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ADDENDUM: ANNEXE

WHITE PAPER

PREPARATION OF THE ASSOCIATED COUNTRIES OF CENTRAL AND EASTERN EUROPE FOR INTEGRATION INTO THE INTERNAL MARKET OF THE UNION

(presented by the Commission)

Free Movement of Capital

Free Movement and Safety of Industrial Products

Pages 1-48

FREE MOVEMENT OF CAPITAL

GENERAL INTRODUCTION

Whereas some decades ago, cross-border capital movements were, relative to merchandise trade or trade in services, rather modest and often confined to a role of financing current account imbalances, capital movements have become the fastest growing type of cross-border transactions. Furthermore, the direction of interaction has gradually shifted: it is more and more international capital allocation which determines international exchange and interest rates and these in turn influence the direction and structure of international trade.

Large free international capital flows allow an optimal international allocation of capital, which is more independent from domestic savings conditions and thus increases efficiency and welfare.

At the same time, such liberalized capital flows have impinged on the instruments of domestic policy, in particular monetary and fiscal policy, and constrained national autonomy in this respect.

The liberalization of this type of cross-border transaction within the Community, although it was one of the four freedoms enshrined in the Treaty of Rome, started more slowly than in the case of the other freedoms. Some of the reasons might have been the relatively minor economic importance of capital movements in the fifties and sixties, later the failed attempt by some Member States to address the macroeconomic imbalances after the first and second oil price shock by capital controls, and until the end of 1993 the somewhat weaker legal basis of this freedom within the Treaty.

DESCRIPTION OF THE LEGISLATION

The EU liberalized capital movements in steps:

A first Directive in 1960 which liberalized most long-term capital movements was supplemented by a second Directive in 1962 on securities trading.

In the seventies and early eighties, when Member States were reacting differently to the oil price shock and other problems, large cross-border capital movements were increasingly capable of threatening the internal balance of economies. However, attempts to control cross-border capital flows increasingly proved not only to be highly ineffective but also counter-productive.

Once those imbalances were corrected, the liberalization of all long-term and medium-term capital movements in 1986 and finally all short-term capital movements in 1988 proved to be highly successful. Not only did this opening not create any major imbalances for the countries involved, but also after the liberalization the countries taking these measures enjoyed typically a net capital inflow, as international capital markets felt comfortable about entering into commitments in these markets, and an overall increased efficiency of capital allocation in the EU was achieved.

This experience created the necessary confidence for the EU similarly to liberalize its capital movements vis-à-vis third countries, by virtue of the Treaty on European Union (Art. G 14) changing the EC Treaty.

EC legislative action in this field has been based on some general principles:

- effective removal of controls on capital and payments not only comprises respective foreign exchange restrictions, but any kind of administrative regulation which effectively discriminates on the basis of the source or destination of the capital;
- the rights to such free transactions are conferred on residents, rather than nationals;
- not only are general prohibitions ruled out by this freedom, but equally any, explicit or implicit, authorization procedures.
- some general exceptions to this freedom continue to be applied. These exceptions include national security and public policy, but do not extend to broader economic interests, such as national interest or monetary policy.

However, the EU experience has to be seen in the light of the changes taking place in international finance. Capital movements have increased out of proportion over the last twenty years, transaction costs have decreased, and international competition for capital inflows has stiffened. Thus liberalization measures become even more critical for attracting foreign capital, for linking into the international economy and for facilitating the growth of a competitive financial sector. This is the obvious experience of a number of non-EU countries which liberalized capital movements in the late eighties and early nineties.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

- A clear and reliable regulatory framework for foreign investment has to be established; in particular clear investment protection guarantees and other parameters important for foreign investors, such as tax legislation.

- Furthermore, a sufficiently efficient and open financial market, in particular the banking system and some forms of securities markets, has to be established in order to ensure that flows are channelled into productive investment.

- Finally a set of instruments for monetary policy has to be developed which allow monetary aggregates to be controlled under the condition of open capital markets.

- There are no particular regulatory or institutional pre-conditions for the liberalization of capital movements: the immediate implication of removing capital controls is to lessen the need for enforcement and hence for administrative structures. The enforcement of capital controls, however, may serve secondary purposes, such as the collection of data on capital flows. When capital controls are removed, it will probably be necessary to put in place alternative administrative arrangements for collecting data.

- The most significant impact of removing capital controls, in particular on short-term operations, is not on administrative structures, but on policy management. In the absence of controls, large outflows or inflows of capital may occur which complicate monetary and exchange rate policy. Policy-makers have to cope with the repercussions on growth, inflation and the current account. To do so, they need to have appropriate policy instruments at their disposal.

  Thus, legislative approximation in this field pre-supposes an overall stable macroeconomic environment, in order to avoid the danger of unmatched capital flight and consequently balance of payments problems.

KEY MEASURES

Given the relative homogeneity of capital, its high mobility and the substitutability between different forms of capital movements, the liberalization commitment and strategy have to be sufficiently consistent and complete, and not only address foreign exchange regulation but the whole set of regulations effectively governing the legal and economic feasibility of capital movements. Thus, a distinction between key and non-key measures is not very meaningful in this area.

- ### *CHOICE OF STAGE I MEASURES*

  DESCRIPTION AND JUSTIFICATION

  The first step for the CEECs would be to liberalize unconditionally their current payments and their medium- and long-term capital movements, that is, of a maturity of more than one year.

  These operations are crucial to other forms of cross-border operations, such as trade in goods and services. Furthermore, normally they do not pose major problems for the conduct of exchange rate or monetary policy. Finally, they are necessary in order to establish the linking of the country into the international capital markets and to generate capital inflows.

  However it should be borne in mind that the classical distinction between long-term and short-term capital movements has, in the wake of innovations on financial markets, such as derivatives on long-term financial contracts, partly lost its meaning. So-called long-term operations are nowadays partly carried out on a very short-term basis, and, on the other hand, restrictions on short-term capital movements have increasingly worked as a deterrent for foreign, even long-term, capital inflow.

Thus the sequencing of liberalization within the Community partly reflected the economic and political reality and the development of the financial markets of the sixties and seventies. As this situation has changed, the actual sequencing of liberalization measures in this field might follow different patterns, which take into account the specificity of the economy and the financial system.

STAGE I MEASURES

Long-term capital movements

First Directive of 11 May 1960 (OJ No 43 of 12 July 1960)	First Council Directive of 11 May 1960 for the implementation of Article 67 of the EEC Treaty
Directive 63/21/EEC (OJ No 8 of 22 January 1963)	Second Council Directive 63/21/EEC of 18 December 1962

Medium-term capital movements

Council Directive 86/566/EEC (OJ No L 332/22 of 26 November 1986)	Council Directive 86/566/EEC of 17 November 1986 amending the First Directive of 11 May 1960 for the implementation of Article 67 of the Treaty

explanatory note:

These three Directives only addressed medium and long-term capital movements. They have been abrogated by Council Directive 88/361/EEC (see stage II measures), which liberalised all forms of capital movements.

Consequently, an equivalent reference for the approximation of legislation would be those parts of the legal acts mentioned under "Stage II measures", that relate to medium and long-term capital movements (as listed under items I, II, III, IV, VII.2, VII.3, VIII.2, VIII.3, IX, X).

- ***CHOICE OF STAGE II MEASURES***

DESCRIPTION AND JUSTIFICATION :

The second and final step of approximation of legislation on capital movements comprises short-term capital movements, the transfer of assets of a maturity of less than one year, such as the admission of, and trade in, money market securities, the opening of deposit accounts abroad and the physical export and import of money.

This second step effectively links the respective country fully into the international financial markets and establishes full capital account convertibility. This step is necessary to achieve the efficient allocation of capital in this country, to support the efficiency of financial markets by cross-border financial services provisions, and to establish sufficient confidence on the part of national and international investors in their ability to re-export such funds, without which such capital will not be attracted in the first place.

This stage requires a sufficient degree of macroeconomic stability and sophistication of monetary policy instruments. Furthermore, the preconditions mentioned above should be fully met. It might be noted that countries with strict exchange controls have often used these controls to implement other objectives, and the complete abolition of controls sometimes shows up gaps in the basic legal framework. Thus, for instance, measures on money laundering, tax evasion etc. will need to stand alone and not depend exclusively on exchange control regulations

Furthermore this stage would include any remaining restrictions on real estate investment, in particular as regards residential real estate purchased by foreigners.

The general relaxation of capital controls will necessitate the adoption of stand-alone legislation for certain special occurrences, such as the application of UN or Community decisions on financial sanctions.

STAGE II MEASURES

all, including short-term, capital movements

Council Directive 88/361/EEC (OJ No L 178 of 8 July 1988) *superseded by the* EC Treaty, Articles 73b - h	Council Directive of 24 June 1988 for the implementation of Article 67 of the Treaty *superseded by the* Treaty establishing the European Community, Chapter 4 (Capital and Payments), Articles 73b - h

REMAINING MEASURES, NOT IDENTIFIED UNDER PREVIOUS HEADINGS:

Effective material freedom of capital movements depends, to a greater or lesser degree, on a large number of other regulatory parameters in related fields, which are primarily based on other considerations.

Such measures may include:

- the taxation of capital income at the corporate and personal level, on a worldwide basis. The conclusion of effective double-taxation agreements can effectively alleviate distorting effects from the tax system.
- the system of prudential supervision of institutional investors (in particular provisions on foreign assets or assets held in foreign currencies). Here a balance has to be struck between justified prudential concerns and openness to foreign capital markets.
- The establishment of sufficiently effective cross-border payment systems
- In order to provide effective material freedom of, mainly inward, foreign direct investment a reassessment of present public monopolies might be indicated. Furthermore, the conclusion of investment protection agreements, entailing a high degree of liberalization and protection, facilitates the inflow and outflow of this type of capital movement.

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GENERAL INTRODUCTION

The principle of mutual recognition of legally marketed goods, technical harmonisation of legislation and mechanisms to prevent the erection of new barriers to trade, such as the information procedure under the 83/189 Directive, constitute the instruments to ensure free circulation of goods within the territory of the Union.

Technical harmonisation is intended to remove regulatory barriers to trade by bringing about convergence in national technical legislation, intended to ensure the achievement of public policy goals such as public health, safety and environmental protection.

In elaborating its technical harmonisation legislation, the Union has adopted two different philosophies, the so-called **New Approach** and a **Sectoral Approach**, which by their different means aim to attain the objective of free circulation.

The technical harmonisation measures described in the following pages are grouped as appropriate under these two different chapters.

I. Prevention of new barriers to trade

INTRODUCTION

New barriers to trade must be prevented in order to ensure that the internal market operates correctly, allowing the parties concerned to tackle and solve any difficulties which might arise as a result of national technical regulations.

To this end, Directive 83/189/EEC is an essential instrument for the management of the internal market. In particular, it guarantees the transparency required in respect of new national technical specifications and makes it possible to eliminate or reduce as far as possible any difficulties which these measures may cause in trade between the Member States of the European Union.

DESCRIPTION OF THE LEGISLATION

Field of application: The procedure for the provision of information in the field of standards and technical regulations laid down by Council Directive 83/189/EEC applies to technical specifications, the observance of which is compulsory *de jure* or *de facto*, in the case of marketing or use of a product in a Member State. The compulsory nature of draft technical regulations covered by the information procedure as distinct from standards (technical specifications, the observance of which is not compulsory) causes problems when it comes to interpreting the provisions of the Directive.

Administrative organization in the Member States: Implementation of the procedure for exchanging information between the Member States requires coordination between the various ministries likely to adopt draft technical regulations. In fact, the Commission requires establishment of a central unit, the composition and organization of which is decided upon by the Member State itself, to serve as a single point of contact with the Commission in order to ensure that the procedure works properly and fairly.

Monitoring the procedure: These central units are responsible for informing and notifying the Commission of draft regulations and must follow the procedure laid down in the Directive. This imposes obligations in terms of deadlines and response to the various reactions from the Commission and/or the Member States to the notified drafts.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

Initially, alignment within the framework of Directive 83/189/EEC should be based not on strict implementation of the Directive by the Central and East European countries (CEECs) but on the establishment of a comparable system for the exchange of information between these countries. Subsequently this should lead to the signing of an agreement between the Union and these countries so that both sides have access to information on technical regulations relating to products. The aim is to achieve transparency and to prevent any obstacles to trade between the two sides.

This means that before legislation can be aligned the CEECs must establish a procedure similar to that laid down by Directive 83/189/EEC which will apply to national draft technical regulations relating to products. Drafts will have to be notified and sent to partner countries irrespective of their effect on trade. Similarly, there will have to be an automatic obligation to postpone adoption for three months after the regulation has been notified to give time for any reactions.

Establishment of a procedure between the CEECs for the exchange of information on technical regulations implies the political will of each of these countries to disclose all their future technical legislation so as to allow other countries to become involved and comment on the content of their drafts. In order to achieve this, these countries must use the same criteria for defining the legal categories concerned and distinguishing between technical standards and technical regulations, making provision for exchange of information on those categories of provision taken by the authorities in the Member State concerned where this is compulsory.

Another potential stumbling block - and this also applies to the Member States of the European Union - is that in order to apply the procedure correctly it is necessary for the government of each country concerned to establish a suitable structure for centralizing the exchange of information, coordinating the position of the country in question and circulating information to the ministries responsible for the preparation of technical regulations.

In order to achieve the main objective, which is to ensure mutual transparency between the CEECs and the European Union, it is necessary to set up two comparable systems so that administrative channels can be established between the two systems without interfering with their own internal procedures. Once this inter-communication is established, the CEECs, like the Member States of the Union, will have to accept that the other side is able and entitled to make comments and request changes to draft technical regulations which could create barriers to trade between themselves and the Union.

KEY MEASURES

- ***CHOICE OF STAGE I MEASURES***

DESCRIPTION & JUSTIFICATION :

Directive 83/189/EEC, as amended, is the only measure laying down a procedure for the provision of information in the field of standards and technical regulations which applies across the board. As such, it should be one of the Stage 1 measures once the essential preconditions for application of the legislation have been fulfilled.

STAGE I MEASURES

Information procedure:

Directive 83/189/EEC OJ L 109 of 26.04.1983, p.8 as amended by Directive 88/182/EEC OJ L 81 of 26.03.1988, p.75 and, Directive 94/10/CEE OJ L100 of 19.04.1994, p. 30	Directive 83/189/CEE of 28 March 1983 laying down a procedure for the provision of information in the field of standards and technical regulations.

II. The New Approach Directives

INTRODUCTION

The Council Resolution of 7 May 1985 on the "New Approach to technical harmonisation and standards" laid down the main lines of this approach to European technical legislation. In contrast with the detailed, product-based Directives of the Sectoral Approach, New Approach Directives are limited to fixing essential requirements on general issues such as safety, health and environment for large families of products and/or for horizontal risks. Voluntary standards, drafted by private-sector European standardization bodies, offer suitable, but not compulsory, technical solutions to meet the essential requirements. Products manufactured in conformity with the essential requirements of the directives can be marketed anywhere in the territory of the European Union. Assessment of conformity with the essential requirements is governed by the "global approach to conformity assessment", adopted through the Council Resolution of 21 December 1989. This provides specific conformity assessment procedures and the institution of independent "notified bodies", mainly from the private sector, authorised to carry out the conformity assessment procedures.

A list of documentary sources on the New and Global Approach is annexed to this chapter.

The effective operation of all the Directives, but particularly those of the New Approach, depends on the existence of an infrastructure of bodies, rules and relationships typical of a market economy. Without these infrastructures, which are particularly concerned with regulatory enforcement, market surveillance, standardization and conformity assessment, the Directives would not achieve their goals. Attention has therefore been paid to these pre-conditions in describing the acquis of the European Union.

DESCRIPTION OF LEGISLATION

Since 1985 a series of Directives have been adopted under the New Approach. They regulate families of products, such as pressure vessels, machinery, personal protective equipment, medical devices, non-automatic weighing instruments, appliances burning gaseous fuels, construction products and equipment for use in potentially explosive atmospheres. Directives on electromagnetic compatibility (EMC) and the 1973 low voltage Directive (LVD), a forerunner of the New Approach, cover horizontal risks. Proposals for new legislation are pending before the EU Council of Ministers concerning, for instance, pressure equipment.

Although the experience with the application of New Approach Directives has some common characteristics, a number of specificities for single measures are worth being mentioned.

EU experience with the application of the Directives on **electromagnetic compatibility, machinery, personal protection equipment, gas appliances** and **pressure vessels** shows that:

- high priority must be given to a timely implementation of the Directives, also through the finalisation of harmonised standards,

- problems with the application of the Directives often result from differing interpretation or misunderstanding of the provisions of the Directives, and,

- supplementary measures are needed to ensure a coherent application, such as informal meetings of all parties concerned: Member States, representatives of manufacturers, standardisation organisations, competent and notified bodies. Such meetings aim to establish guidelines which reflect a common understanding on all upcoming issues.

As far as the **low voltage** Directive is concerned, experience shows that the general operating of this Directive is satisfactory. This is also due to the large number of harmonised standards available today (over 500). Here, too, problems linked to the adoption of the new CE-marking regulation, scope and overlapping are handled within a Commission's working group, which involves all interested parties (public authorities, industry, consumers, trade associations, standardisation bodies). Discussions within this group will help the Commission elaborate written guidelines reflecting a common understanding on all relevant issues.

In the sector of **legal metrology,** one "New Approach" Directive and 20 old style Directives (one framework Directive plus 19 product directives) are currently in force, dealing each with a specific type of measuring instrument.

Because of the difficulty to keep all measures up-to-date with technological progress and to regulate the whole spectrum of measuring instruments subject to legal control, the old style directives, based on OIML recommendations, will be replaced by the year 2002 by a New Approach Directive, called the Measuring Instruments Directive, currently under preparation. This Directive, which is intended to replace all (with the exception maybe of one or two) of the old style directives, will prescribe essential requirements for instruments, make reference to voluntary standards for presumption of conformity and apply conformity assessment procedures foreseeing a Quality Assurance approach. Also, it is the intention that the existing New Approach directive will be absorbed by this new directive. The proposal for this new directive will be transmitted to Parliament and Council in early 1996.

As to the **ATEX** Directive, legislative harmonisation is reached both by the old style directives and by the New Approach one. The first category makes a strict reference to European standards which, through legislative procedures (involving a Committee for adaptation to technical progress), become part of the directive. In fact they replace its technical annex. These directives will be replaced in the year 2003 by the New Approach directive which defines the essential safety requirements to be met by products before placing on the market/putting into service and the certification procedures to be applied by manufacturers.

With the New Approach directive, technical harmonisation will be achieved by the technical specifications prepared by the standardisation bodies with the aim of covering the essential requirements of the Directive. The application of these "harmonised standards" by the manufacturers is voluntary.

A lot of experience has been gained through the application of the old style directives in the ATEX field. Problems occurring are dealt with in existing committees, or expert's working groups, in which the Commission is totally involved. Also the Commission's working party (HOTL - heads of testing stations), intended to co-ordinate the activities of notified bodies and which meets since more than twenty years, is a key element for a proper operation of the system. The New Approach Directive, which is now at the stage of implementation, tried to follow as closely as possible the existing systems and to foresee a sufficient transitional period for introducing eventual changes. During this period a coherent set of new harmonised standards should be adopted.

Concerning **construction products**, the New Approach directive is based on six essential safety and health requirements with which construction products must comply. Although the Directive officially came into effect on 27 June 1991, it can not actually be implemented until various measures now in preparation have been completed.

One first measure, which has already been adopted, is the publication of interpretative documents. Although required by the Directive, these are not binding in nature but constitute a link between the essential requirements with which these products must comply and the European technical specifications which will apply to products. A set of 33 provisional remits for construction products have been sent to the European Committee for Standardization (CEN).

Before the Directive can actually be appled, it is necessary :

- to decide on procedure for certifying the compliance of each product or group of products;

- for the Member States to provide lists of certification bodies, inspection bodies and the test laboratories authorized to carry out the tasks specified in the Directive;

- to decide on European technical specifications, so that those products complying with the specifications can bear an EC trade mark which will allow their free movement, marketing and use.

Until these conditions are met only partial alignment of legislation will be possible. Moreover, it has not yet been possible to try out the whole process.

Pre-conditions for application of New Approach Directives

Legislative alignment involving also technical harmonisation is a complex process where the Member States change or adapt their former rigid system (for instance, mandatory application of national requirements) to a new system, whose objective is to suppress in an effective manner barriers to trade and allow free movement of products within the Union.

Legislative harmonisation is reached by New Approach Directives which state essential safety requirements to be met by products before placing on then the market, and certification procedures to be applied by manufacturers. Technical harmonisation is achieved through technical specifications prepared by standardisation bodies with the aim of covering the essential requirements of the directives. These specifications are called "harmonised standards". Their application by manufacturers is voluntary but confer on the product a presumption of conformity with the essential requirements.

Therefore, a correct application of the directives requires the responsibilisation of accreditation authorities, the nomination of notified bodies, and the preparation of harmonised standards. The latest has proven to be slower than expected.

Adequate market surveillance through enforcement authorities is also a condition for the implementation of the legislation.

A. Standardization

1. Standardization provides a link between the regulator, the producer and the European market, and is characteristic of the European Union's economic and technical environment. In the first stage of integration much will therefore depend on the efforts to bring the CEECs systems of standardization into line with that in the European Union.

   The defining characteristics of standardization, as distinct from regulation, are that standardization is a process based on consensus of interested parties rather than being centrally dictated by authorities and is for voluntary application by economic operators rather than for mandatory application enforced by the public authorities. It will be very important for CEECs to devote efforts to ensuring that this can happen in practice as well as in theory. The granting of a substantial measure of independence to bodies charged with drawing up specifications and the insistence that economic operators are free to chose whether to use these specifications are sufficiently different from the experience of industry under centrally planned economies that positive action will no doubt be required to ensure that remnants of earlier attitudes do not result in undue rigidity in the system.

Achieving the full benefits of this approach can be expected to be difficult where standards bodies remain (as is still the case in some CEECs countries) an arm of government. Such a situation does not fit easily with the concepts of consensus of all parties, regulatory, industrial and user, and of allowing standards to be voluntary documents. It is important that regulators do not regard technical regulation as "one step better than a standard" but as something different in both intention and content; that industry does not expect to win favours from government for being compliant and learns to express itself freely. Thus the CEECs are faced with the task of replacing mandatory specifications with limited regulation accompanied by voluntary European specifications.

Changes in attitudes cannot be done quickly, and legislative or other governmental action are only one element in producing them. Nevertheless, as a first step it will be necessary to ensure that standards bodies have at least "arm's length" autonomy or preferably, independence from Government and the bodies themselves should include representatives from industry and other groups such as the "social partners" in their governing and technical bodies. Furthermore, the authorities should commit themselves openly and firmly to the principle that standards are voluntary and should allow the makers of standards the latitude to adapt their attitudes towards regulation.

2. The first stage for development of the European Union approach to standardisation is for the countries concerned to have standardization bodies with the appropriate class of membership of CEN, CENELEC or ETSI (usually CEN or CENELEC Affiliate, or ETSI National Standards Organisation), that these bodies should be charged by their national authorities with the task of preparing specifications by consensus, coherently with regulatory requirements but intended for voluntary application, and should be capable in practice of carrying out the national work necessary to implement those European and international standards that are used in the context of European policy. Such bodies require the capacity to reach consensus, to formulate national viewpoints, to carry out public enquiry, to transpose European standards as national standards, to ensure that no new national standards are introduced at the preparation phase of the European standard, to transpose European standards into national standards without change, and to withdraw conflicting national standards. Such standards bodies must be capable of covering the entire scope of the European standards bodies, CEN, CENELEC and ETSI.

3. The second stage will involve the complete adoption of the corpus of European standards as voluntary national standards. By this stage, it, will be necessary for the national standards bodies to be playing a full part in the work of the European standards bodies and to have undertaken the full obligations of members. This will imply that the basic measures described above will all have been taken, and that the standards bodies have the full capability to undertake the necessary actions.

B. Conformity assessment

1. A general precondition for the alignment of conformity assessment is respect for the related principles established in the WTO TBT Code, specifically as follows,

- There should be transparency in the regulatory system. A key step towards transparency would be the putting in place of a consultative system to ensure that specific regulations will not cause unnecessary barriers to trade. This function is ensured within the Union by Directive 83/189/EEC.

- Regulations should be restricted to the protection of public policy interests, such as safety, and the protection of health, the environment and consumers. Accordingly, conformity assessment procedures to demonstrate compliance with regulations should be appropriate to the nature of risks involved, and should avoid imposing unnecessarily onerous procedures. Conformity assessment activities based on recognised international systems (e.g. ISO/CASCO) should, as far as possible, be included in regulations themselves.

- The development of conformity assessment bodies that are competent, in terms of experience, human resources, facilities and organisation, and that are independent of the regulatory authorities, is vital. Further, it is essential that there should be convergence between conformity assessment practices in the regulatory field and those in the voluntary field. PHARE programmes in the field of quality (PRAQ 91 and 92) and the bilateral programmes with each CEECs country offer an opportunity to co-operate in work to this end.

2. Policies relating to conformity assessment in the EU have as a cornerstone the Commission Communication to the Council submitted on 15 June 1989, "A global approach to certification and testing-quality measures for industrial products" and the Council Resolution of 21st December 1989 on the Global Approach. Since then, great experience has been gained in the EU in this area. From this it is clear that priority should be given to the application of the modules in technical legislation, the application of the EN ISO 9000 and EN 45000 series of standards, and the promotion of mutual recognition agreements in the voluntary area. In relation to the accreditation principles, three directives in the chemical field should be considered. Directive 87/18/EEC, Directive 88/320/EEC and Directive 90/18/EEC on Good Laboratory Practices, in this field, complement the applicable conformity assessment procedures.

   The two policy documents mentioned above should guide the authorities of the CEECs in the conformity assessment area. The Council Decision of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking which are intended to be used in technical harmonisation directives (93/465/EEC), should be incorporated in due form into CEECs technical legislation.

3. These measures should be complemented by the setting up of a system of market surveillance in line with the EU system. The following EU measures will contribute to the overall operation of this system:

   - The Council Directive of 29 June 1992 on general product safety (92/59/EEC).
   - The Council Regulation of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries (339/93/EEC).

4. Difficulties which will need to be overcome by the CEECs countries in adapting their conformity assessment regulations and systems include:

   - the need for the authorities to abandon the practice of involvement in the control of product quality characteristics that are related to free trade;
   - excessively centralised existing conformity assessment activities;
   - insufficiency and obsolescence of means in testing and metrology;
   - lack of involvement with international conformity assessment activities;
   - the need to develop a culture in which the conformity assessment bodies see themselves as serving industry and helping it to solve its problems.

   The two PHARE regional programmes, PRAQ 91 and 92, and the bilateral programmes address many of the points mentioned in this section. They are mainly addressed to conformity assessment bodies and industry.

C. Market surveillance

EU technical harmonization directives replace national regulations and provide for a high level of protection of the public interest. They prescribe the characteristics to be fulfilled by products, so that they may be placed on the market and enjoy free circulation. They rely on enforcement measures to be taken by Member States to ensure that only those products which conform to the appropriate requirements can be placed on the market.

No directives, except in the foodstuffs sector and, partially in that of pharmaceuticals, harmonize enforcement activities. The obligation to control the market is mentioned as an objective of the directives themselves.

To achieve this objective Member States are obliged:

- to adopt appropriate legislation providing for legal sanctions against fraud and non-conformity with legislative requirements;
- to establish specialized laboratories (public or private) that are able to assess the conformity of products with legislation;
- to train enforcement officers in order to control products already on the market; and,
- to set up enforcement programmes that indicate the products to be controlled over a certain period, the frequency and nature of controls, etc.

The laboratories and officers should be separate from those that certify the conformity with legislation during the phases of design and production (i.e. notified bodies under the New Approach directives). Market surveillance usually involves sampling, instructions to bring products into line with requirements, withdrawal from the market, and perhaps the banning of the product.

At the EU level, the Council has called for co-operation between the administrations responsible for enforcement (Resolution of 16 June 1994). The aim of this administrative co-operation is to develop progressive, reliable and user-friendly communication and a data exchange system between the 15 Administrations and the Commission.

A practical example of pre-conditions for alignment: the sector of medical devices

Taking the sector of medical devices as an example, legislative alignment requires as pre-conditions:

- the adoption of rules to govern the marketing of products: these would be a set of rules which apply to the marketing of medical devices designed to guarantee the protection of the health and safety of patients and users; many Member States of the Union apply these rules in the framework of Community harmonization;
- the establishment of a market control infrastructure: Community legislation requires that the Member States appoint authorities to be responsible for monitoring products on the market; sectoral directorates establish a monitoring system which entails the establishment by manufacturers of procedures for notifying unwelcome incidents to a central body in each Member State; where necessary this control body is required to take measures to protect the public interest;
- the availability of a competent certification infrastructure; the directives follow the New Approach; the use of notified certification bodies is optional, although these do have an advantage for the industry in the area concerned; if a Member State decides to designate such bodies it must ensure that they are continuouly inspected and monitored; the notified bodies must be competent in terms of the technology concerned and all the relevant protection requirements so as to be able to adapt certification procedures for medical devices/quality systems to legal requirement or, where there are none, to voluntary standards;
- the availability of a standardization infrastructure; since these directives follow the New Approach it is essential that there should be a voluntary standardization organization;
- the adoption by industry of good manufacturing practice procedures; in the case of manufactured products, industry must be able to comply with safety requirements and with conformity assessment procedures; for a large proportion of these products this implies that industry should establish and apply quality assurance systems which meet standards EN 29000 and EN 460001/2.

  The industry prefers this conformity procedure to product certification although, because of the risks involved, it accepts this too.

It is essential for the industry to have a high-level organizational infrastructure within the European industrial federations as a means of cooperation so that undertakings can keep abreast of technological developments and changes in regulations in the sector.

KEY MEASURES

The measures listed below represent most of the New Approach acquis. They cover the main areas of product legislation and have a major impact on the free movement of safe industrial products within the Union.

- ***CHOICE OF STAGE I MEASURES***

DESCRIPTION & JUSTIFICATION :

All these directives are one-off measures. They are therefore recommended for adoption as stage I measures, once the pre-conditions for their operation are met.

They regulate, respectively, the maximum electromagnetic disturbance generated by the apparatus and the safety requirements of low voltage electrical equipment, machinery, personal protective equipment, appliances burning gaseous fuels, simple pressure vessels, active implantable medical devices and medical devices in general, recreational craft, non-automatic weighing instruments, equipment and protective systems intended for use in potentially explosive atmospheres and construction products.

STAGE I MEASURES

Electromagnetic Compatibility (EMC) :

Council Directive 89/336/EEC OJ.L 139, 23/05/89 amended by Directive 92/31/EEC of 28 April 1992 (OJ. L 126, 12/05/92) Directive 93/68/EEC of 22 July 1993 (OJ.L 220, 30/08/93)	Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility.

Low Voltage Directive (LVD) :

Council Directive 73/23/EEC (OJ.L 77, 26.3.1973) amended by Directive 93/68/EEC of 22 July 1993 (OJ.L 220, 30/08/93)	Council Directive 73/23/EEC of 19 February 1973 on the approximation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits.

Machinery :

Directive 89/392/EEC (OJ L 183, 29.6.89) amended by - Directive 91/368/EEC (OJ L 198, 22.7.91), - Directive 93/44/EEC (OJ L 175, 19.7.93), - Directive 93/68/EEC (OJ L 220, 30.08.93) horizontal on CE marking.	Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of Member States relating to machinery.

Personal Protective Equipment :

Directive 89/686/EEC (OJ L 399, 30.12.89) amended by - Directive 93/95/EEC (OJ L 276, 09.11.93), - Directive 93/68/EEC on EC marking (see above)	Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of Member States relating to personal protective equipment.

Gas Appliances :

Directive 90/396/EEC (OJ L 196, 26.7.90, p. 15) amended by Directive 93/68/EEC of 22 July 1993 (OJ.L 220, 30/08/93)	Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of Member States relating to gas appliances burning gaseous fuels.

Pressure Vessels :

Directive 87/404/EEC (OJ L 220, 8.8.87, page 48) amended by Directive 93/68/EEC of 22 July 1993 (OJ.L 220, 30/08/93)	Council Directive 87/404/EEC of 25 June 1987 on the harmonisation of the laws of Member States relating to simple pressure vessels.
Proposal for a Council directive * COM(93)319 final - SYN 462 O.J. C 246 of 9/9/93 amended by COM (94) 218 O.J. 207 of 27/7/94	Proposal for a Council directive COM(93)319 final of 14.7.93 on the approximation of the laws of Member States concerning pressure equipment .

Medical Devices :

Directive 90/385/EEC (O.J. n. L 189 of 20.07.90) amended by Directive 93/68/EEC of 22 July 1993 (OJ.L 220, 30/08/93)	Council Directive 90/385/EEC of 20.6.90 on the approximation of the laws of the Member States relating to active implantable medical devices.
Directive 93/42/EEC (O.J. n. L 169 of 12.07.93)	Council Directive 93/42/EEC of 14.06.93 concerning medical devices.

Recreational Craft :

Directive 94/25/EC (O.J. n. L 164 of 30.06.94)	Directive 94/25/EC of the European Parliament and of the Council of 16.06.94 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft.

Legal Metrology :

Directive 90/384/EEC (O.J. n. L 189 of 20.7.90) amended by Directive 93/68/EEC of 22 July 1993 (OJ.L 220, 30/08/93)	Directive 90/384/EEC of 20.6.90 on the harmonisation of the laws of the Member States relating to non-automatic weighing instruments.

Equipment for use in potentially explosive atmospheres (ATEX) :

Directive 94/9/EC (O.J. n. L 100 of 19.4.94)	Council Directive 94/9/EC of 23.03.94 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres.
Directive 76/117/EEC (OJ L 24 of 31.01.1976)	Cuncil Directive 76/117/EEC of 18 December 1975 concerning electrical equipment for use in potentially explosive atmospheres.
Directive 79/196/EEC (OJ L 43 of 20.02.1979)	Council Directive 79/196/EEC of 6 February 1979 concerning electrical equipment for use in potentially explosive atmospheres employing certain types of protection.
Directive 82/130/EEC (OJ L 59 of 02.03.1982)	Council Directive 82/130/EEC of 15 February 1982 concerning electrical equipment for use in potentially explosive atmospheres in mines susceptible to firedamp.

Construction Products :

Directive 89/106/EEC (O.J. n. L 40 of 11.02.89) amended by Directive 93/68/EEC of 22 July 1993 (OJ.L 220, 30/08/93)	Council Directive 89/106/EEC of 21.12.88 on the approximation of the laws, regulations and administrative provisions of the Member States relating to construction products.

DOCUMENTARY SOURCES ON THE NEW AND GLOBAL APPROACH

Titles	Publications
White Paper on the completion of Internal Market (COM(85)310 final)	
Council Directive of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (83/189/EEC)	O.J.. N°. L 109 of 26.04.83
Council Directive of 22 March 1988 amending Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations (88/182/EEC)	O.J.. N°. L 81 of 26.03.88
Directive 94/10/EC of the European Parliament and the Council of 23 March 1994 materially amending for the second time Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations	O.J. N°. L 100 of 19.4.94
Conclusions on standardisation approved by the Council on 16 July 1984 (85/C136/02)	O.J. N°. C 136 of 04.06.85
Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards (85/C/136/01)	O.J. N°. C 136 of 04.06.85
Commission Communication to the Council submitted by the Commission on 15 June 1989 "A global approach to certification and testing quality measures for industrial products" (COM (89) 209 final - SYN 208 (89/C 267/03)	O.J. N°. C 267 of 19.10.89
Council Resolution of 21 December 1989 on a global approach to conformity assessment (90/C 10)	O.J. N°. C 10 of 06.01.90
Council Decision of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonisation directives (90/683/EEC)	O.J. N°. L 380 of 31.12.90

Council Decision of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the EC conformity marking, which are intended to be used in the technical harmonisation directives (93/465/EEC)	O.J. N°. L 220 of 30.8.93
Commission Communication of the development of European Standardisation - Action for faster technological integration in Europe (90/C 20/01) (Green Paper on standardisation)	O.J. N°. C 20 of 28.01.91
Commission Communication - Standardisation in the European Economy (Follow-up to the Commission Green Paper of October 1990) (92/C 96/02)	O.J. N°. C 96 of 15.04.92
Council Resolution of 18 June 1992 on the role of European standardisation in the European economy	O.J. N°. C 173 of 09.07 92
Council Directive of 29 June 1992 on general product safety (92/59/EEC)	O.J. N°. L 228 of 11.08.92
Council regulation of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries (339/93/EEC)	O.J. N°. L 40 of 17.02.93
Council Directive (93/68/EEC) of 22.07.93 amending Directives: 87/404/EEC - simple pressure vessels, (O.J. L 220 8/8/87) 88/378/EEC - safety of toys, 89/106/EEC - construction products, 89/336/EEC - electromagnetic compatibility, 80/392/EEC - machinery 89/686/EEC - personal protective equipment, 90/384/EEC - non-automatic weighing instruments, 90/385/EEC - active implantable medicinal devices, 90/396/EEC - appliances burning gaseous fuels, 91/263/EEC - telecommunications terminal equipment, 92/42/EEC - new hot-water boilers fired with liquid or gaseous fuels 73/23/EEC - electrical equipment designed for use within certain voltage limits	O.J. N°. L 220 of 30.08.93

III. The Sectoral Approach Directives

INTRODUCTION

Before the introduction of the New Approach, product regulation in the European Community was pursued on a sectoral basis, through detailed directives laying down the technical specifications for certain categories of products, often combined with horizontal rules addressing general issues common to all categories.

This approach had been used both for industrial products which are now covered by the New Approach, and in respect of foodstuffs, pharmaceuticals, motor vehicles and chemical products, i.e. sectors where public health and safety are directly concerned. Conformity assessment was carried out by public authorities and regular adaptation to technical progress by way of legislative modifications was necessary. The difficulty of regulating all products and keeping specific directives up-to-date paved the way to a change in the legislative approach in favour of deregulation and flexibility.

Many of the measures adopted in the above sectors are still in force because they are seen as the most appropriate instruments of regulating the products concerned.

The most obvious difference between the New Approach and the Sectoral Approach is that, under the latter, sectors are not regulated through a common model. Thus, regulation of each sector follows an ad hoc pattern, and specific infrastructures are necessary to support and implement the specific regulatory framework of each sector.

1. Type-approval system for motor vehicles and their trailers

DESCRIPTION OF THE LEGISLATION

Operation of the EU Type-Approval System

Framework Directive

In accordance with the General Programme for Elimination of Technical Barriers to Trade of 1969, Directive 70/156/EEC on the approximation of the laws of the Member States relating to the type-approval of motor vehicles intended for use on road, having at least four wheels and a maximum design speed exceeding 25 km/h, and their trailers, was issued in February 1970. This Directive has been amended on a number of occasions, most importantly by Directive 92/53/EEC.

The central objective of this "framework Directive" is to establish a system whereby a vehicle whose type was approved in one Member State of the EC as being in conformity with an exhaustive set of uniform technical requirements should be eligible for free trade throughout the Community without further testing.

The framework Directive replaces national type-approval systems with an EC type-approval procedure and is based on total harmonisation, i.e. respect for EC requirements is a mandatory condition for the registration of new vehicles. The whole vehicle type-approval system will become mandatory for new types of M_1 vehicles on January 1, 1996.

Separate Directives and Technical Requirements

Technical requirements are laid down in separate directives (see Stage II). These directives generally contain the regulatory requirements to be met and the relevant testing procedures. The actual testing is the competence of "technical services" which refer to "approval authorities" (see description of national regulatory system). Both are appointed by the Member State in accordance with the rules laid down in the framework directive and are notified to the Commission and the other Member States. A notified technical service is presumed to satisfy the harmonized standards on the operation of testing laboratories (EN 45001) but, where appropriate, the Commission may request Member States to provide supporting evidence.

Documentation

The system relies on considerable mutual trust between the authorities involved which is a prerequisite for the functioning of the procedures. The EC Type-Approval Procedure is based on a specific amount of documentation papers which pass from one authority to another in order to assure adequate information.

Equivalence between EC Separate Directives and UN-ECE Regulations

An important feature of the EC type-approval system is that system, component and technical unit approvals based on international or third country regulations can, under certain conditions, be accepted as equivalent to separate directive approvals. This applies to regulations adopted under the 1958 Agreement of the UN-ECE[1]. The UN-ECE regulations accepted as equivalent to EC separate directives are listed in Part II of Annex IV to Directive 92/53/EEC (as last amended by Directive 93/81/EEC).

[1] Agreement Concerning the Adoption of Uniform Conditions of Approval and Reciprocal Recognition of Approval for Motor Vehicle Equipment and Parts.

There are, however, important differences between the EC type-approval System and the UN-ECE system:

- whereas the EC type approval system focuses on the approval of a vehicle type as a whole, the UN-ECE system is based on the approval of vehicle sub-systems and components.

- whereas the provisions of EC type approval directives are binding for all Member States, countries that are parties to the 1958 Agreement are free to decide whether to apply an individual regulation or not. Application of a regulation means that the Contracting Party has to accept approvals granted by all other signatories in accordance with that regulation (mutual recognition) and that it must be able to grant the approval markings for the motor vehicle equipment and parts covered by the regulation if a manufacturer applies for these. However, a Contracting Party applying a regulation is not obliged to impose the requirements of the regulation on its domestic market.

- whole vehicle type approval is only provided for by the EC type approval system, not by the UN-ECE 1958 Agreement.

The EU experience for alignment is that the new country must be a signatory to the UN-ECE Regulations in order to establish a recognised testing and approval system. Apart from Bulgaria, all CEECs countries are signatories to the 1958 Agreement but the extent to which they apply the individual regulations varies greatly among them.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

The National Regulatory Systems Required

Legislative approximation in this field pre-supposes the existence of national regulatory systems. These include rule-making and rule-implementing authorities as well as the necessary administrative procedures.

The *rule making ministry* (Ministry of Transport) sets the regulatory framework. It has to appoint a *type approval authority* (for instance the Kraftfahrtbundesamt in Germany or the Swedish Road Administration), responsible for all aspects of the type-approval of a vehicle, system, component or separate technical unit. The approval authority has the responsibility to issue type-approval certificates, to verify the existence of satisfactory arrangements for ensuring compliance of production with the approved type and to take appropriate measures to ensure continued conformity of production with the approval certificates (conformity of production assessment). It also serves as the contact point with approval authorities in other Member States. The type-approval authority appoints a *technical service* (for instance the T.Ü.V. in Germany or the Swedish Motor Vehicle Inspection), which is responsible for the approval tests required in the framework Directive and the separate directives. The type approval authority can also carry out the approval tests itself.

Technical and legislative assistance will be required in order to enable all CEECs to create a national regulatory system meeting the requirements of the type approval system within the EU.

The creation of such a regulatory framework is the prerequisite for the adoption of the framework Directive, the requirements of which are relevant for all separate directives.

KEY MEASURES

The key measures listed below represent the total acquis in this sector. Their implementation is indispensable to ensure the proper functioning of the EC type-approval system.

- ***CHOICE OF STAGE I MEASURES***

  DESCRIPTION & JUSTIFICATION :

  In order to establish a recognised testing and approval system, the implementation of both the framework directive, the requirements of which are relevant for all separate technical directives, and all UN-ECE Regulations equivalent to EC separate directives is essential. Therefore these measures have been selected as stage I measures.

STAGE I MEASURES

Directive 70/156/EEC O.J. L 42, 23.2.1970 as amended by Directive 92/53/EEC O.J. L 225, 10.8.1992 and Directive 93/81/EEC O.J. L 264, 23.10.93	First Council Directive 70/156/EEC of 6 February 1970 on the Approximation of the Laws of the Member States relating to the Type-Approval of Motor Vehicles and their Trailers.
All UN-ECE Regulations equivalent to EC separate directives	

- ***CHOICE OF STAGE II MEASURES***

  DESCRIPTION & JUSTIFICATION :

  In order to have a whole vehicle type-approval system, it is necessary that all separate directives are applied. These lay down the regulatory technical requirements for construction and safety, as well as the relevant testing procedures.

STAGE II MEASURES

Subjects	Directive Numbers	Official Journal reference	Applicability									
			M_1	M_2	M_3	N_1	N_2	N_3	O_1	O_2	O_3	O_4
1. Sound levels	70/157/EEC	L 42, 23. 2. 1970, p. 16	x	x	x	x	x	x				
2. Emissions	70/220/EEC	L 76, 6. 4. 1970, p. 1	x	x	x	x	x	x				
3. Fuel tanks/rear protective devices	70/221/EEC	L 76, 6. 4. 1970, p. 23	x	x	x	x	x	x	x	x	x	x
4. Rear registration plate place	70/222/EEC	L 76, 6. 4. 1970, p. 25	x	x	x	x	x	x	x	x	x	x
5. Steering effort	70/311/EEC	L 133, 23. 6. 1970, p. 10	x	x	x	x	x	x	x	x	x	x
6. Door latches and hinges	70/387/EEC	L 176, 10. 8. 1970, p. 5	x	x	x	x	x	x	x	x	x	x
7. Audible warning	70/388/EEC	L 176, 10. 8. 1970; p. 12	x	x	x	x	x	x				
8. Rear visibility	71/127/EEC	L 68, 23. 3. 1971, p. 1	x	x	x	x	x	x				
9. Braking	71/320/EEC	L 202, 6. 9. 1971, p. 37	x	x	x	x	x	x	x	x	x	x
10. Suppresion (radio)	72/245/EEC	L 152, 6. 7. 1972, p. 15	x	x	x	x	x	x				
11. Diesel smoke	72/306/EEC	L 190, 20. 8. 1972, p. 1	x	x	x	x	x	x				
12. Interior fittings	74/60/EEC	L 38, 11. 2. 1974, p. 2	x									
13. Anti-theft	74/61/EEC	L 38, 11. 2. 1974, p. 22	x	x	x	x	x	x				
14. Protective steering	74/297/EEC	L. 165, 20. 6. 1974, p. 16	x			x						
15. Seat strength	74/408/EEC	L 221, 12. 8. 1974, p. 1	x	x	x	x	x					
16. Exterior projections	74/483/EEC	L 256, 2. 10. 1974, p. 4	x									
17. Speedometer and reverse gear	75/443/EEC	L 196, 26. 7. 1975, p. 1	x	x	x	x	x					
18. Plates (statuory)	76/114/EEC	L 24, 30. 1. 1976, p. 1	x	x	x	x	x	x	x	x	x	x
19. Seat belt anchorages	76/115/EEC	L 24, 30. 1. 1976, p. 6	x	x	x	x	x					
20. Lighting installations	76/756/EEC	L 262, 27. 9. 1976, p. 1	x	x	x	x	x	x	x	x	x	x
21. Reflex reflector	76/757/EEC	L 262, 27. 9. 1976, p.	x	x	x	x	x	x	x	x	x	x
22. Lamps (side, rear,stop)	76/758/EEC	L 262, 27. 9. 1976, p. 54	x	x	x	x	x	x	x	x	x	x
23. Direction indicators	76/759/EEC	L 262, 27. 9. 1976, p. 71	x	x	x	x	x	x	x	x	x	x
24. Lamps (number plate)	76/760/EEC	L 262, 27. 9. 1976, p. 85	x	x	x	x	x	x	x	x	x	x
25. Lamps (including bulbs)	76/761/EEC	L 262, 27. 9. 1976, p. 96	x	x	x	x	x					
26. Fog lamps (front)	76/762/EEC	L 262, 27. 9. 1976, p. 122	x	x	x	x	x					
27. Towing hooks	77/389/EEC	L 145, 13. 6. 1977, p. 41	x	x	x	x	x					
28. Fog lamps (rear)	77/538/EEC	L 220, 29. 8. 1977, p. 60	x	x	x	x	x	x	x	x	x	x
29. Lamps (reversing)	77/539/EEC	L 220, 29. 8. 1977, p. 72	x	x	x	x	x	x	x	x	x	x
30. Lamps (parking)	77/540/EEC	L 220, 29. 8. 1977, p. 83	x	x	x	x	x					
31. Seat belts	77/541/EEC	L 220, 29. 8. 1977, p. 95	x	x	x	x	x					
32. Forward vision	77/649/EEC	L 267, 19. 10. 1977, p. 3	x									
33. Identification of controls	78/316/EEC	L 81, 28. 3. 1978, p. 3	x	x	x	x	x					
34. Defrost / demist	78/317/EEC	L 81, 28. 3. 1978, p. 27	x	x[1)]	x[1)]	x[1)]	x[1)]					
35. Wash / wipe	78/318/EEC	L 81, 28. 3. 1978, p. 49	x	x[2)]	x[2)]	x[2)]	x[2)]					
36. Heating systems	78/548/EEC	L 168, 26. 6. 1978, p. 40	x									
37. Heel guards	78/549/EEC	L 168, 26. 6. 1978, p. 45	x									
38. Head restraints	78/932/EEC	L 325, 20. 11. 1978, p. 1	x									
39. Fuel consumption	80/1268/EEC	L 375, 31. 12. 1980, p. 36	x									
40. Engine power	80/1296/EEC	L 375, 31. 12. 1980, p. 46	x	x	x	x	x					
41. Diesel emissions	88/77/EEC	L 36, 9. 2. 1988, p; 33	x	x	x	x	x					
42. Lateral protection	89/297/EEC	L 124, 5. 5. 1989, p. 1					x	x			x	x
43. Safety glass	92/22/EEC	L 129, 14. 5. 1992, p. 11	x	x	x	x	x	x	x	x	x	x
44. Masses and dimensions (cars)	92/21/EEC	L 129, 14. 5. 1992, p. 1	x									
45. Tyres	92/23/EEC	L 129, 14. 5. 1992, p. 95	x	x	x	x	x	x	x	x	x	x
46. Couplings	94/20/EEC	L 195, 29.7.1994, p.1.	x	x	x	x	x	x	x	x	x	x
47. Anti-spray devices	92/226/EEC	L 103, 24. 4. 1981, p. 5					x	x			x	x
48. External projections of cabs	92/114/EEC	L 409, 31. 12. 1992, p. 17				x	x	x				
49. Speed limiters	92/24/EEC	L 129, 14. 5. 1992, p. 154			x	x	x					
50. Masses & dimension (other than vehicles referred to)	*											
51. Flammability	*											
52. Buses and Coaches	*											
53. Front impact	*											
54. Side impact	*											
55. Animal transport vehicles	*											
56. ADR vehicles	*											

2. Type-approval of two and three wheel motor vehicles - safety and environmental requirements

DESCRIPTION OF THE LEGISLATION

In accordance with the General Programme for removal of technical barriers to trade of 1969, a framework Directive (Directive 92/61/EEC) relating to the type-approval of two and three-wheel motor vehicles was adopted on 30 June 1992. The key objective of this framework Directive is to establish a system whereby a vehicle type, which was approved to be in conformity with a complete set of uniform technical requirements in one Member State of the EU, should be eligible for free trade throughout the EU without any further testing in any of the other Member States.

The framework Directive replaces national type-approval systems with an EC type-approval procedure and is based on total harmonisation, i.e. respect of EC requirements is a mandatory condition for the registration of new vehicles. The whole vehicle type-approval system will become mandatory for new types of two and three wheel vehicles as soon as the last separate directive enters into force. These separate directives contain the regulatory technical requirements to be met and the relevant testing procedures.

An important feature of the EC type-approval procedure is that component and separate technical unit approvals, based on international or third country regulations, can be considered to be equivalent to approvals granted on the basis of EC Directives.

The EU experience for alignment is that new countries must be contracting parties to the UN/ECE 1958 Agreement concerning the adoption of uniform conditions of approval and reciprocal recognition of approval for motor vehicle equipment and parts, in order to establish a recognised testing and approval system.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

Legislative approximation in this field pre-supposes the existence of national regulatory systems, as described in the previous chapter on motor vehicles and their trailers.

The actual testing is the competence of technical services which refer to approval authorities. Both are appointed by the Member States, in accordance with the rules laid down in the framework Directive, and are notified to the Commission and to the other Member States. Their tasks are the same as those described in the chapter on motor vehicles and their trailers.

KEY MEASURES

The key measures listed below represent the total acquis in this sector. Their implementation is indispensable to ensure the proper functioning of the EC type-approval system.

- ***CHOICE OF STAGE I MEASURES***

DESCRIPTION & JUSTIFICATION :

In order to establish a recognised testing and approval system, the implementation of both the framework directive, the requirements of which are relevant for all separate technical directives, and all UN-ECE Regulations equivalent to EC separate directives is essential. Therefore this measure has been selected as stage I measures.

STAGE I MEASURES

Directive 92/61/EEC O.J. L 225,10.8.1992	Directive 92/61/EEC of 30.6.92 relating to the type-approval of two and three-wheel motor vehicles.
All UN-ECE Regulations equivalent to EC separate directives	

- ***CHOICE OF STAGE II MEASURES***

DESCRIPTION & JUSTIFICATION :

In order to have a whole vehicle type-approval system, it is necessary that all separate directives are applied. These lay down the regulatory technical requirements for construction and safety, as well as the relevant testing procedures.

STAGE II MEASURES

Council Directive 93/14/EEC OJ L121, 15.05.1993	Council Directive 93/14/EEC of 5.04.1993 on braking of two or three-wheel motor vehicles.
Council Directive 93/29/EEC OJ L188, 29.07.93, p. 11	Council Directive 93/29/EEC of 14.06.1993 relating to the identification of controls, tell-tales and indicators for two or three-wheel motor vehicles.
Council Directive 93/30/EEC OJ L188, 29.07.93, p. 11	Council Directive 93/30/EEC of 14.06.1993 on audible warning device for two or three-wheel motor vehicles.
Council Directive 93/31/EEC OJ L188, 29.07.93, p. 19	Council Directive 93/31/EEC of 14.06.1993 on stands for two-wheel motor vehicles.
Council Directive 93/32/EEC OJ L188, 29.07.93, p. 28	Council Directive 93/32/EEC of 14.06.1993 on passenger hand-holds of two-wheel motor vehicles.
Council Directive 93/33/EEC OJ L188, 29.07.93, p. 32	Council Directive 93/33/EEC of 14.06.1993 on protective devices intended to prevent the unauthorized use of two or three-wheel motor vehicles.
Council Directive 93/34/EEC OJ L188, 29.07.93, p. 38	Council Directive 93/34/EEC of 29.10.1993 on statutory markings for two or three-wheel motor vehicles.
Council Directive 93/92/EEC OJ L311, 14.12.93, p. 1	Council Directive 93/92/EEC of 29.10.1993 on the installation of lighting and light signalling devices on two or three-wheel motor vehicles.
Council Directive 93/93/EEC OJ L311, 14.12.93, p. 76	Council Directive 93/93/EEC of 29.10.1993 on masses and dimensions of two or three-wheel motor vehicles.
Council Directive 93/94/EEC OJ L311, 14.12.93, p. 83	Council Directive 93/94/EEC of 29.10.1993 on space for mounting the rear registration plate of two or three-wheel motor vehicles.
Council Directive 95/1/EEC OJ L52, 8.03.95, p. 1	Council Directive 95/1/EEC of 2.02.1995 on maximum design speed, maximum torque and maximum net engine power.

DESCRIPTION OF THE LEGISLATION

Dangerous preparations : The Directive on dangerous preparations (mixtures of chemical substances that are dangerous to human beings and/or the environment) is intended to harmonize the following:

1. The classification of dangerous substances as a function of the level of danger that they display;

2. their labelling in order to ensure the safety of the persons handling them;

3. their packaging.

The Directive also incorporates calculation methods enabling an assessment to be made of the health hazards presented by a preparation. The greatest difficulties in implementing that directive arise with small and medium-sized businesses (SMBs). SMBs have fewer technical and financial resources for compiling the safety data sheets required by law, the content of which has been standardized at world level, although the aspects linked with the classification, labelling and packaging of pesticides, which are currently covered by Directive 78/361/EEC of 26 June 1978, could, in the long term, be covered by Directive 88/379/EEC on dangerous preparations.

Restrictions on the marketing of dangerous preparations and substances: Harmonization in this area relates to the action to be taken by the Member States in order that the substances set out in the Annex to the directive are only marketed under certain conditions. The Directive on marketing restrictions requires a certain level of supervision by the Member States. There is no obligation as regards the action to be taken. Member States are free to select and implement the structure which to them seems to be the most adequate. The responsibility for supervision that is incumbent upon a Member State may also be assumed by a centralized or decentralized administration or even be delegated to a competent independent body. The solutions available vary widely from one Member State to another. As a general rule those bodies carry out downstream checks on the market.

Detergents : European directives in this area have enabled biodegradability thresholds to be set for detergents (anionic, cationic, nonionic and ampholytic surfactants) and also analytical methods to be used in order to measure biodegradability (anionic and nonionic surfactants). The transposition of European directives at national level enables the "foaming" effects of certain detergents to be combated. Thought is currently being given to updating all of the directives.

Fertilizers: Harmonization with regard to fertilizers is not mandatory, but optional. It is aimed at virtually all fertilizers, while the categories still not covered continue to be so by the national laws. It has been possible to define forms of action to apply to the composition, detonability and analytical and sampling methods designed for checks on simple ammonium-nitrate-based fertilizers and high-nitrogen-content fertilizers. Compliance with the European directives enables the "EEC fertilizer" label to be obtained.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

Dangerous preparations: The Directive 88/379/EEC on dangerous preparations makes specific reference to the Directive on the packaging, labelling and classification of dangerous substances (67/548/EEC) (see contribution under Environment). Indeed the following are considered to be dangerous:

- preparations of which at least one of the constituent substances are classified as being dangerous by Directive 67/548/EEC;
- preparations considered to be dangerous according to the methods referred to in the Directive on dangerous preparations.

These two conditions are cumulative and not alternative. It is thus necessary to transpose Directive 67/548/EEC simulatneously, or indeed in advance.

As regards the implementation of said Directive 88/379/EEC, Article 12 of said Direcive 88/379/EEC provides that bodies be set up in the Member States that are responsible for receiving information on health. These are bodies of the "poison antidote centre" type.

Restrictions on the marketing of dangerous preparations and substances: the existence of national laws restricting or banning the marketing of certain substances, and also laws on the bodies responsible for conducting market checks in order to ensure that the Regulations are properly applied, are a desirable prerequisite.

Detergents and fertilizers: no specific conditions.

KEY MEASURES

The Directives selected below constitute a comprehensive entity and represent the core of the chemical laws in force. Certain chemical products (solvents) which had been covered by separate directives, are now covered by the dangerous preparations Directive.

- *CHOICE OF STAGE I MEASURES*

DESCRIPTION & JUSTIFICATION :

Owing to their repercussions on both health and the environment and on the proper functioning of the internal market, the laws on chemical products can only be implemented in several stages. They therefore constitute a block, and it is suggested that they be adopted in Stage I.

STAGE I MEASURES

Dangerous preparations:

Directive 88/379/EEC OJ L 187/14, 16.07.88 as last amended by Directive 93/18, OJ L 104 - 29.4.93 as last supplemented by Directive 93/112 OJ L 314 - 16.12.93	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.

Marketing restrictions :

Directive 76/769/EEC OJ L 262/201, 27/09/76, as last amended by Directive 94/60 OJ L 365 - 31/12/94	Directive 76/769/EEC of 27 July 1976 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.

Detergents :

Directive 73/404/EEC OJ L 347/51, 17/12/73	Directive 73/404/EEC of 22 November 1973 on the approximation of the laws of the Member States relating to detergents. This Directive deals with the ban on the use and marketing of detergents where the average biodegradability of the anionic, cationic, nonionic and ampholytic surfactants that they contain is less than 90%.
Directive 73/405/EEC OJ L 347/53, 17/12/73 supplemented by Directive 82/243/EEC, 31 March 1982 OJ L 109/1, 22/04/82	Directive 73/405/EEC of 22 November 1973 on the approximation of the laws of the Member States relating to methods of testing the biodegradability of anionic surfactants. This Directive specifies the analytical methods to be used for anionic surfactants, and prohibits the marketing and use of a detergent if its average biodegradability is less than 80%.
Directive 82/242/EEC OJ L 109/18, 22/04/82	Directive 82/242/EEC of 31 March 1982 on the approximation of the laws of the Member States relating to methods of testing the biodegradability of non-ionic surfactants and amending Directive 73/404/EEC. This Directive deals with the ban on the marketing and use of detergents if the measured biodegradability of the non-ionic surfactants that they contain is less than 80% when the analytical methods specified by the Directive are used.

Fertilizers :

Directive 76/116/EEC adopted OJ L 24/21, 30/01/76 and last amended and supplemented by Directive 93/69 OJ L 185, 28/7/93	Directive 76/116/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to fertilizers.
Directive 77/535/EEC OJ L 213/1, 22/08/77 as last amended by Directive 93/1, OJ L 113, 7/5/93	Directive 77/535/EEC of 22/6/77 on the approximation of the laws of the Member States relating to methods of sampling and analysis for fertilizers.
Directive 80/876/EEC OJ L 250/7, 23/09/80	Directive 80/876/EEC of 15/7/80 on the approximation of the laws of the Member States relating to straight ammonium nitrate fertilizers of high nitrogen content.
Directive 87/94/EEC OJ L 38/1, 07/02/87	Directive 87/94/EEC of 8/12/86 on the approximation of the laws of the Member States relating to procedures for the control of characteristics of, limits for and resistance to detonation of straight ammonium nitrate fertilizers of high nitrogen content.

4. Foodstuffs

DESCRIPTION OF THE LEGISLATION

In 1985, the EU abandoned its previous approach of detailed harmonisation of individual product requirements in favour of a horizontal approach based on the harmonisation of the essential provisions necessary to ensure the safety of foodstuffs, consumer information and protection and the necessary level of official control. Subsequently, detailed legislative provisions have been laid down in respect of food additives, flavours, extraction solvents, materials in contact with foodstuffs, contaminants, food labelling, and nutritional labelling, food hygiene and on official control. This legislation forms a single framework for the effective control of foodstuffs, and it is not possible to prioritise between different provisions. It would, therefore, be necessary to expect the CEECs to move towards the adoption of this legislation as soon as possible, and if not during the first stage, then as soon as possible thereafter. However, consideration would need to be given to various transitional arrangements to take account of the factors outlined below.

On the other hand, the implementation of Community legislation dealing with specific categories of products, such as foodstuffs for nutritional purposes, quick-frozen foodstuffs and the seven so-called vertical directives relating to honey, sugar, preserved milks, coffee extracts, chocolate, fruit juices and jams could be held over to a later stage.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

Legislative approximation in this field pre-supposes the existence of appropriate national regulatory systems, notably through the establishment of risk assessment and risk management systems, and through the development of appropriate systems of regulatory supervision, notably in respect of the official control of foodstuffs. A modern conception of food legislation places increasing emphasis on a self-regulatory approach, i.e. on the responsibilities of manufacturers to develop appropriate systems of hazard analysis and critical control points **(HACCP),** while emphasising the importance of the role of the **official inspection services** in verifying the adequacy of such systems, in accordance with Directive 89/397/EEC.

KEY MEASURES

Most of the legislation regulating the foodstuffs sector was included as key measures. The non-binding measures as well as the existing legislation on additives which will be repealed or replaced by the new legislation were left out of the core acquis.

- *CHOICE OF STAGE I MEASURES*

DESCRIPTION & JUSTIFICATION :

The horizontal legislation on food additives, flavours, extraction solvents, materials in contact with foodstuffs, contaminants, food labelling and nutritional labelling, food hygiene and official control forms a single framework for the effective control of foodstuffs. All the measures listed below are therefore recommended for adoption as stage I measures.

STAGE I MEASURES

Food labelling :

Directive 79/112/EEC OJ L 33, 8.02.1979 as amended by Directive 85/7 (OJ L 002, 3.1.85) Directive 86/197 (OJ L 144, 29.5.86) Directive 89/395 (OJ L 186, 30.6.89) Directive 91/72 (OJ L 42, 15.2.91) Directive 93/102 (OJ L 291, 25.11.93)	Directive 79/112/EEC of 18 December 1978on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate customer.
Directive 89/396/EEC OJ L 186, 30/06/89 as amended by Directive 91/238 (OJ L 107, 27/04/91) Directive 92/11 (OJ L 65, 11/03/92)	Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs.
Directive 90/496/EEC OJ L 276, 06/10/1990	Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs.

Food additives :

Directive 89/107/EEC OJ L 40, 11.02.1989 as amended by Directive 94/34 (OJ L 237, 10.09.94)	Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption.
Directive 94/35/EC OJ L 237, 10.09.1994	Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs.
Directive 94/36/EC OJ L 237, 10.09.1994	Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs.
Directive 95/2/EEC OJ L 61 - 18.3.95	Directive 95/2/EC of 20 December 1995 on food additives other than colours and sweeteners.

Flavourings :

Directive 88/388/EEC OJ L 184, 15.07.1988 as amended by Directive 91/71 (OJ L 42, 15.02.91)	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.

Materials and articles in contact :

Directive 89/109/EEC OJ L 40, 11.02.89	Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs.
Directive 90/128/EEC OJ L 75 21/03/90 as amended by Directive 92/39 (OJ L 168, 23.06.92) Directive 93/9 (OJ L 90, 14.04.93)	Directive 90/128/EEC of 23 February 1990 relating to plastics materials and articles intended to come into contact with foodstuffs.
Directive 84/500/EEC OJ L 277, 20.10.84	Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.

Official control :

Directive 89/397/EEC OJ L 186, 30.03.89 as amended by Directive 93/99/EEC OJ L 290, 24.11.93	Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs.

Hygiene:

Directive 93/43/EEC OJ L 175, 19.07.93	Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs.

Contaminants :

Regulation 315/93 OJ L 37, 13.2.93	Regulation 315/93 of 8 February 1993 on contaminants of food.
Regulation 3954/87 OJ L 371, 30.12.87	Regulation 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency.
Directive 88/344/EEC OJ L 157, 24.06.88 as amended by Directive 92/115 (OJ L 409, 31.12.92) Directive 94/52 (OJ L 331, 21.12.94)	Directive 88/344/EEC of 13 June 1988 on the approximation of the laws of the Member States of extraction solvents used in the production of foodstuffs and food ingredients.

- *CHOICE OF STAGE II MEASURES*

DESCRIPTION & JUSTIFICATION :

The adoption of the legislation dealing with specific categories of products, such as foodstuffs for nutritional purposes and quick-frozen foodstuffs, regulating purity criteria and testing migration, the vertical directives on honey, sugars, preserved milks, coffee and chicory extracts, cocoa and chocolate, fruit juices and jams, or the legislation on natural mineral waters or on caseins and caseinates.

STAGE II MEASURES

Directive 83/463/EEC OJ L 255, 15.09.83	Directive 83/463/EEC of 22.07.1983 on labelling, provisional measures for certain ingredients.
Directive 87/250/EEC OJ L 113, 30.04.87	Directive 87/250/EEC of 15.04.87 on alcoholic strength by volume in the labelling of alcoholic beverages.
Directive 81/712/EEC OJ L 257, 10.09.81	Directive 81/712/EEC of 28.07.81 on additives, verification of purity criteria.
Council Directive 65/66/EEC OJ 22, 09.02.65 as amended by Directive 67/428 (OJ 148 - 11.07.67) Directive 76/463 (OJ L 126 - 14.05.76) Directive 86/604 (OJ L 352 - 13.12.86)	Council Directive 65/66/EEC of 26.01.1965 on purity criteria for preservatives.
Council Directive 78/664/EEC OJ L 223, 14.08.78 as amended by Directive 82/712 (OJ L297 - 23/10/82)	Council Directive 78/664/EEC of 25.07.1978 on purity criteria for antioxidants.
Council Directive 78/663/EEC OJ L 223/78 of 14.08./78 as amended by Directive 82/504 (OJ L 230 - 05.08.82) Directive 90/612 (OJ L 326 - 24.11.90) Directive 92/4 (OJ L 55 - 29.02.92)	Council Directive 78/663/EEC of 25.07.1978 on purity criteria for emulsifiers, stabilizers, thickeners and gelling agent.
Directive 80/590/EEC OJ L 151, 19.06.80	Directive 80/590/EEC of 9.06.1980 determining the symbol that may accompany materials and articles intended to come into contact with foodstuffs.
Council Directive 78/142/EEC OJ L 44, 15.02.78	Council Directive 78/142/EEC of 30.01.1978 on vinyl chloride monomer.
Directive 80/766 OJ L 213, 16.08.80	Directive 80/766/EEC of 8.07.1980 on analysis of the vinyl chloride monomer level.
Directive 81/432 OJ L 167 of 24.06.81	Directive 81/432/EEC of 29.04.1981 on analysis for the official control of vinyl chloride.

Directive 82/711 OJ L 297 of 23.10.82 as amended by Directive 85/572 (OJ L 372, 31.12.85) Directive 93/8 (OJ L 90, 14.04.93)	Council Directive 82/711/EEC of 18.10.1982 on testing migration of the constituents of plastic materials and articles.
Directive 85/572 OJ L 372 of 31.12.85	Council Directive 85/572/EEC of 19/12/1985 concerning the list of simulants to be used for testing migration of the constituents of plastic materials and articles.
Directive 93/10 OJ L 93 of 17.04.93 as amended by Directive 93/111 (OJ L 310, 14.12.93)	Directive 93/10/EEC of 15/03/1993 on regenerated cellulose film.
Directive 93/11/EEC OJ L 93, 17.4.93	Directive 93/11/EEC of 15.3.93 on the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers.
Directive 85/591 OJ L 372 of 31.12.85	Council Directive 85/591/EEC of 20.12.1985 on the methods of sampling and analysis for the monitoring of foodstuffs.
Directive 89/108 OJ L 40 of 11/02/89 amended by Directive 92/1 (OJ L34 - 11/2/92) Directive 92/2 (OJ L34 - 11/2/92)	Council Directive 89/108/EEC of 21.12.1988 on quick-frozen foodstuffs.
Directive 76/621/EEC OJ L 202, 28.07.76	Council Directive 76/621/EEC of 20.07.1976 concerning the maximum level of erucic acid in oils and fats.
Directive 80/891/EEC OJ L 254, 27.09.80	Directive 80/891/EEC of 25.07.1980 on the method of analysis for determining the erucic acid content in oils and fats.

Directive 73/241/EEC OJ L 228, 16.08.73 as amended by Directive 74/411 (OJ L 221, 12/08/74) Directive 74/644 (OJ L 349, 28/12/74) Directive 75/155 (OJ L 64, 11/03/75) Directive 76/628 (OJ L 223, 16/08/76) Directive 78/609 (OJ L 197, 22/07/78) Directive 78/842 (OJ L 291, 17/10/78) Directive 80/608 (OJ L 170, 03/7/80) Directive 85/7 (OJ L 2, 3/1/85) Directive 89/344 (OJ L 142, 25/5/89)	Council Directive 73/241/EEC of 24.07.1973 concerning cocoa and chocolate.
Directive 73/437/EEC OJ L 356, 27.12.73	Council Directive 73/437/EEC of 11.12.1973 on sugars.
Directive 79/796/EEC OJ L 239, 22.09.79	Council Directive 79/796/EEC of 22.09.1979 on methods of analysis for certain sugars.

Council Directive 74/409/EEC OJ L 221, 12.08.1974	Council Directive 74/409/EEC of 22.07.1974 concerning honey.
Council Directive 93/77/EEC OJ L 244, 30.09.93	Council Directive 93/77/EEC of 21.9.93 concerning fruit juice.
Directive 93/45/EEC OJ L 159 of 01.07.1993	Council Directive 93/45/EEC of 17.06.1993 concerning manufacture of nectars.
Council Directive 79/693/EEC OJ L 205 of 13.08.1979 as amended by Directive 80/1276 (OJ L 375, 31.12.80) Directive 88/593 (OJ L 318 - 25.11.88)	Council Directive 79/693/EEC of 24.07.79 concerning fruit jams, jellies and marmalades and chesnut purée.
Council Directive 76/118/EEC OJ L 24 of 31.01.1976 amended by Directive 78/630 (OJ L 206, 29.7.78) Directive 83/635 (OJ L 357, 21.12.83)	Council Directive 76/118/EEC of 18.12.75 concerning preserved milk.
Directive 79/1067/EEC OJ L 327 of 24.12.1979	Directive 79/1067/EEC of 13.11.1979 concerning the methods of analysis for testing certain partly or wholly dehydrated preserved milk.
Directive 87/524/EEC OJ L 306, 28.10.87	Directive 87/524/EEC of 6.10.1987 concerning the sampling methods for the analysis or preserved milk products.
Council Directive 83/417/EEC OJ L 237, 26.08.1983	Council Directive 83/417/EEC of 25.07.1983 concerning lactoproteins (caseins and caseinates).
Directive 85/503/EEC OJ L 308, 20.11.1985	Directive 85/503/EEC of 25.10.1985 concerning the methods of analysis for edible caseins and caseinates.
Directive 86/424/EEC OJ L 243, 13/12/1986	Directive 86/424/EEC of 15.07.1986 concerning the methods of sampling for chemical analysis of edible caseins and caseinates.
Council Directive 80/777/EEC OJ L 229, 30.08.1980 as amended by Directive 80/1276 (OJ L 375, 31.12.80) Directive 85/7 (OJ L 2, 3.01.1985)	Council Directive 80/777/EEC of 15.07.1980 concerning the exploitation and marketing of natural mineral waters.
Council Directive 80/778/EEC OJ L 229, 30.8.80	Council Directive 80/778/EEC of 15.7.80 concerning the quality of water intended for human consumption.
Council Directive 77/436/EEC OJ L 172, 12.7.1977 as amended by Directive 85/7 (OJ L 2, 3.01.1985) Directive 85/573 (OJ L 372, 31.12.1985)	Council directive 77/436/EEC of 27.06.1977 concerning coffee extracts and chicory extracts.
Directive 79/1066/EEC OJ L 327, 24.12.1979	Directive 79/1066/EEC of 13.11.1979 on methods of analysis for testing coffee extracts and chicory extracts.

5. Medicines for human use

DESCRIPTION OF THE LEGISLATION

European Union medicine regulations concern medicines for human and veterinary use. The legislation concerning veterinary medicines has largely been inspired by that concerning medicines for human consumption. However, in order to take account of the specific aspects of both of these two bodies of rules have been drawn up. In addition, the ministers responsible are not always the same in certain Member States - a situation which might recur in the CEECs (e.g. Minister for Health for Human Medicines and Minister for Agriculture for Veterinary Medicines). This chapter will therefore be devoted to human medicines, while the one following will deal more specifically with veterinary medicines.

Pharmaceuticals is one of the most regulated sectors of the industry for public health and social security reasons. European harmonization of the national rules on the issue of marketing authorizations was completed in 1992. No medicine may be placed on the market in any Member States without receiving prior authorization from the authorities responsible, on completion of a procedure intended to demonstrate the quality, safety and effectiveness of the medicine in question. The tests intended to determine medicine quality, safety and effectiveness, several aspects of the authorization procedure applying to the marketing of medicines (limit dates, justification, publication) of manufacture (quality control, inspections) and of the marketing of medicines, (wholesale distribution, classification, labelling, advertising), are harmonized.

Community regulation of pharmaceuticals will henceforth extend to all industrially-produced medicines, including vaccines, blood-derived medicines and radio-pharmaceutical products.

In order to ensure harmonization of the individual sales authorizations, a new sales authorization system will have been introduced within the Union on 1 January 1995 and will centre upon the European Agency for the Evaluation of Medicinal Products. Depending upon the medicinal product concerned this new system will either permit direct access to the Community market on the basis of a Commission decision, or easier, quicker access to the various national markets on the basis of the principle of mutual recognition.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

In view of the specific nature of medicines and of precedence given to their public health aspects, the sale and production of medicinal products are subject to the issue of authorizations requiring:

- that the Community's *acquis*, or in other words all that the Community has achieved in this area the applied, thus guaranteeing that medicines meet the three scientific criteria of quality, safety and effectiveness when made available to patients;

- that national structures be set up in order to issue the sales authorizations based on those criteria;

- that the conditions under which these medicines are manufactured are at a high quality level as laid down in the guide to good manufacturing practice (BPF/GMP), and the setting up of an inspection structure that was responsible for issuing manufacturing authorizations.

The provisions of a legal framework guaranteeing protection of the intellectual property that is linked with medicinal products is also an essential prerequisite. The pharmaceuticals industry is particularly concerned by the true level of protection conferred by industrial property rights. All of the Member States have signed the Munich Convention, which grants formal protection for a twenty-year period (see contribution on intellectual, industrial and commercial property).

In actual fact this period of exclusive rights is reduced to roughly eight-ten years owing to the time needed for the development tests and then for obtaining a sales authorization. Since it is aware of the anomalous situation the Council has adopted Regulation 1678/92/EEC, which is intended to increase protection for pharmaceutical innovation by restoring some of the protection offered by pharmaceutical patents. Since 1993 a certificate granting an extension for a maximum of five years enables effective protection to be given for 15 years, dating from the first sales authorization within the Community.

It is clear that nothing can be done within the pharmaceutical sector unless the CEECs formally undertake unconditionally to accept and ensure adequate protection of medicines by means of patents.

Following the example of the Community, it is essential, with regard to economic regulation, that the national repayment systems and possibly the prices of medicines obey the rules of transparency: the requirement that individual decisions are justified, where those decisions are based on objective, verifiable criteria and on procedural rules (deadlines and advertising).

KEY MEASURES

Priority has always been given in the pharmaceuticals sector to the protection of patients. Thus the free movement of medicines for human use is inconceivable outside a context of harmonized public health rules. It is for this reason that all the Community has achieved in this area must be included in stages I and II.

- *CHOICE OF STAGE I MEASURES*

DESCRIPTION & JUSTIFICATION :

Distinguishing between action under Stage I and likewise under Stage II is particularly difficult in this sector. However, it may be felt that initially it is appropriate to take account of the horizontal directives on manufacturing authorizations, the selling of medicines, their marketing and also of that directive on the transparency of the national action taken on medicine prices and repayment.

STAGE I MEASURES

Council Directive 65/65/EEC (OJ No L 22, 9.2.65)	Council Directive 65/65/EEC of 26.1. 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.
Council Directive 75/319/EEC (OJ No L 147, 9.6.75)	Council Directive 75/319/EEC of 20.5.1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (with the exception of Chapter III - Committee on proprietary medicinal products) (With the exception of Chapter III - Committee on proprietary medicinal products)
Council Directive 75/318/EEC (OJ No L 147, 9.6.75)	Council Directive 75/318/EEC of 20.5.1975 on the approximation of laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products.
Council Directive 91/356/EEC (OJ No L 193, 17.7.91)	Council Directive 91/356/EEC of 13.6.91 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.
Council Directive 92/25/EEC (OJ No L 113, 30.4.92)	Council Directive 92/25/EEC of 31.3.92 on the wholesale distribution of medicinal products for human use.
Council Directive 92/26/EEC (OJ No L 113, 30.4.92)	Council Directive 92/26/EEC of 31.3.92 concerning classification for the supply of medicinal products for human use.
Council Directive 92/27/EEC (OJ No L 113, 30.4.92)	Council Directive 92/27/EEC of 31.3.92 on the labelling of medicinal products for human use and leaflets on package.
Council Directive 92/28/EEC (OJ No L 113, 30.4.92)	Council Directive 92/28/EEC of 31.3.92 on the advertising of medicinal products for human use.
Council Directive 89/105/EEC (OJ No L 40, 11.2.89)	Council Directive 89/105/EEC of 21.12.88 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national insurance systems.

- *CHOICE OF STAGE II MEASURES*

DESCRIPTION & JUSTIFICATION :

In addition to the horizontal directives mentioned above, Community pharmaceuticals legislation has taken account of the specific nature of certain medicines in Directives covering product types and needing to be included in Stage II. These Directives and regulations are listed below. It should also be borne in mind that the restrictive provisions applying to pharmaceuticals have been supplemented by a standard note to applicants for sales authorizations within the Community, and by guidance notes on the tests conducted prior to offering for sale.

The new system for authorizations to offer for sale mentioned above has been operational from 1.1.1995. It will therefore be appropriate to see to what extent the CEE countries join this system. If they do, there will of course be no doubts. On the other hand, even if there is very close association the question remains open. During the negotiations on the EEA Agreement this point caused difficulties and it seemed difficult purely and simply to extend these procedures to non-Member States.

STAGE II MEASURES

Council Directive 89/342/EEC (OJ No L 142, 25.5.89)	Council Directive 89/342/EEC of 3.5.89, extending the scope of Directives 65/65/EEC and 75/319/EEC, and providing for additional requirements concerning immunological medicines consisting of vaccines, toxins, serums or allergens.
Council Directive 89/343/EEC (OJ No L 142, 25.5.89).	Council Directive 89/343/EEC of 3.5.89, expanding the scope of Directives 65/65/EEC and 75/319/EEC, and providing for additional requirements with regard to radiopharmaceutical medicines.
Council Directive 89/381/EEC (OJ No L 181, 28.6.89)	Council Directive 89/381/EEC of 14.6.89, expanding the scope of Directives 65/65/EEC and 75/319/EEC and providing for special requirements with regard to medicines derived from human blood or plasma.
Council Directive 92/73/EEC (OJ No L 297, 13.10.92)	Council Directive 92/73/EEC of 22.9.92, expanding the scope of Directives 65/65/EEC and 75/319/EEC widening 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 medicinal products and laying down additional provisions on homeopathic medicinal products.

Council Directive 78/25/EEC (OJ No L 11, 14.1.78)	Council Directive 78/25/EEC of 12.12.77 on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products.
Council Regulation 2309/93/EEC (OJ No L 214, 24.8.93)	Council Regulation 2309/93/EEC of 22.7.93 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.
Council Directive 75/319/EEC (OJ No L 147, 9.6.75)	Council Directive 75/319/EEC of 20.5.75 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. (Chapter III - Committee on proprietary medicinal products)

6. Medicines for veterinary use

DESCRIPTION OF THE LEGISLATION

As stressed in Item 5 veterinary pharmaceutical legislation is largely inspired by the legislation on medicines for human use. The offering for sale of any veterinary medicine presupposes prior authorization. The authorization criteria are similar: quality, effectiveness and safety. The content of the latter criterion differs significantly as regards veterinary medicines since it is necessary to ensure that not only animals but also users and consumers of animal-based foods are protected. A more pressing problem, also, is that of the impact of veterinary medicines on the environment.

The procedures set up by the new system of sales authorizations within the Community, which enter into force on 1.1.95, also apply to veterinary medicines.

As stated above the safety criterion as applying to veterinary medicines is more far-reaching than in the case of human medicines. More particularly close attention is paid to protecting consumers of animal-derived foods. For this purpose the Community has armed itself with Council Regulation (EEC) No 2377/90 of 26 June 1990.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

In view of the prime consideration given the public health aspects of veterinary medicines intended for animals used for food, and of animal health, the manufacture and offering for sale of veterinary medicines are subject to the issue of authorizations requiring:

- application of those Community achievements in this area which guarantee that medicines meet the three scientific criteria of quality, safety and effectiveness when they are made available to their users;

- the provision of national structures for issuing sales authorizations on the basis of those criteria;

- conditions of manufacture of those medicines which meet the high level of quality laid down in the guide for good manufacturing practice (BPF/GMP) and the creation of an inspection structure for the issue of manufacturing authorizations.

The provision of a legal framework guaranteeing suitable protection of the intellectual property linked with medicines is also an essential prerequisite. The pharmaceutical industry is particularly concerned by the true level of protection provided by industrial property rights. All of the Member States are party to the Munich Convention which grants formal protection for a period of 20 years.

In fact this exclusive period of use is reduced to roughly 8-10 years owing to the time needed for the development tests, followed by the receipt of a sales authorization. Since it is aware of the anomaly in the situation the Council has adopted Regulation 1768/92/EEC, which is intended to provide increased protection for pharmaceutical innovation by means of restoring some of the protection provided by pharmaceutical patents. Since 1993 an extension certificate covering a maxium of 5 years enables effective protection of 15 years to be achieved, dating from the first sales authorization within the Community.

It is clear that nothing can be done within the pharmaceutical sector without the unfailing commitment of the Central and East European countries to recognizing and adequately protecting medicines by means of patents.

KEY MEASURES

Pharmaceutical legislation is intended to protect human and animal health. The free movement of medicines for veterinary use is thus inconceivable outside a context of harmonized rules. It is for this reason that all of the Community's achievements in this area must be included in stages I and II.

- ***CHOICE OF STAGE I MEASURES***

DESCRIPTION & JUSTIFICATION :

By analogy with human medicines it may be felt that it is suitable to take the horizontal legislation concerning manufacturing, marketing and sales authorizations in stage I.

STAGE I MEASURES

Council Directive 81/851/EEC (OJ No L 317, 6.11.81)	Council Directive 81/851/EEC of 28.9.81 on the approximation of the laws of the Member States relating to veterinary medicinal products (with the exception of chapter IV - Committee for Veterinary Medicinal Products) (with the exception of chapter IV - Committee for Veterinary Medicinal Products)
Council Directive 81/852/EEC OJ L 317, 6.11.81)	Council Directive 81/852/EEC of 28.9.81 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.
Council Directive 91/412/EEC (OJ No L 228, 17.8.91)	Council Directive 91/412/EEC of 23.7.91 laying sown the principles and guidelines of good manufacturing practice for veterinary medicinal products.

Council Regulation (EEC) 2377/90 (OJ No L 224, 18.8.90)	Council Regultion (EEC) 2377/90 of 26.6.90 laying down a Community procedure for the establishment of maximum residue limits for veterinary medicinal products in foodstuffs of animal origin. (11 regulations have already been adopted in order to implement this basic regulation)

- ***CHOICE OF STAGE II MEASURES***

DESCRIPTION & JUSTIFICATION :

The legal measures that are specific to the veterinary medicines to be included in stage II are listed below. As in the case of human medicines the restrictive provisions in the veterinary field have been supplemented by a notice to applicants for standard sales authorizations within the Community, by guidance notes on tests prior to products being offered for sale, and also by a handbook intended to guide establishment applicants on the maximum residue limits.

STAGE II MEASURES

COUNCIL REGULATION 2309/93/EEC (OJ No L 214, 24.8.93)	COUNCIL REGULATION 2309/93/EEC of 22.7.1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.
COUNCIL DIRECTIVE 81/851/EEC (OJ No L 317, 6.11.81)	COUNCIL DIRECTIVE 81/851/EEC of 28.9.81 on the approximation of the laws of the Member States relating to veterinary medicinal products. (Chapter IV - Committee for Veterinary Medicinal Products)
COUNCIL DIRECTIVE 92/74/EEC (OJ No L 297, 13.10.92)	COUNCIL DIRECTIVE 92/74/EEC of 22.9.92 . widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products.
COUNCIL DIRECTIVE 78/25/EEC (OJ No L 11, 14.1.78)	COUNCIL DIRECTIVE 78/25/CEE of 12.12.77 on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products.