ENGLISH

COMPLETING THE INTERNAL MARKET

CURRENT STATUS DECEMBER 1988

A NEW COMMUNITY STANDARDS POLICY

The New Approach in Harmonization

Motor Vehicles

Tractors and Agricultural Machinery

Food

Pharmaceuticals

Chemicals

Construction Products

Other Items

COMMISSION OF THE EUROPEAN COMMUNITIES

DECEMBER 1988

In June 1985, the Commission of the European Communities issued a White Paper "Completing the Internal Market" setting out a target of achieving by 1992 a single European market for goods, services, people and capital.

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

In March 1988, the Commission issued its "Third Report on the Implementation of the White Paper on Completing the Internal Market". This updated and modified the original legislative timetable contained in the White Paper.

This brochure is one of a series of five intended to summarize the current problems, the 1992 objectives and the measures and proposals contained in the White Paper and Third Report.

The complete series of brochures covers

A common market for services

The elimination of frontier barriers and fiscal controls

Conditions for industrial cooperation
A single public procurement market

A new Community standards policy

Veterinary and plant health controls

These brochures will be updated and reissued at regular intervals until 1992. Details about availability are given on the inside back cover.

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A NEW COMMUNITY STANDARDS POLICY

How To Use This Brochure

The aim of this series of brochures is to

- Inform the interested European public about the steps which are being taken to bring about the single market
- Summarize the approach which is being taken in individual business sectors
- Provide a first reference to the content and current status of each proposal which the Commission has drafted to bring about the 1992 Internal Market.

This brochure contains

- A brief description of how the Community makes laws and recommendations
- A general introduction to the issues and problems in creating an Internal Market in technical standards
- Specialized introductions to the approach being adopted in individual sectors for standards
- Brief summaries of every measure which has been adopted or proposed to create the Internal Market for standards. Proposals mentioned in the White Paper but not yet issued by the Commission will be summarized in the future updates of the brochure.

The reader should

- Ensure he is familiar with how the Community makes laws and recommendations. If not, he should turn to page iii
- Read the general introduction to standards for an overview of the issues (page 1)
- Select the section(s) which cover sector(s) of interest from the contents (page vii).

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 information offices listed inside the back cover.

HOW THE EUROPEAN COMMUNITY MAKES LAW AN OUTLINE

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

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

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

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

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

1. LAWS AND OTHER MEASURES

Regulations

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

Directives

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

Decisions

A *decision* is binding entirely on those to whom it is addressed. No national implementing legislation is required. The *decisions* summarised in this brochure 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 brochure are *Council Directives*.

EEC Legislation from Start to Finish (Directives and Regulations)

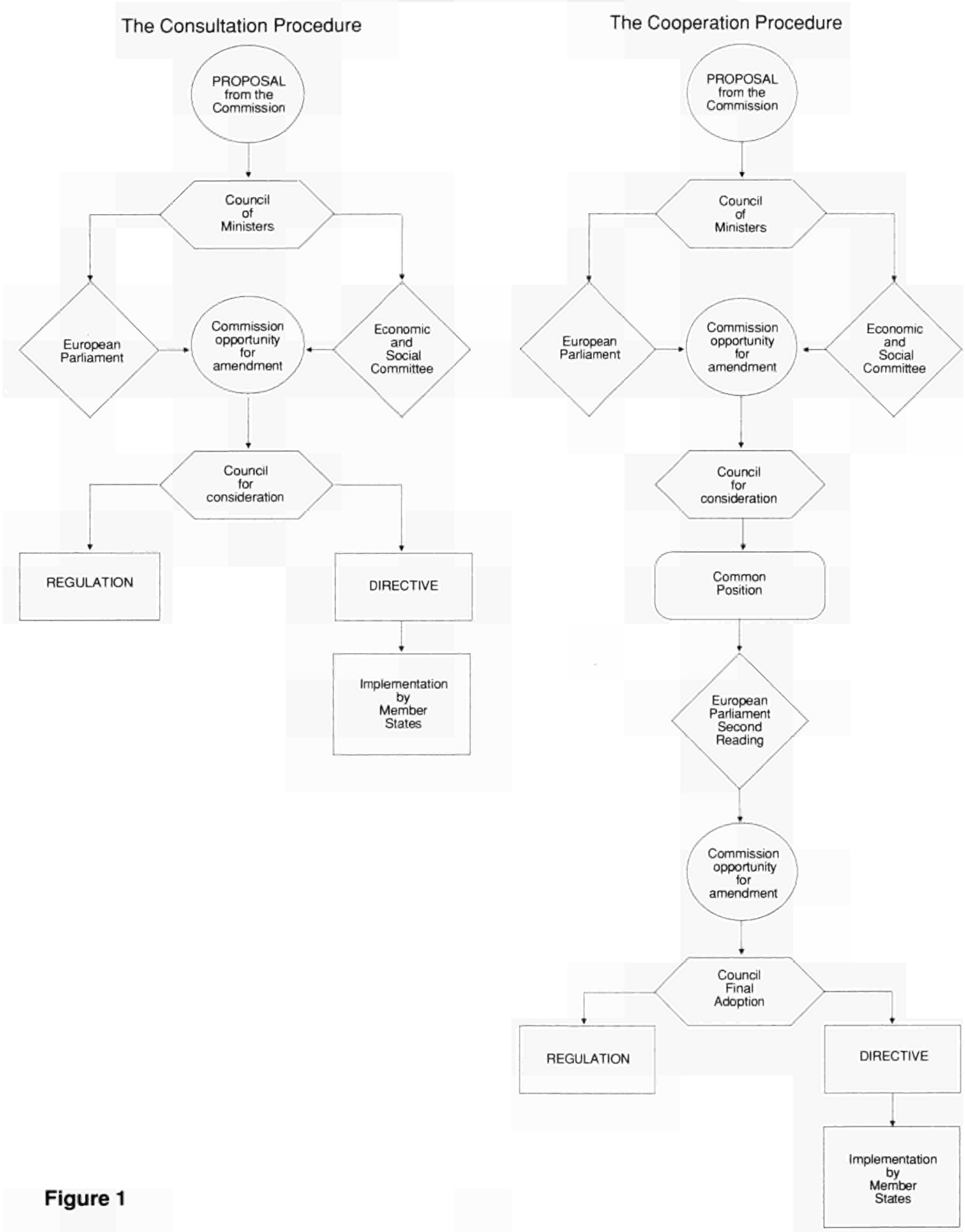

Figure 1

2. PROCEDURES FOR MAKING LAWS

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

Since the entry into force of the Single European Act on 1.7.87 there are two distinct procedures for the adoption of a *directive*; the *consultation procedure* and the *cooperation procedure*. The EEC Treaty article upon which a proposal is based dictates which procedure is followed.

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

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

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

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

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

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

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

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

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

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

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

3. PUBLICATION OF TEXTS

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

This brochure 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 Official Journal 'C' series references for the Commission proposal(s) and the opinions of the European Parliament and the Economic and Social Committee, if published by 31.12.88.

The Commission's 1985 White Paper "Completing the Internal Market" contains a legislative programme. In the course of carrying out this programme, certain proposals have been withdrawn and others have been added. Where the Commission has not yet submitted proposals listed in the programme, these are mentioned in the sector introduction.

A NEW COMMUNITY STANDARDS POLICY

4. FOOD

5. PHARMACEUTICALS

INTRODUCTION
WHY HARMONIZATION OF STANDARDS AND TECHNICAL REGULATIONS?

1957 Treaty of Rome

This was intended to create a single market across the European Community, with free movement of goods, persons, services and capital. In the particular case of goods, Article 30 of the Treaty prohibited not only quantitive 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 the protection of health and life, industrial and commercial policy, on condition that these grounds are not used as a means of arbitrary discrimination or disguised restrictions on trade.

1985 White Paper

The continued maintenance of internal barriers perpetuated the costs and disadvantages of separate national markets. Only when these barriers are eliminated will the Community have a genuine single market. The need for substantial further action was realised; the Commission published a White Paper 'Completing the Internal Market' which listed over 300 legislative proposals and a timetable for their adoption; it was endorsed by the Heads of State and Government.

1987 Single European Act

This Act, which modified the EEC treaty and therefore had to be ratified by the governments and parliaments of all Community countries, confirmed the objective of achieving a single European market by 1992 and the timetable of the 1985 White Paper. It adapted the Community's procedures for decision making, and increased the scope for a type of majority (as opposed to unanimous) voting in the Council. The Single European Act should facilitate the adoption of the White Paper measures within the proposed timeframe.

1988 Current Situation

In quantitive terms, about 50% of the legislative proposals made by the Commission to achieve this single market in standards and technical regulations have been adopted. A further 40% are still under consideration, and 10% remain to be tabled. The new approach to harmonization (see below) has increased the pace of legislation on essential technical requirements, mostly concerning health and safety, but the necessary accompanying development of European standards by standardization bodies will have to be speeded up. In the case of measures which have had to follow the earlier approach of detailed legislative harmonization, the improved decision-making procedure introduced by the 1987 Single European Act has permitted the White Paper programme to be completed in some areas and has given new impetus to the others.

1992 Single Market

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

Standards

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

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

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

- *Technical regulations* lay down the legal requirements enacted by the national parliaments mainly in the interests of health and safety and the environment: often these regulations refer to standards
- *Standards* are produced by private national standardization bodies (like DIN in Germany or BSI in Britain): whilst they are only voluntary codes they often assume a quasi-legal status because of their use as a reference in technical regulations or insurance claims
- *Type testing and certification* is used to check that a product complies either with voluntary standards or with statutory regulation : a typical problem is that one Member State does not recognize another's type test, thus causing the costs and delays of additional testing.

The original approach to dismantling these barriers was to attempt to harmonize national regulations across the Community. However, this proved a very difficult and protracted process; the relevant technology had sometimes even changed by the time that eventual agreement was reached. At the same time, increased concern for health, safety and the environment, and the rapid growth in technical innovation was multiplying the occasions on which differences in national approaches and regulations were occurring.

The Community responded to this challenge with a *new approach*. This is described in more detail in section 1, but its key elements are:

- *minimum harmonization* of Member State regulations
- creation of *harmonized European standards* by European standardization bodies
- as a transitional measure, *mutual recognition* of national standards until appropriate European standards are created.

This brochure contains examples from both the *new approach* and previous approaches to harmonization. As yet, the *new approach* has only been in operation for a short time but there is already evidence that it is effective in reducing the time it takes to adopt new legislation. The other measures on technical regulations contained in the White Paper are grouped into various industry sectors and in general are primarily concerned with safety, health and type approval. Harmonization of these requirements, combined with mutual recognition of tests, test results and certification will remove the barriers to trade due to differing standards within these industry sectors.

1. NEW APPROACH IN HARMONIZATION

CURRENT PROBLEMS AND 1992 OBJECTIVES

- The problems caused by the existence of different technical regulations and national standards within the Community have been recognized for many years, and much progress has been made in the elimination of such barriers to trade. However, if the creation of the internal market is to be completed by 1992 then more rapid progress must be made than has been the case in the past.
- To move towards the goal of removing technical barriers to trade a *new approach* has been developed. It is based on the following principles:
  - a distinction will be drawn in future internal market initiatives between what it is essential to *harmonize* in legislation and what may be left to be harmonized by European standardization bodies;
  - legislative harmonization will in the future be restricted to laying down health, safety and other essential requirements;
  - harmonization of industrial standards will be achieved by the elaboration of European Standards. These European standards will be developed by the European Committee for Standards (CEN) or the European Committee for Electrotechnical Standardization (CENELEC), as appropriate. As a transitional measure, and in so far as harmonized standards do not yet exist, national standards may be recognized as equivalent through an appropriate procedure of approval by the Commission. The result will be that a product manufactured in one Member State in conformity with EEC legislation as regards its essential safety requirements and with a standard in other respects will be guarantied automatic access to the markets of all other Member States.
- In 1983, the Community adopted a directive which required Member States to notify the Commission of new regulations and standards for certain products prior to their enactment. The Commission was given the power to freeze introduction of these new regulations for up to a year if it decided that a Community initiative would be more appropriate. This measure has been successful in preventing new technical barriers arising, and the Council has now adopted a proposal to increase its scope to all product sectors (summary 1.1).
- In 1987, the Council adopted the first *new approach* directive (summary 1.2 on pressure vessels) and adopted the second on toys (summary 1.3) during 1988. Several other *new approach* proposals have now been put forward including ones on machine safety, electromagnetic compatibility, measuring instruments, mobile machines (earth moving equipment), medical equipment, gas appliances and personal protective equipment (summaries 1.4 - 1.10). One further proposal covering lifting and loading equipment will be submitted in 1989. All of these *new approach* Directives take account of the objectives contained within the Single European Act which commits the Commission to table proposals based on a high level of health, safety, consumer and environmental protection.

1. NEW APPROACH IN HARMONIZATION

1.1 Extension of information procedures on standards and technical rules

1) Objective	The Community adopted a Directive in 1983 which required Member States to inform the Commission of new standards and regulations in certain fields prior to their enactment. The Directive aims at preventing the creation of new barriers to trade by imposing on all Member States an absolute obligation to notify all draft standards and regulations before their adoption and allow time for comment on them. It gives the Commission and the Member States the power to delay the introduction of these new regulations for six months if they consider that barriers to trade may be created, and up to to one year if the Commission decides that they should be replaced by a Commission initiative. This amendment extends the coverage of that legislation to all products.
2) Community Measure	**Council Directive 88/182/EEC of 22 March 1988** amending Directive 83/189 laying down a procedure for the provision of information in the field of technical standards and regulations.
3) Contents	1. This measure broadens the definition of *product* in the 1983 Directive to include agricultural products, foodstuffs, medicinal products and cosmetics, so that standards and technical rules applying to these are now subject to the information procedures. 2. If the Commission has submitted a proposal concerned with a particular product to the Council, Member States must not adopt technical regulations on that product for 12 months from the date of submission.
4) Deadline for implementing Member State legislation	1.1.89
5) Application date (if different from 4)	
6) Date for further coordinating proposal (if specified)	
7) References	Council Adoption — Official Journal L 81, 26.3.88

1. NEW APPROACH IN HARMONIZATION

1.2 Simple Pressure Vessels

1) Objective	The primary aim of this Directive is to ensure a minimum level of safety throughout the Community for pressure vessels. The harmonization of safety standards will also aid the free movement of such products. In addition, a universally recognised testing procedure and mark of conformity will prevent wasteful checks being carried out in each Member State.
2) Community measure	**Council Directive 87/404/EEC of 25 June 1987** on the harmonization of laws of the Member States relating to simple pressure vessels.
3) Contents	1. This Directive applies to simple pressure vessels, ie any welded vessel subjected to an internal gauge pressure greater than 0.5 bar which is intended to contain air or nitrogen and which is not intended to be fired. Those designed for nuclear use, for installation on ships and aircraft, and fire extinguishers are excluded from the scope of the Directive. 2. Vessels must conform with certain requirements to qualify for marketing authorisation, eg the pressurised parts must be capable of being welded; when designing a vessel the manufacturer must define its use and select maximum and minimum working temperatures and maximum working pressure; parts must be of a minimum thickness, etc. 3. If a vessel bears the EC mark Member States have to assume conformity with essential safety requirements. 4. Manufacturers can either submit their design for inspection prior to production, or submit a prototype vessel to EC type-examination followed by a verification to ensure that manufactured vessels conform with the approved prototype. 5. If a prototype vessel passes the type-examination a type-examination certificate is issued. Type-examination has to be carried out by an approved body. 6. Verification that manufactured vessels conform with the approved prototype is carried out on batches of vessels submitted by the manufacturer. Tests are performed to ensure compliance. The EC mark is affixed to complying vessels. 7. If an EC mark is wrongly affixed (if, for example, manufactured vessels do not conform to the standards or the approved prototype) then the body responsible must report to the Member State concerned and, where appropriate, withdraw the EC type-examination certificate. 8. The EC mark must be visible, easily legible and indelible. Any other inscription which is likely to be confused with it is prohibited.
4) Deadline for implementing Member State legislation	1.1.90
5) Application date (if different from 4)	1.7.90

6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 220 8.8.87

1. NEW APPROACH IN HARMONIZATION

1.3 Toys

1) Objective

To harmonize the safety regulations on toys throughout the Community in order to protect child health and facilitate trade. Toys are one of the few products for which essential requirements have been adopted.

2) Community Measure

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

3) Contents

1. For the purpose of the Directive a toy is defined as any product or material designed or clearly intended for use in play by children of less than 14 years of age. Several products are, however, excluded from the scope of the Directive, including Christmas decorations, fireworks, playground equipment, and sports equipment.
2. Toys can only be marketed if they do not jeopardize the health and/or safety of their users or third parties; these essential safety requirements are defined in an annex.
3. If a toy satisfies the requirements of the Directive, no Member State may prohibit its sale, distribution or placing on the market. Any toy bearing an EC mark will be assumed to conform to the essential requirements or to a model examined by an approved body.
4. If a Member State feels that a toy is wrongly bearing the EC mark action shall be taken to withdraw it from the market.
5. Before being marketed, toys manufactured in accordance with harmonized standards or conforming to an examined model, must have an EC mark attached to them by the manufacturer or his authorised representative established within the Community.
6. The manufacturer or his representative in the Community shall keep information on the product for inspection by authorities, eg product design and manufacture details, EC certificates etc. Authorities shall ensure the confidentiality of this information.
7. Provision for the establishment of approval bodies.
8. Procedure for EC-type examination and certification of a product.
9. Member States are required to perform random checks to ensure that toys comply with the Directive.
10. The EC mark and the name and address of the manufacturer (or his representative) must be visible, easily legible and indelible. Any inscription likely to be confused with the EC mark is prohibited. The EC mark shall consist of the symbol *CE*.
11. Provision for changing harmonized standards where a Member State considers that they do not meet the Directive's requirements.
12. The annexes contain detailed essential safety requirements for toys. For example, parts of toys for use by children under 36 months should not be of a size so that they can be easily swallowed; toys intended for use in water should be designed to reduce any risks of the toy sinking; toys should only be made of materials that are not readily flammable; they should not contain dangerous substances which are used to operate the toy; they must not be explosive, etc.
13. The annexes also contain conditions to be fulfilled by approved bodies, (eg technically qualified personnel must carry out the relevant tests), and precautions to be taken when using toys (eg don't give unsuitable toys to very young children).

4) Deadline for implementing Member State legislation	30.6.89	
5) Application date (if different from 4)	1.1.90	
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 187, 16.7.88

1. NEW APPROACH IN HARMONIZATION

1.4 Machine safety

1) Objective	Member States have existing national legislation to ensure the health and safety of workers and other people using hazardous machinery. The proposal aims to harmonize these national laws concerning the responsibility for ensuring health and safety of people using machinery.
2) Proposal	**Proposal** for a Council Directive on the approximation of the laws of the Member States relating to machinery.
3) Contents	1. The Directive applies to machinery and lays down essential safety and health requirements. *Machinery* means a powered assembly with mechanically linked parts of which at least one is moveable. There are exemptions, eg mobile site equipment, lifting equipment. 2. Member States must ensure that appropriate measures are taken to ensure that machinery is only marketed if it complies with the Directive, that is if it does not endanger the health or safety of persons, animals or property. 3. The marketing and use of machinery which complies with the Directive, bears the EC mark and is accompanied by the EC declaration of conformity must be permitted by Member States. 4. Where a Member State considers that the harmonized standards do not satisfy the objectives in (2) the matter will be brought to a Standing Committee who shall deliver an opinion. The Commission will then inform the Member State as to whether or not the machine must be withdrawn. 5. Where a Member State ascertains that a machine bearing the EC mark is liable to endanger the safety of persons it shall take all the measures necessary to withdraw it from the market. The Member State will then inform the Commission of its action and the reason for its decisions. 6. In order to certify machinery in accordance with certain standards laid down in the Annexes to the Directive, the manufacturer shall draw up documentation including a technical construction file composed of overall drawings and detailed drawings etc. When the machinery conforms to the requirements the manufacturer will issue an *EC declaration of conformity*. 7. The EC mark will consist of the symbol CE. 8. Wood working machines are included. A more stringent certification procedure is proposed for machine types considered as presenting higher risks and greater hazards (eg chain saws, metal sheers). 9. Annexes containing the safety and health requirements, *an EC declaration of conformity* form and a model EC mark.
4) Opinion of the European Parliament	The Parliament approved the proposal subject to certain recommendations for amendments.
5) Current status	The Council adopted a common position on 21.12.88. This is now before the Parliament for a second reading within the framework of the cooperation procedure.

6) References	Commission Proposal	Official Journal C 29, 3.2.88
	Amended Proposal	Official Journal C 214, 16.8.88
	European Parliament Opinion	
	Economic and Social Committee Opinion	

1. NEW APPROACH IN HARMONIZATION

1.5 Electromagnetic interference

1) Objective	To harmonize national provisions on permissible electromagnetic disturbance and immunity levels caused by electronic apparatus in order to guarantee the free movement of these goods.
2) Proposal	**Proposal** for a Council Directive on the approximation of the laws of the Member States relating to electromagnetic compatibility
3) Contents	1. The Directive applies to apparatus liable to cause or be affected by electromagnetic disturbance. Definitions of *apparatus*, *electromagnetic disturbance*, *immunity* and *electromagnetic compatibility*. 2. Member States shall ensure that: - the electromagnetic disturbance generated by the apparatus should not exceed a level which allows radio and telecommunications equipment and other apparatus to operate as intended - the apparatus shall have an adequate level of intrinsic immunity to electromagnetic disturbance. 3. The conformity of apparatus with the Directive shall be certified by a Community declaration of conformity. This will be issued either by the manufacturer or an authorized representative established within the Community. An *EC conformity mark* shall be affixed to the apparatus or the packaging. 4. Where a Member State considers that the harmonized standards do not satisfy the objectives in (2) the matter will be brought to a Standing Committee who shall deliver an opinion. The Commission will then inform the Member State as rapidly as possible as to whether standards must be withdrawn. 5. Where a Member State determines that an apparatus accompanied by a declaration of conformity does not comply, it shall take all the measures necessary to withdraw it from the market. The Member State will then inform the Commission of its action and the reason for its decision. 6. Provisions for a technical file describing apparatus to which standards have not yet been applied and including a technical report obtained from a technical body.
4) Opinion of the European Parliament	The Parliament approved the proposal subject to certain recommendations for amendment which have since been incorporated into the amended proposal.
5) Current status	The Council adopted a common position on 7.11.88. The proposal is now before the Parliament for a second reading within the framework of the cooperation procedure.

6) References	Commission Proposal Amended Proposal	Official Journal C 322, 2.12.87 Official Journal C 272, 21.10.88
	European Parliament Opinion	Official Journal C 262, 10.10.88
	Economic and Social Committee Opinion	Official Journal C 134, 24.5.88

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1. NEW APPROACH IN HARMONIZATION

1.6 Non-automatic weighing instruments

1) Objective

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

2) Proposal

Proposal for a Council Directive on the harmonization of the laws of the Member States relating to non-automatic weighing instruments.

3) Contents

1. Definitions of *weighing instrument, system, non-automatic weighing instrument.*
2. The Directive applies to all non-automatic weighing instruments. Instruments to be used for:
   - commercial transactions
   - the determination of a toll, tariff, bonus, penalty, indemnity or similar payment
   - law enforcement and expert opinion
   - health monitoring, diagnosis and treatment of illness and disorders in human and veterinary practice must satisfy the essential requirements set out in Annex 1 to the Directive and must carry the CE mark of conformity. Other instruments must be manufactured according to the sound engineering practice of a Member State. However, their manufacturers may opt to conform to the essential requirements.
3. Member States must ensure that only those instruments complying with the provisions of the Directive may be placed on the market and put into service.
4. Member States shall not impede the placing on the market and the putting into service of instruments meeting the provisions of the Directive. Member States shall presume that instruments complying with national standards implementing the harmonized standards that meet the essential requirements are in conformity with these requirements. Publication of standards. Procedures in the case of non-compliance with the Directive, examination by the Commission and consultation with a Standing Committee. Provision for withdrawal in cases where the EC mark has been affixed to instruments not conforming to the relevant essential requirements.
5. Instruments which must satisfy the essential requirements must be subject to a EC type examination, followed by either an EC declaration of production conformity or EC verification. Other instruments may be voluntarily submitted to these procedures by the manufacturer. Distinction is made between manufacture of standard instruments and manufacture of non-standard instruments (unit or limited series manufacture).
6. Provision for control of instruments in service, re-verification etc.
7. Annexes to the Directive including essential metrological requirements, design and construction requirements, details of EC type examination, declaration of production conformity, EC verification, CE mark of conformity and other inscriptions on instruments.

4) Opinion of the European Parliament	Not yet given.	
5) Current status	The proposal is currently before the Parliament and the Economic and Social Committee for their opinions.	
6) References	Commission Proposal	Not yet published.
	European Parliament Opinion	
	Economic and Social Committee Opinion	

1. NEW APPROACH IN HARMONIZATION

1.7 Mobile machinery

1) Objective	To ensure a single Community market in mobile machinery (eg earth-moving equipment, mining equipment etc) by setting essential health and safety requirements and certification rules.
2) Proposal	**Proposal** for a Council Directive on the approximation of the laws of the Member States relating to mobile machinery.
3) Contents	1.The Directive lays down essential health and safety requirements for a wide range of mobile machinery from those of a very simple design to more complex installations used in the construction field or for site work. The field of application is defined by very broad definitions of *mobile machinery* and *working areas* combined with specified exclusions including types already covered by existing EEC Directives containing health and safety requirements. 2. Member States may not prohibit, restrict or impede the placing on the market, putting into service or use of mobile machinery complying with the Directive bearing the EC mark and accompanied by the EC declaration of conformity. 3. Obligation on Member States to publish relevant national standards implementing the harmonized standards and to communicate these to the Commission. Member States shall presume that devices conforming with each other's national standards comply with the Directive's essential safety requirements. Provisions for those devices and national standards considered not to meet the essential health and safety requirements; examination by the Commission, consultation with a Standing Committee and withdrawal of a product. 4. The conformity of machinery with the Directive shall be certified by an EC declaration of conformity. This shall be issued either by the manufacturer or an authorized representation established in the Community. An EC mark shall be affixed to the machinery. For some machinery considered as more dangerous, an EC type examination issued by a notified body shall be required. 5. Annexes containing essential safety requirements for machinery, conformity assessment procedure, EC type examination, declaration of product conformity, surveillance, model CE mark, minimum criteria to be taken into account by Member States when appointing inspection bodies, and manufacturer's declaration.
4) Opinion of the European Parliament	Not yet given.
5) Current status	The proposal is currently before the Parliament and the Economic and Social Committee for their opinions.
6) References	Commission Proposal — Not yet published. European Parliament Opinion Economic and Social Committee Opinion

1. NEW APPROACH IN HARMONIZATION

1.8 Electromedical equipment

1) Objective	To ensure that active implantable electromedical devices used in human medicine, eg cardiac stimulators, meet a high and clearly-defined level of safety both for the users of such equipment and for those receiving treatment. To harmonize the national provisions ensuring such a safety level so as to guarantee a single Community market in implantable devices without lowering existing levels of safety.
2) Proposal	**Proposal** for Council Directive on the approximation for the laws of the Member States relating to active implantable electromedical equipment.
3) Objective	1. Definitions include *medical device, active implantable electromedical device, permanently implanted.* 2. Member States shall not impede the placing on the market, the free circulation and the implantation of devices which meet the essential safety requirements specified in the annex and which bear the CE mark. Marketing and implantation of devices without the CE mark will be permitted where the device is intended for clinical evaluation or is a prototype intended for research purposes. 3. Obligation on Member States to publish relevant national standards implementing the harmonized standards and to communicate these to the Commission. Member States shall presume that devices conforming with the above harmonised standards, comply with the Directive's essential safety requirements. Provisions for those devices and national standards considered not to meet the essential health and safety requirements; consultation with a Standing Committee and withdrawal of a product or of a standard. 4. Devices shall be subject to a conformity assessment procedure. Member States shall designate bodies responsible for such procedures. 5. Annexes containing essential safety requirements for devices, conformity assessment procedure, model CE mark, minimum criteria to be taken into account by Member States when appointing inspection bodies, clinical evaluation.
4) Opinion of the European Parliament	Not yet given.
5) Current status	The proposal is currently before the Parliament and the Economic and Social Committee for their opinions
6) References	Commission Proposal — Not yet published. European Parliament Opinion Economic and Social Committee Opinion

1. NEW APPROACH IN HARMONIZATION

1.9 Gas appliances

1) Objective	To ensure a single Community market in appliances burning gaseous fuels by laying down the essential safety requirements and certification rules.
2) Proposal	**Proposal** for a Council Directive on the approximation of the laws of the Member States relating to appliances burning gaseous fuels.
3) Contents	1. The Directive applies to the broad area of appliances burning gaseous fuels and used for cooking, heating, hot water production, refrigeration, lighting or washing regardless of whether those appliances are manufactured in series or are produced as a single unit and whether used for domestic, commercial or industrial purposes. Appliances specifically designed for use in industrial processes are excluded. 2. Definitions of *gaseous fuel, normally used appliance.* 3. Obligation for Member States to ensure that the appliances specified may only be placed on the market if they satisfy essential requirements set out in an Annex to the Directive. Member States must not impede the placing on the market or the putting into service of appliances which satisfy these requirements and of safety and controlling devices designed to be part of an appliance. 4. Member States shall presume compliance with the relevant essential requirements in respect of appliances and safety and controlling devices which are designed for incorporation in an appliance when conforming to the relevant national standards implementing the harmonized standards. 5. Obligation on Member States to publish relevant national standards implementing the harmonized standards and to communicate these to the Commission. 6. Annexes containing details of essential requirements, procedures for attestation of conformity, use of the CE marks of conformity etc.
4) Opinion of the European Parliament	Not yet given.
5) Current status	The proposal is currently before the Parliament and the Economic and Social Committee for their opinions.
6) References	Commission Proposal — Not yet published. European Parliament Opinion Economic and Social Committee Opinion

1. NEW APPROACH IN HARMONIZATION

1.10 Personal Protective Equipment

1) Objective	To remove barriers to trade between Member States in personal protective equipment (PPE) by harmonizing basic requirements for the design, manufacture, testing and certification of these goods.
2) Proposal	**Proposal** for a Council Directive on the approximation of the laws of the Member States relating to the design of personal protective equipment.
3) Contents	1. PPE means any device or appliance worn or held for protection against safety and health hazards, eg breathing apparatus. The Directive applies to all PPE intended for professional and private use except that covered by other EC legislation and that specifically stated as excluded, eg PPE used by Armed Forces or Police. 2. This Directive, which runs parallel to the Directive dealing with the choice and use of PPE at the work place, does not contain detailed design and manufacturing provisions but defines the basic safety requirements in terms of design, efficiency and information to be supplied by manufacturers. 3. There are general requirements applicable to all PPE, additional requirements specific to certain types of PPE (eg equipment to protect eyes must minimise restriction of vision) and also additional requirements specific to particular risks. 4. Basic safety requirements may be satisfied either by national standards which implement harmonized standards, or by other technical specifications assessed by an approved inspection body as giving equivalent protection. 5. The harmonized standards may be changed should a Member State consider that they do not meet the Directive's basic safety requirements. 6. An EC-type examination of product models prior to manufacture will be required for most PPE, although a less stringent procedure is permitted through the simple EC declaration of the manufacturer for PPE providing protection against minimal risks. A more stringent approach will be required for PPE providing protection against lethal risks, with the basic procedure being supplemented by a surveillance of the production. 7. Member States may not hinder the marketing of PPE's bearing the EC mark. Any such PPE will be presumed to satisfy basic safety requirements. Member States will immediately remove any PPE bearing an EC mark from the market if it threatens health or safety. 8. The EC conformity mark consists of the letters EC followed by the last two figures of the year in which the EC mark is affixed and the number of the Approving Body if any.
4) Opinion of the European Parliament	Not yet given.
5) Current status	The proposal is being submitted to the Council, and before the Parliament for its opinion.

6) References	Commission Proposal	Official Journal C 141, 30.5.88
	European Parliament Opinion	Due on 13 December
	Economic and Social Committee Opinion	Official Journal C 175, 4.7.88

2. MOTOR VEHICLES

CURRENT PROBLEMS AND 1992 OBJECTIVES

- The Community has been striving for many years to bring about a comprehensive EC *type approval* for passenger cars. This will allow a car approved in one Member State to be marketed in another without having to obtain new type approval, which is both costly and time consuming. Since 1970, the Community has adopted over 50 measures harmonizing technical standards and type approval of individual vehicle components in order to bring this about. Some further measures are necessary to bring about the comprehensive approval for complete passenger cars, and in addition the Council has reached a common position on a proposal for providing lateral protection for goods vehicles. Summaries 2.1-2.6 cover these items.
- It is important that the Community keeps up to date appropriate measures to safeguard the environment from pollution caused by engine exhaust emissions. This must be uniform throughout the Community, both to ensure full protection for citizens and the environment, and to prevent emission requirements becoming a non-trade barrier, necessitating modifications to engines sold in different national markets. Controls are being:
  - modified for gaseous emissions from petrol and diesel engines
  - introduced for particulate emissions from diesel engines.

  Summaries 2.7 - 2.10 address these issues.
- In addition, a measure on harmonizing requirements for tyre pressure gauges has already been adopted (summary 2.11).

Many of the proposals and measures in this section are optional, which means that Member States may maintain national standards in their domestic markets in parallel with the Community standards which they must accept. Thus, in practice, a producer exporting to a given market has a choice of standards.

2. MOTOR VEHICLES

2.1 Type-approval: motor vehicles and trailers

1) Objective	To abolish the existing 12 national *type-approvals* for motor vehicles and trailers and replace them with one Community-wide type-approval. This will simplify the administrative burden for the industry and facilitate the free circulation and use of motor vehicles.	
2) Community measure	**Council Directive 87/358/EEC of 25 June 1987** amending Directive 70/156/EEC on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers.	
3) Contents	1. For the purpose of this Directive a *vehicle* is defined as any motor vehicle intended for use on the road, and its trailers, with the exception of vehicles which run on rails and agricultural tractors and machinery. EEC *type approval* is defined as the procedure where one Member State certifies that a vehicle type satisfies the technical requirements of appropriate Directives. 2. The Directive contains several clauses clarifying the type-approval procedure. These include the following: Member States have to approve all vehicles which satisfy the requirements in the appropriate Directives; spot checks should be carried out to ensure that production models conform to the approved type; Member States have to inform others, on a regular basis, of the type-approvals they have granted and refused.	
4) Deadline for implementing Member State legislation	1.10.88	
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 192, 11.7.87

2. MOTOR VEHICLES

2.2 Weights and dimensions

1) Objective

To harmonize the different national type-approvals for motor vehicles, in relation to permissible weights and dimensions.

2) Proposal

Proposal for a Council Directive on the approximation of the laws of the Member States relating to the weights and dimensions of certain motor vehicles.

3) Contents

1. The Directive applies to motor vehicles
- designed for use on the road
- having at least four wheels
- a maximum design speed greater than 25 km/hour
- permissible laden weight of not more than 3500 kg.

2. Member States may not refuse to grant EC type-approval or national approval, refuse to register or prohibit the sale, entry into service or use of a vehicle on grounds relating to its weights and dimensions if the vehicle satisfies the requirements of the Directive as laid out in an annex.
3. The Directive may be updated to take account of technical progress.
4. Annexes containing permissible dimensions and weights and an EC type approval form.

4) Opinion of the European Parliament

The Parliament approved the proposal, urging the Council to adopt it as soon as possible.

5) Current status

The proposal is before the Council for its consideration. The cooperation procedure will apply giving the European Parliament the opportunity of a second reading once it has received the view of the Council at the end of its first examination.

6) References

Commission Proposal	Official Journal C 15, 20.2.77
European Parliament Opinion	Official Journal C 118, 16.5.77
Economic and Social Committee Opinion	Official Journal C 114, 11.5.77

2. MOTOR VEHICLES

2.3 Tyres

1) Objective

To bring into line the different national type-approvals for tyres for motor vehicles and their trailers.

2) Proposal

Proposal for a Council Directive on the approximation of the laws of the Member States relating to tyres for motor vehicles and their trailers.

3) Contents

1. *Tyre* means any radial or belted cross-ply tyre intended for vehicles designed for a maximum speed less than or equal to 210 km/h, or any new cross-ply tyre intended for vehicles having a maximum speed less than or equal to 200 km/h. (A vehicle is as defined in summary 2.1).
2. Member States shall grant EC marks for those tyres conforming to the requirements in the Directive (listed in the annexes).
3. Member States shall inform each other when issuing an EC mark to a type of tyre.
4. It is the responsibility of the Member States to ensure that authorised tyres conform to EC requirements.
5. If a Member State considers an authorized tyre dangerous it may temporarily remove it from the market. It shall inform the Commission which will examine the grounds for its decision and take the appropriate steps.
6. Member States may not prohibit or restrict the placing on the market of tyres bearing the EC mark.
7. Annexes containing conditions for the issue of EC mark, definitions, markings, specifications, technical specifications and procedure for testing tyres, etc.

4) Opinion of the European Parliament

The Parliament approved the proposal, urging the Council to adopt it as soon as possible.

5) Current status

The proposal is before the Council for its consideration. The cooperation procedure will apply giving the European Parliament the opportunity of a second reading once it has received the view of the Council at the end of its first examination.

6) References

Commission Proposal	Official Journal C 37, 14.2.77
European Parliament Opinion	Official Journal C 118, 16.5.77
Economic and Social Committee Opinion	Official Journal C 114, 11.5.77

2. MOTOR VEHICLES

2.4 Safety glass

1) Objective

Member States currently have a variety of national type approvals for safety glass used in motor vehicles. This proposal aims to introduce a single Community type approval for vehicle safety glass, so as to promote the single market for motor vehicles. The use of *laminated* glass is mandatory (rather than the use of the less safe *toughened* glass).

2) Proposal

Proposal for a Council Directive concerning the approximation of Member State legislation relating to safety glass for motor vehicles.

3) Contents

1. Member States shall replace national type approvals with EC type approvals for certain types of safety glass (as defined in the annex) and in particular windscreens.
2. It is the responsibility of the Member State to ensure conformity of the manufacture of safety glass with EC type approval.
3. An EC mark must be attached to each model of safety glass.
4. Member States may not refuse the marketing of glass bearing the EC type approval mark.
5. Member States must inform each other of those types of glass given EC type approval.
6. In the case of non conformity of one type of safety glass bearing an EC mark in a Member State, that Member State must take action to ensure its conformity and inform the other States of its action.
7. Member States cannot refuse the entry of vehicles with safety glass bearing an EC type approval on the basis of their safety glass.
8. Annexes containing technical specifications for safety glass.

4) Opinion of the European Parliament

The Parliament approved the proposal.

5) Current status

The proposal is before the Council for its consideration. The cooperation procedure will apply giving the European Parliament the opportunity of a second reading once it has received the view of the Council at the end of its first examination.

6) References

Commission Proposal	Official Journal C 119, 16.11.72
European Parliament Opinion	Official Journal C 37, 4.6.73
Economic and Social Committee Opinion	Official Journal C 60, 26.7.73

2. MOTOR VEHICLES

2.5 Motorcycle exhaust system noise

1) Objective

There is an existing Directive which regulates the permissible sound levels of motorcycle exhaust systems. This proposed amendment aims to bring existing national type-approval for motorcycle exhaust systems closer together and include replacement exhaust systems within its scope.

2) Proposal

Proposal for a Council Directive amending Directive 78/1015/EEC on the approximation of the laws of Member States relating to the permissible sound level and exhaust system of motorcycles.

3) Contents

1. Details of the different existing national type-approvals in different Member States, eg:

Belgium	agréation par type
Denmark	standardtypegodkendelse

2. The national model certificate shall be replaced by the model EEC type-approval certificate.
3. From 1 October 1988, Member States in which motorcycles are subject to national type-approval shall apply harmonized technical requirements in the place of the national requirements.
4. From 1 October 1989 Member States may refuse to grant type-approval to a motorcycle which does not comply with the Directive.
5. From 1 October 1990, Member States may prohibit the entry into service of motorcycles whose sound and exhaust levels do not comply with the Directive.
6. Annex containing new conformity testing methods, application for type approval and markings.

4) Opinion of the European Parliament

The Parliament approved the proposal subject to certain recommendations for amendments.

5) Current status

The Council adopted a common position on 14.10.88. The proposal is now before the Parliament for a second reading within the framework of the cooperation procedure.

6) References

Commission Proposal	Official Journal C 44, 17.2.88
European Parliament Opinion	Official Journal C 262, 10.10.88
Economic and Social Committee Opinion	Official Journal C 175, 4.7.88

2. MOTOR VEHICLES

2.6 Lateral protection for goods vehicles

1) Objective

In certain accidents, *unprotected road-users*, ie pedestrians and cyclists, are often caught under the wheels of heavy goods vehicles and thereby killed or seriously injured. In order to minimize risk, the proposed Directive requires that sides of goods vehicles should be built or equipped with continuous surfaces or rails.

2) Proposal

Proposal for a Council Directive 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 N2, N3, O3 and O4 as defined in the 1970 Directive on type approval of motor vehicles and their trailers) having a maximum design speed above 25 km/h. It does not apply to buses as their normal bodywork fulfils the requirements.
2. No Member State may refuse to grant type-approval to vehicles which meet the requirements set out in the Annex or prevent their sale, registration and use. Any modifications to parts referred to in the Annex shall be transmitted to the Member State which carried out the *EC type-approval*. The Member State may then decide whether to hold fresh tests on the modified type.
3. Annexes containing technical requirements for side protection and application for EC type-approval. Appendix containing model of annex to type-approval certificate with information on side protection.
4. Consultation of a Standing Committee by the Commission when adapting the Annex to technical progress.

4) Opinion of the European Parliament

The Parliament approved the proposal subject to certain amendments.

5) Current status

The Council adopted a common position on 18.11.88. The proposal is now before the Parliament for a second reading within the framework of the cooperation procedure.

6) References

Commission Proposal	Official Journal C 265, 5.10.87
Amended Proposal	Official Journal C 230, 6.9.88
European Parliament Opinion	Official Journal C 94, 11.4.88
Economic and Social Committee Opinion	Official Journal C 80, 28.3.88

2. MOTOR VEHICLES

2.7 Air pollution: gaseous emissions from engines of motor vehicles

1) Objective	To reduce car pollution in order to avoid adverse effects such as acid rain. To this end legislation in the field of pollution control was adapted in line with USA testing methods. Technical specifications were adapted in order to permit the use of lead free petrol.	
2) Community measure	**Council Directive 88/76/EEC of 3 December 1987** on the approximation of the laws of the Member States relating to measures to be taken against air pollution by gases from the engines of motor vehicles.	
3) Contents	1. Amendments to the technical annexes of earlier legislation to move towards standards which will have an effect on the European environment equivalent to that produced by US standards, bearing in mind particular differences between Europe and the USA. These include reduced limits for pollutants and adapted testing procedures. 2. No Member State may refuse to grant type-approval or prevent the entry into service of any vehicle that conforms with the requirements of this Directive. 3. National type-approvals for vehicles whose engines do not comply with the Directive may be refused. Member States may prohibit the entry into service of such vehicles at a later stage. 4. The Commission is to table a new proposal which will further reduce the permitted pollution levels.	
4) Deadline for implementing Member State legislation	1.7.88	
5) Application date (if different from 4)	1.10.88 for refusing type-approval to vehicles with engine capacity greater than 2 litres which do not comply with the Directive. 1.10.89 for refusing type-approval for other vehicles whose engines do not comply with the Directive. 1.10.90 for prohibiting the entry into service of vehicles whose engines do not comply with the Directive.	
6) Date for further coordinating proposal (if specified)	31.12.87	
7) References	Council Adoption	Official Journal L 36, 9.2.88

2. MOTOR VEHICLES

2.8 Air pollution: gaseous pollutants from diesel engines

1) Objective	To approximate the technical requirements of diesel vehicle engines within the Community to combat gaseous pollution and promote the free movement of goods.
2) Community measure	**Council Directive 88/77/EEC of 3 December 1987** on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous pollutants from diesel engines for use in vehicles.
3) Contents	1. For the purpose of this Directive a *vehicle* is any vehicle propelled by a diesel engine, excluding: those which run on rails, agricultural tractors and machines, and public works vehicles. 2. From 1.7.88 Member States may not refuse to grant EEC type-approval or prohibit the entry into service of vehicles whose engines satisfy the requirements of this Directive. From 1.10.90 Member States may prohibit the entry into service of vehicles whose engines do not comply with this Directive. 3. If an engine which has received type-approval is modified Member States must decide whether fresh tests need be performed and take the appropriate action. If the engine then fails subsequent tests the modifications will not be approved. 4. The procedure to be followed for updating the annexes to take account of technical progress is that laid down in the original 1970 Directive on type-approval of motor vehicles. 5. The technical annexes include detailed information on type-approval procedures; testing procedures (with specification of limits for emission of toxic gases).
4) Deadline for implementing Member State legislation	1.7.88
5) Application date (if different from 4)	30.9.90 for particular diesel engines as specified in the annex.
6) Date for further coordinatingp roposal (if specified)	By 12.12.88
7) References	Council Adoption — Official Journal L 36, 9.2.88

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2. MOTOR VEHICLES

2.9 Gas emission standards for cars below 1400 cc

1) Objective	To amend a previous directive on measures relating to air pollution by gases from motor vehicles below 1400 cc.	
2) Proposal	**Proposal** for a Council Directive amending Directive 70/220/EEC on the approximation of the laws of Member States relating to measures to be taken against air pollution by gases from the engines of motor vehicles.	
3) Contents	1. Member States may not refuse to grant EEC type-approval on grounds relating to air pollution for an engine of less than 1400 cc that meets the requirements of the Directive. The date from which this will be the case will be decided when the Directive is adopted. 2. As of 1 October 1992 Member States may not grant EEC type approval for vehicles which do not meet the requirements of the Directive and may refuse to grant national type-approval. As of 1 October 1993 Member States may refuse the registration of new motor vehicles not meeting these requirements.	
4) Opinion of the European Parliament	At first reading Parliament approved the proposal subject to nine amendments. The Commission rejected all but one of these.	
5) Current status	The Council adopted a common position on 21.12.88. This is now before the Parliament for a second reading within the framework of the cooperation procedure.	
6) References	Commission Proposal	Official Journal C 56, 27.2.88
	European Parliament Opinion	Official Journal C 262, 10.10.88
	Economic and Social Committee Opinion	Official Journal C 208, 8.8.88

2. MOTOR VEHICLES

2.10 Air pollution: diesel particulates

1) Objective	To extend previous legislation relating to passenger cars to include particulate emissions from diesel engines and to adopt the dates for the implementation of the new Community requirements.	
2) Community Measure	**Council Directive 88/436/EEC of 16 June 1988** amending Directive 70/220/EEC on the approximation of the laws of the Member States relating to measures to be taken against air pollution by gases from engines of motor vehicles. (Restriction of particulate pollutant emissions from diesel engines).	
3) Contents	1. Amendment of the title and the annexes of the original Directive so as to extend its scope to cover pollution from vehicles equipped with compression-ignition (diesel) engines. In addition, particulate emissions are included. Other amendments to the annexes include new testing procedures to take account of particulates. 2. From 1.10.88 no Member State may refuse to grant EEC type-approval or prohibit the entry into service of vehicles whose engines comply with the Directive. 3. From 1.10.89, according to the type of the vehicle, Member States must refuse EEC type-approval and may refuse national type-approval and prohibit entry into service of vehicles whose engines do not comply.	
4) Deadline for implementing Member State legislation	1.10.88	
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)	Further reductions in particulate pollutant emission limits must be decided upon before 31.12.89.	
7) References	Council Adoption	Official Journal L 214, 6.8.88

2. MOTOR VEHICLES

2.11 Tyre pressure gauges for motor vehicles

1) Objective	To bring national provisions relating to tyre pressure gauges, including technical specification, closer together so as to facilitate intra-Community trade in these products.	
2) Community measure	**Council Directive 86/217/EEC of 26 May 1986** on the approximation of the laws of the Member States relating to tyre pressure gauges for motor vehicles.	
3) Contents	1. This Directive applies to pressure gauges intended to measure the inflation pressure of motor vehicle tyres. 2. To obtain an EEC mark, pressure gauges are subject to EEC pattern approval and verification. Requirements that they must satisfy include robust and careful construction so that they maintain their metrological characteristics; ability to accurately read-off the pressure measured; the dial must specify the symbol for the quantity measured, and the symbol for the unit of measurement. (More detail is found in the technical annex). 3. No Member State may refuse, prohibit or restrict the marketing and use of tyre-pressure gauges if they bear the EEC pattern approval mark.	
4) Deadline for implementing Member State legislation	30.11.87	
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 152, 6.6.86

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3. TRACTORS AND AGRICULTURAL MACHINERY

CURRENT PROBLEMS AND 1992 OBJECTIVES

- The White Paper programme in this area was completed in December 1988.
- The existence of differing national product regulations and standards was a major problem in the manufacture of agricultural machinery. Production lines could not be centralised which prevented manufacturers from taking advantage of economies of scale. A further problem was the absence of Community-wide type-approval procedures. Individual Member States thus required national testing and certification for components; a costly and wasteful process.
- Measures for a Community-wide type-approval procedure are covered by summaries 3.1 and 3.2: the first measure harmonizes technical requirements throughout the Community and ensures recognition of a single type test: the second provides for an EC wide type-approval standard. A further measure tackles the specific area of front-mounted roll-over protection structures (summary 3.3).
- Once all of these measures have been implemented, the Community will have achieved a single market for these products and a high uniform level of safety standards.

3. TRACTORS AND AGRICULTURAL MACHINERY

3.1 Tractors: type-approval

1) Objective	To harmonize the technical requirements of tractors in all Member States to allow, in particular, implementation of the type-approval procedure laid down in previous legislation, and to promote free trade within the Community.	
2) Community measure	**Council Directive 88/xxx/EEC of 21 December 1988** on the approximation of the laws of Member States relating to certain components of wheeled agricultural or forestry tractors.	
3) Contents	1. The Directive applies only to tractors which are fitted with pneumatic tyres and have a maximum speed of between 6 and 30 km/h. 2. No Member State may refuse type-approval of a tractor, refuse its registration or prohibit its entry into service if it complies with the provisions of this Directive. 3. Any amendments that have to be made to the Directive to take account of technical progress shall be adopted by the Commission after it has obtained the opinion of the relevant committee. 4. The annexes contain detailed technical requirements. These include minimum safety margins, weights and dimensions, driveshaft requirements, engine stopping device requirements, requirements concerning the quality of windscreens; testing procedures, type-approval procedures.	
4) Deadline for implementing Member State legislation		
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Not yet published.

3. TRACTORS AND AGRICULTURAL MACHINERY

3.2 Tractors: type-approval

1) Objective	To replace Community rules by verification of the particulars supplied by the manufacturers.	
2) Community Measure	**Council Directive 88/297/EEC of 3 May 1988** amending Directive 74/150/EEC on the approximation of laws of the Member States relating to the type-approval of wheeled agricultural or forestry tractors.	
3) Contents	The parts or characteristics of the tractor must be checked to ensure conformity with the particulars in the information document *CONF* rather than with the harmonized requirements *SD*.	
4) Deadline for implementing Member State legislation	31.12.88	
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 126, 20.5.88

3. TRACTORS AND AGRICULTURAL MACHINERY

3.3 Tractors: front-mounted protection structures

1) Objective	To harmonize the technical requirements for front mounted roll-over protection structures on *narrow track* tractors. This will both improve safety and also ensure that the EEC type-approval procedure can be uniformly applied throughout the Community, allowing reciprocal recognition of testing procedures in all the Member States	
2) Community measure	**Council Directive 87/402/EEC of 25 June 1987** on roll-over protection structures mounted in front of the driver's seat on narrow-track wheeled agricultural and forestry tractors.	
3) Contents	1. The Directive applies to *narrow track* tractors; ie those with axle widths of less than 1150 mm, and unladen weight of between 600 and 3000 kg. 2. No Member State can prevent the marketing of a tractor, or refuse to grant type-approval, if it satisfies the requirements of the Directive. 3. All tractors covered by the Directive must be fitted with a roll-over protective structure. 4. The Directive will be amended where necessary to take account of technical advances. 5. The annexes deal with type-approval and testing procedures.	
4) Deadline for implementing Member State legislation	26.6.89	
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)	26.12.88	
7) References	Council Adoption	Official Journal L 220, 8.8.87

4. FOOD

CURRENT PROBLEMS AND 1992 OBJECTIVES

- One of the fundamental rules of the European Community, laid down in the EEC Treaty of 1957, is the free movement of goods. The European Court of Justice has upheld this principle on numerous occasions, ruling that the Treaty prohibits any national measure which hinders intra-Community trade. In the well-known *Cassis de Dijon* case (1979), the Court ruled that the Treaty does not permit Member State laws which prevent the marketing of a product lawfully produced and marketed in another Member State. This means *mutual recognition* by the Member States of each others' product standards.
- However, this legal principle does not eliminate all practical difficulties for exporting manufacturers. The Cassis de Dijon case does not prohibit national laws necessary for the protection of public health and consumer interests. Clearly, such rules cannot always be easily applied to a given set of circumstances. Community-level harmonization of regulations in these areas is necessary. For these reasons, the Community had adopted directives in a number of areas prior to 1985.
- However, in the Commission's White Paper of 1985, it was recognized that a genuine common market for food could not be achieved by 1992 if the Community relied exclusively on past methods. In its Communication "Completion of the Internal Market: Community legislation on foodstuffs" issued in November 1985, the Commission therefore recommended a new strategy combining:
  - *sufficient harmonization* of national regulations and standards to
    - protect public health
    - provide consumers with clear labelling and protection in matters other than health
    - ensure fair trading
    - provide for the necessary public controls.
  - in all other respects *mutual recognition* of each Member States regulations and standards, so that a product acceptable for sale in one country should be acceptable throughout the Community. This follows from the European Court's caselaw discussed above.
- This new approach would be implemented in the first instance by *framework horizontal* directives which lay down the philosophy and controls for a particular area, eg additives. These directives would be complemented by *specific horizontal* directives detailing how these requirements are to be applied to specific segments of a wider area, eg flavourings as a category of additives. In addition, there is a need for commodity or product directives on certain types of foods, eg jams. Finally, it is necessary to keep up to date in the light of technical progress the existing Community management directives.
- The division of legislative powers between the Council and Commission is of major practical importance. The Commission, advised by the Scientific Committee for Food, draws up and manages the technical and detailed aspects of the directives. This then leaves the Council free to concentrate on the essential political criteria forming the basis of the directives.

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

Summary 4.1	additives
Summary 4.7	contact materials
Summary 4.9	labelling
Summary 4.12	food for particular nutritional uses
Summary 4.14	official inspection of foodstuffs
Summary 4.20	compulsory nutrition labelling
Summary 4.22	irradiation of foodstuffs

Of these framework measures, the Council has adopted two of these (summaries 4.1 and 4.7) and reached common positions on three more (summaries 4.9, 4.12 and 4.14).

- Proposals for *specific* directives have been adopted for several categories of additives. Proposals concerned with modifying provisions on labelling, advertising and packagings are under consideration by the Council.

4. FOOD

4.1 Authorized food additives

1) Objective

To ensure that the free movement of food within the Community is not compromised by different national regulations on food additives. This is to be accomplished by:
- this *framework* directive on food additives
- directives on all *specific* food additives.

2) Community Measure

Council Directive 88/xxx/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives for use in foodstuffs intended for human consumption.

3) Contents

1. The scope of the Directive covers food additives used as ingredients during the manufacture or preparation of food (a food additive being any substance not normally consumed as a food itself).
2. The Directive prohibits the use of substances not appearing in lists to be established for purposes specified in Annex I, eg preservatives, emulsifiers, sweeteners, raising agents.
3. The Council will draw up:
- a list of substances whose use is authorized to the exclusion of all others
- 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 as necessary purity criteria.

4. A special procedure permitting the Commission to legislate if in agreement with the Standing Committee on Foodstuffs will apply to:
- the drawing up of purity criteria
- where necessary, the methods of analysis needed to verify that the criteria of purity are satisfied
- where necessary, the procedure for taking samples and the methods for the qualitative and quantitative analysis of food additives in and on foodstuffs
- other rules necessary to ensure compliance with the rule that only listed additives may be used

5. Provisions for action by Member States on listed additives which are subsequently considered to carry a health risk.
6. Conditions for provisional authorization by a Member State for the marketing and use of unlisted additives belonging to the categories listed in Annex 1 to the Directive in the light of scientific and technical progress provided that certain conditions are respected, eg maximum limit of three years circulation, official control of foodstuffs in which the particular additive is used. Information requirements on labelling and packaging of additives for sale to both the consumer and the manufacturer.

4) Deadline for implementing Member State legislation

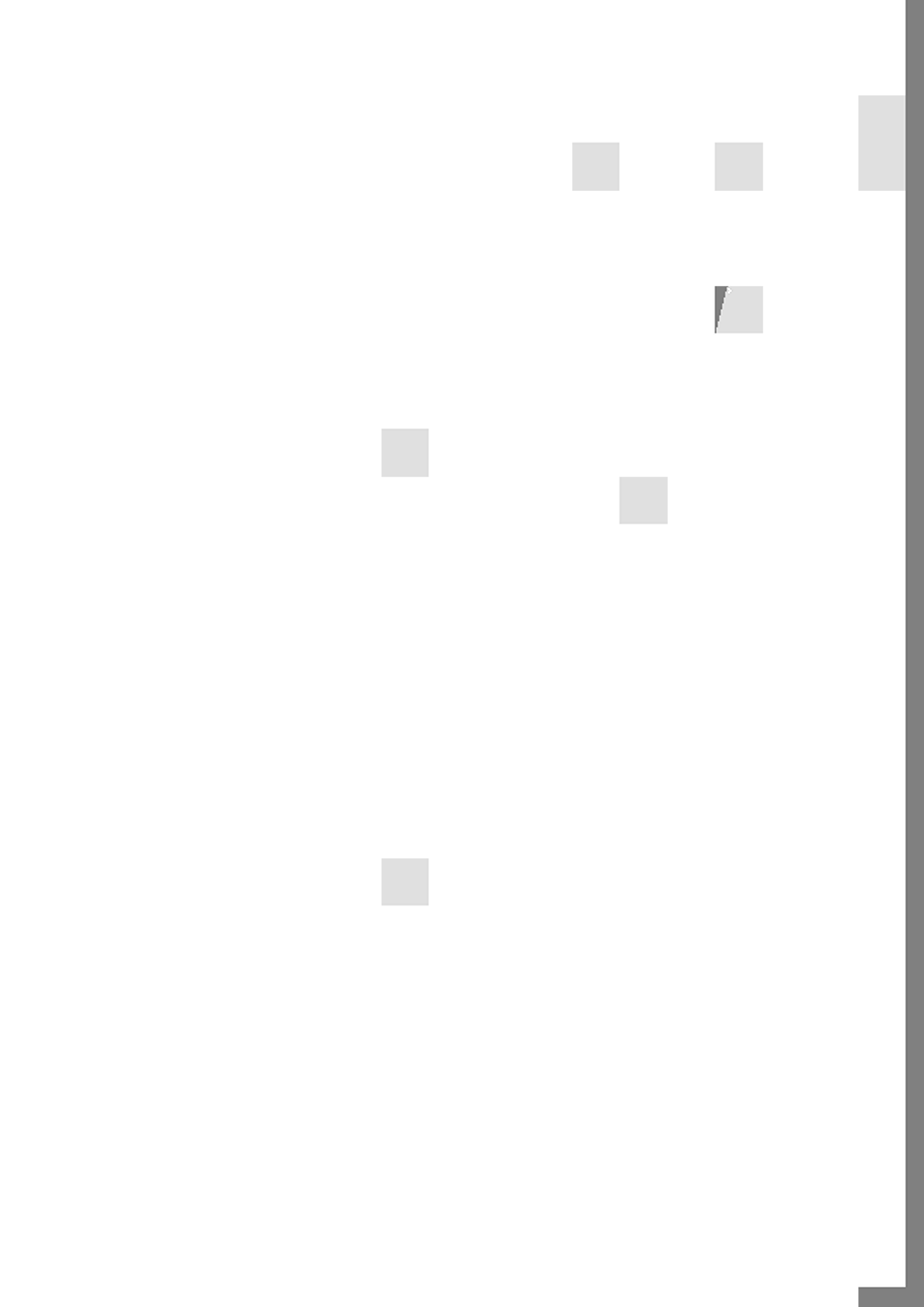
5) Application date (if different from 4)

6) Date for further coordinating proposal (if specified)	Specific measures for applying the Directive to be taken in the near future.	
7) References	Council Adoption	Not yet published.

4. FOOD

4.2 Additives: flavourings

1) Objective	To harmonize the laws relating to flavourings so as to facilitate the free movement of food in the Community whilst protecting health.
2) Community Measure	**Council Directive 88/388/EEC of 22 June 1988** on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production.
3) Contents	1. The Directive will apply to flavouring agents intended for use to impart odour or taste to food. 2. Requirement for Member States to ensure that any flavourings marketed or used satisfy the conditions laid out in the Directive such as purity criteria and percentage composition by weight of additive. 3. Provision for the adoption of specific directives applicable to certain groups of flavourings, eg chemically synthesized flavouring substances. 4. The Commission working with the Standing Committee on Foodstuffs will adopt a list of authorized additives and where necessary, criteria and methods of analysis of flavourings. 5. By 1.7.90 labelling rules for flavourings intended for sale to the final consumer will be issued. 6. Procedures to be followed if a Member State believes an authorized flavouring to be dangerous to human health. 7. Labelling requirements for flavourings for sale to the final consumer, eg the name and address of the manufacturer or producer, the sales description, substances used. 8. Procedures for updating the directives. 9. Technical annexes on maximum limits for certain substances found in flavourings.
4) Deadline for implementing Member State legislation	22.12.89
5) Application date (if different from 4)	22.6.90 - authorisation of flavourings complying with the Directive. 22.6.91 - prohibition of flavourings not complying with the Directive.
6) Date for further coordinating proposal (if specified)	
7) References	Council Adoption — Official Journal L 184, 15.7.88



4. FOOD

4.3 Additives: extraction solvents

1) Objective	To harmonize laws relating to extraction solvents so as to facilitate the free movement of food within the Community, whilst protecting health.
2) Community Measure	**Council Directive 88/344/EEC of 13 June 1988** on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.
3) Contents	1. The Directive applies to extraction solvents used in the production of foodstuffs or food ingredients including those imported into the Community. It does not apply to extraction solvents used for the production of additives not listed in the Annex to the Directive nor to those exported from the Community. Member States must, however, ensure that the use of these additives does not result in dangerous levels of extraction solvent residue in foodstuffs. 2. Definition of *solvent* and *extraction solvent*. 3. Member States shall authorize the use of extraction solvents listed in the Annex to this Directive. They shall not authorize any others. 4. Member States may, on their territory, allow substances used for diluting or dissolving flavourings to be used as solvents for the extraction of flavourings from natural flavouring materials, until Community provisions on these substances are adopted. 5. Other extraction solvents including water to which substances regulating acidity or alkalinity may have been added, ethanol, and other food substances which possess solvent properties, are authorised as extraction solvents in the manufacture of foodstuffs and food ingredients. 6. Within two years of adoption of this Directive, the Commission will re-examine the provisions relating to parts I and III of the Annex (extraction solvents for which conditions of use are specified) and propose any necessary amendments. 7. Purity criteria for extraction solvents, eg they shall not contain a toxicologically dangerous amount of any substance. 8. If a Member State believes an authorized solvent to be dangerous to human health that Member State may temporarily suspend authorization of the solvent. The Commission shall then examine the grounds given by the Member State. 9. Labelling requirements including the name of the substance, indication that the material is of suitably good quality, the business name of the manufacturer or packager, etc. 10. Annex containing list of authorized extraction solvents and conditions of use.
4) Deadline for implementing Member State legislation	13.6.91
5) Application date (if different from 4)	

6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 157, 24.6.88

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4. FOOD

4.4 Additives: preservatives (potassium bisulphite and thiabendazole)

1) Objective	To include potassium acid sulphite (potassium bisulphite) which is used in wine production in the list of permitted preservatives. To fully authorize the use of thiabendazole (E233). The Commission proposal also included the addition of natamycin to the list of permitted preservatives. This, however, was not adopted and is still undergoing consideration by the Council. This specific Directive must be seen as one element in the continuing process of keeping up to date the list of permitted additives.
2) Community measure	**Council Directive 85/585/EEC of 20 December 1985** amending Directive 64/54/EEC on the approximation of the laws of the Member States concerning the preservatives authorized for use in foodstuffs intended for human consumption.
3) Contents	1. Potassium acid sulphite (potassium bisulphite) is added to the list of permitted preservatives. 2. The use of thiabendazole (E233) is now fully authorized and will no longer be subject to temporary authorization. This will remove doubts about its suitability. However, this does not exclude further general EEC rules on surface treatment of fruit.
4) Deadline for implementing Member State legislation	31.12.86
5) Application date (if different from 4)	
6) Date for further coordinating proposal (if specified)	
7) References	Council Adoption — Official Journal L 372, 31.12.85

4. FOOD

4.5 Additives: emulsifiers, stabilizers, thickeners and gelling agents

1) Objective	To extend the period of temporary authorization for certain emulsifiers, stabilizers, thickeners and gelling agents. To prohibit the use after 31 March 1987 of polyoxyethylene (8) stearate, polyoxyethylene (40) stearate, lactylated fatty acid esters of glycerol and propylene glycol, and dioctyl sodium sulphosuccinate. This will allow for the re-evaluation of an additive in light of any new information, the completion of an investigation of a temporarily authorized additive or the sale of any products containing the additives which are already on the market. This specific Directive must be seen as one element in the continuing process of keeping up to date the list of permitted additives.	
2) Community measure	**Council Directive 86/102/EEC of 24 March 1986** amending for the fourth time Directive 74/329/EEC on the approximation of the laws of the Member States relating to emulsifiers, stabilizers, thickeners and gelling agents for use in foodstuffs.	
3) Contents	1. Extension of the temporary authorization period for Tragacanth and Karaya gum pending an enquiry. 2. Extension of the temporary authorization period for certain other emulsifiers, stabilizers, thickeners and gelling agents as detailed above to allow for the sale of foodstuffs containing these substances which are already on the market.	
4) Deadline for implementing Member State legislation	1.10.85 24.3.87	(Article 1) (the remainder)
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 88, 3.4.86

4. FOOD

4.6 Additives: modified starches

1) Objective	To harmonize legislation on food starches in order to facilitate the free movement of foodstuffs within the Community and to protect health.
2) Proposal	**Proposal** for a Council Directive on the approximation of the laws of the Member States relating to modified starches intended for human consumption.
3) Contents	1. A modified starch is defined as a product obtained by one or more chemical treatments of edible starches. 2. The marketing and use of modified starches is restricted to those listed in the Directive. 3. Provisions relating to the authorization of non-permitted starches for a limited period of up to three years. During this time a Member State may request the Commission to include the modified starch in its list of authorized starches. 4. If an authorized starch is believed to be harmful to human health a Member State may temporarily restrict the use of that starch. The Commission shall examine the reasons for restriction and if necessary proceed to the adoption of the necessary measures. 5. Labelling requirements include the term *modified starch*, the words *for human consumption*, the net quantity, the date of manufacture (if sold to food processing companies), etc. 6. Sampling and analysis methods shall be adopted. 7. Annexes containing a list of authorized modified starches and general purity criteria.
4) Opinion of the European Parliament	The Parliament recommended several amendments to the proposal which the Commission refused to accept. The Parliament's vote on the motion for a resolution was thus postponed.
5) Current status	The proposal is currently before the Council and Parliament for consideration. The cooperation procedure will apply giving the Parliament the opportunity of a second reading once it has received the view of the Council at the end of its first examination.
6) References	Commission Proposal — Official Journal C 31, 1.2.85 European Parliament Opinion Economic and Social Committee Opinion — Official Journal C 218, 29.8.85

4. FOOD

4.7 Contact materials

1) Objective	To supplement existing legislation on food packagings, wrappings etc. This is to be accomplished by: - this *framework* directive on contact materials - directives on certain *specific* contact materials.
2) Community Measure	**Council Directive 88/xxx/EEC of 21 December 1988** on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs.
3) Contents	1. The Directive applies to materials and articles intended to come into contact with foodstuffs. Covering and coating substances such as cheese rinds or skins on meat products which may be consumed together with the food do not belong to this category. 2. Materials must be manufactured so that they do not transfer their constituents to food in quantities which could: - endanger human health - bring about an unacceptable change in the composition of the food. 3. Specific directives will be adopted for plastics, regenerated cellulose film, elastomers and rubber, paper and board, ceramics, glass, metals and alloys and paraffin wax or microcrystalline wax. The directives will include such topics as a list of the authorized substances, conditions of use, purity standards, etc. 4. The Commission will adopt these specific directives after consulting with the Standing Committee on Foodstuffs. 5. When a Member State has grounds to believe that a material endangers human health although it complies with a specific directive that Member State may temporarily suspend the use of that material. The Commission will then examine the grounds and take appropriate action. 6. Requirements for marketing materials and articles coming into contact with foodstuffs, eg they must bear an indication that they are for use with food such as the words *for food use*; they must bear the name and address of the manufacturer or a trademark. This information must be in indelible ink.
4) Deadline for implementing Member State legislation	
5) Application date (if different from 4)	
6) Date for further coordinating proposal (if specified)	Specific measures for applying the Directive to be taken in the near future.
7) References	Council Adoption — Not yet published.

4. FOOD

4.8 Contact materials: testing

1) Objective	To implement previous legislation on plastic packaging material to take account of technical progress in the field of migration tests.	
2) Community measure	**Council Directive 85/572/EEC of 19 December 1985** laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.	
3) Contents	1. The simulants prescibed for use for testing migration of the constituents of plastic materials intended to come into contact with foodstuffs are restricted to those indicated in the Annex. 2. Annex containing list of authorized simulants.	
4) Deadline for implementing Member State legislation	Same as for Directive 82/711/EEC.	
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 372, 31.12.85

4. FOOD

4.9 Labelling, presentation and advertising

1) Objective

To amend existing legislation on labelling of food to end national exemptions. This will improve the flow of information throughout the Community, improve consumer awareness and facilitate trade. This is accomplished by:

- the proposal of this amendment to the existing *framework* directive on labelling
- directives on certain *specific* groups of food.

2) Proposal

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 for sale to the ultimate consumer.

3) Contents

1. The Directive applies to the labelling, presentation, and advertising of foodstuffs. The scope now includes foodstuffs intended for supply to mass catering establishments such as restaurants, hospitals and canteens as well as for sale to the final consumer.
2. Clarification of requirements on labelling and listed ingredients.
3. Dating regulations do not apply to food such as fresh fruit and vegetables, wines, beverages containing 10% or more by volume of alcohol, solid sugar, etc.
4. Update of annex to the earlier Directive to include aromatizers among products requiring the designation of flavouring.
5. The Commission will adopt specific provisions following consultation with the Standing Committee on Foodstuffs.

4) Opinion of the European Parliament

The Parliament welcomed the proposal but recommended several amendments. Some of these were adopted by the Commission in its amended proposal, including new labelling requirements for foodstuffs containing irradiated ingredients, and provisions relating to the sale and marketing of goods at intermediate stages.

5) Current status

The Council adopted a common position on 21.12.88. This included the addition of:

- the indication on the labelling of the drained net weight of foodstuffs presented in a liquid medium (definition of *liquid medium*)
- Member States may permit until 11.12.92 the minimum durability period to be expressed in their own territories otherwise than in terms of the date of minimum durability
- special conditions relating to milk and milk products in glass bottles intended for re-use.

The common position is now before Parliament for a second reading within the framework of the cooperation procedure.

6) References

Commission Proposal	Official Journal C 124, 23.5.86
Amended Proposal	Official Journal C 154, 12.6.87
European Parliament Opinion	Official Journal C 99, 13.4.87
Economic and Social Committee Opinion	Official Journal C 328, 22.12.86

4. FOOD

4.10 Labelling: alcoholic drinks

1) Objective	To extend food labelling requirements to include the percentage of alcohol in alcoholic drinks to ensure that consumers are adequately informed. The original proposal has been only partially adopted. Some points are still under consideration including additions to the list of ingredients that need not be specifically named.
2) Community measure	**Council Directive 86/197/EEC of 26 May 1986** amending Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer.
3) Contents	Extension of labelling requirements to include compulsory indication of alcoholic strength for beverages containing more than 1.2% by volume of alcohol.
4) Deadline for implementing Member State legislation	1.5.88 Products not labelled in accordance with the Directive may nevertheless be sold until 1.5.89 in order to allow for disposal of existing stocks.
5) Application date (if different from 4)	
6) Date for further coordinating proposal (if specified)	
7) References	Council Adoption — Official Journal L 144, 29.5.86

4. FOOD

4.11 Labelling: spirits, vermouths and other aromatized wines

1) Objective

To set out common rules for labelling alcoholic drinks. This will facilitate the free movement of these products within the Community whilst ensuring that consumers receive adequate information about the origin, alcohol content and certain other characteristics of products.

2) Proposal

Proposal for a Council Regulation laying down general rules on the definition, description and presentation of spirituous beverages and of vermouths and other wines of fresh grapes flavoured with plants or other aromatized substances.

3) Contents

1. Definitions including *gin, rum, whisky, spirituous beverage, sugar, mixing, coupage*, etc.
2. Restrictions on the sale of spirituous beverages, eg whisky sold in the Community must have a minimum alcoholic strength per volume of 40%; geographical restrictions on products such as scotch whisky.
3. Specifications with which aromatized wine must comply in order to be marketed in the Community, for example the total alcoholic strength must be a minimum of 17% by volume. There are exceptions to the regulations.
4. Addition of substances to the products. Water may be added, provided it meets quality requirements of water intended for human consumption. Only natural aromatic substances and preparations may be used as flavourings.
5. Regulations concerning the naming and labelling of the products with particular reference to origin and method of manufacture; eg the alcoholic strength must be expressed to the nearest half percent, the name under which the beverages are sold must be supplemented by the term *coupage* and the term *blend* where the product has undergone these procedures.
7. Annexes containing maximum levels of impurities in ethyl alcohol of agricultural origin and geographical descriptions for different categories of products.

4) Opinion of the European Parliament

The Parliament approved the proposal subject to several recommendations for amendment. Some of these were incorporated in the amended proposal including changes in definitions and provision for transitional arrangements.

5) Current status

The Council adopted a common position on 14.12.88 solely for spirituous beverages. This included amendments to definitions such as:

- list of spirit drinks which may not bear given generic names, eg *whisky, brandy* if they contain ethyl alcohol of agricultural origin
- spirit drinks marketed for human consumption may not be described by associating words or phrases, eg *like, type*.

The common position is now before Parliament for a second reading within the framework of the cooperation procedure.

6) References	Commission Proposal Amended Proposal	Official Journal C 189, 23.7.82 Official Journal C 269, 25.10.86
	European Parliament Opinion	Official Journal C 127, 14.5.84
	Economic and Social Committee Opinion	Official Journal C 124, 9.5.83

4. FOOD

4.12 Foodstuffs for particular nutritional uses

1) Objective

To amend and codify the existing Directive (77/94/EEC) which has established the general principles governing foodstuffs for particular nutritional uses. To identify the categories of foods for particular nutritional uses for which specific Directives are needed. To define procedures for the adoption of these Directives. To eliminate national derogations when they are still permitted under the existing Directive. To regulate the free circulation of foodstuffs for particular nutritional uses which will not be covered by existing Directives. This is to be accomplished by:

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

2) Proposal

Proposal for a Council Directive on the approximation of the laws of Member States relating to foodstuffs intended for particular nutritional uses.

3) Contents

1. The Directive applies to foodstuffs intended for particular nutritional uses. They must be suitable for their claimed nutritional purposes, and marketed in such a way as to indicate their suitability. A particular nutritional use should satisfy the nutritional requirements of:
   - certain categories of persons whose digestive system or metabolism is disturbed
   - certain categories of persons who are in a special physiological condition
   - infants or young children in good health.
2. Labelling, presentation and advertising of normal foodstuffs may not use the words *dietetic* or *dietary*.
3. Specific provisions for groups of food shall be laid down in specific Directives. These may include compositional requirements, hygienic requirements, list of additives, purity criteria etc. Specific labelling requirements in addition to those required for foodstuffs in general, eg declaration of energy, cabohydrate and fat content.
4. Procedures to be followed if a particular foodstuff, although complying with a specific Directive, is believed to endanger human health.
5. Provisions for the adoption of future specific Directives.

4) Opinion of the European Parliament

The Parliament approved the proposal in principle but recommended several amendments. Some of these were adopted in the Commission's amended proposal, including changes in the contents of future specific Directives and inclusion of procedures to be followed when an authorized foodstuff is believed to be dangerous.

5) Current status

The Council adopted a common position on 21.12.88. This included a number of important amendments such as:

- procedure for informing the competent authorities when a foodstuff not covered by a specific Directive is placed on the market
- the introduction of a safeguard clause for a product not covered by a specific Directive in the case that the competent authorities do not comply with the definitions of the Directive
- adoption of future Directives by the Commission following the regulatory committee procedure with a simple *safety net* except in the case of additives which is yet to be decided
- the original list given in Annex 1 of four categories of foodstuffs for particular nutritional uses for which specific Directives are to be elaborated is now expanded to nine.

The common position is now before Parliament for a second reading within the framework of the cooperation procedure.

6) References

Commission Proposal	Official Journal C 124, 23.5.86
Amended Proposal	Official Journal C 161, 19.6.87
European Parliament Opinion	Official Journal C 99, 13.4.87
Economic and Social Committee Opinion	Official Journal C 328, 22.12.86

4. FOOD

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

1) Objective

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

2) Proposal

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

3) Contents

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

4) Opinion of the European Parliament

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

5) Current status

The modified proposal is currently before the Council for its consideration. The cooperation procedure will apply giving the Parliament the opportunity of a second reading once it has received the view of the Council at the end of its first examination.

6) References

Commission Proposal	Official Journal C 28, 30.1.85
Amended Proposal	Official Journal C 285, 12.11.86
European Parliament Opinion	Official Journal C 120, 20.5.86
Economic and Social Committee Opinion	Official Journal C 303, 25.11.85

4. FOOD

4.14 Official inspection of foodstuffs

1) Objective	To provide for official inspections of food in order to protect the health and economic interests of consumers, whilst maintaing the legitimate rights of undertakings, eg manufacturing secrecy and right of appeal. To harmonize legislation which will facilitate the free movement of foodstuffs within the Community by establishing mutual confidence between the various systems of inspection in the Member States.
2) Proposal	**Proposal** for a Council Directive on the official inspection of foodstuffs.
3) Contents	1. The Directive lays down the general principles for the performance of official inspections of foodstuffs. These consist of the inspection of foodstuffs and materials in contact with them to ensure that they conform with the provisions aimed at preventing risks to public health or fraud in the matter of risks and presentation. 2. Procedures concerning the carrying out of inspections both on a regular basis and in those instances when non-conformity is supected. 3. Items subject to inspection include raw materials, semi-finished products, finished products, cleaning and maintenance products used in the production of foodstuffs etc. 4. Analysis of samples shall be carried out at official laboratories. 5. Those responsible for carrying out the inspections must have the right to carry out their inspections. They are bound by professional secrecy. 6. Each year Member States shall draw up forward programmes for sampling of foodstuffs.
4) Opinion of the European Parliament	The Parliament welcomed the principle of a directive on the official inspection of foodstuffs, but called on the Commission to modify its proposal to incorporate some amendments. However, only some of these have been included by the Commission in its amended proposal.
5) Current status	The Council adopted a common position on 21.12.88. This is now before Parliament for a second reading within the framework of the cooperation procedure.
6) References	Commission Proposal — Official Journal C 20, 27.1.87 Amended Proposal — Official Journal C 88, 5.4.88 European Parliament Opinion — Official Journal C 345, 21 12 87 Economic and Social Committee Opinion — Official Journal C 347, 22.12.87

4. FOOD

4.15 Sampling and analysis of foodstuffs

1) Objective	To allow the Commission to adopt Community methods for the sampling and analysis of food where necessary.
2) Community measure	**Council Directive 85/591/EEC of 20 December 1985** concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption.
3) Contents	1. Methods of sampling and analysis should be adopted by the Commission when - there is a need to ensure that Community law is uniformly applied - without them there would be a barrier to intra-Community trade. 2. Member States to apply their own testing procedures provided this does not hinder the free movement of products recognized as complying with the Community's regulations. 3. Testing methods believed to be inappropriate may be temporarily suspended pending examination by the Commission.
4) Deadline for implementing Member State legislation	23.12.87
5) Application date (if different from 4)	
6) Date for further coordinating proposal (if specified)	
7) References	Council Adoption — Official Journal L 372, 31.12.85

4. FOOD

4.16 Quick-frozen food

1) Objective	To harmonize Member State laws on quick-frozen foods to facilitate their free movement within the Community.	
2) Community Measure	**Council Directive 88/xxx/EEC of 21 December 1988** on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption.	
3) Contents	1. The Directive applies to quick frozen foodstuffs. Quick freezing is a process whereby the temperature zone of maximum crystallization is spanned as rapidly as necessary with the result that the temperature of the product is -18°C or lower (after thermal stabilization). 2. Quick freezing must be carried out with the aid of appropriate equipment immediately after the product has been processed. 3. A list of authorized cryogenic fluids is included. 4. Compulsory temperatures for quick-frozen foods during storage (3°C), transport and retail display (6°C). 5. Member States shall conduct random checks on quick-freezing equipment and on temperature levels. 6. Labelling requirements including the net quantity, batch identification (for sale to food producers), and the period during which the goods may be stored. The sales name shall be supplemented by the term *quick-frozen*. 7. Procedure for adopting methods of sampling and analysis. 8. Transitional period of eight years for local distribution and retail display cabinets.	
4) Deadline for implementing Member State legislation		
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Not yet published.

4. FOOD

4.17 Coffee and chicory extracts

1) Objective	To remove restrictions on the constituents of coffee and chicory products. This is to protect them from unfair competition from similar products manufactured outside the Community.
2) Community measure	**Council Directive 85/573/EEC of 19 December 1985** amending Directive 77/436/EEC on the approximation of the laws of the Member States relating to coffee extracts and chicory extracts.
3) Contents	1. Removal of previous restrictions relating to manufacture and sale of the above-mentioned products. 2. New labelling requirements; eg the term decaffeinated may be used provided that the anhydrous caffeine content does not exceed 0.3% by weight of the coffee-based dry material, the minimum coffee-based dry matter content expressed as percentage by weight must be stated. 3. Annex containing descriptions and definitions of coffee extracts and chicory extracts to which the Directive applies.
4) Deadline for implementing Member State legislation	1.1.87. Products not meeting with the requirements of the Directive may nevertheless be sold until 1.7.88 in order to allow for disposal of existing stocks.
5) Application date (if different from 4)	
6) Date for further coordinating proposal (if specified)	
7) References	Council Adoption — Official Journal L 372, 31.12.85

4. FOOD

4.18 Fruit juices and similar products

1) Objective

To update existing legislation on fruit juices in the light of technical developments in the production of some juices.

2) Proposal

Proposal for a Council Directive amending for the third time Directive 75/726/EEC on the approximation of the laws of the Member States concerning fruit juices and certain similar products.

3) Contents

1. Definition of *fruit nectar* as the unfermented, but fermentable product obtained by the addition of water, with or without the addition of sugar, to fruit juice, fruit puree or to a mixture of these products.
2. Freedom to replace sugars by honey.
3. Citric acid may be used in the production of fruit nectars obtained from apples, pears, or peaches.
4. Restrictions on the use of sweeteners; there is a maximum percentage limit on the sugar content; sweetening (for fruit juice only) must be indicated in the name.
5. The Directive will be updated to take account of technical progress. The Commission will decide on these amendments after consulting with the Standing Committee on Foodstuffs.

4) Opinion of the European Parliament

The Parliament approved the proposal at the first reading subject to one amendment which has since been incorporated into the amended proposal.

5) Current status

The Council adopted a common position on 18.11.88. The proposal is now before the Parliament for a second reading within the framework of the cooperation procedure.

6) References

Commission Proposal	Official Journal C 24, 31.1.87
Amended Proposal	Official Journal C 214, 16.8.88
European Parliament Opinion	Official Journal C 122, 9.3.88
Economic and Social Committee Opinion	Official Journal C 150, 9.6.87

4. FOOD

4.19 Fruit jams, jellies and marmalades and chestnut puree

1) Objective	To update existing legislation on fruit jams, jellies and similar products in the light of technical developments in their production.	
2) Community Measure	**Council Directive 88/593/EEC of 18 November 1988** amending Directive 79/693/EEC on the approximation of the laws of the Member States relating to fruit jams, jellies and marmalades and chestnut puree.	
3) Contents	1. Minor changes in wording of the English and Spanish versions of the Directive, eg *chestnut puree* is changed to *sweetened chestnut puree.* 2. Identity and purity criteria shall be determined where necessary in accordance with Commission procedures. 3. The Directive will be updated to take account of technical progress. The Commission will decide on these amendments after consulting the Standing Committee on Foodstuffs. 4. Obligation on the Commission to propose new Directives on jams containig less than 60% of dried matter. 5. Amendments to annexes, eg to allow the use of red fruit juices for the colouring of jams.	
4) Deadline for implementing Member State legislation	31.12.89 1.1.91	permit trade in products complying with the Directive prohibit trade in products not complying with the Directive
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 318, 25.11.88

CB-09-91-92

4. FOOD

4.20 Compulsory nutrition labelling

1) Objective	To enable the Commission to adopt a measure introducing compulsory nutrition labelling of foodstuffs when it is absolutely necessary. This allows consumers to make an informed choice of the food they consume and arrive at a balanced diet. The Commission has proposed two directives in this area. The first is summarized below and the second proposal is summarized in summary 4.21.	
2) Proposal	**Proposal** for a Council Directive on the introduction of compulsory nutrition labelling of foodstuffs intended for sale to the ultimate consumer.	
3) Contents	1. The Commission is granted powers to adopt appropriate legislation at the request of a Member State or on its own initiative, when compulsory nutritional labelling is necessary. It will submit its draft legislation to a Standing Advisory Committee. The Commission will take account of the Committee's opinion but will not be bound by it. 2. The Commission will base its decision as to the need for compulsory nutrition labelling on evidence of links between certain foods and specific diseases among the population, the need to improve the nutrition status of the population in general or substantial groups. 3. The Commission's choice of measures will take account of different means of achieving the desired objective.	
4) Opinion of the European Parliament	Not yet given.	
5) Current status	The proposal is before the Parliament and the Economic and Social Committee for their opinions.	
6) References	Commission Proposal	Official Journal C 282, 5.11.88
	European Parliament Opinion	
	Economic and Social Committee Opinion	

4. FOOD

4.21 Nutrition labelling rules for foodstuffs

1) Objective

To ensure that if nutritional labelling claims are made in any labelling or advertising, these claims must meet common Community requirements. This will ensure the free circulation of food products throughout the Community while guaranteeing a high level of consumer information. To provide a uniform and stable format for government information and education programmes.

2) Proposal

Proposal for a Council Directive on nutrition labelling rules for foodstuffs intended for sale to the ultimate consumer.

3) Contents

1. The Directive concerns nutrition labelling of foodstuffs for sale to the ultimate consumer and shall also apply to foodstuffs intended for supply to restaurants, hospitals, canteens and similar mass caterers.
2. Nutritional labelling shall be compulsory when a claim is made.
3. Definitions of *nutrition labelling* as meaning any information appearing in labelling as related to energy content and nutrients, i.e. protein, carbohydrate, fat, dietary fibre, vitamins and minerals. Definition of *nutrition claim* as meaning any representation that a food has particular energy and nutrient properties. Any declaration referring to quantity or quality of certain nutrients, if required by law, is not a nutrition claim. Definitions of various nutrients and methods of calculating their content
4. Labelling to be provided in full when a nutrition claim is made. Specified methods of calculating and declaring both energy value and nutrient content. These figures shall be derived from the manufacturer's analysis of the food. The declared amounts of nutrients shall be those of the food as it is sold rather than those capable of being consumed, as this latter definition appears to differ from Member State to Member State.
5. Information on vitamins and minerals may be expressed as a percentage of the *Recommended Daily Allowance* as defined in the Annex to the Directive.
6. Procedures to be followed for implementing the Directive including consultation with the Food Advisory Committee.

4) Opinion of the European Parliament

Not yet given.

5) Current status

The proposal is before the Parliament and the Economic and Social Committee for their opinions.

6) References

Commission Proposal	Official Journal C 282, 5.11.88
European Parliament Opinion	
Economic and Social Committee Opinion	

4. FOOD

4.22 Irradiation of foodstuffs

1) Objective

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

2) Proposal

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

3) Contents

1. The Directive applies to the processing and marketing of foodstuffs and food ingredients treated by 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 overall average radiation doses. Permitted radiation sources are listed in Annex 2 and Annex 4 specifies how the overall average absorbed dose is to be calculated. Provision is made for amending these annexes.
4. Foodstuffs may not be re-irradiated. However the full dose needed for a specific technological function may be given as the sum of fractionated doses. Irradiation may be used in conjunction with other processes. A procedure is established for exceptions to these provisions.
5. Member States are to ensure that irradiated foodstuffs are only marketed if their packaging or containers bear specific information. Where products are intended for sale to the final consumer, the information requirements of Directive 79/112/EEC on the labelling, presentation and advertising of foodstuffs have to be complied with. Foodstuffs not intended for sale to the ultimate consumer must bear information such as the fact that the product has been irradiated and the name and address of the irradiation unit. It may bear the logo depicted in Annex 3.
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, eg 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 record requirements will be adopted.

8. Irradiated foodstuffs may not be imported from a third country unless they comply with the provisions of the Directive. Documents accompanying the foodstuffs must provide the name and address of the irradiation unit and the necessary records. It must be confirmed that irradiation has been officially supervised ensuring that the irradiation conditions are equivalent to those required by the Directive. The Commission may make arrangements with third countries regarding mutual notification of irradiation plants and Community inspection in third countries.
9. Appropriate materials shall be used for the packaging of foodstuffs to be irradiated.
10. The Commission, after consultation of the Standing Committee for Foodstuffs and certain other Standing Committees where appropriate, is empowered to:
- amend the annexes to take account of scientific and technological developments
- adopt detailed rules for the records to be kept by approved irradiation units
- take appropriate measures should a Member State conclude that the irradiation of a foodstuff is harmful to human health, although conforming to the Directive.

4) Opinion of the European Parliament

Not yet given.

5) Current status

The proposal is before the Parliament and the Economic and Social Committee for their opinions.

6) References

Commission Proposal	Official Journal C 336, 31.12.88
European Parliament Opinion	
Economic and Social Committee Opinion	

5. PHARMACEUTICALS

CURRENT PROBLEMS AND 1992 OBJECTIVES

- The EEC market for pharmaceutical products is still divided into distinct national markets. Although there is a body of Community legislation on the manufacture, testing and marketing of pharmaceuticals and procedures for consultation among the national regulatory authorities, marketing authorizations remain national. National price control and social security refund systems also contribute to the partitioning of the markets.
- Since publication in 1985 of the White Paper, Completion of the Internal Market, the Council has adopted a package of five proposals (summaries 5.1, 5.2, 5.6 - 5.8) which constitute a major step towards the establishment of a Single European Market in pharmaceutical products. In particular, there are new Community rules on the marketing and development of medicines produced by biotechnology and the protection of highly innovative pharmaceutical products.
- Another important area that has been tackled by the Commission in a recent proposal is that of the pricing of pharmaceutical products and reimbursement by national social security schemes. This proposal has now been adopted by the Council. An existing communication on price controls (summary 5.9) is already in existence. Proposals still to be tabled by the Commission are concerned with the harmonization of the conditions of distribution of pharmaceutical products to patients and the provision of information to doctors and patients. These proposals will be submitted in 1989 and 1990.
- A further package of four proposals, which was presented to the Council early in 1988, is intended to extend the current Community rules to cover immunological products, products derived from human blood or plasma, radiopharmaceuticals used for diagnostic purposes and generic medicines. In addition one of the proposals will improve the guarantees of the quality of medicines manufactured in Europe and package information for patients (summaries 5.11 - 5.14).
- During 1988, the Commission presented proposals amending the current rules relating to veterinary medicines in order to eliminate barriers to trade and improve the guarantees of safety both for the animals treated and for consumers of foodstuffs of animal origin (summaries 5.3 - 5.5).

5. PHARMACEUTICALS

5.1 High-technology medicinal products: marketing authorization

1) Objective	To coordinate Member State procedures for authorizing high technology medicines, especially those based on biotechnology. Whilst the primary purpose of the Directive is to protect public health, it is also intended to liberalize the European market in high-tech medical products.	
2) Community measure	**Council Directive 87/22/EEC of 22 December 1986** on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology.	
3) Contents	1. The Directive covers such products as those developed by means of DNA technology; genetic coding; any biotechnological process which is deemed to be a significant innovation. 2. Before any Member State takes a decision on an application for marketing authorization or a decision to withdraw or suspend an authorization it must first consult either the Committee for Proprietary Medicinal Products or the Committee for Veterinary Medicinal Products, as appropriate. 3. When applying for marketing authorization the producer must provide information concerning characteristics of the products, reports of the analytical pharmocotoxilogical,and all available evaluation reports. 4. The Committee has to issue its opinion within a specified time period; the Member State must then inform the Committee of any action it will take (for example, grant, refusal or withdrawal of marketing authorization).	
4) Deadline for implementing Member State legislation	1.7.87	
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)	22.12.87	
7) References	Council Adoption	Official Journal L 15, 17.1.87

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5. PHARMACEUTICALS

5.2 Proprietary medicinal products: testing

1) Objective	Technology advances very quickly in this area, and the aim of the Directive is to adopt a new, quicker procedure for making technical updates to the legislation on testing of pharmaceuticals. This will make it more effective.
2) Community measure	**Council Directive 87/19/EEC of 22 December 1986** amending Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products.
3) Contents	1. The Directive delegates power to the Commission to update the legislation on testing to keep pace with technical advancement. It sets up a "Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Proprietary Medicinal Products Sector", which the Commission must consult prior to making any changes. Only if the Commission does not agree with the Committee does the matter have to be referred to the Council. 2. This Directive also makes changes to the requirements for *single dose toxicity*, *physico-chemical*, *biological* or *microbiological*, and *toxicological and pharmacological* tests.
4) Deadline for implementing Member State legislation	1.7.87
5) Application date (if different from 4)	
6) Date for further coordinating proposal (if specified)	
7) References	Council Adoption — Official Journal L 15, 17.1.87

5. PHARMACEUTICALS

5.3 Veterinary medicines: free circulation

1) Objective

To remove remaining barriers to trade in veterinary medicinal products.

2) Proposal

Proposal for a Council Directive amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products.

3) Contents

1. Obligation on Member States to ensure that no person has substances which may be used as veterinary medicinal products on his premises unless national legislation expressly permits it. Member States shall maintain a register of producers, dealers and others who are permitted to have, in their possession, active substances used in the manufacture of veterinary medicinal products which are available only on prescription. These persons will be required to maintain detailed records of the use made by them of these substances.
2. No veterinary medicinal product may be marketed or administered to animals in a Member State unless it has been previously authorised by the relevant authorities of that Member State. Certain exceptions to this rule are allowed, eg veterinary medicinal products prepared extemporaneously by a vet or a pharmacy in accordance with the terms of a veterinary prescription and to be administered only to a particular animal or a small group of animals.
3. The Directive outlines the manner in which a market authorization may be applied for and the information required to be included in the application, particularly the information on tests and clinical trials.
4. If a marketing authorisation has been awarded in one Member State, the holder of this authorisation may use the documentation which accompanied this application if he intends to seek marketing authorizations in at least two other Member States. Obligations related to such applications are detailed in the Directive.
5. The Committee for Veterinary Medicinal Products set up by the earlier Directive will facilitate the adoption of common positions by the Member States on applications for marketing authorization. At the request of the Commission or a Member State, the Committee shall examine questions relating to the refusal, suspension or withdrawal of an authorization.
6. To protect innovation, a second applicant for a marketing authorization for a product already authorized in the name of the original manufacturer will have to wait ten years from the first authorization unless he either has the consent of the original manufacturer for use of the application file references or himself provides the required information.
7. Obligation on Member States to ensure that the manufacture of veterinary medicinal products is subject to a manufacturing authorization even if the products being manufactured are for export only. When issuing a certificate of manufacturing authorization, Member States shall have regard to the prevailing administrative arrangements of the World Health Organization and shall supply a summary of *product characteristics as approved* for veterinary medicinal products intended for export which are already authorized on their territory. Obligations relating to application for a manufacturing authorization are outlined in the Directive. Obligation on companies and Member States to consider the potential impact of

	the use of a veterinary product on the environment. 8. The person responsible for the marketing of a veterinary medicinal product shall be obliged to notify the Member States of his reasons should he suspend the marketing of a product or withdraw it from the market. 9. Amendments are included in the Directive to Directive 81/851/EEC where it relates to labelling and package inserts of veterinary medicinal products. 10. Obligations on Member States to ensure that wholesale dealing in veterinary medicinal products is subject to the holding of an authorization. They must ensure that the time taken for granting an authorization does not exceed 90 days. 11. Obligation on persons applying for wholesale authorization to have sufficient and suitable premises at their disposal for storage and handling of products. The holder of an authorization shall be required to keep detailed records regarding matters outlined in the Directive. 12. Obligation on Member States to ensure that wholesalers supply veterinary medicinal products only to persons permitted to carry out retail activities or permitted to receive veterinary medicinal products from wholesalers. 13. Obligation on Member States to ensure that the retail supply of veterinary medicinal products is carried out only by persons expressly permitted to do so by national legislation. Obligation on retailers to maintain detailed records in respect of all incoming and outgoing transactions. Member States may dispense with this requirement in respect of companion animals, eg cats and dogs.
4) Opinion of the European Parliament	Not yet given.
5) Current status	The proposal is currently before the Parliament and the Economic and Social Committee for their opinions.
6) References	Commission Proposal — Not yet published. European Parliament Opinion Economic and Social Committee Opinion

5. PHARMACEUTICALS

5.4 Veterinary medicines: provisions for immunological products

1) Objective

To remove hindrances to intra-Community trade in immunological veterinary medicines and maintain a high level of protection of public health by extending to these products the provisions of existing Directives relating to veterinary medicinal products.

2) Proposal

Proposal for a Council Directive extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products.

3) Contents

1. The Directive extends the field of application of Directive 81/851 to include immunological veterinary medicinal products subject to the provisions laid down in the proposed Directive. The Directive does not apply to autogenous vaccines manufactured from the organisms found in discharges from an animal and used for the treatment of the individual animal from which the organisms are derived.
2. Definition of *immunological veterinary medicinal product*, and redefinition of the expressions *qualitative and quantitative particulars of the constituents* and *qualitative and quantitative composition.*
3. Provision for expression of quantitative particulars in specified units as appropriate to the product concerned.
4. Provisions for competent authorities to ensure the validation of manufacturing processes and batch-to-batch consistency. The person responsible for marketing immunological products may be required by the competent authorities to produce copies of control reports and/or to provide them with samples from batches. The samples may also be submitted for examination by State or other designated laboratories, unless the batch in question has already been approved by another competent authority within the Community.
5. Use of an immunological veterinary medicinal product may be prohibited in the absence of specific Community legislation if certain facts are established, eg that the administration of the product to animals will interfere with the operation of a national or Community programme for the control or eradication of animal disease or will cause difficulties in certifying the absence of contamination of foodstuffs obtained from treated animals.
6. Procedure for amending for immunological medicinal products the testing requirements for veterinary medicinal products.

4) Opinion of the European Parliament

Not yet given.

5) Current status

The proposal is currently before the Parliament and the Economic and Social Committee for their opinions.

6) References

Commission Proposal	Not yet published.
European Parliament Opinion	
Economic and Social Committee Opinion	

5. PHARMACEUTICALS

5.5 Veterinary medicines: residues

1) Objective

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

2) Proposal

Proposal for a Council Regulation laying down a Community procedure for the establishment of tolerances for residues of veterinary medicinal products.

3) Contents

1. Definition of *residues of veterinary medicinal products* and *tolerance* for the purposes of this Regulation.
2. The Regulation introduces a general system for establishing tolerance levels for residues. In the case of veterinary medicinal products for which application for marketing authorization is made after the Regulation comes into force, a tolerance will have to be established before authorization is granted. In the case of products already on the market, tolerances will be established for groups of compounds over a period, estimated at about eight years. They will be inserted in the annexes to the Regulation when established. The Regulation lays down the procedure for this.
3. A tolerance expressed in terms of micrograms per kilogram on a fresh meat basis shall be established after consideration of all available information and in accordance with generally recognized principles of safety assessment. This tolerance may however be reduced in certain circumstances, eg if residues cause difficulties for the industrial processing of foodstuffs. Specific tolerances may be established for particular foodstuffs, eg liver, kidney, eggs. The list of substances used as active ingredients in veterinary medicinal products for which tolerances are to be established will be contained in annex I to the Regulation.
4. Annex II to the Regulation will give a list of substances for which it is not necessary to establish a tolerance having regard to their nature and pattern of use. A substance shall be included in annex II according to the procedure laid down in this Regulation.
5. A provisional tolerance may be adopted for a substance used as an active ingredient in veterinary medicines as long as there is no evidence that the level of its residues presents a hazard to the consumer. A provisional tolerance shall apply for a defined period of time which shall not exceed three years and which shall not be renewed more than once. A list of substances for which a provisional tolerance has been established will be provided for by annex III to the Regulation.
6. Annex IV shall contain a list of substances used as active ingredients in veterinary medicinal products for which a tolerance level cannot be established because residues of the substance constitute a hazard to the health of the consumer at whatever level. The administration of such substances to food-producing animals shall be prohibited throughout the Community.

7. Member States shall not authorise the marketing of veterinary medicinal products which are intended for administration to food-producing animals and which contain an active substance which was not authorised for use in such products at the date of entry into force of this Regulation unless the substances concerned have been included in annexes I, II or III of the Regulation.
8. An individual wishing to have an active substance referred to in 7. above included in annexes I, II or III shall submit an application to the Commission of the European Communities which shall process the application according to the rules and within the time limits set down in this Regulation.
9. If a Member State considers that the urgent amendment of a provision of annexes I to IV is necessary in order to protect human or animal health, it may temporarily suspend the operation of that provision in its territory immediately notifying the Commission and the other Member States and giving reasons for its action. The Commission shall examine the Member State's reasons and, after consultation of the Member States in the Committee for Veterinary Medicinal Products, it shall take appropriate measures. Any Member State may refer the Commission's decision to the Council within 15 days of such notification. The Council may, by qualified majority, take a different decision within a further 15 days.
10. Member States may not prohibit or impede the putting into circulation within their territory of foodstuffs of animal origin on the ground that they contain residues of veterinary medicinal products if this residue does not exceed the tolerance provided for in annexes I or III, or if the substance concerned is listed in annex II.
11. With effect from 1st January 1997, the administration to food-producing animals of veterinary medicinal products which contain active substances not mentioned in annexes I, II or III shall be prohibited within the Community except in clinical trials which have been approved by the competent authorities.

4) Opinion of the European Parliament

Not yet given.

5) Current status

The proposal is currently before the Parliament and the Economic and Social Committee for their opinions.

6) References

Commission Proposal	Not yet published.
European Parliament Opinion	
Economic and Social Committee Opinion	

5. PHARMACEUTICALS

5.6 Veterinary medicinal products: testing

1) Objective	The technology of veterinary medicines advances very quickly and the aim of the Directive is to adopt a new, quicker procedure for making technical updates to legislation covering testing. This will make it more effective.	
2) Community measure	**Council Directive 87/20/EEC of 22 December 1986** amending Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products.	
3) Contents	1. The Directive delegates power to the Commission to update the legislation to take account of scientific advances. It sets up a "Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector" which must be consulted by the Commission before any changes can be made. Only if the Commission does not agree with the Committee does the matter have to be referred to the Council. 2. The Directive also makes changes to the requirements for *analytical, single dose toxicity, physico-chemical, biological, microbiological,* and *toxicological and pharmacological* tests.	
4) Deadline for implementing Member State legislation	1.7.87	
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 15, 17.1.87

5. PHARMACEUTICALS

5.7 Proprietary medicinal products: marketing

1) Objective	To adopt new guidance measures for the marketing of proprietary medicines to facilitate their movement within the Community.	
2) Community measure	**Council Recommendation 87/176/EEC of 9 February 1987** concerning tests relating to the placing on the market of proprietary medicinal products.	
3) Contents	The recommendation sets out notes for guidance for the relevant authorities concerning the granting of marketing authorization for pharmaceuticals, including a) Procedures for testing the mutagenic potential of pharmaceuticals b) Clinical investigation of oral contraceptives and information to be provided to users c) Presentation of information on pharmaceuticals d) Testing procedures for a range of pharmaceuticals and guidelines on interpreting the results of such tests.	
4) Deadline for implementing Member State legislation	Not applicable.	
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 73, 16.3.87

5. PHARMACEUTICALS

5.8 Proprietary medicinal products: testing

1) Objective

When seeking marketing authorization for a new pharmaceutical producers have to provide detailed results of tests performed, even though there may be many similar products already on the market. The Directive seeks to avoid repetitive testing on humans and animals by relaxing those requirements where similar products have already been authorized.

2) Community measure

Council Directive 87/21/EEC of 22 December 1986 amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.

3) Contents

Cases in which detailed test results are not required to be supplied with applications for marketing authorization:

- when the new product is essentially similar to a product already on the market in that country, and the person responsible for the existing product is willing to allow the use of his clinical information in the examination of the new product;
- if there is detailed scientific evidence available showing that the constituents of the pharmaceutical have an acceptable level of safety;
- when the new product is essentially similar to a product that has been authorized elsewhere in the Community for 6 or 10 years, and is marketed in the Member State in question. However, if the product is to be used differently, new tests must be performed and results provided.

4) Deadline for implementing Member State legislation	1.7.87 1.1.92	(except Greece, Portugal and Spain) (Greece, Portugal and Spain)
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 15, 17.1.87

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5. PHARMACEUTICALS

5.9 Pharmaceutical products: price control and reimbursements

1) Objective	The Communication sets out Member States' obligations under the rules of the EEC Treaty, as interpreted by the Court of Justice, and as the Commission intends to apply them in the area of price controls and reimbursement of medical products.
2) Community measure	**Communication** from the Commission on the compatibility with Article 30 of the EEC Treaty of measures taken by Member States relating to price controls and reimbursement of medical products.
3) Contents	1. In the absence of Community provisions, Member States are free to adopt legislation which controls the prices of pharmaceutical products, provided that it does not represent an obstacle to free trade in such products within the Community. 2. The general principles to be observed when setting up price control systems are that they must be *realistic* and *transparent* : that is to say they must be based on their real cost and it must be obvious as to how the price was arrived at. 3. Member States may not introduce price controls that discriminate against imported medicines. Price freezes may or may not be permitted in light of this depending on their precise terms. 4. When deciding which medicines can be supplied under their national health insurance scheme Member States must not discriminate against imported products. 5. The Commission has the right to begin proceedings against any Member State which does not fulfil its obligations under the EEC Treaty.
4) Deadline for implementing Member State legislation	Not required.
5) Application date (if different from 4)	
6) Date for further coordinating proposal (if specified)	
7) References	Commission Communication — Official Journal C 310, 4.12.86

5. PHARMACEUTICALS

5.10 Medicinal products: pricing

1) Objective

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

2) Community Measure

Council Directive 88/xxx/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of the national health insurance system.

3) Contents

1. The definition of *medicinal products* to be found in Directive 65/65/EEC applies to this Directive.
2. For those products which can only be marketed when the price of the product has been approved, the appropriate authority is obliged to take a decision within 90 days.
3. A list of medicines whose prices have been fixed must be published at least twice a year.
4. Points 2 and 3 also apply to applications for price increases.
5. If a price freeze is imposed on all, or just certain categories, of medicinal products, Member States must ensure that prices are adjusted at least once a year, or when the Retail Price Index increases by more than 10%. Manufacturers may request exemptions from price freezes.
6. Where a Member State imposes controls on the profitability of pharmaceutical manufacturers or importers, certain information has to be given to the Commission, eg target profitability, definition of profit etc.
7. Member States have to publish a list of all medicines where the cost is reinvested or otherwise borne by their national health insurance system, and inform the Commission. Likewise, if it is decided that certain medicines should not be included, this should also be published.
8. Member States must inform the Commission of their systems of classification of medicinal products; the Commission may produce future legislation to harmonize such classification systems. In addition, the Commission will table a proposal to eliminate any remaining obstacles to the free movement of medicines throughout the Community.
9. The Directive establishes the Consultative Committee for the implementation of the Directive.

4) Deadline for implementing Member State legislation

5) Application date (if different from 4)

6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Not yet published.

5. PHARMACEUTICALS

5.11 Medicinal products: amendments to existing directives

1) Objective	To amend previous directives relating to proprietary medicinal products to cover non-proprietary medicinal products. To improve the information available to consumers about medicinal products. To lay down certain provisions governing the export of medicinal products. To improve the guarantees of the quality, safety and efficiency of all medicinal products.
2)Proposal	**Proposal** for a Council Directive amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.
3) Contents	1. Definitions of *magistral formula* and *official formula*. 2. Extension of the scope of previous directives to include ready-made medicinal products. Some medicinal products remain exempt, eg those intended for research and development trials and those made up according to the prescription of an authorised health care professional for an individual patient. 3. Information requirements are increased to include special precautions for the disposal of unused product or waste materials and batch numbers. 4. The inclusion of a package leaflet for *all medicinal products* is obligatory unless all information can be conveyed on external packaging itself. 5. Measures relating to exports to non-EC countries. For example, supply to the destination country of proof of manufacturing authorization, product summaries. 6. Competent authorities in Member States must carry out repeated inspections and report periodically on whether or not a manufacturer complies with principles and guidelines of good manufacturing practice. The manufacturer will be informed of the contents of these reports and may demand a second inspection. 7. The principles and guidelines of good manufacturing practice will be the subject of a future Commission directive and detailed guidelines to be published by the Commission. 8. The person responsible for the marketing of a medicinal product shall be obliged to notify the Member States of any action to suspend the marketing of a product or to withdraw it. 9. The Commission shall publish an annual list of medicinal products prohibited in the Community or subject to special restrictions.
4) Opinion of the European Parliament	The Parliament approved the proposal subject to several recommendations for amendments, most of which were incorporated in the Commission's amended proposal.
5) Current status	The Council adopted a common position on 18.11.88. This is now before the Parliament for a second reading within the framework of the cooperation procedure.

6) References	Commission Proposal Amended Proposal	Official Journal C 36, 8.2.88 Official Journal C 308, 3.12.88
	European Parliament Opinion	Official Journal C 290, 14.11.88
	Economic and Social Committee Opinion	Official Journal C 208, 8.8.88

5. PHARMACEUTICALS

5.12 Immunological products

1) Objective

To extend the scope of previous directives relating to proprietary medicinal products to include immunological medicinal products, allergen products, vaccines, toxins, and serums.

2) Proposal

Proposal for a Council Directive extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and laying down additional provisions for immunological medicinal products consisting of vaccines, toxins or serums and allergens.

3) Contents

1. Definitions of *allergen product*, *vaccines*, *toxins*, and *serums*. Previous directives on the manufacturing and marketing of proprietary medicinal products now include these products within their scope.
2. The quantitative particulars of an immunological medicinal product shall be expressed by mass or by units of biological activity or by specific protein content where possible
3. Requirement to include details about any special precautions to be taken by persons handling immunological products in information summaries about the product.
4. Product documents using the name of an immunological medicinal product should also include the common or scientific name of the active constituents.
5. Member States are required to ensure that the manufacturing processes of these products are properly validated and that there is batch to batch consistency.
6. Power is delegated to the Commission to adapt the 1975 Directive on analytical, pharmaco-toxicological and clinical standards and protocols to take account of the specific characteristics of these products.

4) Opinion of the European Parliament

The Parliament approved the proposal subject to several recommendations for amendments, most of which were incorporated in the Commission's amended proposal.

5) Current status

The Council adopted a common position on 18.11.88. This is now before the Parliament for a second reading within the framework of the cooperation procedure.

6) References

Commission Proposal	Official Journal C 36, 8.2.88
Amended Proposal	Official Journal C 308, 3.12.88
European Parliament Opinion	Official Journal C 290, 14.11.88
Economic and Social Committee Opinion	Official Journal C 208, 8.8.88

5. PHARMACEUTICALS

5.13 Medicinal products derived from human blood or plasma

1) Objective

To extend the scope of previous directives relating to proprietary medicinal products to include products derived from human plasma.

2) Proposal

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

3) Contents

1. Definition of *medicinal products derived from human plasma*. These products include in particular albumin, coagulating factors and immunoglobins of human origin. The Directive will not apply to whole blood, plasma or blood cells of human origin
2. The quantitative particulars of a medicinal product derived from human plasma shall be expressed by mass or by units of biological activity.
3. Member States shall take measures to prevent the transmission of infectious diseases. These shall at least comprise the measures recommended by the Council of Europe and the World Health Organisation in particular for the selection and testing of blood donors.
4. Member States shall ensure that when human blood is traded, the origin of the blood donation centre is always clearly identified.
5. Every guarantee must be given as to the safety and purity of imports of human blood from countries outside the Community.
6. Member States shall promote the self-sufficiency of the Community in human blood. Voluntary unpaid donation of blood shall be encouraged.
7. Member States are required to ensure that the manufacturing processes of these products are properly validated, that there is batch to batch consistency, and to guarantee the absence of viral contaminants.
8. The procedure laid down in Directive 87/22/EEC relating to high technology medicinal products (Summary 5.1) shall be extended to medicinal products derived from human blood or plasma.
9. Power is delegated to the Commission to adapt the 1975 Directive on analytical, pharmaco-toxicological and clinical standards to take account of the specific characteristics of these products.

4) Opinion of the European Parliament

The Parliament approved the proposal subject to several recommendations for amendment, including the substitution of medicinal products derived from plasma for those derived from blood, some of which were subsequently incorporated into the amended proposal.

5) Current status

The Council adopted a common position on 21.12.88. This is now before the Parliament for a second reading within the framework of the cooperation procedure.

6) References	Commission Proposal Amended Proposal	Official Journal C 36, 8.2.88 Official Journal C 308, 3.12.88
	European Parliament Opinion	Official Journal C 290, 14.11.88
	Economic and Social Committee Opinion	Official Journal C 208, 8.8.88

5. PHARMACEUTICALS

5.14 Radiopharmaceuticals

1) Objective

To extend the scope of previous directives relating to proprietary medicinal products to include radiopharmaceuticals.

2) Proposal

Proposal for a Council Directive extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and laying down additional provisions for radiopharmaceuticals.

3) Contents

1. Definition of *radiopharmaceutical*, *generator*, *kit*, *precursor*. Previous directives on the manufacture and marketing of proprietary medicinal products now include these radiopharmaceuticals within their scope.
2. Authorization shall be required for generators, kits, precursor radiopharmaceuticals and industrially prepared radiopharmaceuticals. Authorisation shall not be required for a radiopharmaceutical prepared at the time of use by a person or establishment authorized by national legislation to use such products.
3. The application for authorization of a generator has a further information requirement. This is a general description of the system, a detailed description of the components and qualitative and quantitative particulars of the eluate.
4. The summary of product characteristics for radiopharmaceuticals must include full details of radiation dosimetry, instructions for preparation and storage.
5. Containers of radionuclides shall be labelled in accordance with International Atomic Energy Agency regulations as well as EEC legislation.
6. Member States must ensure that a detailed instruction leaflet is enclosed with the packaging of radiopharmaceuticals, generators, kits, and precursor radiopharmaceuticals.
7. Power is delegated to the Commission to adapt the 1975 Directive on analytical, pharmaco-toxicological and clinical standards and protocols to take account of the specific characteristics of these products

4) Opinion of the European Parliament

The Parliament approved the proposal subject to several recommendations for amendments, most of which were incorporated in the Commission amended proposal.

5) Current status

The Council adopted a common position on 21.12.88. This is now before the Parliament for a second reading within the framework of the cooperation procedure.

6) References

Commission Proposal	Official Journal C 36, 8.2.88
Amended Proposal	Official Journal C 308, 3.12.88
European Parliament Opinion	Official Journal C 290, 14.11.88
Economic and Social Committee Opinion	Official Journal C 208, 8.8.88

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6. CHEMICALS

CURRENT PROBLEMS AND 1992 OBJECTIVES

- Differing regulations for chemical products give rise to a multitude of problems. Divergent levels of health and safety protection are a clear obstacle to the creation of the internal market. Free movement of chemical products throughout the Community cannot be guarantied if classification, packaging and labelling requirements differ in the individual Member States.
- In this area the emphasis is on protecting the health and safety of man and his environment, and, at the same time, ensuring users are adequately provided with information about products placed on the market.
- The measures appearing in the White Paper and summarized in this brochure have to be seen as part of a continuing process which already has a long history. For example, the Community first adopted a Directive on the classification, packaging and labelling of dangerous substances in 1967 and this has been amended and adapted to technical progress 9 times. The Community's legislation on the classification, packaging and labelling of dangerous preparations has a similar history, going back to 1973. Again, a Directive relating to restrictions on marketing and use of dangerous substances and preparations was adopted in 1976 and has been amended 7 times. Thus, the measures summarized here represent the latest stage in a dynamic process which must keep pace with the advances in scientific knowledge.
- The White Paper programme consists of:
  - the implementation of the *umbrella* directive in order to extend to the Community some national protections for health purposes (such as polychlorinated biphenyls and asbestos which are covered in summaries 6.1 and 6.2);
  - the reorganization of the 1973 directive in order to cover all the dangerous preparations and to update the labelling taking into account any new risks (Summary 6.3 covers the directive in this area which was adopted by the Council in June 1988);
  - specific measures for individual chemical products such as detergents and fertilizers (summaries 6.4 - 6.7).

6. CHEMICALS

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

1) Objective	To update previous legislation to prohibit the marketing and use of PCBs and PCTs (polychlorinated biphenyls and polychlorinated terphenyls) except in special circumstances. Substitutes have been developed which are considered less dangerous to human beings and the environment.	
2) Community measure	**Council Directive 85/467/EEC of 1 October 1985** amending for the sixth time (PCBs/PCTs) 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. Prohibition on the use of PCBs and PCTs except under certain conditions: - closed-system electrical equipment transformers, resistors and inductors - large condensers - heat transmitting fluids in closed-circuit heat-transfer installations - hydraulic fluids for underground mining equipment. These uses of PCBs and PCTs will come to an end on 30.6.86. 2. New labelling requirements: equipment and plant containing PCBs and PCTs must display instructions concerning their disposal and maintenance.	
4) Deadline for implementing Member State legislation	30.6.86	
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 269, 11.10.85

6. CHEMICALS

6.2 Restrictions on marketing and use of dangerous substances: asbestos

1) Objective	To update previous legislation in order to prohibit certain uses of asbestos. This will ensure adequate public health protection throughout the Community.	
2) Community measure	**Council Directive 85/610/EEC of 20 December 1985** amending for the seventh time (asbestos) 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 on the use of asbestos for: - toys - preparations applied by spraying - products in powder form - items for smoking - filters and insulation devices for use in catalytic heaters using liquefied gas - paints and varnishes.	
4) Deadline for implementing Member State legislation	31.12.87	
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 375, 31.12.85

6. CHEMICALS

6.3 Classification, packaging and labelling of dangerous preparations

1) Objective	To harmonize national measures on classification, packaging and labelling of dangerous preparations to facilitate the establishment of a single market and to provide protection for public health.
2) Community Measure	**Council Directive 88/379/EEC of 7 June 1988** on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.
3) Contents	1. The Directive applies to dangerous preparations as defined in Article 1.2 of the Directive which have been placed on the market with certain exceptions, eg medicinal or veterinary products, foodstuffs, substances in transit which are under customs supervision etc. 2. Classification of preparations such as explosive, oxidizing, extremely flammable, highly flammable etc with an extra provision on aerosols. 3. Provisions relating to the marketing of dangerous preparations. 4. Provision for the assessment of the health hazards of a product, ie those considered to be toxic, harmful, corrosive, irritant, carcinogenic, mutagenic, teragenic, and as having special effects on health. 5. Packaging requirements, eg containers of dangerous preparations sold to the public must not have a shape and/or graphic design likely to attract children. They must be strong and resistant and have a suitable fastening system. 6. Labelling requirements including indelible marking of the package with the trade name of the preparation and the chemical name of the substance etc. Also provision for the labelling of a product which has not yet been fully tested. 7. Manufacturers or those responsible for placing the preparation on the market shall hold the data used for the classification and labelling of the preparation at the disposal of the authorities of the Member States. Member States will appoint bodies responsible for receiving and ensuring the confidentiality of this information. 8. Member States shall set up a system of specific information (in safety data-sheet form) relating to dangerous products. This will primarily be used by industry to ensure health and safety at work. 9. Member States may temporarily suspend the sale of a product believed to be harmful. They may do so if it constitutes a hazard by reason of its classification, packaging or labelling. The Member State must immediately notify the Commission and other Member States of such action. 10. Member States may not prohibit the marketing of goods which comply with this Directive. 11. Annexes containing concentration limits of dangerous substances and special provisions on the labelling of certain preparations.
4) Deadline for implementing Member State legislation	7.6.91

5) Application date (if different from 4)	Preparations in conformity with Directives 73/173/EEC and 77/728/EEC may be marketed until 7.6.92.	
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 187, 16.7.88

6. CHEMICALS

6.4 Detergents

1) Objective	To extend until 31.12.89 the existing exemptions from the requirement of a minimum biodegradability level for certain detergents.
2) Community measure	**Council Directive 86/94/EEC of 10 March 1986** amending for the second time Directive 73/404/EEC on the approximation of the laws of the Member States relating to detergents.
3) Contents	Extension of the exemption period quoted in the original Directive until 31.12.89 for a range of detergents including - low-foaming alkene oxide additives on such substances as alcohols, alkyphenols, glycols, polyols, fatty acids, amides or amines used in dish-washing products - alkali-resistant terminally blocked alkyl and alkylaryl polyglycol ethers and substances of the type referred to in the paragraph above, used in cleaning agents for the food, beverage and metal working industries.
4) Deadline for implementing Member State legislation	Not stated.
5) Application date (if different from 4)	Exemptions for certain detergents extended until 31.12.89.
6) Date for further coordinating proposal (if specified)	
7) References	Council Adoption — Official Journal L 80, 25.3.86

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6. CHEMICALS

6.5 Marketing of fertilizers: liquid fertilizers

1) Objective	To extend the laws on the marketing of fertilizers to include liquid fertilizers.	
2) Community Measure	**Council Directive 88/183/EEC of 22 March 1988** amending Directive 76/116/EEC in respect of fluid fertilizers.	
3) Contents	1. Marketing requirements for liquid fertilizers. Only fertilizers listed in this Directive may be designated *EEC fertilizers*. Fluid fertilizers may only be marketed if directions for their correct storage and prevention of accidents are provided. 2. Lists of fluid fertilizers, type designation, data on method of production, minimum content of nutrients, nutrient content to be declared and any other relevant data.	
4) Deadline for implementing Member State legislation	25.3.89	
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 83, 29.3.88

6. CHEMICALS

6.6 Marketing of fertilizers: solid and fluid fertilizers

1) Objective	To extend the existing legislation on fertilizers to include their calcium, magnesium, sodium and sulphur content or to market them as EEC fertilizers.
2) Proposal	**Proposal** for a Council Directive supplementing and amending Directive 76/116/EEC in respect of the calcium, magnesium, sodium and sulphur content of fertilizers.
3) Contents	1. Declaration of the magnesium, sodium and sulphur content of fertilizers must be made. 2. Declaration of calcium content considered to be a nutrient need be made only for calcium sulphate and calcium chloride solution fertilizers. 3. Fertilizers complying with the Directive may be marked *EEC fertilizer*. 4. Required marking for identification purposes includes "EEC FERTILIZER", the designation of the type of fertilizer and the guaranteed nutrient content. 5. Annex containing list of fertilizers containing calcium, magnesium and sulphur as principal nutrients.
4) Opinion of the European Parliament	The Parliament approved the proposal.
5) Current status	The Council adopted a common position on 14.10.88. This is now before the Parliament for a second reading within the framework of the cooperation procedure.

6) References	Commission Proposal	Official Journal C 20, 26.1.88
	European Parliament Opinion	Official Journal C 262, 10.10.88
	Economic and Social Committee Opinion	Official Journal C 134, 24.5.88

6. CHEMICALS

6.7 Marketing of fertilizers: oligo-elements

1) Objective	To extend existing Community legislation on fertilizers (see 6.5 and 6.6) to include specific nutrients in fertilizers.	
2) Proposal	**Proposal** for a Council Directive 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 fertilizers*. 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, eg 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) Opinion of the European Parliament	Not yet given.	
5) Current status	The proposal is currently before the Parliament and the Economic and Social Committee for their opinions.	
6) References	Commission Proposal	Official Journal C 304, 29.11.88
	European Parliament Opinion	
	Economic and Social Committee Opinion	

7. CONSTRUCTION PRODUCTS

CURRENT PROBLEMS AND 1992 OBJECTIVES

- The construction sector raises problems of two kinds. Firstly, there is the problem of obstacles to the free movement between Member States of construction equipment. Secondly, there is the problem of differing standards for buildings, which can mean different levels of protection for occupants.
- The lack of common standards for construction equipment restricts manufacturers to national rather than Community-wide markets. In order to promote their products throughout the Community costly modifications have to be made, frustrating the ideal of the internal market. As with motor vehicles and agricultural machinery, the lack of EC type-approval procedures leads to repeated testing and certification of components. Costs mount and valuable resources are wasted.
- The completion of the internal market is intended to remove all these barriers, and, at the same time, lay down Community-wide minimum standards of health, safety and environment.
- Safety requirements are essential not only for construction equipment but also for buildings. Safety in hotels is particularly important because of the number of persons at risk, particularly at night, and of the fact that many hotels are older buildings.
- There are three measures remaining in this sector in the Third Progress Report which have all been adopted by the Council. These relate to noise levels of tower cranes (summary 7.1), safety measures in hotels (7.2) and construction products (summary 7.3). This last directive is based on the *new approach* principles described in section 1.

7. CONSTRUCTION PRODUCTS

7.1 Tower cranes: sound levels

1) Objective	The aim of this Directive is to harmonize national legislation relating to tower cranes, so as to remove differences that constitute trade barriers. It is also intended to consolidate all the legislation relating to this subject into one Directive making the requirements more comprehensible.	
2) Community measure	**Council Directive 87/405/EEC of 25 June 1987** amending Directive 84/534/EEC on the approximation of the laws of the Member States relating to the permissible sound power level of tower cranes.	
3) Contents	1. This Directive applies to the permissible sound power level, and sound pressure level at the operator's position, of noise emitted from tower cranes used on industrial and building sites. 2. EEC-type examination certificates shall be issued to tower cranes which satisfy the following requirements: the lifting mechanism must emit less than 102 dB/pW (to be reduced to 100 dB/pW in 1992); the sound pressure level at the operator's position must not exceed 85 dB/ Pa (to be reduced to 80 dB/µPa in 1992). 3. Cranes which satisfy the requirements must bear a mark indicating the sound power and sound pressure levels, and the symbol epsilon. 4. The annexes contain technical information on the measurement of airborne noise and diagrams of the marks to be put on complying cranes.	
4) Deadline for implementing Member State legislation	26.12.88 26.6.89 26.6.92	for standards of 102 dB (pW) for standards of 85 dB (µPa) for standards of 100 dB (pW) and 80 bB (µPa)
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)	To be specified in due course.	
7) References	Council Adoption	Official Journal L 220, 8.8.87

7. CONSTRUCTION PRODUCTS

7.2 Fire safety in hotels

1) Objective	To ensure that all hotels throughout the Community are covered by minimum safety requirements.	
2) Community measure	**Council Recommendation 86/666/EEC of 22 December 1986** on fire safety in existing hotels.	
3) Contents	1. Member States are recommended to ensure that fire precautions in hotels should, at the very least, satisfy certain minimum requirements. For example, safe escape routes should be available, unobstructed, and clearly marked; buildings should be stable enough to allow adequate time for the evacuation of occupants; warning systems should be installed and in full working order; staff should be given suitable training. 2. The annex contains technical guidelines for the construction of hotel buildings. 3. Member States are advised to inspect hotels periodically. 4. Member States must inform the Commission of the national regulations which they intend to introduce in the next five years to meet the above requirements.	
4) Deadline for implementing Member State legislation	Not applicable.	
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Official Journal L 384, 31.12.86

7. CONSTRUCTION PRODUCTS

7.3 Construction products

1) Objective	To harmonize national legislation in the domain of health and safety requirements of construction products. To set out those essential requirements which will eventually form the basis of European standards. To enable the Commission to adopt guidelines in line with the *new approach* to harmonization before the actual standardization process is complete.	
2) Community Measure	**Council Directive 88/xxx/EEC of 21 December 1988** on the approximation of the laws, regulations and administrative provisions of the Member States relating to construction products.	
3) Contents	1. The Directive applies to *construction products*, which are defined as products with a view to their incorporation in construction works, eg cement, tiles, doors, drainage etc. 2. All products must be fit for their intended use and meet other essential requirements concerning stability, safety in the case of fire, hygiene, safety in use, protection against noise and economy of energy during an economically reasonable working life. 3. European standards for *construction products* shall be established by the European standardization bodies following consultation with the Standing Committee for construction (which is established by the Directive). 4. System of European technical approval designed to assess new products in light of the essential requirements mentioned in (2). 5. Where neither a European standard or guidelines for European technical approval yet exist products may be assessed by compliance with national requirements. 6. Products which bear the *EC mark* shall be assumed to conform with requirements. Inspection for conformity according to the relevant decisions by the Standing Committee. 7. Products conforming with required standards, but which are thought to present a safety threat, may be temporarily withdrawn from the market. 8. Annexes containing information including details of the essential requirements, European technical approval procedure and procedures for ensuring that approved products conform with appropriate requirements.	
4) Deadline for implementing Member State legislation		
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)		
7) References	Council Adoption	Not yet published.

8. OTHER ITEMS

CURRENT PROBLEMS AND 1992 OBJECTIVES

- In many areas of the economy the lack of common standards and product regulations frustrates the creation of a common market. Goods cannot move freely from one Member State to another, testing and certification procedures have to be repeated for each Member State, and consumers are provided with varying levels of protection and information. Clearly the harmonization of essential product regulations and standards is necessary to create a truly common market, and to allow the Community to become an effective force of competition in world markets.
- A number of different areas are covered in this section of the brochure. All of the proposals contained in the White Paper have now been adopted by the Council.
- As explained in the general introduction to this brochure, 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 (8.3), 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 (8.4) and noise emissions from construction products (8.8).
- In addition, there are three measures (8.5 - 8.7) which aim to protect the consumer and harmonize national regulations for product pricing (both for food and non-food items) and for labelling of cosmetics.

8. OTHER ITEMS

8.1 Household appliances: noise

1) Objective	The Directive aims to • ensure that the public get as much information as possible about the household products they are buying, and • aid the free movement of household appliances throughout the Community. It is not intended to harmonize national standards at present; rather to ensure that national regulations follow a common pattern.
2) Community measure	**Council Directive 86/594/EEC of 1 December 1986** on airborne noise emitted by household appliances.
3) Contents	1. The Directive covers: the general principles relating to the publication of information on noise levels emitted from household appliances; methods of measuring noise; arrangements for monitoring noise emitted by household appliances. 2. Where Member States require information to be published on the noise level of such appliances it shall be the responsibility of the manufacturer (or the importer if the manufacturer is outside the Community) to supply such information and ensure its accuracy. 3. The information supplied may be subject to spot checks. If it is found to be inaccurate Member States must ensure that appropriate action to correct it without delay is taken by the manufacturer (or importer). 4. Where appliances have to have labels detailing other types of information, information on the noise emitted shall also be included. 5. Member States must inform the Commission of their national regulations. 6. The Directive also gives details of the testing methods to be used for determining levels of noise.
4) Deadline for implementing Member State legislation	4.12.89
5) Application date (if different from 4)	
6) Date for further coordinating proposal (if specified)	1.1.91 and when necessary.
7) References	Council Adoption — Official Journal L 344, 6.12.86

8. OTHER ITEMS

8.2 Lawnmowers: noise

1) Objective	To harmonize legislation relating to noise emissions from lawnmowers so as to remove any barriers to trade that exist due to differences in national provisions.
2) Community Measure	**Council Directive 88/180/EEC and Council Directive 88/181/EEC of 22 March 1988** amending Directive 84/538/EEC on the approximation of the laws of the Member States relating to the permissible sound power level of lawnmowers.
3) Contents	**Directive 88/181/EEC** 1. The Directive establishes common standards for noise emission from lawnmowers. 2. The permitted sound-power level ranges between 96 dB pW and 105 dB pW according to the corresponding cutting width of the lawnmower. 3. Lawnmowers shall display clearly visible marks identifiying 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 120cm shall indicate the sound pressure level expressed in dB(A)/20 Pa at the operator's position. 4. Two annexes containing the method of measuring airborne noise emitted by lawnmowers with a cutting width exceeding 120 cm at the operator's position and giving the model for a mark stating the sound pressure level at the operator's position. **Directive 88/180/EEC** 1. The Directive enlarges the field of application of Directive 84/538/EEC by including motorized cylinder mowers. 2. The cutting devices of cylinder lawnmowers shall be adjusted with a cylinder/cutting edge gap specified by the manufacturer according to three different criteria.
4) Deadline for implementing Member State legislation	1.7.91
5) Application date (if different from 4)	
6) Date for further coordinating proposal (if specified)	
7) References	Council Adoption — Official Journal L 81, 26.3.88

8. OTHER ITEMS

8.3 Non-clinical laboratory tests

1) Objective	To ensure that laboratories in all Member States claiming to follow good laboratory practice (GLP) are subject to regular controls by public authorities. This will allow for mutual recognition of test results throughout the Community.
2) Community Measure	**Council Directive 88/320/EEC of 9 June 1988** on the inspection and verification of Good Laboratory Practice
3) Contents	1. The Directive applies to the inspection and verification of the conditions under which non-clinical tests are performed on chemical products in order to assess health and safety implications. The principles of good laboratory practice (GLP) to be followed are found in Directive 87/18/EEC 1986. 2. Member States must designate particular authorities to carry out inspections of laboratories. 3. Every year a report must be produced containing a list of inspected laboratories and a summary of the conclusions of the inspections. 4. Commercially sensitive and confidential information will be made available only to specified bodies, eg the Commission, national regulatory and designated authorities etc, but GLP compliance status will be publically available. 5. If it is thought that a laboratory has not carried out a test according to GLP further information may be sought by the Member States from the inspecting authorities. A further inspection of the laboratory may be necessary. Member States shall inform the Commission of laboratories claiming GLP status but which fail to meet the requirements. 6. Amendments to the technical clauses of the Directive can be made by the Commission in consultation with the relevant committee. 7. Annex referring to OECD guidelines containing detailed information on the procedures to be followed when carrying out inspections.
4) Deadline for implementing Member State legislation	1.1.89
5) Application date (if different from 4)	
6) Date for further coordinating proposal (if specified)	
7) References	Council Adoption — Official Journal L 145, 11.6.88

8. OTHER ITEMS

8.4 Dangerous products resembling foodstuffs

1) Objective	There are some toys which look like sweets, or can easily be confused with foodstuffs, which present a significant danger to children. The aim of the Directive is to harmonize all national legislation relating to the marketing of such products so that consumers are protected equally in all Member States.	
2) Community measure	**Council Directive 87/357/EEC of 25 June 1987** on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health of safety of consumers.	
3) Contents	1. The Directive applies to products which are not edible but could easily be confused with foodstuffs by their appearance, smell or packaging. 2. Member States must prohibit the marketing, import and manufacture or export of such products. 3. Checks must be carried out to ensure that such products are not sold. 4. If a Member State bans a product under the terms of this Directive it must inform the Commission and provide relevant information so that other Member States can be informed. 5. The Directive may be updated by the Council in 1991.	
4) Deadline for implementing Member State legislation	26.6.89	
5) Application date (if different from 4)		
6) Date for further coordinating proposal (if specified)	26.6.91	
7) References	Council Adoption	Official Journal L 192, 11.7.87

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8. OTHER ITEMS

8.5 Cosmetic products

1) Objective	To improve the existing EEC regulations relating to the labelling of cosmetic products.
2) Community Measure	**Council Directive 88/xxx/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 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 5g or 5ml (eg 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 1.1.92.
4) Deadline for implementing Member State legislation	31.12.89
5) Application date (if different from 4)	Cosmetic products whose labelling does not comply with the provisions of the Directive may not be marketed after 1.1.92. Products not complying with the Directive may not be sold to the final consumer after 31.12.92
6) Date for further coordinating proposal (if specified)	Further amendments to Directive 76/768/EEC will be proposed by the Commission in due course
7) References	Council Adoption — Not yet published.

8. OTHER ITEMS

8.6 Prices of foodstuffs

1) Objective	To inform and protect consumers whilst liberalizing trade in food within the Community by harmonizing requirements for indicating unit prices on labels.
2) Community Measure	**Council Directive 88/315/EEC of 7 June 1988** amending Directive 79/581/EEC on consumer protection in the indication of the prices of foodstuffs.
3) Contents	1. The Directive does not apply to foodstuffs sold in hotels, cafes etc, or to food which is purchased for trade or commercial activities, or to food supplied in the course of the provision of a service. 2. Definitions of *prepackaged foodstuffs* as foodstuffs packaged other than in the consumer's presence and *unit price*, eg price per litre for products sold by volume, price per kilo for products sold by weight. 3. Member States may decide that this Directive shall not apply to foodstuffs sold on farms or to private sales. 4. Prices, and where appropriate unit prices, must be indicated on foodstuffs offered for sale to the ultimate consumer. 5. The Directive gives details of which products must display unit prices and those which are exempt, in particular foodstuffs prepacked in pre-established quantities. 6. Advertisements or catalogues must mention the unit price as well as the selling price. 7. Annex containing list of products pre-packaged in certain quantities referred to in the Directive.
4) Deadline for implementing Member State legislation	7.6.90
5) Application date (if different from 4)	7.6.97 Transitional measures exist in respect of the Imperial System used in the UK and in Ireland.
6) Date for further coordinating proposal (if specified)	A Council Resolution of 7 June 1988 requested further proposals from the Commission as soon as possible to extend the range of categories of product covered by the Directive and to revise the existing range.
7) References	Council Adoption — Official Journal L 142, 9.6.88

8. OTHER ITEMS

8.7 Prices for non-food products

1) Objective	To inform and protect consumers whilst liberalizing trade in non-food products within the Community and by harmonizing the obligations to indicate the retail price and the unit price.
2) Community measure	**Council Directive 88/314/EEC of 7 June 1988** on consumer protection in the indication of prices for non-food products.
3) Contents	1. The Directive does not apply to products bought for trade, private sales or sales by auction. 2. Prices, and where appropriate unit prices, must be indicated in an unambiguous, easily identifiable and clearly legible manner on products offered for sale to the ultimate consumer. Definitions of *unit price*, eg price per litre for products sold by volume, price per kilo for products sold by weight, and of *pre-packaged* products as products packaged other than in the consumer's presence. 3. The Directive gives details of which products must display unit prices and those which are exempt, in particular products prepacked in preestablished quantities. 4. Annex containing list of products prepackaged in pre-established quantities referred to in the Directive.
4) Deadline for implementing Member State legislation	7.6.90
5) Application date (if different from 4)	7.6.97 Transitional measures exist in respect of the Imperial System used in the UK and in Ireland.
6) Date for further coordinating proposal (if specified)	A Council Resolution of 7 June 1988 requested further proposals from the Commission as soon as posible to extend the range of categories of product covered by the Directive and to revise the existing range.
7) References	Council Adoption — Official Journal L 142, 9.6.88

8. OTHER ITEMS

8.8 Noise emissions from construction plant

1) Objective	Differences in national requirements concerning the limitation of noise from construction equipment effectively act as a barrier to free trade in these products. The Directive aims to harmonize national legislation whilst ensuring adequate environmental and health protection.
2) Community Measure	**Council Directive 86/662/EEC of 22 December 1986** on the limitation of noise emitted by hydraulic excavators, rope-operated excavators, dozers, loaders and excavator-loaders.
3) Contents	1. The Directive applies to the sound-power level of noise emitted into the environment, and the sound-pressure level of noise emitted at the operator's position of *earth-moving machines* used to perform work on civil-engineering and building sites. The four particular types of *earth-moving machines* are defined in detail. 2. The permitted sound-power level is between 106 dB(A)/1pW and 118 dB(A)/1pW according to the net installed power in kw of the machinery. All machines that comply will be issued with an EC type-examination certificate. 3. Member States must ensure that the marketing and use of earth-moving machines that do not comply with the Directive are prohibited. 4. Member States may limit the use of these machines in certain areas. 5. Six annexes containing technical information. 6. The Commission will submit to the Council before 29.6.90 a proposal aimed at introducing the real, dynamic method of measurement of airborne noise thus superceding the stationary method used at present
4) Deadline for implementing Member State legislation	29.12.88
5) Application date (if different from 4)	
6) Date for further coordinating proposal (if specified)	29.6.90
7) References	Council Adoption — Official Journal L 384, 31.12.86

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