests are performed on chemical products in order to assess health and safety implications for humans, animals and the environment. The principles of good laboratory practice (GLP) to be followed are found in Council Directive 87/18/EEC (Official Journal L 15, 17.1.1987). 2. Member States must designate particular authorities to carry out inspections of laboratories. 3. Every year a report must be produced by Member States containing a list of inspected laboratories and a summary of the conclusions of the inspections. 4. Commercially sensitive and confidential information will be made available only to specified bodies, e.g. the Commission, national regulatory and designated authorities, etc., but GLP compliance status will be publicly available. 5. If it is thought that a laboratory has not carried out a test according to GLP, further information may be sought by the Member States from the inspecting authorities. A further inspection of the laboratory may be necessary. Member States shall inform the Commission of laboratories claiming GLP status but which fail to meet the requirements. 6. Amendments to the technical clauses of the Directive can be made by the Commission in consultation with the relevant committee. 7. Annex referring to OECD guidelines containing detailed information on the procedures to be followed when carrying out inspections.
(4) Deadline for implementation of the legislation in the Member States	1.1.1989
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 145, 11.6.1988
(7) Follow-up work	
(8) Commission implementing measures	Directive 90/18/EEC — Official Journal L 11, 13.1.1990 Commission Directive adapting to technical progress the annex to Directive 88/320/EEC on the approximation of the laws of the Member States relating to the permissible sound-power level of lawnmowers.

This Directive is to incorporate into the Directive OECD guidelines on procedures for laboratory inspection verification and the carrying out of inspections.
The Member States must undertake to implement the Directive before 1 July 1990.

8. OTHER AREAS

8.5. Dangerous products resembling foodstuffs

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

8. OTHER AREAS

8.6. Cosmetic products: labelling (colouring agents — fourth amendment)

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

8. OTHER AREAS

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

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

8. OTHER AREAS

8.8. Cosmetic products: labelling (constituents — sixth amendment)

(1) Objective	To increase consumer protection; to remove the remaining barriers to free movement; to ban experiments involving animals in the cosmetic products industry.
(2) Community measures	Council Directive 93/35/EEC of 14 June 1993 amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products.
(3) Contents	1. The Commission is to draw up, not later than 18 months following the adoption of the proposal by the Council, a guideline list of the constituents used in cosmetic products. This list, periodically updated and published by the Commission, must contain various items of information and, in particular, information relating to the identity of the constituent and any compulsory warnings to be included on the labelling. 2. Cosmetic products may be placed on the Community market only if their constituents are listed clearly, legibly and indelibly on their containers and packages. However, provision has been made for exemptions. 3. The manufacturer or his authorized representative must, if requested by the competent authorities of the Member State concerned, make available, in the language of that Member State, information relating in particular to physico-chemical and microbiological specifications, purity and microbiological monitoring criteria and the method of manufacture. 4. Before the cosmetic products are placed on the Community market, the manufacturer or his authorized representative — or, in the case of imported products, the person responsible for placing them on the market — must notify the competent authorities of the address of the place of manufacture or point of initial importation of these products. 5. The Directive lays down a new deadline of 1 January 1998 for the banning of experiments involving animals. However, this time limit could be extended in specific circumstances.
(4) Deadline for implementation of the legislation in the Member States	14.6.1995
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 151, 23.6.1993
(7) Follow-up work	
(8) Commission implementing measures	

8. OTHER AREAS

8.9. Foodstuff prices

(1) Objective	To inform and protect consumers whilst liberalizing trade in food within the Community by harmonizing requirements for indicating unit prices on labels.
(2) Community measures	Council Directive 88/315/EEC of 7 June 1988 amending Directive 79/581/EEC on consumer protection in the indication of the prices of foodstuffs. Council Resolution 88/611/EEC of 7 June 1988 regarding the protection of consumers on prices of foodstuffs and non-foodstuffs.
(3) Contents	Directive 88/315/EEC 1. The Directive does not apply to foodstuffs sold in hotels, cafés, etc., or to food which is purchased for trade or commercial activities, or to food supplied in the course of the provision of a service. 2. Definitions: — 'prepackaged foodstuffs' means foodstuffs packaged other than in the consumer's presence; — 'unit price', means the price per litre for products sold by volume, and the price per kilo for products sold by weight. 3. Member States may waive the obligation to indicate the unit price of prepackaged foodstuffs in a series of cases, particularly for foodstuffs sold by certain small retail businesses. They may provide that the Directive will not apply to foodstuffs sold on the farm or to private sales. 4. Prices, and where appropriate unit prices, must be indicated on all foodstuffs offered for sale to the final consumer. 5. The Directive gives details of which products must display unit prices and those which are exempt, in particular foodstuffs prepacked in pre-established quantities. 6. Advertisements or catalogues must mention the unit price as well as the selling price. 7. An annex contains a list of the products prepackaged in pre-established quantities referred to in the Directive. Resolution 88/611/EEC The Resolution requests further proposals from the Commission as soon as possible to extend the range of categories of products covered by the Directive and to revise the existing range.
(4) Deadline for implementation of the legislation in the Member States	7.6.1990
(5) Date of entry into force (if different from the above)	7.6.1995. Transitional measures have been included in respect of the imperial system used in the UK and in Ireland.

(6) References

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

(7) Follow-up work

(8) Commission implementing measures

8. OTHER AREAS

8.10. Non-food product prices

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

8. OTHER AREAS

8.11. Waste: waste disposal

(1) Objective

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

(2) Community measures

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

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

(3) Contents

Directive 75/442/EEC

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

Directive 91/156/EEC

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

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

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

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

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

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

(6) References

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

(7) Follow-up work

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

(8) Commission implementing measures

8. OTHER AREAS

8.12. Waste: disposal of toxic and dangerous wastes

(1) Objective

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

(2) Community measures

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

(3) Contents

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

	12. The competent authorities shall monitor and check the facilities, establishments and undertakings holding or disposing of wastes, which will cooperate fully.
(4) Deadline for implementation of the legislation in the Member States	— 24 months from the date of notification; — exemption up to 31 December 1995 in implementation of Council Directive 90/656/EEC (Official Journal L 353, 17.12.1990) for the older facilities in the former GDR, which do not comply with Directive 78/319/EEC.
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 84, 31.3.1978
(7) Follow-up work	
(8) Commission implementing measures	

8. OTHER AREAS

8.13. Waste: disposal of hazardous waste

(1) Objective	To manage the correct disposal of hazardous waste.
(2) Community measures	Council Directive 91/689/EEC of 12 December 1991 on hazardous waste.
(3) Contents	This Directive will replace Directive 78/319/EEC, which it repeals with effect from 12 December 1993 (summary 8.12). 1. A list of the hazardous wastes covered by the Directive will be drawn up on the basis of the categories, constituents and properties set out in the annexes to the Directive by 12 June 1993. Domestic waste is not covered by the Directive. Waste not covered by the Directive is subject to Directive 75/442/EEC (summary 8.11). 2. Member States ensure that hazardous waste is recorded and identified; they also ensure that different categories of hazardous waste are not mixed and that hazardous waste is not mixed with non-hazardous waste, save where the necessary measures have been taken to safeguard human health and the environment. 3. Any establishment or undertaking which carries out disposal operations must obtain a permit. This applies also in the case of operations which may lead to recovery. However, the permit requirement may be waived in the latter case if the method of recovery is such that there is no danger to human health or the environment, or if the Member State has adopted general measures laying down conditions for various methods of recovery, provided the conditions have been communicated to the Commission. 4. Establishments or undertakings which carry out disposal operations or operations which may lead to recovery and producers of hazardous waste are subject to periodic inspections covering in particular the origin and destination of the waste. Transporters, producers, establishments and undertakings keep a record of their activities and make this information available to the competent authorities designated by each State. 5. The competent authorities publish plans for the management of hazardous waste and the Commission evaluates these plans. 6. In case of emergency or grave danger, Member States may derogate temporarily from the Directive. They must inform the Commission of any such derogations. 7. The annexes to the Directive can be adapted to scientific and technical progress in accordance with the procedure referred to in Article 18 of Directive 75/442/EEC.
(4) Deadline for implementation of the legislation in the Member States	12.12.1993
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 377, 31.12.1991

(7) Follow-up work

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

(8) Commission implementing measures

On 27 June 1994 the Council adopted a Directive amending Directive 91/689/EEC on hazardous waste.
The aim of this Directive is to revise the definition of 'hazardous waste' and alter the dates on which Directive 91/689/EEC takes effect and Directive 78/319/EEC on toxic and hazardous waste is repealed, in order to avoid a legal vacuum. On 21 February 1994, the Council adopted a common position.
On 20 April 1994, Parliament adopted the Council's common position without amendment.

8. OTHER AREAS

8.14. Waste: incineration of dangerous waste

(1) Objective

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

(2) Proposal

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

(3) Contents

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

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

(4) Opinion of the European Parliament

First reading: Parliament approved the Commission's proposal subject to certain amendments. The principal amendment aimed at turning the guide value proposed by the Commission for the dioxin and furan concentrations emitted into a value to apply with effect from 1 January 1997.
Reconsultation: For the purposes of changing the legal basis, Parliament approved the Council's proposal subject to certain amendments.

(5) Current status of the proposal

Cooperation procedure

The Commission presented the proposal on 19 March 1992.

On 10 March 1993 Parliament approved the Commission proposal subject to amendments. The Commission has accepted some of the amendments.

On 8 September 1993 the Council reconsulted Parliament on this proposal. Parliament approved the proposal subject to certain amendments. The Commission has yet to give its opinion on these amendments.

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

(6) References

Commission proposal	
COM(92) 9 final	Official Journal C 130, 21.5.1992
Amended proposal	
COM(93) 296 final	Official Journal C 190, 14.7.1993
European Parliament opinion	
First reading	Official Journal C 115, 26.4.1993
Reconsultation	Not yet published
Economic and Social Committee opinion	Official Journal C 332, 16.12.1992

8. OTHER AREAS

8.15. Waste: disposal of PCBs and PCTs

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

8. OTHER AREAS

8.16. Waste: disposal of spent batteries and accumulators

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

8. OTHER AREAS

8.17. Waste: titanium dioxide: disposal

(1) Objective	To prevent, gradually reduce and ultimately eliminate pollution from titanium dioxide industrial waste.
(2) Community measures	Council Directive 78/176/EEC of 20 February 1978 on titanium dioxide industrial waste.
(3) Contents	1. The Member States will take steps to ensure that waste-disposal procedures take due account of human-health and environmental considerations. They will actively encourage waste prevention and recycling and the re-use of waste as raw materials. 2. Any discharge, dumping, storage, accumulation or injection of waste will require prior authorization, for a limited but renewable period, by the competent Member State authority: — on whose territory the waste is produced; — on whose territory the waste is discharged or dumped; — from whose territory the waste is discharged or dumped. 3. Periodical checks will be carried out on the waste, and on the ambient environment in question, by bodies designated by the Member State responsible for issuing the licence, with a view to assessing the physical, chemical, biological and ecological aspects. 4. The Member States will draw up programmes for the gradual reduction, and ultimate elimination, of pollution caused by waste from old manufacturing facilities. 5. In the case of new manufacturing facilities, prior authorization must be obtained from the competent authorities in the Member State on whose territory it is planned to construct them. The issuing of any such authorization will be preceded by environmental impact studies and will be conditional on an undertaking by the companies concerned to use only those materials, procedures and technology that are least damaging to the environment. 6. Under the terms of the Directive, Member States are empowered to introduce more stringent rules.
(4) Deadline for implementation of the legislation in the Member States	12 months from the date of notification
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 54, 25.2.1978
(7) Follow-up work	See summaries 8.18 and 8.19.
(8) Commission implementing measures	

8. OTHER AREAS

8.18. Waste: titanium dioxide: surveillance and monitoring

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

8. OTHER AREAS

8.19. Waste: titanium dioxide: programmes for the reduction of pollution

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

(6) References

(7) Follow-up work

(8) Commission implementing measures

Official Journal L 409, 31.12.1992

8. OTHER AREAS

8.20. Waste: disposal of waste oil

(1) Objective

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

(2) Community measures

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

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

(3) Contents

Directive 75/439/EEC

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

Directive 87/101/EEC

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

	4. Where appropriate Member States shall carry out public awareness and promotion campaigns aimed at ensuring efficient storage and collection. 5. Authorizations enabling companies to carry out collection and disposal operations may only be issued by the competent authorities where these have assured themselves that appropriate environmental and health protection measures have been taken. 6. When waste oils are reclaimed Member States shall take any action needed in order to avoid any damage to the environment which may be caused by operation of the facilities involved. 7. Where waste oils are burnt Member States shall ensure that the relevant facilities operate without polluting the atmosphere or exceeding the limit values for the substances laid down by this Directive or by any more stringent national requirements. 8. The Directive prohibits the mixture of waste oils with PCBs and PCTs (polychlorobiphenyls and polychloroterphenyls). 9. Member States may adopt measures that are more restrictive than those provided for in this Directive.
(4) Deadline for implementation of the legislation in the Member States	Directive 75/439/EEC — Twenty four months dating from the notification of the Directive; — Four years from the date of notification of operating authorizations granted to companies on that date. Directive 87/101/EEC — 1.1.1990; — Seven years from the date of notification in the case of operating authorizations granted to companies on that date.
(5) Date of entry into force (if different from the above)	
(6) References	Official Journal L 194, 25.7.1975 Official Journal L 42, 12.2.1987
(7) Follow-up work	
(8) Commission implementing measures	

8. OTHER AREAS

8.21. Waste: packaging and packaging waste

(1) Objective

To prevent the production of packaging waste, to reduce the quantity of packaging waste arising and to promote the recovery of packaging waste, the production of which cannot be avoided.

(2) Proposal

Proposal for a Council Directive on packaging and packaging waste.

(3) Contents

1. The Directive applies to all packaging and packaging waste, including that regarded as hazardous which will in addition be the subject of specific management plans.
2. The Directive sets targets for recovery and the minimization of final disposal for all packaging waste to be achieved no later than 10 years from the date of implementation of the Directive in national law. However, provision is made for a review of the targets on the basis of scientific research and progress achieved in the Member States, four years after the date by which the Directive must be implemented in national law.
3. The reuse of packaging and the recovery of packaging waste are two ways of reducing environmental impact to a minimum.
4. All packaging must bear a harmonized mark indicating that it is reusable or recoverable and showing the type of packaging materials used. The identification system is indicated in Annex I.
5. The Directive outlines essential requirements to be met by packaging and packaging waste which may replace the relevant national provisions; this presupposes the establishment of harmonized standards.
6. Provision is made for the establishment of databases for packaging and packaging waste; the formats for these are indicated in Annex III. In addition, consumers will be properly informed about the proposed arrangements for managing used packaging.
7. A series of measures, to be introduced on the basis of standardization, have to be taken at Community level concerning the manufacture and use of packaging.
8. The Member States will report to the Commission on the implementation of the Directive. To adapt the provisions of the Directive to technical progress it is proposed that an Advisory Committee be set up. The same procedure will be used for primary packaging for medical devices and pharmaceutical products and for small packagings.

(4) Opinion of the European Parliament

First reading: Parliament approved the Commission's proposal subject to certain amendments relating in particular to changes in the scope of the proposal and to limit the contents of certain dangerous substances.

Second reading: Parliament approved the Council's common position subject to several technical amendments designed to put the accent on prevention with regard to the production of packaging and on processes for the recovery of packaging waste.

(5) Current status of the proposal

Cooperation procedure

The Commission presented the proposal on 15 July 1992.

First reading: On 23 June 1993 Parliament approved the Commission proposal subject to amendments. The Commission has accepted some of the amendments.

The Commission presented an amended proposal on 9 September 1993.

On 4 March 1994 the Council adopted its common position.

Second reading: On 4 May 1994 Parliament approved the Council's common position subject to amendments. The Commission has accepted all the proposed amendments.

On 25 May 1994 the Commission presented an opinion amending the proposal and incorporating all of Parliament's amendments.

The opinion is currently before the Council for final adoption.

(6) References

Commission proposal	
COM(92) 278 final	Official Journal C 263, 12.10.1992
Amended proposal	
COM(93) 416 final	Official Journal C 285, 21.10.1993
Re-examined proposal	
COM(94) 204 final	Not yet published
European Parliament opinion	
First reading	Official Journal C 194, 19.7.1993
Second reading	Not yet published
Economic and Social Committee opinion	Official Journal C 129, 10.5.1993

8. OTHER AREAS

8.22. Waste: landfill of waste

(1) Objective

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

(2) Proposal

Proposal for a Council Directive on the landfill of waste.

(3) Contents

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

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

(4) Opinion of the European Parliament

(5) Current status of the proposal

Cooperation procedure

The Commission presented the proposal on 22 May 1991.

First reading: On 28 October 1992 Parliament approved the Commission proposal subject to amendments. The Commission has accepted some of the amendments.

The Commission presented an amended proposal on 10 June 1993.

On 8 June 1994 the Council reached political agreement on a common position. Formal adoption of this common position is scheduled for the next meeting.

(6) References

Commission proposal	
COM(91) 102 final	Official Journal C 263, 12.10.1992
Amended proposal	
COM(93) 275 final	Official Journal C 212, 5.8.1993
European Parliament opinion	
First reading	Official Journal C 305, 23.11.1992
Opinion of the Economic and Social Committee	Official Journal C 40, 17.2.1992

8. OTHER AREAS

8.23. Labelling of footwear

(1) Objective	To lay down the means to be used for the labelling of footwear, and as a result provide general, harmonized information for consumers throughout the Community.
(2) Community measures	Parliament and Council Directive 94/11/EC of 24 March 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to a final consumer.
(3) Contents	1. The provisions concerning labelling apply to the materials used in footwear, a precise definition of which is given in the Directive. 2. Labels must convey information relating to the upper, the lining and insole sock, and the outersole of the footwear article. The information must be conveyed by means of agreed pictograms or textual information, as defined and illustrated in the annex to the Directive, and must relate to the material which constitutes at least 80% of the surface area of the upper, the lining and insole sock of the footwear article, and at least 80% of the volume of the outersole. However, if no one material accounts for at least 80%, information must be given concerning the two principal materials in the composition of the article. 3. Given that the aim of the above measures is to provide information, the label must be legible, firmly secured and accessible, and the manufacturer or his authorized agent established in the Community is responsible for supplying the label and for the accuracy of the information contained in it. Only the information provided for in the Directive has to be supplied, but there is nothing to prevent additional information being given on the label.
(4) Deadline for implementation of the legislation in the Member States	24.11.1995, unless otherwise specified.
(5) Date of entry into force (if different from the above)	
(6) References	Not yet published.
(7) Follow-up work	
(8) Commission implementing measures	

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