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)

Environment

Direct Taxation

Free Movement of Persons

Public Procurement

Financial Services

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**GENERAL INTRODUCTION**

Environmental policy is an essential component of the creation of the Internal Market. Both policies are mutually supportive. This special relationship is already recognised in the Single European Act (Article 100a, paragraphs 3 and 4) and is reinforced by Article 2 of the Treaty on European Union, where it is clearly indicated that the completion of the Internal Market will be an important means to reach, inter alia, "a sustainable and non-inflationary growth respecting the environment".

Article 130r (2) provides, inter alia, that Community environment policy shall aim at a high level of protection and that it shall be based on the precautionary principle, of the polluter pays principle, and that environmental damage, as a priority, should be rectified at the source. It goes on to stipulate that environmental protection requirements must be integrated into the definition and implementation of other Community policies.

These tasks are in particular addressed in the 5th Community programme of policy and action in relation to the environment and sustainable development ("Towards Sustainability"), endorsed by the Council on 1 February 1993, which embodies a strategy and programme for environmental action to the end of the present century and beyond. The guiding principles are "shared responsibility", in terms of a broadly-based involvement, active participation and "integration" into all policies of all economic and social players, including local, regional and national administration.
An integrated approach, to enable a more sustainable path of social and economic development, is not only vital for the environment itself but also for the long-term success of the Internal Market. Its success is dependent on the sustainability of the policies pursued in the fields of industry, energy, transport, agriculture and tourism, which are in turn dependent on the capacity of the environment to sustain them.

1. **Environment and the Central and Eastern European countries**

These considerations are of particular relevance in the perspective of creating a European market between the European Union and the CEECs. In view also of the transeuropean, transboundary nature of environmental problems, it is of utmost importance that environmental considerations are from the very beginning part of the process of the commercial and economic integration of the Associated Central and Eastern European countries, as part of the pre-accession strategy. This is clearly expressed in the Europe Agreements where, in relation to 'Economic co-operation', it is stated that "policies and other measures will be guided by the principle of sustainable development. These policies ensure that environmental considerations are incorporated from the outset..." (Title VI, Article 1).

The necessity to give a high priority to the structured dialogue in the environmental field was particularly highlighted at the Joint Meeting of the Union's Council of Environment Ministers and the Environment Ministers from the Associated Central and Eastern European countries, which took place on 5 October 1994. Meetings of this kind are agreed to be held on an annual basis. In the conclusions, the Ministers recommend notably "to evaluate priorities for a programme aiming at the convergence of environmental policies and the approximation of the environmental legislation of the Associated states of Central and Eastern Europe."

2. **EU environmental legislation**

To date, EU legislation in the field of the environment comprises about 200 legal acts which cover a wide range of sectors, including water and air pollution, management of waste and chemicals, biotechnology, radiation protection and nuclear safety, and nature protection. Further to that, several horizontal measures relating, *inter alia*, to the environmental impact assessment of certain public and private projects and access to environmental information, have been adopted. Sector a) of the following is covered in depth in the following fiches. Sectors b), c), d) and e), a very important part of environmental legislation, falls outside the scope of this White Paper, and is therefore not included in the annex.

a) **Product-related environmental standards**

A substantive number of product-related harmonisation measures follow an environmental objective, whether they are based on Article 100a, or Article 130s. Under this heading comes legislation on chemicals (restrictions on marketing; classification and labelling; environmental control of existing and new substances; export/import of certain dangerous chemicals; ozone-depleting substances; genetically modified organisms; motor vehicle emissions, fuel standards, product-related noise, radiation protection and radioactive contamination of foodstuffs, and the transfer of waste.
These sectors, which are part of the core of the 'Internal Market' legislative body, are outlined in more detail in the descriptive part of this contribution.

However, these product-related legal acts cannot be seen in isolation from the overall environmental framework required to ensure the sustainability of the Internal Market. To illustrate this with the example of the waste sector, alignment of rules relating to the free circulation must go hand in hand with the establishment of a sound waste-management policy and legislation. This comprises, in particular, an integrated network of treatment facilities as well as the harmonisation of standards for the treatment of waste.

b) Legislation in relation to pollution from stationary sources

In general terms, approximation of legislation in relation to stationary sources is of importance not only from an environmental point of view, but also with a view to remedying to distortions of competition which would be created by differing environmental standards and regulations.

EU legislation on the environmental control of industrial installations includes:

- Council Directive 84/360/EEC (OJ L188 - 16/7/84) on combating air pollution from industrial plants, and its daughter Directives on large combustion plants, municipal waste incineration plants and hazardous waste incineration plants;

An important proposal on the integrated pollution prevention and control, to deal with all forms of pollution from stationary sources, is under discussion in the Council.

These measures are complemented by Council Regulation 1836/93/EEC of 28/6/93 (OJ L168 - 10/7/93) establishing a voluntary eco-audit scheme enabling firms to have their environmental performance certified.

c) Further legislation on air and water pollution

Legislation on emissions to the air from mobile and stationary sources is completed by air quality standards relating to SO2/particulates, NO2 and lead and Council Directive 92/72/EEC of 21 September 1992 (OJ L297 - 13/10/92) on air pollution by ozone, which also provide for monitoring and information exchange.
In relation to water pollution, in addition to those Directives relating to discharges from stationary sources, or pollution from specific industries, a number of legal acts lay down quality objectives or other requirements for water intended for specific uses; water for human consumption, bathing waters and the quality of water required for fish or shellfish.


d) Nature protection


In relation to international trade, Council Regulation 82/3626/EEC of 3 December 1982 (OJ L384 - 31/12/82), implementing the Washington Convention on international trade in endangered species of wild fauna and flora (CITES), subsequently added to by a series of modifications, is a central piece of EU legislation in this area.

e) Horizontal measures

A fundamental tool of environmental legislation is Council Directive 85/337/EEC of 27 June 1985 (OJ L175 - 5/7/85) on the assessment of the effects of certain public and private projects on the environment ('Environmental impact assessment'), which requires Member States to ensure that an environmental impact assessment is carried out before development consent is granted for the types of project specified in the Directive. Therefore, it is a basic tool to uphold the implementation of environmental legislation in general.

Lastly, the Directive 90/313/EEC of 7 June 1990 (OJ L158 - 23/6/90) on access to environmental information is to contribute to more transparency for the individual citizen, and the voluntary ecolabel scheme, established by Council Regulation 92/880/EEC, of 23 March 1992, contributes to 'informed choice' of consumers in relation to the environmental performance of products.

Conclusion

As is illustrated by the above, the present exercise covers only a small part of EU environmental legislation, namely those acts directly related to the free circulation of products. An important part of the EU environmental acquis relating to air and water pollution, to nature protection, but also to the overall framework for waste management, and horizontal instruments, falls out of the scope of the present document.
The "Internal Market" approach needs to be complemented by an overall assessment of present EU environmental policy and legislation in relation to the future approximation of laws by the Central and Eastern European countries, in order to define priorities within a timescale. This process will take some time, and needs to be followed up closely and in a coherent way in the frame of the structured dialogue, and in other fora like the 'Environment for Europe' process. In the meantime, the PHARE programme will continue to be used to improve the situation.

The major task will be to assist the Central and Eastern European countries in such a way that they will be able to take over EU legislation together with a system capable of practical implementation and enforcement.

I. RADIOACTIVE CONTAMINATION OF FOODSTUFFS

DESCRIPTION OF THE LEGISLATION

All foodstuffs placed on the market for human consumption and all animal feedingstuffs offered for sale have been required to comply with contamination limits since the Chernobyl accident and as a precautionary measure in the event of any future accident.

It has been found to be necessary for the proper management of Regulation 737/90/EEC for the Member States to submit regular reports of the measures carried out to the central body (the Commission).

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

An inspection and control system is essential for the application of the legislation. It must be possible to carry out tests, in the event of any future accident, to determine the level of (radioactive) contamination of food products available on the national market. Regulation Euratom/90/737 applies in the present situation following the Chernobyl accident and requires similar controls to be carried out at the external frontiers to determine the level of contamination of imported foodstuffs.

KEY MEASURES

In view of the implications of this legislation for public health, it is not possible to separate its various parts. It is a body of legislation within which individual measures cannot be categorized, in a hierarchy of importance, as being essential, a priority (Stage I) or a lower priority (Stage II).
CHOICE OF STAGE I MEASURES

DESCRIPTION & JUSTIFICATION:

Regulation EEC/90/737, which extends Regulation EEC/3955/87 and is due to expire on 31 March 2000, lays down the present conditions governing imports of agricultural products processed within the European Union following the Chernobyl nuclear accident. It specifies maximum permissible levels of radioactive contamination for a limited list of products to be marketed (for the products' list see Regulation EC/3034/94).

Regulation Euratom/87/3954 defines the procedure to be followed for laying down maximum permitted levels of radioactive contamination of foodstuffs and feedingstuffs sold following a nuclear accident. Contrary to Regulation EEC/90/737, this Regulation does not apply to the current situation following the Chernobyl accident.

STAGE I MEASURES

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<tr>
<th>Regulation EEC/90/737</th>
<th>Council Regulation EEC/737/1990 of 22 March 1990 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power-station</th>
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<td>OJ L 82 of 29.3.1990</td>
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<td>Regulation Euratom 3954/87</td>
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<td>- Regulation Euratom 944/89</td>
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<td>OJ L 101 - 13/04/89</td>
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<tr>
<td>Council Regulation Euratom/3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following nuclear accident or any other case of radiological emergency.</td>
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II. RADIATION PROTECTION

DESCRIPTION OF THE LEGISLATION

The purpose of radiation protection legislation is to protect the general public, workers and the environment against the dangers of ionizing radiation. Economic activities which involve the use of products that emit ionizing radiation are therefore subject to a reporting or authorization requirement.

Directive 80/836/Euratom provides for a general requirement for reporting and obtaining prior authorization and is due to be revised. This Directive does not constitute total harmonization since exemption is optional and because the Member States themselves decide whether to justify (or prohibit) an activity and are able, for some activities, to decide whether to require reporting or prior authorization.

In view of the flexibility given to the Member States, no major problems have arisen in the Member States with regard to the transposition of the Directive.

The recent application of the legislation regarding the shipment of radioactive substances and radioactive waste has also not given rise to any particular difficulties.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

Legislative approximations in this area presupposes the existence of a national regulatory authority with administrative powers of authorization, surveillance and inspection:

- Implementation of the requirements concerning the reporting and authorization of the production, processing, handling, use, holding, storage, transport and disposal of radioactive substances (Article 2 of Directive 80/836/Euratom) and authorization of the manufacture and importation of consumer goods, medicinal products and medical devices containing radioactive substances (Article 5 of the Directive) presupposes the existence of authorities of this kind;

- the total of the contribution of each of these activities to the exposure of the population as a whole must be kept under review (Article 13 of the Directive);

- each Member State is required to establish a system of inspection to supervise the protection of the health of the population (Article 45 of the Directive).
Infrastructure

The authorities must be able to call on the services of approved radiochemistry or radiophysics laboratories in order to measure the quantity of radioisotopes (radioactivity) present in products for which marketing authorization is planned.

The authorities must also have the necessary equipment so that, after marketing, they are able to keep a record of all radioactive sources above a certain radioactivity threshold which are used in industry, agriculture, the medical sector or for research purposes. It must also be possible to monitor the use of the most radioactive sources at all stages up to and including disposal.

The Directive on the shipment of radioactive waste requires that, in the case of shipments from the European Union to the CEEC, the latter countries have at their disposal the technical, legislative and administrative resources needed for the safe management of the radioactive waste (see Article 11 of the Directive).

KEY MEASURES

In view of the implications of this legislation for public health, it is not possible to separate its various parts. It is a body of legislation within which individual measures cannot be categorized, in a hierarchy of importance, as being essential, a priority (Stage I) or a lower priority (Stage II).

STAGE I MEASURES

|---|---|
Regulation 93/1493/EURATOM: Following the abolition of frontier controls in the Community on 1 January 1993, the aim of this Regulation is to lay down a Community system for the declaration and provision of information relating to shipments of radioactive substances between the Member States. This system does not apply to radioactive waste covered by Directive 92/31/Euratom.

- **CHOICE OF STAGE II MEASURES:**

**DESCRIPTION & JUSTIFICATION:**

Supplementary regulations may be found to be necessary for radiation protection in respect of the use of particular types of equipment or sources which emit ionizing radiation, e.g. medical devices, accelerators, consumer goods.
III. CHEMICAL SUBSTANCES

INTRODUCTION

Responsibility for the control of chemicals and their derivatives is allocated between several Directorates-General of the European Commission depending on the particular chemical properties and their use and impact on health and the environment.

This allocation is also due to the way in which specific tasks are assigned to each Directorate-General and the history of Commission policy in the chemical sector.

DG IX (Environment) is responsible for regulations concerning dangerous substances, the control of existing and new substances, non-agricultural pesticides (biocides) and the import/export of certain dangerous chemicals.

Certain other aspects are covered by other Directorates-General:

- the use of chemicals at the workplace is the responsibility of DG V (Social Affairs);
- the agricultural use of phyto-pharmaceutical products is managed by DG VI (Agriculture);
- the transport of dangerous chemical products is dealt with by DG VII (Transport).

Aspects of a more commercial nature concerning the marketing of products or dangerous preparations are covered by DG III (Industry). This Directorate-General is also responsible for Directives and Regulations concerning the placing on the market of dangerous substances and preparations, detergents and fertilizers and the framework regulations on dangerous preparations.

All of these legal instruments are therefore closely interlinked as regards the concept of control, the definitions and their scope.

Each Directorate-General that is responsible for one or more legal instruments (Regulations or Directives concerning the control of chemical products) works in close cooperation with the other Directorates-General concerned both in framing the proposal for a Regulation or amendments to it and in consulting the Member States or industries concerned.
I. THE PLACING ON THE MARKET OF DANGEROUS SUBSTANCES

INTRODUCTION:

The placing on the market of dangerous substances is governed at Community level by requirements concerning the labelling, packaging and classification of the products or preparations containing them.

The aim of the Community instruments is to achieve harmonization by laying down, in particular, general classification criteria and the individual classification of each substance on the basis of the risk to man and the environment.

The rules are laid down in Directive 67/548/EEC (OJ L 196 of 16.8.1967) on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, as amended (seven amendments so far), and adapted to technical progress (21 adaptations). See "Stage I measures".

DESCRIPTION OF THE LEGISLATION:

The aim of Directive 67/548/EEC is to harmonize the classification of dangerous substances according to risk, including the environmental risk, their labelling in order to ensure the safety of the people who handle them and their packaging.

These provisions in particular permit the application of Directive 88/379/EEC (OJ L 187 of 16.7.1988) relating to dangerous preparations (see also contribution on the free movement and safety of industrial products).

If the Directive does not specify the particular kind of control infrastructure to be set up, this together with the degree of control must be decided by the Member State itself.

It is importers and small or medium-sized enterprises (SME) which seem to have most difficulty and most work in applying the current provisions (including toxicological data searches, the preparation of appropriate labels and the drafting of appropriate "Safety data sheets").

There are also difficulties with regard to international trade in products and their authorization for use in third countries (these concern missing information, the improper interpretation of classifications, indirect measures to restrict the market and even economic dumping).
In principle, there are two aspects to the regulatory provisions of Directive 67/548:

- the classification, labelling, packaging and safety data sheets for all dangerous substances;
- the notification of new substances and their classification/labelling (see point 2).

The classification of a substance serves to identify the particular hazard it poses. It is based on the intrinsic properties of the substance (or preparation) in accordance with one of the hazard categories defined in Article 2 supplemented by the detailed information given in Annex VI.

The criteria in Annex VI include a general reference to the methods for the determination of the dangerous properties described in Annex V to the Directive.

The labelling depends on the classification of the substance and provides information on the hazard posed to the user of the product under normal conditions of use.

The information is given in the form of:

- hazard symbols, as described in Annex II;
- risk phrases ("R" phrases), as given in Annex IV;
- safety phrases ("S" phrases), as given in Annex IV.

The wording of the phrases must not be changed. Annex VI (Guide to classification and labelling) clearly stipulates the conditions for the use of the S and R phrases in order to guarantee a uniform system of presentation throughout the European Union.

For some substances, the classification and labelling are agreed at Community level, these being given in Annex I to the Directive concerned.

This Annex is not a definitive version since other substances are also being developed. A large number of adaptations to technical progress have already been made and more will follow.

If no Community classification of a particular product exists, the producer or importer is obliged, in accordance with the rules laid down in Annex VI (provisional labelling), to classify and label the substance on the basis of the information available to him.

Articles 22, 23 and 24 provide for the introduction by the Member States of national legislation on the labelling, packaging and classification of dangerous substances.
Furthermore, Article 30 provides for the inclusion of a clause concerning the free movement of products provided the requirements of the basic Directive, as supplemented and amended to date, are complied with.

In addition to transposing this Directive, the Member States are also required to provide the structures and administrative mechanisms to enable its application by producers and users to be monitored.

The Directive also places a number of obligations on producers and importers, compliance with which must be monitored by the Member States.

**KEY MEASURES**

The following Articles are the basic Articles which appear in Directive 67/548, as amended until now.

- Articles 22-23-24
- Article 30

**Basic Directive**


**Supplementary and amending Directives:**

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<tr>
<td>Codified version. 1958 pages, O.J. No. C7, 11.1.94, p. 2. The document has the following order number from the Office for Official Publications : CB-C0-93-734-XX-C where &quot;XX&quot; is the language code, i.e. EN for English, DA for Danish, etc.</td>
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Council Directive 67/548/EEC and related Adaptations to technical progress, Commission Decisions and Commission Communications that are now relevant are listed below:

|---|---|
| Commission Decision 81/437/EEC  
| Commission Decision 85/71/EEC  
| Commission Decision 90/420/EEC  
| Commission Decision 92/3/EEC  
| O.J. No. L383, 29.12.1992, p. 113;  
| Commission Directive 93/21/EEC  
| O.J. No. L110, 4.5.1993, p. 20;  
| Commission communication 93/C130/01  
O.J. No. C130, 10.5.1993, p. 1  | Commission communication 93/C130/01 - third publication of ELINCS |
|------------------------------------|---------------------------------------------------------------|
| Commission Communication 93/C130/02  
O.J. No. L258, 16.10.1993, p. 29;  
| Commission Directive 93/105/EC  
| Commission Directive 93/101/EC  
| Commission Directive 93/112/EC  
The Annexes of Directive 67/548/EEC can be found in the following publications.

        OJ L 13, 15.1.1994 (20th Adaptation)

Annex II: OJ L 110 A, 4.5.1993 (18th Adaptation)

Annex III: OJ L 110 A, 4.5.1993 (18th Adaptation)

Annex IV: OJ L 110 A, 4.5.1993 (18th Adaptation)

Annex V: OJ L 133, 30.5.1987 (9th Adaptation)
          OJ L 110 A, 4.5.1993 (18th Adaptation)

Annex VI: OJ L 110 A, 4.5.1993 (18th Adaptation)


Annex VIII: OJ L 154, 5.6.1992 (7th Amendment)


- **CHOICE OF STAGE I MEASURES**

**DESCRIPTION & JUSTIFICATION:**

Stage I should include:

- Analysis of existing classification systems in the light of the criteria set out in Article 2(2) of Directive 67/548/EEC

- Harmonization of classification systems

- Adaptation of the national criteria to the Community criteria

- Examination of the lists of classified substances on a national basis and under the Community system
CHOICE OF STAGE II MEASURES

Stage II should include:

- The establishment and the communication of the criteria for the national classifications and the lists of classified substances;

- The harmonization of these lists on the Community lists based on Directive 67/548/EEC, as amended.

CHOICE OF STAGE III MEASURES

Stage III should include:

- The transposition into national law of the lists of substances with an indication as referred to in Annex I to Directive 67/548/EEC.

- Setting up of a competent authority responsible for verifying and establishing the controls on the effective application of the labelling of products placed on the market.
DESCRIPTION OF THE LEGISLATION

This fiche deals with the information those (e.g. manufacturers, importers) placing new chemical substances on the market have to provide. This information is called a notification. The notification has to be made in an EU Member State to be a Competent Authority (CA). The CA is specified in domestic legislation and is required under Directive 92/32/EEC. A new substance is any chemical substance not on a list of chemicals placed on the market between 1971 and 1981 (EINECS - European Inventory of Existing Commercial Chemical Substances). The notification requirements are specified in 67/548/EEC (the "Dangerous Substances" Directive) which has been amended 7 times and has been subject to 22 adaptations to technical progress. The most recent amendment (the seventh) is 92/32/EEC. 67/548/EEC is due to be consolidated in 1995.

The measure referred to in the table below is Directive 67/548/EEC (the "Dangerous Substances Directive).

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

(i) There has been, and still is to a lesser extent, a considerable disparity between the knowledge and skills of different Member State Competent Authorities which the Commission with the Member States has tried to reduce through exchange visits, funding for training etc. Such measures will undoubtedly be necessary for the CEECs.

(ii) The system does depend to a large extent on the cooperation of the chemicals industry for its success. Much of the European Union chemicals industry follows the "responsible care" programme. The CEECs industry may not follow such a programme. The EU chemicals industry would have a major role to play in promoting the principle of "responsible care".

(iii) There may be a shortage of knowledge facilities to provide the services industry will need to participate in the system (e.g. test houses with the necessary equipment, scientific expertise and technical support).

(iv) National regulatory systems are essential. Such systems must have a high level of technical and scientific expertise as this is a detailed and scientifically complex subject. All Member States must have a Competent Authority (CA) to oversee the system for notifications. The Directive puts specific duties on all CAs. The CEECs CAs must be capable of fulfilling these duties. The CEECs should also have the capability to enforce the requirements in the Directive/domestic legislation.
The CEECs will therefore need substantial technical assistance in, for example, toxicology, ecotoxicology, physico-chemical effects, testing methods and good laboratory practice. The system is also computer based, so assistance may be required for software and hardware and training in informatics. One of the requirements under the Directive is for a risk assessment to be carried out of notified new substances. This again is a complex task and new, even to existing EU Member States. CEECs will undoubtedly also need assistance in this area.

**KEY MEASURES**

Directive 67/548/EEC (see point 1: Classification and labelling of dangerous substances).

- **CHOICE OF STAGE I MEASURES**

**DESCRIPTION & JUSTIFICATION:**

It is not possible to put in place a system for the assessment of risks posed to people and the environment from new chemical substances by just choosing one or two of the "associated" directives. The large number of directives is a result of the technical nature of much of the system (eg. changing knowledge of effects of chemicals). The system for the notification of new substances is essential to the process for the classification and labelling of new substances (see point 1).

In practice the 'key' directive is 92/32/EEC (the 7th Amendment to the Dangerous Substances Directive). The other directives are essential but deal with the more technical and scientific aspects of the system.
IV. CONTROL OF RISKS OF EXISTING SUBSTANCES

DESCRIPTION OF THE LEGISLATION

The aim of the legislation (Council Regulation (EEC) No. 793/93) is to evaluate the risks of existing substances to man and the environment and to recommend appropriate control measures and risk reduction strategies, where necessary. The evaluation is preceded by a data collection of all substances listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) which are produced or imported in quantities above 10 tonnes per annum. The data are collected in three phases dependant on the tonnage. Regularly priority chemicals are selected applying criteria laid down in the legislation. The risk of the substances appearing on the priority lists are subsequently assessed following agreed principles (Commission Regulation (EC) No 1488/94).

Regulation 793/93 requires that the risk assessment principles, the priority lists and the risk assessments on the priority substances including any risk reduction strategies be adopted by a Committee procedure. The same would apply for any amendments of the Annexes to Regulation 793/93.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

The experience in the EU is particularly relevant as the EU programme on existing chemicals has followed very closely that of the OECD. Both programmes have very similar principles and practices for the actual carrying out of a risk assessment. CEECs as candidate members of OECD under the PIT (Partners in Transition), Poland, Hungary, Czech Republic, Slovakia would by aligning themselves with Regulation 793/93 also conform to the OECD Council Act on chemicals.

Whereas control measures to limit the risks of existing substances can be implemented by various instruments, including pollution or emission control, worker protection and restrictions on marketing and use, the starting point for many such considerations is the existence of a report outlining the risks to man and the environment of that substance.
To distinguish between those substances already in commerce (i.e. existing) and those which are new, it is necessary to establish or adapt an inventory of those chemicals which at a certain point in time were on the market (as the EINECS) and to require pre market notification of those subsequently placed on the market. Such provisions would require a piece of legislation as Directive 67/548 on the classification, packaging and labelling of dangerous substances which, as amended 7 times and adapted for technical progress 21 times (see point III), outlines which data elements are required to be submitted with a notification of new substances and are needed to carry out an evaluation of the risks as well as a series of test methods (based on those of OECD) which should be used to generate data. Regulation 793/93 also foresees recommendations for risk reduction (i.e. control measures based on the risk assessment which are recommendations but not prescriptions for control which should be taken up under the appropriate control legislation).

The implementation of such a programme of risk evaluation requires a certain staffing of the national authorities with experts in toxicology, ecotoxicology, chemistry and modelling.

**KEY MEASURES**

- **CHOICE OF STAGE I MEASURES**

**DESCRIPTION & JUSTIFICATION**

The priority measures are Regulation 793/93 itself and the daughter legislation laying down the principles on how to carry out a risk assessment, allowing mutual recognition of the risk assessments.

**STAGE I MEASURES**

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- **CHOICE OF STAGE II MEASURES**

The various instruments of control of risks regarding water quality, drinking water, emission control, consumer protection and market and use restrictions need to be in place to ensure that the findings of the risk assessment are implemented. As control measures need not actually be in place until the first assessments are complete, their existence is not, as it might be otherwise, a precondition.
V. EXPORT/IMPORT OF DANGEROUS CHEMICALS

INTRODUCTION

The aim of the legislation is to provide third countries, particularly developing countries, with a minimum set of information concerning particularly dangerous chemicals. This information will allow them to take their own decisions concerning these chemicals in order to protect their population and their environment from the risks associated with the marketing and use.

DESCRIPTION OF THE LEGISLATION


The Regulation aims to:

- provide countries which import dangerous chemicals from the EU, with information concerning these chemicals either by export notification (Chemicals listed in Annex I to the Regulation) and/or by labelling of dangerous chemicals according to EU legislation. Information includes risks of their use for health and/or environment, and safety measures;
- make exporters comply with import decisions of third countries concerning PIC\(^1\) chemicals;
- make exporters package and label dangerous chemicals exported to third countries according to EU legislation.

Experience shows that difficulties might arise at the level of small and medium size enterprises, in meeting the requirements of Council Regulation 2455/92 (e.g. research for export reference numbers assigned; import decisions of third countries; establishment of appropriate labelling of chemicals). Chemicals or preparations listed in Annex I may not be exported to a third country unless an export reference number has been assigned. A PIC chemical may not be exported to a third country contrary to its decision, which is listed in Annex II. PIC chemicals may not be imported contrary to the import decision of the European Commission listed in Annex II. Member States are required to establish a system of control for compliance with the provisions of the Regulation. Member States are free of choice of an adequate control system. The responsibility for control, which is with the Member State, may be operated in a centralised, decentralised system, or even be delegated to an independant and competent body.

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\(^1\) Prior Informal Consent.
CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

Legislative approximation in this field pre-supposes

- The adoption of national legislation in line with:
  EU legislation on classification, packaging and labelling of dangerous chemicals and preparations (Directive 67/548/EEC and Directive 88/379/EEC) see point III 1);

Close link with:

- the existence of a designated national authority according to Art. 3 of the Regulation;
- the existence of adequate infrastructure concerning the above legislation and bodies for control of compliance (e.g. customs control system regarding import and export of dangerous chemicals);

KEY MEASURES

STAGE I MEASURES

VI. ENVIRONMENTAL CONSEQUENCES OF DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS

INTRODUCTION

The deliberate release of genetically modified organisms obtained through modern genetic engineering techniques is accelerating. Presently the number of deliberate releases for research purposes constitutes the main body of activities. However, the number of products containing genetically modified organisms is expected to rise in the coming year.

The Community regulatory framework was designed in the late 1980s in order to provide the necessary legislation to ensure adequate protection of health and the environment, while at the same time creating the internal market for biotechnology products.

DESCRIPTION OF THE LEGISLATION

Directive 90/220/EEC concerning the deliberate release into the environment of genetically modified organisms came into force in October 1991. The Directive covers the environmental assessment and release approval of all GMOs through all the stages of release to the environment. Both small scale and large scale experimental introductions, as well as releases through product marketing, fall within the scope of the Directive.

The Member States are in Article 4 of Directive 90/220/EEC obliged to designate the national Competent Authority responsible for carrying out the requirements of the Directive and its annexes.

Directive 90/220/EEC foresees a standard procedure to be followed in the case of research and development releases, whereby a notification consisting of a technical dossier is submitted to the Competent Authority of the Member State where the release is intended to take place. The Competent Authority has to give its consent or reject the notification within 90 days. The procedure also foresees a system for exchange of information between the Competent Authorities through the circulation of a summary of the dossier to all other Competent Authorities. The Commission has adopted a decision 94/211/EC establishing the Summary Notification Information Format to be used when circulating the information.
The Directive also foresees a procedure for environmental clearance of products consisting of or containing genetically modified organisms. According to this procedure a notification has to be submitted with a technical dossier to the Competent Authority of the choice of the notifier. Following a favourable opinion from the originating Competent Authority, the dossier together with a summary of the notification is circulated to all other Competent Authorities for opinion. The Commission has adopted a decision 92/146/EEC establishing the Summary Notification Information Format to be used when circulating the dossiers.

Other Competent Authorities receive the dossier through the Commission and have 60 days to express comments or raise an objection. If an objection is raised then the Commission has to adopt a Decision following the consultation of a Regulatory Committee.

Due to the fact that a number of notifications and consequently also the summaries circulated to other Member States may contain confidential information, it is necessary for the Competent Authorities to establish a system for the protection of confidential information.


**CONDITIONS NECESSARY TO OPERATE THE LEGISLATION**

Modern biotechnology involves the use of modern genetic modification of organisms, which will affect many different products and processes. The Community regulatory framework was designed in the late 1980s in order to provide the necessary legislation to ensure adequate protection of health and the environment, while at the same time creating the internal market for biotechnology products.

For the implementation of the legislation the establishment of the necessary administrative authorities. As the legislation lays down the requirements for environmental risk assessment of releases of genetically modified organism including for instance scientific experience with molecular biology, ecology, toxicology, agriculture etc. It is important to establish the necessary scientific expertise either inside the authorities or in advisory bodies.
KEY MEASURES

The key measure is the introduction of the necessary provisions for regulation of genetically modified organisms in the national legislation, and in particular a consent procedure for experimental and commercial releases involving genetically modified organisms. It is also necessary to establish the necessary provisions in the national legislation for the protection of confidential business information.

- CHOICE OF STAGE I MEASURES

STAGE I MEASURES


Directive 90/220/EEC concerning the deliberate release into the environment of genetically modified organisms covers the procedures for the environmental assessment and release consent for all genetically modified organisms through all stages of release to the environment. Both experimental introductions as well as releases through product marketing fall within the scope of the Directive. The Directive includes procedures for the exchange of information on notifications between member states and contains also annexes specifying the information requirements for the risk assessment.


Directive 90/220/EEC states that Member States authorities in countries other than the one where an application for a release for experimental or developmental purposes have been filled will have the opportunity to make relevant observations within a 30-day period on basis of the summary information provided. To facilitate the exchange of information on experimental releases between Member States, the above Summary Notification Information Format has been established.

For approval of products containing or consisting of genetically modified organisms, Directive 90/220/EEC lay down that the Competent Authority receiving the notification is responsible for carrying out the main environmental risk assessment. If the assessment is satisfactory, the authority then forwards the application to the Commission with a favourable opinion for consent. The dossier forwarded must include a summary of the notification in accordance with the above Summary Notification Information Format.


The information requirements in Annex II of Directive 90/220/EEC has been amended by Commission Directive 94/15/EC in order to establish specific information requirements for genetically modified higher plants.

**STAGE I MEASURES**

|-------------------------------------------|---------------------------------------------------------------------------------------------------|
CHOICE OF STAGE II MEASURES

DESCRIPTION & JUSTIFICATION:

The Directive 90/220/EEC foresees the possibility for establishment of simplified procedures for releases for research and developmental purposes. The simplified procedures has to be proposed by the Member States and is required to fulfill the criteria for simplified procedures concerning the deliberate release into the environment of genetically modified plants as established by Commission Decision 93/584/EEC (OJ L279 - 12/11/93).

Simplified procedures for plants were established by Commission Decision 94/730/EEC (OJ L292 - 12/11/94).

In Decision 94/730/EEC a list was established of Member States which would apply the simplified procedures. For Member States not on the list but wishing to be put on list it requires a change of Decision 94/730/EEC.

STAGE II MEASURES

A request to be put on list of countries which will apply the simplified procedures for plants.
Proposal for simplified procedures.
VII. WASTE MANAGEMENT POLICY

DESCRIPTION OF THE LEGISLATION

The overall objective of waste management policy is to reduce as far as possible the impact of waste on the environment. This policy therefore aims firstly at preventing, recycling, recovering and, only as a last resort, safely disposing of waste. Furthermore it is based on the overall principles of proximity and self-sufficiency. The "frame" of the legislation in this field is laid down in a framework Directive concerning all types of waste as well as in a Directive on hazardous waste. These basic legislative acts are specified in a series of directives which are focussed on specific waste streams such as waste oils, polychlorinated byphenyls and polychlorinated terphenyls, sewage sludge, batteries, packaging waste. The latter legislative acts foresee concrete timetables, limit values and targets. Finally a regulation sets up conditions for the shipment of waste.

EU experience on waste management shows that any attempt at alignment has to start with the "hard ware" of this policy, such as the establishment of clear definitions, e.g. the distinction between "waste" goods and "normal" goods. The main principles of waste management policy have to give guidance for this "hard ware" even if the specific implementation also in EU Member States needs time. The availability of trained personnel including that of competent authorities has turned out to be of paramount importance as well. Experience also shows that in order to succeed, any legislative action in the field of waste management has to be accompanied by promoting public awareness and transparency and ensuring effective practical application.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

Legislative approximation in this field presupposes first of all the setting up of a framework for a waste management legislation. Particular attention has to be given to a clear definition of "waste" and "hazardous waste", "producer of waste", "recovery", "disposal" etc. in line with EC-legislation. Responsibilities have to be allocated. Possibilities for the sound treatment of waste without endangering human health or the environment have to be identified. The framework legislation has to be based on the hierarchy of waste treatment, such as prevention, recovery, and final disposal and has to be in line with the basic principles such as the principles of self-sufficiency and proximity. It also includes the obligation to establish an integrated network of waste treatment facilities ensuring that human health or the environment are not endangered.

Efforts should from the very beginning be focusing also on the implementation of the main principles of the EC legislation mentioned above.
Furthermore, the establishment of an administrative infrastructure is of paramount importance, including authorities enabled to control and supervise waste management activities. This includes in particular the capacity to identify the different types of waste and possible ways of suitable treatment. The personnel also has to be familiar with control and authorization procedures including the handling of documentation and financial security schemes.

The same is true for personnel in industry, trade and, if the case may be, consumers given that these sectors are exposed directly to hazards generated by waste, in particular hazardous waste. It is, therefore, first of all their responsibility to handle waste properly.

Intensive technical assistance and training of both staff of local authorities and persons responsible for waste management in general are therefore of paramount importance.

Given that the location of waste management facilities needs sound planning on different levels, the competent authorities have to draw up as soon as possible waste management plans.

Finally, public awareness has to be promoted from the very beginning given the direct impact of a wide range of legislative action (e.g. batteries, packaging) on individuals.

KEY MEASURES

- **CHOICE OF STAGE I AND II MEASURES**

DESCRIPTION & JUSTIFICATION:

As explained above the legislation on waste management policy is one complex which, with a view to the functioning of the Internal Market but also to the protection of the environment, cannot be split into different bits of specific legal acts. The Framework Directive does not work without the specific directives and the shipment Regulation, nor do the latter make sense without the framework given that basic definitions are laid down there.
DESCRIPTION OF THE LEGISLATION

The Directives covering this sub-sector establish provisions for construction plant and equipment and also introduce a test method for determining noise emissions by machines and outdoors. The test procedures must be applied to determine the maximum sound emission levels as laid down in separate directives on the approximation of the laws of the Member States relating to permissible sounds power level.

On request of the manufacturer Member States can authorize, refuse, or suspend EU type-approval on the basis of different cases described in the framework Directive 84/532/EEC, all equipment referred in separate Directives, the competent national authorities can act similarly for the EU type-examination.

The Commission has made a commitment to present to the Council five years at the latest after the adoption of this Directive, a proposal for stricter reduction of noise levels. However, concerns have been expressed that in the present situation only a few types of construction plant and equipment are covered by directives, leaving most without any noise regulation. It has therefore been argued that a general approach through a directive covering all types of equipment could give a better protection against noise.

The Commission is investigating in possibilities for a general directive on noise emissions from machinery. A proposal to this effect will be published later this year. A data base on measurement will also be established.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

Member States (at Federal or State level) appoint approval bodies, notify them to other Member States and the Commission and ensure that they carry out their tasks correctly.

Member States shall withdraw approval from a body if this is necessary (conditions are laid down).

Approved bodies (private organisation or under public laws) carry out EEC-type examination. They grant, refuse, suspend or withdraw EEC-type examination certificates in accordance with the provisions of Directive 84/532/EEC and the other machine specific directives.

Approved bodies send copies of all certificates to the Commission and the other approved bodies.
Approved bodies shall take the necessary measures to ensure the conformity of manufactured equipment with the type examined.

An EU working group composed of representatives of approved bodies meets on regular basis to discuss questions relative to noise emissions for construction plant and equipment.

Up to now there is no training requirements for the approved bodies. However, they have to meet special requirements when appointed by Member States.

A Committee on the adaptation to technical progress of the Directives concerning the elimination of technical barriers to trade in construction plant and equipment have been set up. It consists of representatives of the Member States and is chaired by a representative of the Commission.

With regard to legislation relative to noise emissions, common provisions have been established for the requirements concerning machinery, appliances, plant and installations. The two Directives establish common rules and methodologies which are then further specified in the relevant separate Directives. These concern first of all the common provisions for construction plant and equipment, i.e. inspection and verification methods, and secondly the determination of the noise emission of construction plant and equipment.

Council Directive 84/532/EEC lays down general provisions on the procedures for the verification of technical requirements and methods for inspecting such plant and equipment. These procedures concern the following: EEC type-approval, EEC type-examination, EEC verification and EEC self-certification.

EEC type-approval means the procedure whereby a Member State establishes, following tests, and certifies that a type of equipment conforms to the requirements harmonized under the relevant separate Directives.

EEC type-examination means the procedure whereby a body approved for that purpose by a Member State establishes, following tests, and certifies that a type of equipment conforms to the requirements harmonized under the relevant separate Directives.

EEC verification means the procedure whereby a Member State can affirm following tests that each item of equipment conforms to the harmonized requirements.

EEC self-certification means the procedure whereby the manufacturer, or the authorized representative certifies, on his own responsibility that an item of equipment conforms to the harmonized requirements.
Moreover, the EEC type-approval and the EEC type-examination when stipulated in the separate Directives constitute a prerequisite for the introduction of the equipment to the market, for putting into operation, and for the use of this equipment.

Council Directive 79/113/EEC introduced a test method for determining noise emissions by machines used outdoors. The test procedures must be applied to determine the maximum sound emission levels as laid down in separate directives on the approximation of the laws of the Member States relating to the permissible sound power level, and these are listed in point 4.

Technical requirements are laid down in separate Directives which generally contain the regulatory requirements to be met and the relevant testing procedures. These procedures are of the competence of technical services appointed by Member States in accordance with the rules laid down in the framework Directive, and are notified to the Commission and the other Member States.

**KEY MEASURES**

All measures described in the below mentioned directives are considered as key measures. In the present situation only a few types of construction plant and equipment are covered by directives, leaving most without any noise regulations.

- *CHOICE OF STAGE I & II MEASURES*

**DESCRIPTION & JUSTIFICATION:**

As stated above, the first two Directives give a framework to the other 7 directives in terms of technical requirements i.e. test methods for determining noise emissions and inspection and verification methods. These framework Directives address issues relevant separate directives, i.e. machinery and equipment.

The separate Directives are relative to the permissible sound power levels of the following equipment and machinery: compressors, tower cranes, welding generators, power generators, concrete breaker and picks, lawnmower, excavators, dozers, loaders.

The implementation of all sectorial Directives could be conceived in a second step.
**STAGE I MEASURES**

*Noise Emissions from construction plant and equipment*

|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**STAGE II MEASURES**

|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
INTRODUCTION

The protection and improvement of public health and of the environment is one of the items of major concerns for all industrialised countries. Air pollution caused by substances emitted in the exhaust gas of vehicles must be regarded as serious owing to the continuous increase in the volume of motor vehicle traffic. Fuel quality plays an important role in reducing air pollution by vehicle exhaust emissions. Moreover, one of the Community's objectives is to preserve, protect and improve the quality of the environment and to contribute towards protecting human health, by rectifying environmental damage at source.

DESCRIPTION OF THE LEGISLATION

This contribution concerns the approximation of legislative acquis in the field of air quality and it particularly addresses the issues of lead and sulphur contents in petroleum products.

The first Directive (85/210/EEC) concerns the lead content in petrol. Without adverse effects on the quality of petrol, the Directive sets out to reduce the levels of lead compound content in petrol. The different types of petrol and their lead contents have been established, and Member States have been requested to take appropriate steps to ensure that neither the reduction of the lead content of petrol nor the introduction of unleaded petrol causes a significant increase in the quality and/or quantity of pollutants in the gases emitted from motor vehicles.

Since the adoption of the Directive on 20.03.1985, Member States have been given until 1.10.1989, to take necessary measures to ensure the availability and balanced distribution within their territories of unleaded petrol. Moreover, the benzene content of leaded and unleaded petrol as well as the octane ratings have been set up. The procedures to measure according to reference methods, the different contents of petrol are specified in the annexes as regards the following:

- the lead content of petrol,
- the benzene content of petrol,
- the determination of octane ratings.

The second Directive concerns the sulphur contents in certain liquid fuels.

In order to improve air quality with regard to sulphur dioxide, a Council Directive 93/12/EEC have been issued relative to sulphur content of certain liquid fuels. It concerns the following petroleum products:

- "gas fuels" - used for self propelling vehicles and which by reason of its distillation limits, falls within the category of middle distillates.

The Directive does not apply to gas oils contained in fuel tanks of vessels, aircraft or motor vehicles crossing a frontier between a third country and a Member State, or intended for processing prior to final combustion. The sulphur contents limits have been set up for the fuels mentioned above:

- as of the 01.10.1994 sulphur contents for gas oils should not exceed 0,2 % by weight, with the exception of aviation kerosene.
- as of the 01.10.1996 sulphur contents for diesel fuels should not exceed 0,05 % by weight.

Member States have been requested to prohibit, restrict or prevent the placing on the market of gas oils if their sulphur content exceeds the percentages by weight set in the Directive. Provisions have been made for Member States to take all necessary measures complying with the requirements of this Directive to check by sampling the sulphur content of gas oils which are put on the market.

**CONDITIONS NECESSARY TO OPERATE THE LEGISLATION**

For the purpose of implementing in Member States the Directive relative to lead content in petrol, a Committee on Adaptation to Scientific and Technical Progress have been set up consisting of representatives from Member States and chaired by the Commission. The role of this Committee is to follow up the adaptation of the Directive to technical progress and the development of reference methods for measuring the following:

- lead content of petrol,
- the benzene content of petrol,
- and for the determination of octane ratings.

Provisions have been made for procedures for sampling and analysing by Member States the sulphur content of gas oils which are placed on the market. The statistical interpretation of the results of the checks made to determine the sulphur content has been established in accordance with ISO standard 4259.

The Commission has been asked to prepare a progress report concerning the control of sulphur dioxide emissions and a proposal setting new limit values.

The Commission is currently preparing a proposal for a more general framework of the policy to improve air quality, for transition to a second phase prescribing lower limits for sulphur dioxide emissions and setting new limit values for aviation kerosene.
**KEY MEASURES**

In order to improve air quality with regard to CO2 and other emissions, the Community has to take measures to reduce progressively the sulphur and lead content of certain liquid fuels used for self-propelling vehicles, aircraft, vessels, for heating, industrial and marine purposes.

- **CHOICE OF STAGE I MEASURES**

**DESCRIPTION & JUSTIFICATION:**

Member States have been asked to reduce the content of sulphur and lead in fuels. The limits have been established within the permitted time framework. The Commission is currently preparing a proposal for a more general framework of the policy to improve air quality, for transition to a second phase prescribing lower limits for CO2 emissions and setting new limit values for aviation kerosene.

**STAGE I MEASURES**

|------------------------------------------|-------------------------------------------------------------------------------------------------|
INTRODUCTION

The legislation mentioned below addresses the issue of air pollution by VOCs and in particular the measures to be taken so as to reduce evaporation of VOCs from petrol in storage installation and in distribution operations. It is important to note that this Directive does not cover the total emissions of the VOCs and that other important emission sources such as solvents, exhaust fumes, for instance will have to be regulated.

DESCRIPTION OF THE LEGISLATION

Directive 94/63/EC relates to measures to be taken so as to reduce evaporation of VOCs from petrol in storage installations and in the distribution operations from one terminal to another or from one terminal to a petrol station. It is limited to petrol fuels for motor vehicles only, excluding Liquid Petroleum Gaz (LPG) and Diesels. These provisions are designed to reduce and to tend to recover the total annual loss of petrol resulting from loading and storage at each storage installation at terminals to below the target reference value.

Because of the large number and the diversity of installations required to be controlled, the implementation of different technical measures will be phased.

Phase I will start one year after coming into force of the Directive and will last three years.

Phase II will start four years after coming into force of the Directive and will last four years.

A distinction will be made between new and existing installations.

The aim will be to have large facilities with the most cost effective controls included in phase I. Phase II would then cover a large number of smaller facilities having a poorer cost-effectiveness.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

The requirements for storage installations at terminals concern construction measures for roof tanks, vapour recovery units and heat reflecting measures.

Requirements are also given for loading and unloading installations at terminals. They concern safe vapour recovery units for regeneration at the tankers terminal, and at the storage facilities.
The Directive aims to reduce VOC emissions from petrol at each significant emission source in the distribution chain. It envisages that there will be controls applied to:
- above ground tanks at refinery terminals and intermediate depots holding petrol
- loading gantries at petrol terminals and depots
- unloading petrol into storage tanks at service stations
- mobile delivery vessels e.g. road tanks, rail cars, barges and ships.

KEY MEASURES

• CHOICE OF STAGE I MEASURES

JUSTIFICATION

These are the only key measures concerning the reduction of evaporation of VOCs from petrol. These measures are called Stage I because they are not covering all distribution operations.

The Commission is currently preparing a communication on VOCs Stage II emission control which will cover distribution operations from petrol stations to individual cars.

STAGE I MEASURES


• CHOICE OF STAGE II MEASURES

Not applicable. It should be noted however, that the Commission is preparing a communication on VOCs Stage II emission control which will be published later this year.
DESCRIPTION OF THE LEGISLATION

Council Regulation (EC) 3093/94 on ozone depleting substances, adopted on the 15 December 1994 implements the Copenhagen amendments to the Montreal Protocol agreed in November 1992. The Regulation consolidates all previous texts on the control of all ozone depleting substances - CFCs, Halons, Carbon Tetrachloride, 1,1,1 - Trichlorethane as well as the newly controlled substances HCFCs and methyl bromide.

The Regulation (EC) 3093/94 contains in Part II a general phase out schedule of control of production and of supply of controlled substances, as well as control measures of the use of HCFCs. Part III represents the trade regime of the description of the importation regime for imports from third countries. Part IV on emissions control adds two new measures in the context of the recovery of used controlled substances and an Article on leakage prevention of controlled substances.

Article 16 of the Regulation lays down the areas of competences of the Management Committee of the Regulation which advises the Commission an important implementation measures.

The EU experience in this field has shown that co-operation with the Member State authorities in the implementation of the measures foreseen under EU legislation is essential. Council Regulation EC No. 3093/94 on ozone depleting substances consolidates all previous texts on the control of ozone depleting substances (Regulations EC 594/91 - OJ L67, 14/3/91 and EC 3952/92 - OJ L405, 31/12/92) and implements the Copenhagen Amendments to the Montreal Protocol by introducing controls for HCFCs and methyl bromide. The controls foreseen for the latter two substances go further than those determined in Copenhagen.

In order to ensure the effective phase out of ozone depleting substances in the EU the Commission needs to rely on the relevant authorities in charge of the implementation and the control of the measures foreseen by the EC Regulation. In the past this has involved the cooperation from the customs authorities in the Member States in order to ensure the verification of import licences of ozone depleting substances into the EU and the control measures foreseen at administrative and customs level in this respect. This is particularly important with respect to avoiding potential illegal imports of ozone depleting substances into the EU from, amongst others, the Eastern European countries. Lack of regulatory, monitoring and control mechanisms and the lack of information and border control on the substances in question could encourage the occurrence of such illegal imports.
The EU legislation in the area of the control of ozone depleting substances consists mainly in the EC Regulation No. 3093/94, adopted on 15 December 1994. This Regulation consolidates all previous legislation in this area and implements the 1992 Copenhagen amendments to the Montreal Protocol on substances that deplete the ozone layer. The Regulation does not only implement the phase out measures as foreseen under the Protocol but also goes further than these international agreements for a number of substances, namely the newly controlled HCFCs and methyl bromide.

The existence of national legislation on the control of ozone depleting substances as well as relevant administrative authorities in charge of the implementation and the control of this legislation are a necessary precondition for the implementation of the EU legislation on the control of ozone depleting substances in the CEECs. The necessary regulatory system would not only include legislation on the control of ozone depleting substances in line with the international commitments (the Montreal Protocol and its amendments) on substances that deplete the ozone layer but would also require the establishment of the relevant administrative authorities (national experts in the ministries responsible for the subject, customs authorities, data gathering on production and consumption of ozone depleting substances...).

As the phase out process accelerates in the industrialised countries, signatories to the Protocol, the implementation process and the necessary associated infrastructural and administrative measures become increasingly important. Specific measures which will have to be ensured with respect to the CEECs will therefore include: the installation of monitoring and control authorities, the coordination between these and the customs authorities, mechanisms for information exchange, technology cooperation and technology choices, public awareness...

KEY MEASURES

- **CHOICE OF STAGE 1 MEASURES**

DESCRIPTION & JUSTIFICATION:

The control of ozone depleting substances in the European Union is legislated by the newly adopted Council Regulation (EC) 3093/94. The Regulation encompasses all the measures for the control of production and placing on the market and importation of ozone depleting substances in the Community. These measures are directly applicable in all Member States. The Regulation therefore contains in its entirety all the key measures to ensure the effective control of these substances in the EU.
Considering the fact that the EU legislation on the protection of the ozone layer constitutes one single piece of legislation (EC Regulation 3093/94) it is difficult to differentiate between Stage I and Stage II measures.

The Regulation implements the commitments signed under the Montreal Protocol and its amendments and even goes further than these measures to control the production and the supply onto the EU market for a number of controlled substances.

In the framework of the commitments signed under the Montreal Protocol a distinction has to be made between the different groups of controlled substances and the urgency of their phase out.

**CFCs**

A number of controlled substances such as the chlorofluorocarbons (CFCs), other fully halogenated CFCs, halons and carbon tetrachloride will be phased out entirely under the Protocol by the 1 January 1996, with the exception of a limited number of essential uses, such as specific medical, uses for which these substances can be used after this date.

In the light of future alignment with EU legislation the CEECs have the possibility to fulfil these commitments concerning the phase out of these established ozone depleting substances in the next few years.

**HCFCs and methyl bromide**

The category of newly controlled substances under the Protocol and the EC Regulation 3093/94 (HCFCs and methyl bromide) might represent more difficulties for alignment of control measures in the medium term future. A necessary precondition for alignment at EU level remains the ratification and implementation of the Montreal Protocol and all its amendments. In the case of HCFCs and methyl bromide it is the Copenhagen amendment (1992) which would need to be ratified and implemented.

The control measures foreseen under EC Regulation for the above substances go further than the Protocol. The basic principle of control for HCFCs for example, is a quantitative limit (cap) based on the percentage of placing on the market of CFCs and HCFCs in a reference year. For this group of substances there might therefore be room for negotiation with the CEECs prior to alignment with EU legislation in the form of allowing for raising this quantitative limit in line with their consumption of these substances in the reference year or in the past.

In the area of the EU legislation where the free movement of products containing controlled substances is concerned there might be potential internal market problems which will have to be dealt with.

Once the control measures foreseen at international level under the Montreal Protocol can be signed and implemented, the necessary institutional framework will have to be established in order to assist the implementation process.
The implementation of the EC Regulation on ozone depleting substances is accompanied by the implementation of technical measures, such as the setting up of import quotas and the determining of essential uses exemptions every year, for example.

**STAGE I MEASURES**

GENERAL INTRODUCTION

Telecommunications are of crucial importance for all European countries, both socially and economically. Socially, broad access to telecommunications services contributes substantially to the creation and maintenance of an open society. Economically, a fully functioning and efficient private sector cannot be developed when telecommunications are inadequate. Likewise, in an age of world-wide capital mobility, the effect of such a deficiency on the economy in terms of investment is self-evident.

The basic policy principles relating to the telecommunications sector and development targets tend to be similar, both in Western and Eastern Europe. What varies is the approach taken by each country when managing these changes, their individual priorities, financing methods, and their choice of technology. These policy principles include keeping up with latest technological developments and improving networks standards to match those of more developed trading partners. Other important principles are the liberalisation of the markets for Equipments, services, and infrastructure as well as the harmonisation of network access, type approval, standards and other technical features.

Development of EU policy and regulation in the field of posts and telecommunications

The main direction of EU telecommunications policy has been set by the consultative process initiated by the Commission on the basis of the 1987 Green Paper\(^1\) and its successors, by key Resolutions adopted by the Council and European Parliament, and by the European Court of Justice\(^2\).

The main steps since the 1987 Green Paper have been:

- the satellite Green paper of 1990\(^3\)
- the Telecommunications Review Consultation of 1992/93\(^4\)
- the Green Paper on mobile and personal communications in 1994\(^5\)
- the Green Paper on the liberalisation of telecommunications infrastructure and cable television networks, part 1 and part 2 adopted 1994/1995\(^6\)
- the Council Resolutions of June 1988, December 1991, July 1993 and December 1994\(^7\) which adopted the results of the consultative process carried out at each of the major steps.

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1 Green Paper on the Development of the Common Market for Telecommunications Services and Equipment, COM (87) 290 of 30.06.87
2 Case 202/88 France v. Commission as well as Cases 271/90 and 281/90 Spain, Belgium and Italy v. Commission which upheld the Commission's Art. 90 Directives in the telecommunications sector.
3 COM (90) 490 of 20.11.90
4 COM (93) 159 of 28.04.93
5 COM (94) 145 of 27.04.94
6 Part I: COM (94) 440 of 25.10.94; Part II: COM (94) 682 of 25.01.95
The common theme of the policy which has emerged in the progressive removal of barriers to pan-European operation, service provision and equipment supply across the EU's telecommunications market, is the evolving balance to be struck between liberalisation and harmonisation, competition and public service.

In the field of postal policy, the Commission has issued the Green Paper on the development of the single market for postal services in June 1992 and a Communication to the Council and the European Parliament on Guidelines for the development of Community postal services in June 1993. On the basis of these Communications the Council has adopted on 7 February 1994 a Resolution on the development of postal services, and the Commission has been invited to propose the measures necessary for implementing a Community policy on postal services.

In the meantime, the Commission's services are preparing legislative proposals providing for a definition at Community level of the universal service and relating also to the improvement of quality of service and the promotion of technical standardisation and providing also for a definition at Community level of the scope of postal services which may be reserved for universal service providers.

As an acquis communautaire has not yet been established in the field of postal services, the following chapter will only deal with the EU telecommunications regulation and those draft regulations which are expected to be adopted in the near future.

**DESCRIPTION OF THE LEGISLATION**

As laid down in the telecommunications policy documents, EU action has addressed equipment, services and infrastructure separately, and with different time scales, according to the economic situation in each of these sub-sectors.

Competition has been introduced in the terminal equipment market by a Commission Directive based on Article 90 (later supplemented for satellite communications) in parallel with a Council Directive harmonising the laws and regulations of the Member States in this field.

In the services and infrastructure field the main steps were:

1) liberalisation of data transmission, voice telephony for closed user groups, satellite and mobile communications, i.e. removal of special or exclusive rights and introduction of licensing regimes for these services

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7 88/C 257/01, OJ C257/1 of 04.10.88; 92/C 8/01, OJ C8/1 of 14.01.92; 93/C 213/01, OJC 213/1 of 06.08.93; 94/C 379/03 of 22.12.94
8 COM (91) 476 of 11.06.92
9 COM (93) 247 of 02.06.93
10 94/C 48/02, OJ 16.02.94
11 see footnotes 1-6 of the introduction
2) in parallel to 1), development of harmonised conditions for access to public networks by providers of liberalised services, through "Open Network Provision" (ONP)

3) extension of liberalisation to the economically very significant service public voice telephony (due by 1 January 1998, with transitional periods up to 1 January 2003 for Member States with less developed and small networks)

4) liberalisation of telecommunications infrastructure according to the same timetable as under 3)\(^1\)

5) in parallel to 4), development of a regulatory framework governing inter alia licensing conditions and procedures, interconnection of networks and universal service obligations.

The ONP approach mentioned above under 2) has been elaborated as a Framework Directive \(^1^5\) which was followed by a Directive applying the ONP principles to leased lines\(^1^6\). The next step will be the application of ONP to voice telephony, for which a revised proposal will be probably submitted to the next Telecommunications Council. ONP principles should continue to serve as a basis for the regulatory framework in the Union, and should be adapted as necessary in the light of further liberalisation in respect of the entities covered and of issues such as universal service, interconnection and access charges.

The Commission is to make proposals for legislative measures as a consequence of the recent decisions, referred to under 4) and 5) above, by the end of 1995. By 1998 these will have to be implemented by most of the Member States. The structure of the acquis may be significantly changed in the process ("reform package").

In any case, whether a comprehensive or a gradual approach to competition is followed, liberalisation measures must go hand in hand with an effective regulatory framework. A central political objective for the EU has been maintaining and developing universal service. This is certain to be a key objective in the preparations of the pre-accession countries in this area. The political agreement on the full liberalisation of voice services and now infrastructure reflects a EU consensus that monopoly is not the answer to universal service. Instead, what is required is an appropriate period of preparation to rebalance tariffs, and the putting in place of a regulatory framework that allows new market players to make a fair contribution to the cost of universal service.

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\(^{13}\) Council Directives 91/263, 93/68, 93/97

\(^{14}\) see footnote 6 of the introduction

\(^{15}\) Council Directive on the establishment of the internal market for telecommunications services through the implementation of open network provision, 90/387 of 24.07.90

\(^{16}\) Council Directive on ONP applied to Leased Lines, 92/44 of 19.06.92
CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

The specific requisites in the field of telecommunications are as follows:

- the existence of a well-developed regulatory mechanism for competition governing both the private and the public sector\(^\text{17}\)

- the effective separation of the regulatory function for the sector as a whole, which will continue to be exercised by the public authorities, from the operational responsibility for the public network\(^\text{18}\)

- the development of cost accounting systems which make it possible to identify relevant costs for the different services and infrastructures provided by the operators and other service providers

- the designation and accreditation, by the government, of "notified bodies", which will issue type approvals and other authorisations, in order to effectively implement the Community's new approach to Technical Harmonisation and Standards\(^\text{19}\) also in this sector; mechanisms for a posteriori checks (market surveillance) and dispute resolution must be put in place.

In addition, liberalisation cannot be effective unless telecommunications operators and service providers apply a non-discriminatory, transparent and cost-related tariff structure. This requires early attention to re-balancing tariffs for local vs long-distance traffic and the definition and costing of clear universal service obligations.

For the allocation of frequencies and numbers/codes (numbering), the European Union and its Member States are co-operating with the other countries of Europe in the framework of CEPT (Conférence Européenne des Administrations des Postes et Télécommunications). It is intended that measures at European Union level will only be proposed when decisions on these matters by the CEPT bodies ERC (European Radiocommunications Committee) and ECTRA (European Committee of Telecommunications Regulatory Authorities) are not implemented by their members in a timely manner\(^\text{20}\). Therefore, the effective participation of the associated countries in the bodies mentioned (of which they are all members) will contribute to the conditions for alignment.

The Community can provide assistance with the setting up of the organisations and mechanisms referred to under the regulation and standards headings, as well as with the introduction of cost accounting systems.

\(^{17}\) The Commission has adopted Guidelines on the application of EEC Competition Rules in the Telecommunications Sector, 92/C 233/02 of 06.09.91

\(^{18}\) Similarly, the responsibility for the manufacturing sector must be effectively separated as well. This becomes highly relevant with the introduction of public procurement regulation for the public network operator by the Council Directives 93/38 and 92/13

\(^{19}\) selected references: Council Recommendation 84/549, Council Decision 87/95, Council Resolutions 85/C 136/01 and 93/C 219/02,

\(^{20}\) Council Resolutions 90/C 166/02, 92/C 318/01, 92/C 318/02
KEY MEASURES

In the Telecoms sector all EU Internal Market related legislation is considered key, both these adopted or likely to be adopted in the near future.

- **CHOICE OF STAGE I MEASURES**

**DESCRIPTION & JUSTIFICATION:**

The stage I measures are the essential provisions already simultaneous implementation.

**STAGE I MEASURES**

**Equipment:**

<table>
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<th>Directive</th>
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**Frequency Allocation and Numbering:**

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<th>Directive</th>
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Council Decision 92/264/EEC on the introduction of a standard international telephone access code in the Community.

(Note: this code has already been introduced in each of the pre-accession countries)

**Services:**

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<th>Directive</th>
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**CHOICE OF STAGE II MEASURES**

**DESCRIPTION & JUSTIFICATION:**

As for the legislation already adopted, the Directive 94/46/EC on the liberalisation of the markets for satellite terminals and services should be part of the stage II measures (Category 1), because the relevant technical regulations have not been adopted yet in the European Union.

The second category of stage II concerns draft legislation in the field of infrastructure, ONP, mutual recognition of licences for satellite services and data protection, which is likely to be adopted within the next two years.
### STAGE II MEASURES

**Legislation already adopted:**


**Legislation likely to be adopted in the near future:**

| COM (94) 210 of 10.06.94 | (further reference: the Commission's "Communication on Satellite Communications: the Provision of - and Access to - Space Segment Capacity" should be taken into consideration). |
| Proposal for a Council Directive COM (92) 422 of 15.10.92 OJ C311 of 27.11.1992 common position reached by Council on 03.02.95 Council ref. 12003/1/94 | Proposal for a Council Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data; this may be adopted in the near future (see also contribution on personal data protection). |
GENERAL INTRODUCTION

Direct taxes are not harmonised at EC level; attempts to harmonize corporation taxes have been abolished. EC measures in this field aim at facilitating administrative co-operation between the national tax authorities and at removing obstacles to cross-border activities of enterprises. However, the fundamental Treaty principles, in particular that of non-discrimination, have to be respected by the national tax rules.

The only harmonisation which has taken place in the field of company taxation is that of capital duty. The relevant directive is, however, much more important as a barrier against the creation of similar levies than as a harmonisation of capital duty.

It would also be useful to keep in mind the two existing recommendations in the field of direct taxation, when the national systems are being shaped; these are the Recommendations 94/79/EC of 21.12.1993 (OJ L39 of 10.02.94) on the taxation of certain items of income received by non-residents and 94/390/EC of 25.05.1994 (OJ L177 of 9.07.94) concerning the taxation of small and medium-sized enterprises.

DESCRIPTION OF LEGISLATION

Art. 100 of the Treaty is the only basis for EC measures in the field of direct taxation.

No appreciable progress was possible due to the unanimity requirement of Art. 100, confirmed by the Single European Act which excluded taxation explicitly from the majority principle normally applicable to internal market measures under Art. 100A.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

Taxes are administered at national or sub-national level. Co-operation between national administrations takes place mainly under bilateral tax conventions, but also according to the harmonized rules on mutual assistance. Informal co-ordination is being done rather through OECD than through Community action.
**KEY MEASURES**

All adopted measures are considered to be key measures.

- **CHOICE OF STAGE I MEASURES**

  **DESCRIPTION & JUSTIFICATION:**

  The two basic measures which should be implemented from the outset, are Directive 77/799 on mutual assistance in direct and indirect taxation and Directive 69/335 on capital duty. The first of these would immediately integrate the CEEC authorities into the system of exchange of information, whereas the second would limit the danger of taxing company formation at a rate higher than 1% of the assets.

**STAGE I MEASURES**

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<tr>
<td>OJ L 249, 3.10.69, p.25</td>
<td>as amended by Directive 73/79 (OJ L103 of 18.04.73); Directive 74/553 (OJ L303 of 13.11.74); Directive 85/303 (OJ L156 of 15.06.85)</td>
</tr>
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- **CHOICE OF STAGE II MEASURES**

  **DESCRIPTION & JUSTIFICATION:**

  The structural adaptations for cross-border activities should be envisaged, once modernised tax systems have been satisfactorily established.
STAGE II MEASURES

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<td>OJ L 225, 20.8.90, p.1</td>
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<td>OJ L 225, 20.8.90, p.6</td>
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Complementary to EC Law

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<tr>
<th>Convention 90/436</th>
<th>Convention (of the Member States) 90/436 of 23 July 1990 on the elimination of double taxation in connection with the adjustment of profits of associated enterprises.</th>
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<td>(OJ L 225, 20.8.90, p.10)</td>
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Remaining Key measures not identified in preceding stages

* The proposals on:
  
  - carry-over of losses of undertakings COM(84)404 (OJ C253 of 29.09.84);
  - a common system of withholding tax on interest income COM(89)60 (OJ C141 of 7.06.89);
  - losses of permanent establishments and subsidiaries COM(90)595 (OJ C53 of 28.02.91)

should be taken into consideration, once they are adopted by the Council
GENERAL INTRODUCTION

The market concept refers to a trading area devoted wholly to the sale of products. The single market rests on the assumption that goods traded on the market of one Member State of the Community can move freely through the other Member States of the Community. This is the practical expression of the principle of free movement of goods.

Hence to ensure the free movement of goods within a single market all tariff barriers (customs duties and charges having equivalent effect) and non-tariff barriers (any other measure making imports more difficult or more costly) must be removed.

The Treaty contains a string of provisions aimed at eliminating customs duties and charges having equivalent effect (Articles 9-12) and quantitative restrictions on imports or exports and measures having equivalent effect (Articles 30-36). In addition, the Treaty requires Member States to adjust state monopolies of a commercial character (Article 37), lays down rules governing the activities of undertakings and the granting of exclusive rights by Member States (Articles 85-86 and 90), establishes rules governing the grant of state aids to undertakings (Articles 92-93) and outlaws discriminatory tax treatment as between national products and products from other Member States of the Community (Articles 95-99).

The free movement of goods is dealt with more particularly in Article 30 et seq. of the Treaty.

However, none of these provisions defines the concept of the goods concerned. The Treaty goes no further than to establish that its provisions apply to products originating in the Member States and those from non-Community countries in free circulation in the Member States (these are products from non-Community countries in respect of which import formalities have been completed and any customs duties and charges having equivalent effect that are due have been collected in a Member State). Only the case law established by the Court of Justice has shed light on the scope of the concept and made it possible to define goods subject to the rules of the Treaty as any product on which a monetary value can be set.

Article 30 et seq. likewise failed to define what constitutes a trade barrier; they merely stipulate that quantitative restrictions on imports or exports and charges having equivalent effect are prohibited. The trade barrier concept has been clarified as a result of statements of position by the Commission and the case law established by the Court of Justice.
Trade barriers may take the form, for example, of import or export licenses, the requirement to meet statutory national specifications with regard to the weight, shape or dimensions of products, incentives to buy national products or the requirement to have a legal representative in a country in order to sell products there.

Thus, in order to overcome the barriers stemming from different sets of national rules, the principle of mutual recognition of legislation was derived from Court of Justice case law, and more particularly its judgment in the "Cassis de Dijon" case. As a result of this judgment, a product legally manufactured and/or marketed in one Member State must be able to circulate freely in the other Member States of the EU, regardless of whether it corresponds to the rules laid down by those Member States.

This is because the aims of national laws which might underlie certain product specifications relating, for example, to protection of health, safety or the environment are in many cases identical. It follows that the rules and monitoring arrangements established to attain those aims are equivalent, even though they may take different forms, and should in normal circumstances be recognized in all Member States.

It remains the case, however, that mutual recognition, resting as it does on the national rules of the Member States, cannot function in sectors where the disparities between bodies of legislation are so substantial that agreement on equivalence is impossible. In such cases it is necessary to adopt common rules allowing products to be marketed on all the markets of the Member States, provided they meet requirements laid down at Community level. The harmonization at Community level of rules governing a sector provides undertakings with a level playing field throughout the Community.

**Limits to the application of the principle of mutual recognition**

The free movement of goods comes up against its limits where the Member States appeal to overriding necessity or the reasons given in Article 36 of the Treaty to justify the retention of measures restricting trade. They are made the object of the contribution on the free circulation and safety of industrial products. Examples include the question of what constitutes fair trade, and also protection of the environment, consumer protection and protection of public health, public policy and protection of industrial and commercial property. Moreover, the Court of Justice has set outer limits to the application of Article 30 of the Treaty, by removing from its scope certain methods of selling goods provided they are not discriminatory.

**DESCRIPTION OF THE LEGISLATION**

One of the fundamental aims with a view to completing the internal market has been, since the entry into force of the EC Treaty, the abolition of quantitative restrictions and measures having equivalent effect which constitute barriers to trade within the EU, as laid down by Article 30 et seq. of the Treaty, formally establishing the principle of freedom of movement of goods.
The concept of measures having an effect equivalent to that of quantitative restrictions was worked out by Commission statements of position and above all by the case law of the Court of Justice. Such measures include those aimed solely at imported products (measures that are discriminatory by their nature, such as import licenses); measures which, while applying both to national products and to imported products, are in practice more restrictive of imports (measures that have a de facto discriminatory effect such as indication of origin or the requirement to have a representative on the territory of the country); and, lastly, measures which, though affecting both national products and imports, are found to be disproportionate to the aim in view, which may for example be to protect the consumer, to ensure fair trade or to protect health.

In the EU, the principle of mutual recognition as described above, stemming from Article 30 of the EC Treaty, has been applied since the 1980s. However, as it is not always possible to find equivalence between national laws because of substantial disparities between bodies of national legislation, harmonized provisions have been adopted (for example in the case of the rules on labeling of foodstuffs). Once a climate of mutual trust had been established between the authorities of the Member States, trade barriers fell away with effect from 1 January 1993. As border controls by definition affect only imported products, they no longer have any justification in the context of a single market.

It has to be remembered, however, that even in sectors in which harmonization has taken place, the Treaty rules still apply. Such is the case, for example, with Directive 89/398/EEC concerning foodstuffs intended for particular nutritional uses, which makes provision for the marketing of products listed in Annex 1 to be subject to authorization, the detailed rules for which have to be considered in the light of Court of Justice case law relating to Article 30 of the Treaty.

Thus the concept of measures having an effect equivalent to that of quantitative restrictions and the concept of mutual recognition as interpreted by the Court of Justice were clarified in interpretative communications, information documents produced by the Commission and made available to business people and the authorities of the Member States. They include the interpretative communication on the "Cassis de Dijon" case, dated 20 February 1979; the communication on parallel imports of proprietary medicinal products for which marketing authorization has already been granted, dated 6 May 1982; the interpretative communication of 4 December 1986 on price controls and reimbursement of the medicinal products; the notice concerning type approval and registration procedures for vehicles previously registered in another Member State, dated 4 November 1988; the communication on the free movement of foodstuffs within the Community dated 24 October 1989; the communication on the names under which foodstuffs are sold, of 15 October 1991; and the "Peeters" communication on the use of languages in the marketing of foodstuffs, dated 23 December 1993.

Lastly, it should be pointed out that mutual recognition is but one instrument for achieving the aim of ensuring free trade, others being observance of certain principles governing the detailed arrangements for authorization procedures, the time limits for the issue of an authorization, the costs of such procedures (which must not be excessive), the abolition of reservations favouring national products such as "buy national" clauses, and the elimination of preferential arrangements in favour of supposedly disadvantaged national producers or products.

Preventive measures: Directive 83/189/EEC
One device for preventing trade barriers being erected by means of legislation is provided by Directive 83/189/EEC, which stipulates that Member States must notify draft technical rules to the Commission before they are adopted. This enables the Commission to comment and where necessary gives Member States an opportunity to amend drafts before adoption, thus ensuring that trade barriers are not created (see section on free movement and safety of industrial products).

Retrospective checking

The aim of the Commission proposal* for a Council and Parliament Decision establishing a mutual information procedure on national measures derogating from the principle of free movement of goods within the EU is to require the Member States to give notice of measures to prohibit the marketing of products for reasons which they consider justified under Article 36 of the Treaty or in the light of the circumstances of overriding necessity recognized by the case law of the Court of Justice. This is because transparency offers the only means of dealing swiftly with barriers to the movement of goods and hence of checking the application of the principle of freedom of movement. The proposed Decision would, however, apply only to national measures which are not notifiable already under other Community instruments which provide for similar notification arrangements.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

Preconditions for the application of mutual recognition

Application of this principle may be considered at three levels:

- recognition of certification bodies,
- recognition by Member States of the Union of tests already carried out in the CEECs and vice versa;
- recognition by Member States of the EU of products legally manufactured and/or marketed in the CEEC countries and vice versa.

Hence the primary conditions for application of this principle must be:

(a) the existence of product safety certification bodies operating in accordance with the same rules as similar bodies in existence in the EU (i.e. in accordance with the EN 45000 standards);

(b) the existence of laboratories carrying out tests on products requiring it, e.g. certain food products containing additives or vitamins). These would be either private or public laboratories whose tests would be recognized in other Member States of the EU;
(c) the existence of product monitoring machinery (e.g. authorization procedure for products containing certain substances such as vitamins or additives: authorization procedures for parallel imports of medicinal products).

The monitoring machinery for foodstuffs in the various Member States of the Union is under the care of the relevant departments of the health ministry in each country. Some of the work involved may also be delegated to private monitoring bodies, as for example in the case of analysis of the composition of certain products presenting health problems.

It must also be noted that "pre-emptive" checks can be justified only where the products concerned may entail a health risk. This is because the normal rule is that where a product is marketed legally in another Member State of the Community, further checks should not be necessary.

KEY MEASURES

The abolition of quantitative restrictions and the elimination of discriminatory measures affecting only imported products are prerequisites for the application of the principle of free movement of goods in trade between the Member States and the CEEC countries. Merely abolishing this type of trade barrier is not sufficient, however, for the establishment of free movement of products between the European Union countries and the CEECs. It is also essential to abolish other protectionist measures which, while affecting both national products and imports, are discriminatory in effect (as for example in the case of indications of origin or the requirement to have a national representative).

• CHOICE OF STAGE I MEASURES

DESCRIPTION & JUSTIFICATION:

To establish the principle of non-discrimination and to abolish quotas. All discriminatory provisions or practices have to be abolished. These might include the following: measures imposing, for imports only, maximum or minimum prices above or below which the imports would be prohibited, reduced or subject to conditions likely to make importing difficult; measures subjecting imports only to payment of a security or deposit; "buy national" incentives or measures laying down time limits that are inadequate or, on the other hand, excessive in relation to the normal procedure for carrying out the operations concerned; and measures giving national products preferential treatment over imports.
DESCRIPTION & JUSTIFICATION:

It may be necessary to review national measures covering the weight, composition, labeling, manufacture and description of products. National rules on, for example, the composition of a product (e.g. pasta), where harmonized rules at Community level do not exist, even though there are rules applying to products manufactured on national territory and the territory of other Member States, may have the effect of hampering trade.

A producer in a Member State has to modify his production according to the country where the export market is situated, and the effects can be substantial. Abolition of this type of barrier depends on the CEEC markets having the capacity to withstand the market presence of products from the Member States of the EU. Such a presence would in any case occur as a result of the abolition of quantitative restrictions and formally discriminatory measures.

Abolishing this second type of barrier, which is admittedly more difficult to deal with, would open up more extensively the markets concerned to EU products.

In this connection, detailed acquaintance with Court of Justice case law relating to Article 30 is essential for carrying out the task of amending legislation or adjusting administrative practices.
GENERAL INTRODUCTION

One of the fundamental principles of the single market is that all firms must have a fair chance of winning public contracts, i.e. contracts awarded by public authorities and by entities operating in the water, energy, transport and telecommunications sectors. There are considerable economic interests at stake in public contracts, whether these be for works, supplies or services, since out of an estimated gross domestic product of ECU 3,891 billion for the Community in 1990, public expenditure is estimated at ECU 1,790 billion and public procurement at ECU 595 billion, equivalent to around 15% of GDP.

The Community institutions have clearly opted for full and effective competition in the public procurement field, thereby ensuring economic growth in the Union. It is in the interests of all players in the economy that there should be competition for public purchasing: competitive procurement enables governments to use public funds more efficiently, offers industry greater commercial opportunities, and affords consumers the assurance that funds transferred to public bodies are used efficiently and that the services rendered are of a high standard.

To that end, the Council, Parliament and the Commission have created a Community legislative framework covering works, supply and service contracts awarded both by traditional contracting authorities (bodies belonging to central government and regional and local authorities) and by public, semi-public and private entities operating in the water, energy, transport and telecommunications sectors (utilities). Application of this Community legislation is monitored by the Commission and by the Court of Justice and national courts, which has made it possible to develop a body of case-law that usefully supplements the legislative framework.

In addition to the principles enshrined in the Treaty, a number of directives have been adopted. These harmonize the rules governing the award of contracts by requiring proper advertising and transparency, establishing an order of preference between award procedures, laying down common rules on technical specifications and fixing criteria for selecting candidates and awarding contracts. They also make remedies available to firms in the event of a breach of Community law on public procurement or of the national rules transposing it.

Substantial results have already been achieved, demonstrating that the single market is effectively opening up and that all firms, including SMEs, now have more opportunities than ever before to bid for contracts in fair conditions.
The European Union has also launched a large number of support measures. One scheme focuses on training of staff involved in procurement; training is deemed essential if the applicable legislation is to be implemented correctly and efficiently. Another project is intended to boost the effectiveness of the transparency and advertising required by the directives; it involves standardizing the presentation of, and the terminology used in, notices that have to be submitted for publication in the Official Journal of the European Communities, so that the information disseminated is precise and easy to use by firms, and also upgrading computerized information systems. A further initiative is aimed at promoting the development of consultancy firms which help businesses, and SMEs in particular, to tender for contracts.

DESCRIPTION OF THE LEGISLATION

Community legislation on public procurement covers three main areas:

- procurement by public contracting authorities, i.e. central government and regional or local authorities;
- procurement by contracting entities operating in the water, energy, transport and telecommunications sectors;
- the remedies, or review procedures, which must be available in the event of a breach of the Community legislation.

Procurement by contracting authorities at central, regional or local government level

The contracts concerned are therefore those awarded by central government, regional or local authorities and public or private bodies under their control. These contracting authorities award supply, works and service contracts to meet their own operating requirements and in order to provide public services. The contracts can vary widely in value since they may relate, for example, to the purchase of educational materials by a municipality or the construction of a new item of infrastructure such as a motorway, offices for a government department, a university or a hospital.

These contracts fall within the scope of Directives 93/36/EEC, 93/37/EEC and 92/50/EEC, the provisions of which have been incorporated into Member States' national laws.

They must be awarded in accordance with a number of rules relating to the publication of tender notices, the allowance of long enough deadlines for the submission of applications and tenders, the use of European standards for defining technical specifications, the choice of procedures ensuring the widest possible competition for contracts, and the choice of criteria for selecting candidates and awarding contracts.
Procurement by contracting entities operating in the water, energy, transport and telecommunications sectors

Contracts awarded by entities operating in the water, energy, transport and telecommunications sectors are extremely important economically. They consist of supply, works and service contracts awarded in connection with the activities involved in:

- providing or operating networks for the production, transport or distribution of drinking water, electricity, gas or heat;

- exploiting a geographical area for the purposes of exploring for or extracting oil, gas or coal or providing carriers with airport or maritime or inland port facilities;

- operating rail, tram or bus transport networks;

- providing or operating public telecommunications networks or providing public telecommunications services.

The fact that some of these entities come under public law and others under private law prompted the Community to make the rules somewhat more flexible than those applicable to contracting authorities at central, regional or local government level. These rules are laid down in Directive 93/38/EEC.

Review procedures

The opening-up of public procurement to Community-wide competition calls for guarantees of transparency and non-discrimination. For this to become effective, review procedures, or remedies, must be available to firms in the event of an infringement of Community law: a lack of proper remedies deters firms from bidding for contracts in other Member States.

The review procedures must be effective and swift, in order to cater for the specific features of the award of contracts, in particular the fact that the process is completed quickly. The review bodies must therefore deal with any infringements as a matter of urgency in order to enable unlawful decisions to be set aside and damages to be awarded to firms that have been harmed as a result of the infringements.

Review procedures are provided for by Directive 89/665/EEC in the case of contracts awarded by contracting authorities at central, regional or local government level and by Directive 92/13/EEC in the case of contracts awarded by entities operating in the water, energy, transport and telecommunications sectors.
CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

To determine the conditions that need to be met prior to any alignment of the CEECs on the European Union in the public procurement field, some aspects of the situation prevailing in the European Union deserve to be mentioned. The context is one of a market economy in which private initiative and price-formation mechanisms can develop. Within this economic framework, legal instruments are in place to ensure the free movement of goods and services, together with transparency and competition in public procurement.

Consequently, the adoption of a body of legislation aimed at opening up public procurement to competition presupposes the existence of a legal environment that creates the necessary conditions for the free movement of goods and services, competition between economic operators and the control of public aid. This must be regarded as an essential precondition that must be met no later than the time the legislation on public procurement is set in place.

As regards the implementation of such legislation, special attention should be devoted to the structures responsible for the areas concerned. The entities awarding contracts must therefore be precisely defined. Entities could initially be brought within the scope of the legislation according to the amount of their purchases (central entities, the most important local entities, management entities in the water, energy, transport and telecommunications sectors). It is also necessary to design and set up a body responsible for managing the different aspects of public procurement policy; its tasks would include ensuring that the rules are properly applied, giving expert advice on public purchasing and providing information and training on public procurement. It is important to ensure that tender notices are published nationwide; a body which is familiar to the business community must therefore publish these notices at frequent enough intervals. Lastly, it is essential for there to be monitoring and review bodies, whether these be judicial or quasi-judicial in nature.

A gradual, differentiated approach

The Member States of the European Union have had to apply very gradually rules on the award of works contracts, supply contracts and then contracts in the water, energy, transport and telecommunications sectors, followed by service contracts and finally rules on review procedures. Similarly, Spain, Portugal and Greece have been granted transitional periods to enable them to adjust to the new European rules; these periods have not yet expired for some of the directives.

- The same gradual approach should therefore be adopted for the CEECs. Those responsible for procurement decisions will have to be familiarized with completely new rules for putting contracts up for competition; private enterprise will also have to be made aware of the resulting opportunities for winning contracts. The acquisition of these new patterns of behaviour can only be a gradual process.
The approach should also be differentiated. Even if all the CEECs have already introduced legislation on public procurement or are poised to do so, certain differences should be taken into account. These differences are to be found in the content of the legislation itself, but also, more generally, in the economic and legal situation prevailing in each of the CEECs. It would therefore be difficult to imagine that all the CEECs could adjust to the EU public procurement legislation at the same speed; individual timetables could be drawn up following bilateral contacts between European Union representatives and each of the CEECs.

**KEY MEASURES**

The principles enshrined in the Treaty and the six directives on public procurement form a consistent whole which covers all the sectors in which public contracts are awarded and makes it possible to impose penalties in the event of a breach of Community law on public procurement or of the national rules transposing it. (Treaty: - Article 30: principle of the free movement of goods, - Article 59: principle of the freedom to provide services, - Article 52: principle of the right of establishment; Case-law of the Court of Justice: principle of equal treatment of tenderers (judgment of 22 June 1993 in Case C-243/89 Commission v Denmark)

All these rules should therefore ultimately be incorporated into the legislation of the CEECs.

- **CHOICE OF STAGE I MEASURES**

**DESCRIPTION & JUSTIFICATION**

The CEECs have by now all adopted, or are poised to adopt, legislation covering public procurement in varying degrees of detail, based largely on the model procurement code developed by the United Nations Commission on International Trade Law (Uncitral) and on some of the Community public procurement directives.

The first stage would therefore involve analysing this existing or draft legislation with a view to identifying:

- the presence of the essential features on which the "acquis communautaire" is based;
- the essential features which have not been included;
- any points which are incompatible with the "acquis communautaire".
For guidance, the analytical matrix would include the following provisions:

### STAGE I MEASURES

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<tbody>
<tr>
<td>OJ No L 199, 9.8.1993</td>
<td>- Title I, at least Article 1(d), (e) and (f) and Article 6</td>
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<td>- Title II, Article 8</td>
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<td>- Title III, at least Article 18</td>
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<td>- Title V, at least Article 34</td>
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<tr>
<td>OJ No L 295, 30.12.1989</td>
<td>- Articles 1 and 2</td>
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</table>
CHOICE OF STAGE II MEASURES

DESCRIPTION & JUSTIFICATION:

The second stage would be aimed at setting in place in the CEECs the entire "acquis communautaire" in the public procurement field. The approach could, of course, be progressive. This comprehensive body of binding rules could thus be applied initially to the most important entities and subsequently to all entities corresponding to those covered by the Community directives.

STAGE II MEASURES

|--------------------------------------------|---------------------------------------------------------------------------------------------------|
GENERAL INTRODUCTION

One of the cornerstones in a successful transformation from a centralised economy to a market economy is the creation of a well-developed financial sector. The financial sector is one of the key elements for economic performance because it is via the financial sector that private savings and other available capital is allocated to investment. Another important function for the financial sector is to co-ordinate economic activities toward the most productive use of available capital. Therefore a market economy cannot function without a well-developed and competitive financial sector.

A financial sector cannot be established overnight but has to be created in stages. The order in which the different elements have to be implemented depends on the type of financial system which has been chosen. Independently of this, it is of the greatest importance that the users of the financial system (both domestic and internationally) have full confidence in the system. This trust can only be created via prudential legislation and the creation of efficient supervision or control of the companies in the financial sector.

The aim of EC co-ordination within the financial sector has been to establish a single market for financial services. This was done on the basis of already existing - and in most cases - correctly functioning financial sectors in the Member States. The main purpose was therefore not to build up the financial systems but more to co-ordinate the minimum requirements for the different type of institutions in order to create a uniform minimum standard and a more level playing field as the basis for home country control and the single licence.

This is not to say that no developments took place during the process of co-ordination but the fundamentals were already there.

The three elements needed in order to develop a correctly functioning financial sector are: a) trained and reputable personnel, b) appropriate legislation and c) effective supervisory bodies to ensure that the financial institutions are respecting the laws and regulations under which they work. Financial services in a centralised economy are quite different from financial services in a market economy. Therefore training is one of the most urgent needs, not only for the employees in the industry but as much for the staff of the supervisory bodies.
When drafting laws and regulations for the financial sector it is important to have the actual "know how" level of the industry in mind and not to allow the sector to do more than it is qualified to do. Finally, qualified supervisory bodies mean that the supervisory staff must be well trained but also be sufficient in number to make it possible to supervise or control all the authorised firms on a timely basis. Without a correctly functioning supervisory body even the most advanced regulations will make no sense. Therefore, every effort must be made to strengthen the quality of the supervisory bodies so that they are able to perform their duties adequately.

It should be stressed that the order in which the EC directives within the financial sector have been adopted and the different elements they have co-ordinated do not always reflect the most logical order for a country which has to build up a financial sector from scratch. The different directives include elements and principles for which co-ordination was needed at the time of adoption. Before then national discretion was sufficient. This means that the CEECs ought to make themselves acquainted with all the directives within a sector and implement in the first stage some of the elements which first might be mentioned in the stage two measures. An example is the minimum start up capital for credit institutions which was co-ordinated in the second banking directive at a minimum of ECU 5 mio. The CEECs must decide (from the beginning) upon what they want as minimum start up capital.

I. **Financial Institutions**

**INTRODUCTION**

Financial institutions will in this context be interpreted in a broad way as covering all institutions within the financial sector but excluding insurance undertakings. Correctly functioning financial institutions are essential in a modern market economy. That is not to say that all the different types of financial institutions should have same high priority when it come to the order in which they are established because some of them depend on the existence of the others.

The creation of an efficient banking system in which savings are transformed into loans to industry on market (economy) terms is of the utmost importance. The creation of an efficient payments system is also needed. Furthermore, the capital market can contribute to the allocation of capital to industry via correctly functioning stock exchanges, just as the establishment of collective or mutual investment funds together with other institutional investors such as pension funds can provide valuable capital for investment in industry and the private sector, especially the housing sector, while at the same time giving a larger section of the population a stake and interest in the financial markets.

At the time when the EC started its co-ordination of the financial sector all Member States already had well-developed financial sectors. The co-ordination which has taken place was therefore more a question of fixing minimum standards for the industry in the preparation for the Internal Market rather than an attempt to develop the financial sector.
DESCRIPTION OF THE LEGISLATION

Financial institutions are service providers and in many respects are not different from other service industries. Their success depends on their ability to provide the right products at the right price in competition with other providers. The difference between them is that financial institutions are handling customers' money and the failure of a financial institution, and a credit institution in particular, could lead to substantial losses for its customers. This is not acceptable for the community and therefore much stricter regulations are needed for financial institutions than for other service providers in general. The main purpose of those regulations or prudential rules is on one hand to protect the institutions customers but to protect the financial industry from contagion risk stemming from the failure of one of the financial institutions.

The main purpose of the co-ordination which has taken place within the financial institutions has been the creation of the Single Market. The break-through came with the adoption in 1985 of the directive on collective investment funds (UCITS) in which the three basic principles for the creation of the Internal Market were laid down. The principles are: a) harmonisation of the authorisation conditions and the prudential standards, b) home country control and c) mutual recognition of the national supervisory standards. The same principles were later adopted in the field of credit institutions and for investment firms.

As already mentioned in the general introduction to the financial sector the main problem within the EU was not to establish financial institutions but to agree on the minimum harmonisation needed in order to create the basis for mutual recognition of the different national supervisory systems. One could also say that what was needed was mutual trust between the national authorities, trust that the other supervisors would be able to carry out their supervisory obligations in the same qualified way as the national supervisor would do. Again, trust and confidence is essential for a correctly functioning financial system, not only trust in the way in which the institutions themselves are doing business but also in the way the supervisory authorities are performing their duties.

CONDITIONS NECESSARY TO OPERATE THE LEGISLATION

Legislative approximation in the field of financial sector legislation in general presupposes the existence of a basic legislative environment. Included in this basic legislation or regulation are regulations concerning the establishment of companies, regulations concerning accounting and rules for controlling or auditing the companies. The level of this regulation corresponds to the levels described under Company law, and Accounting - conditions necessary to operate the legislation.
A condition (but not necessarily a pre-condition) for the functioning of the financial sector is the establishment of an effective settlement system to deal with transactions between the different financial institutions. Until now no directives have been adopted concerning settlement systems but a proposal dealing with the effectiveness of existing schemes is under discussion.

Credit institutions.

With those basic pre-conditions of alignment in place the most important first step will be the establishment of a supervisory authority to oversee the credit institutions (or banks as they normally are called). The role of the supervisory authority is to make rules for granting the authorisation to credit institutions and rules on prudential requirements and then to control that the credit institutions fulfil these requirements (especially solvency).

The pre-conditions mentioned above will be sufficient for most of the different banking activities but not all of them. One very important activity, and especially in economies transforming themselves into market economies, is mortgage credit. A correctly functioning mortgage credit sector cannot exist without a legal infrastructure, such as clear rules for ownership of real estate, transparency concerning old claims (e.g. taxes) on the property and a correctly functioning land-register, where mortgages can be registered and legal provisions to enforce the mortgages. Development of a valuation profession could also be recommended.

Securities.

Before stock exchanges can be established it is necessary that laws concerning issue and ownership of securities be adopted.

Collective investment funds

A pre-condition for the establishment of collective investment funds is that securities are issued and traded on regulated markets.

KEY MEASURES

All directives or measures which are an integr sector have been included as key measures, wh has been to facilitate the functioning of the market have been left out.

- CHOICE OF STAGE I MEASURES

DESCRIPTION & JUSTIFICATION:

As mentioned above the EU directives dealing with financial institutions have not been tailored to serve as a model for creating a financial sector.
The directives chosen to form the first stage measures are those which introduce the basic principles for establishment of financial institutions, but there are elements in the second stage measures which it could be beneficial to introduce at an early stage. In the first stage efforts should be concentrated on implementing the principles laid down in the following directives from each of the following financial sectors:

A. Credit institutions.

1. The first banking Directive which lays down the principles of right of establishment and the freedom to provide services and the establishment of a supervisory authority. It applies to the taking-up of the business of credit institutions i.e. the business of receiving deposits from the public and granting loans, and establishes the essential requirements for authorisation, such as the possession of adequate minimum own funds and that at least two persons effectively direct the business (and are of sufficiently good repute and possess sufficient experience to perform such duties).

2. The own funds Directive which defines which capital elements can be counted as regulatory capital. The Directive divides the elements in two categories: core capital (original own funds) consist of the highest quality items (equity capital, disclosed reserves and funds for general banking risks) and supplementary capital (revaluation reserves, securities of indeterminate duration, hidden reserves, commitments of members of cooperative societies and subordinated loans. Supplementary capital must not exceed the core capital.

3. The solvency ratio Directive, the main purpose of which is to harmonise the prudential supervision and to strengthen solvency standards among Community credit institutions, thereby protecting both depositors and investors as well as maintaining banking stability. The principle is that a credit institution at least shall hold own funds equal to 8% of its risk-adjusted values of its assets and off-balance sheet business. This calculation is meant to capture the inherent credit risk in the banking business (for other risks see stage two).

4. The deposit guarantee Directive, which will guarantee depositors their savings - up to a fixed maximum - in case of insolvency of a credit institution. The principle of this directive will strengthen the trust of the depositors in the banking system.
B. Securities.

1. The Directive on public offer prospectus applies to securities which are offered to the public for subscription or sale for the first time in a Member State. The prospectus must include all information needed to make an informed financial assessment of the securities. A competent authority shall be appointed to agree prior scrutiny of the prospectus. Co-operation between Member States and provisions for the mutual recognition of prospectuses when securities are offered simultaneously in more than one Member State.

2. The Directive on stock exchange listing particulars of securities, which are admitted or are the subject of an application for admission to official listing on a stock exchange. Such securities must comply with the conditions and fulfil the obligations set out in the annex to the Directive. Member States may require issuers of securities to publish information regularly on their financial position and on the general course of their business. A competent authority to decide on the admission of securities and the application of the Directive shall be designated.

3. The Directive on notification of major holdings which is meant to give investors adequate information on persons who acquire or dispose of major holdings in listed companies. When the voting rights of holdings held by one person exceed or fall below certain thresholds the company and the public must be notified. The competent authorities can grant exceptions only when the disclosure would be seriously harmful to the companies involved.

4. The Directive on insider dealing the main purpose of which is to protect investors against improper use of inside information. This directive is also helpful in creating confidence in the market place.

C. Investment funds.

Directive on undertakings for collective investment in transferable securities (UCITS) provides principles for the authorisation of "open ended" investment funds, rules for sale and repurchase of their units, obligations concerning management, investment (at least 90% of investment must be in transferable securities listed on a stock exchange or on another regulated market), depositaries and prospectuses, designation of authorities responsible for authorisation and supervision of funds. Some of the basic principles of this Directive should be implemented in the first stage (but pre-suppose the existence of transferable securities and regulated markets) in order to give small investors an alternative to bank savings.
D. *Money Laundering*

The Council Directive of 10 June 1991 on prevention of the use of the financial system for the purpose of money laundering is a horizontal directive covering credit institutions, financial institutions and insurance companies. The Community strongly recommends the CEECs to establish suitable standards against money laundering as soon as possible in order to avoid their financial sectors being used for laundering of proceeds from criminal activities in general and drug offences in particular. Without such measures the confidence in their financial systems might be jeopardised. The existing European Agreements contain an Article concerning this.

The right of establishment has been an important element in the EU simply due to the Treaty obligation. In the Europe Agreements between the EU and CEECs which have been made until now it is agreed that EU financial companies shall have the right to set up operations in the territory of the respective CEEC, at the latest by the end of the transitional period of the Agreement. Nevertheless, the Community strongly recommends to the CEECs to make such establishments possible as soon as possible because it would be very much to the benefit of the countries in question to benefit from the know how of such companies.

Finally, there is as yet no EU directive dealing with the establishment of stock exchanges. Today all the CEECs have established one or more stock exchanges and for those exchanges the basic principles should be clear and transparent rules for the functioning of the exchanges and establishment of a qualified body to supervise the operation of the exchanges. Firms dealing on the exchanges should be regulated and supervised, but in the first stage, membership rules (including a fit and proper test) should be sufficient as long as the confidence in the business taking place is not jeopardised.

**STAGE I MEASURES**

*Credit institutions:*

<table>
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<th>Directive</th>
<th>Summary</th>
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</table>
Securities:


Investment funds:


Horizontal directive for whole financial sector:


• **CHOICE OF STAGE II MEASURES**

**DESCRIPTION & JUSTIFICATION:**

As soon as one of the above mentioned financial sectors has implemented its first stage programme it should continue to its own specific second stage measures without waiting for the other sectors. The measures in the second stage will aim in particular to strengthen the prudential regulation for the firms in order to bring them up to international standards.

Some of the key directives which are proposed for the second stage will include provisions directly related to the creation of the Community Internal Market, such as the freedom of establishment and the freedom to provide cross-border services without further authorisation and the principle of home country supervision. Those provisions could be disregarded in the second stage.
The directives to be implemented in the second stage would be the following:

A. **Credit institutions.**

1. The second banking Directive is the main instrument for completing the single market in banking. It promotes both the right of establishment and the freedom to provide services. It requires that only credit institutions are allowed to take deposits or other repayable funds from the public. It fixes the minimum initial capital of a credit institution to ECU 5 million. The competent authorities may not grant authorisation before they are satisfied as to the suitability of the shareholders. The Directive introduces the principle of a single banking licence or authorisation which grants banks the right to establish branches in other Member States or to provide cross-border services without a new authorisation (but after notification of the host authorities). The Directive also introduces the principle of home country control for the core banking activities listed in its annex, and further allocates the supervisory functions between home country and host country authorities. It harmonises the conditions relating to the pursuit of banking activities, maintenance of initial capital, control powers in respect of the acquisition of qualifying holdings in credit institutions, the existence of sound administrative and accounting procedures and adequate internal control mechanisms.

2. The Directive on the annual accounts and consolidated accounts of banks and other financial institutions specifically addresses this sector but has to be read together with the fourth and seventh Company Law Directives. It establishes a standard balance sheet layout where assets and liabilities are presented in decreasing order of liquidity and with special provisions for certain of the balance sheet items. It has two standard profit and loss account layouts, a vertical and a horizontal layout, again with special provisions for certain of the items. Special valuation rules for assets, financial fixed assets and advances, variable-yield securities and assets and liabilities denominated in foreign currency. The Directive authorises hidden reserves in certain circumstances and has a detailed list of the required contents of the notes and accounts. Separate provisions are made relating to consolidated accounts and the publication of annual accounts.

3. The Directive on capital adequacy of investment firms and credit institutions deals with risks other than credit risk (solvency directive), to which investment firms and banks are exposed. The Directive divides the books of a bank into its trading book and the "non-trading book" and the "requirements" are calculated in relation to the trading book part. The provisions relevant for banks are those dealing with the calculation of position risk, where hedged positions carry much reduced requirements, foreign exchange risk and settlement risk.
Furthermore new types of capital, which banks and investment firms may use as own funds to cover capital requirements to form the trading book, are introduced. Finally the Directive introduces rules for large trading book positions which shall be seen as a supplement to the directive on large exposures (see next item).

4. Large exposures Directive which limits the exposure a bank can have to a single client to a maximum of 25% of its own funds. All large exposures (more than 10% of own funds) shall be reported to the competent authorities four times a year. A credit institution must not incur large exposures which, in the aggregate, exceed 800% of own funds.

5. The Directive on supervision of credit institutions on a consolidated basis applies to all banking groups including those the parent undertaking of which are not credit institutions. The Directive has provisions on the competent authority or authorities responsible for consolidated supervision and how the authorities shall co-operate. The competent authorities must require full consolidation of all the credit and financial institutions which are subsidiaries of a parent undertaking.

Supervision on a consolidated basis is all the more effective if it can be exercised on a world-wide basis or at any rate on the widest possible geographical basis. It is therefore necessary to ensure that there are no impediments in third countries to the transfer of the necessary information and, where such impediments exist, to endeavour to make agreements with the countries in question.

B. Securities.

1. The investment services Directive applies to investment firms. It requires the Member States to establish competent authorities who shall grant and withdraw authorisations of investment firms and supervise their activities. To be authorised, an investment firm must: have sufficient initial financial resources; be managed by people with sufficient professional integrity and experience; and, holders of qualified participations must be suitable persons. The principles of home country control and a single licence are also applied (as for banks).

2. The Directive on capital adequacy of investment firms and credit institutions applies to investment firms and to banks as mentioned above. Furthermore, some of the provisions in the Directive are specific to investment firms. First of all the Directive fixes the minimum initial capital needed for investment firms. The amount of capital is determined by the type of activities and operations of the firm and varies from ECU 125 000 to ECU 730 000. Secondly, the Directive requires consolidation where two or more investment firms belong to the same group (i.e. if a bank is in the group then the banking consolidation directive will apply).
C. Investment funds.

UCITS (see stage I) for the part not introduced in Stage I.

**STAGE II MEASURES**

*Credit institutions*:

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<th>Measure</th>
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<tr>
<td>Annual accounts and consolidated</td>
<td>Council Directive of 8 December 1986 on the annual accounts and consolidated accounts of banks and other financial institutions</td>
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*Securities*:

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*Investment funds*:

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<th>Measure</th>
<th>Directive/Announcement</th>
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Remaining measures not identified in preceding stages

The three directives within the sector of financial institutions which are not regarded as key measures are:

a) Council Directive 89/117/EEC of 13 February 1989 on the obligation of branches established in a Member State of credit institutions and financial institutions having their head offices outside that Member State regarding the publication of annual accounting documents (OJ L 44 of 16.02.1989). The main purpose of this Directive is to facilitate life for such branches and not to require more information than is necessary.

b1) Council Directive 80/390/EEC of 5 March 1980, co-ordination the requirements for drawing up, scrutiny and distribution of the listing particulars to be published for the admission of securities to official stock exchange listing (OJ L 100 of 17.04.1980) and


The two last mentioned directives are giving important information to the market but the most important information will already be covered by the directives mentioned as key-measures.
INTRODUCTION

The EU has long regarded the creation of a single common market for insurance as a policy firmly based on the EEC Treaty, which provided the means through the rights of establishment and of free provision of services (Treaty Chapters 2 and 3). Indeed, in 1961 the Council adopted an ambitious programme envisaging the realisation of successive rapid stages: both freedoms would first be achieved in the field of reinsurance, followed successively by freedom of establishment in direct non-life insurance, freedom of establishment in direct life insurance, freedom of services for direct non-life insurance and finally freedom of services for direct life insurance. Although the time frame of this programme has been overtaken by events, the main objectives of an EU Internal Market in insurance still are:

- insurers having their headquarters in any one Member State must be free to take up business in any other Member State and to market the full range of their insurance products throughout the Community, without having to use branches or any other form of establishment;
- insurers should be subject to essentially the same main supervisory rules, to be applied by separate national authorities;
- the purchaser of insurance, whether business or private, must be able to buy his insurance wherever he likes in the Community;
- there must be enough control over selling methods and the nature of the products to prevent the public from being misled without being so heavy that it stifles innovation;
- brokers and other intermediaries must be free to operate on equal terms throughout the market;
- adequate and comparable financial information must be available about all the insurers in the market;
- contract law does not necessarily have to be uniform throughout the Community, but there must be rules which protect the public and ensure that the choice of law is not an element of competition;
- there must be no restrictions on the currency movements of any of the parties involved in the transactions;

These objectives have been fulfilled with the adoption of numerous separate measures over the years, some of which are not specific to insurance.

Insurance is traditionally seen as a financial arrangement that redistributes the costs of unexpected losses. Its legal vehicle is a contract whereby one party agrees to compensate another party for losses.
The interest of the State in intervening in the operation of the insurance market is heightened by the common perception that insurance, both non-life and life, through spreading the cost of taking risks, benefits society. This leads logically to certain insurances being made compulsory - but also in a more general way has given rise to a feeling, more prevalent in some States than others, that insurance is not a marketplace activity like any other but is a sort of private extension of social security in which the State properly maintains a close interest.

However, because hardly anybody advocates a complete "free for all" insurance, it is an area where protectionism may easily disguise itself as consumer protection. It is equally true, however, that different perceptions of the public interest and different degrees of State intervention produce a situation in which mutual recognition of standards between Member States is a sine qua non since insurers based in countries where State control is tight inevitably feel themselves at a disadvantage if they have to compete with insurers based in countries where regulation is less strict or less comprehensive.

Not all insurance is a consumer product bought by the man in the street. A substantial part is taken out by industrial, commercial and transport enterprises, by professional people, by farmers and by small traders, as a necessary part of their business activity. For them insurance is simply one more input, representing an essential underpinning of their activities. In principle, their choice of insurance is just one more business decision.

Insurance markets are essentially made up of buyers (policyholders), sellers (insurance undertakings) and intermediaries (brokers and agents). Their interests and aspirations have to be taken into account when setting up any insurance system.

Insurance may in theory be sold in three ways, namely by a contact between the insurer and the prospective buyer made directly, without the services of an intermediary or, through agents who are independent in the sense that they are not employees, but who are nevertheless tied to the insurance undertaking in such a way that they represent its interests and not those of the buyer. Finally it may be sold by a broker who ideally may be thought of as completely independent of both insurers and policyholders.

Creating a common market in insurance does not mean dealing with a single coherent activity, but rather with a family of related businesses. The main divisions are between non-life insurance, life insurance and reinsurance, although there are important distinctions within each of these groups.

Non-Life insurance, in most of its manifestations is not easily substituted by services provided by other financial institutions. The choice is usually between insuring a risk and bearing the whole or part of it oneself (self-insurance).
Life insurance, on the other hand, is a concept with less clear boundaries. As an insurance against the risk of premature death it is very like non-life insurance, but in all other forms it contains savings or investment elements which may become preponderant. It occupies a space between social security and the pure savings media provided by other financial institutions.

Reinsurance and retrocession present a quite different picture. They are transactions engaged in between insurance professionals. The extent to which they are practised and the ways in which they are conducted vary from one Member State to another, but for reasons which remain entirely within the bounds of insurance.

**DESCRIPTION OF THE LEGISLATION**

In the history of the Union, two directives constitute the foundation of the Internal Market for insurance together with the provisions of the Treaty of Rome, on the freedoms of capital movement, establishment and services.


The main objective of these two directives is to co-ordinate Member States provisions relating to:

a) the taking up of the business of direct insurance, and

b) the carrying out of direct insurance.

The purpose of these directives was to make it possible for insurance undertakings in one Member State to carry out their business in another Member State on the conditions of the host country with a minimum of red tape.

In order to do this, harmonisation took place in the following areas:

- **conditions of admission** (i.e. the principle that an authorisation is necessary, that a company must limit its activities to insurance, that a scheme of operations must be submitted, that a minimum start-up capital is necessary etc.);

- **conditions of operation** (i.e. that a company must establish sufficient technical reserves, covered by equivalent and matching assets, and that a solvency margin is established etc.);

- **conditions of withdrawal of authorisation**;

- **rules applicable to branches** established within the Union but whose head offices are outside the EU.
The EU Directives extend supervision to all insurance activities. In the Non-Life sector a list of classes of insurance was established to cover the whole (non-life) insurance sector.

To understand the solution adopted in the First Generation Directives, it should be kept in mind that the distinction between different classes of insurance activities underlies both the authorization procedure and the application of prudential norms to specific risks.

In principle the list is, therefore, based on a "single risk" approach, which makes it possible to establish Community-wide a uniform relationship between a specific risk and the applicable prudential norms.

The single risk concept has been made subject to two nuances in order to avoid that those Member States, whose supervisory practice was based on a multi-risk approach, had to redefine their approach.

First, there is a possibility to group together certain classes for which an authorization may be granted simultaneously (e.g. accident and health insurance, motor insurance, marine and transport insurance).

Secondly, the system permits (except for risks classified as credit and surety and, partially, as legal expenses), all risks to be considered as ancillary to a principal risk and thus not requiring separate authorization, if such ancillary risks:

- are connected with the principal risk,
- concern the object which is covered by the principal risk, and
- are covered by the contract insuring the principal risk.

In order to allow the freedom of establishment to develop in an orderly manner throughout the Community, the First Directive seeks to confirm the principle of universality of prudential supervision. As a rule, therefore, all undertakings are covered who seek to underwrite the risks falling within any of the classes of business in the Annexes to the First Directives.

Nevertheless, certain exceptions to the general rule proved necessary. These relate firstly to the insurance operations themselves, and secondly to the undertakings carrying-out those operations. Thus, as far as the first category is concerned, insurance covered by a statutory system of social security is excluded except when covered by private insurers at their own risk.

As far as the second category is concerned, the First Generation Directives provides a list of institutions, by Member State, that are excluded from the scope of application of the Directive. The institutions listed in the Directives, which mostly cover fire insurance, are largely public institutions linked to local authorities.
The license is the authorisation granted to an insurance undertaking by the competent authorities of a Member State where the risk is situated or where its head office is established, to carry out direct life or non-life insurance activities. It permits a preventive form of supervision by giving the authorities the possibility of assessing the viability of the undertaking and its capability of operating in conformity with the applicable rules. This authorization requirement is the key element of insurance supervision.

The First Generation Directives also establish that, in respect to company law, the creation of an insurance undertaking is the subject of specific legal and financial conditions.

The legal forms an insurance undertaking may adopt are listed by Member States in the First Generation Directives. The list, following an approach of mutual recognition, is essential as a basis for the freedom of establishment. This freedom would be seriously restricted if a Member State were to refuse authorization to a branch of an insurance undertaking that had been set up under the laws of its country of origin, on the grounds that the legal form chosen by that undertaking was unknown to the country of establishment. The mutual recognition of legal forms of companies is even more essential in the context of the third generation directives, which introduce the single license concept.

An insurance undertaking is also obliged to limit its business activities to the business of insurance and operations directly arising from it to the exclusion of all other commercial business.

As far as financial conditions are concerned, the First Generation Directives prescribe that insurance undertakings possess a solvency ratio and a minimum guarantee fund. Although both the solvency ratio and the guarantee fund are of importance during the whole life of an insurance undertaking, the guarantee fund also constitutes the minimum capital required to ensure that sufficient capital is available to honour commitments when starting business.

An undertaking is required to address itself to the competent authorities of its Member State of incorporation in order to receive authorisation to engage in insurance activities. In requesting authorisation, the undertaking will need to show that it can function in accordance with all current regulations and that it is able to meet its commitments under all circumstances. The request has to be accompanied by three types of information: the identity of the undertaking, the nature of its activities and its activity forecasts.

A third fundamental step towards the creation of a correctly functioning insurance market is the establishment of rules on the accounts of Insurance undertakings. Although EC rules on accounting have existed since 1978, it was only 13 years later that such rules were adopted for insurance with Directive 91/674/EEC on the annual accounts and consolidated accounts of insurance undertakings.
An element of supervision of insurance companies in all Member States is disclosure, that is the requirement to disclose a certain amount of financial information to the public in standard form. In addition, the supervisory authorities require detailed financial statements from the insurers in the exercise of their functions. These supervisory (or internal) returns are different in nature and purpose from the commercial (or external) accounts of insurers. It does not apply to the internal returns. There is no distinction in the accounting requirements between large and small insurers. All insurers must supply the information required by the Directive.

The Insurance Accounts Directive takes account of the fact that there is a considerable convergence in the field of non life insurance in the Community. In life insurance, however, the differences are considerable. This concerns such matters as premium calculation - the choice of the technical interest rate, the mortality table and treatment of costs, investment rules and policies, the valuation of assets, etc.

The principal objective of the Insurance Accounts Directive is the extent of the financial information that should be made available to the public by the companies that are in competition with one another. It is obvious that in an Internal Market a basic standard of comparability of insurance accounts is of interest to policyholders, shareholders, insurers, intermediaries and other third parties who have an interest in an insurer's financial strength and performance.

Finally, the Insurance Accounts Directive does not contain any provision relating to branch accounts. Member states are, therefore, free to require branches to publish separate annual accounts or to supply additional information on the branch activities.

**CONDITIONS NECESSARY TO OPERATE THE LEGISLATION**

The differences between Member States' prudential regulation of insurance products up to 1972 when the first EU insurance Directive was adopted were such that they constituted one of the main restrictions for the application of the fundamental freedoms of the Treaty. Thus, although supervision extended over all classes of direct non-life insurance in France, Italy and Luxembourg, Germany, e.g. did not control transport insurance. In Belgium occupational hazards and certain other specific types of risk received most attention. In the Netherlands or in United Kingdom, only life assurance was supervised until the beginning of the 1970's.

Therefore, at the time it was thought unavoidable to opt for a detailed approach of harmonising existing legislation in Member States, in order to facilitate the Treaty-given right of freedom of establishment, while allowing each Member State to maintain its own supervisory approach.
Facilitating the right of freedom to provide services (Article 59 of the TEU) was left out of the first "generation" of EU insurance directives.

Legislative approximation in the field of insurance pre-supposes the existence of national regulatory systems. All EU States have set up prudential authorities or supervisory bodies in the area of insurance. Experience in the EU with harmonisation demonstrates that certain minimum features of the market must characterise the overall supervision system. These include regulation of market entrance; strict supervision of the solvency of economic operators, both new and existing; the supervision of the calculation and investment of necessary technical reserves; supervision of insurance products offered on the market; and, systematic analysis and auditing of financial information.

KEY MEASURES

The directives mentioned as key measures (i.e. the 1st and 3rd Non-Life and Life Directives and the Annual Accounts Directive) all relate to the basic characteristics of any insurance system, i.e. the setting up of a regulatory, prudential framework within which a balance of interests between the suppliers and the consumers of insurance in conjunction with increased competition within a large Internal Market was ensured.

It will be clear from what has been said above that there can be no competition within an Internal Market unless companies are allowed to operate in another Member State with a minimum of constraints. The purpose of the 1st and 3rd Generation Directives was to do away with such barriers to an Internal Market in Insurance.

But it is equally clear that if such a market is to come about, consumers, financial consultants, investments companies and other interested parties must have access to information concerning the financial situation of the insurance company, information which must be clear and easily accessible, but - above all - comparable between companies from all Member States. This is the purpose of the Annual Accounts Directive.

CHOICE OF STAGE I MEASURES

DESCRIPTION & JUSTIFICATION:

The measures included under Stage I all concern a EU wide harmonisation of the conditions for allowing an insurance company to establish itself in another Member State in order to carry out insurance business. They constitute the EU insurance system from 1975 up until early 1990s.
**STAGE I MEASURES**

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**CHOICE OF STAGE II MEASURES**

**DESCRIPTION & JUSTIFICATION:**

The Stage II Measures introduce a single passport in insurance and allow insurance companies to freely decide whether to sell their insurance products through an establishment in another Member State or directly without being established. They abolish prior control of premiums and tariffs.

The subsequent development of a single passport in the insurance field is a result of the trust and co-operation between supervisory authorities established under Stage I. It presupposes a higher degree of market integration and close relationships, de facto and de jure, between supervisory authorities in a context of supra-national co-operation. The main elements of Stage II approximation comprise measures establishing the procedures for closer-co-operation between supervisory authorities, the introduction of a single licence, deregulatory measures liberalising the control of products and tariffs, and measures laying down minimum rules for the investment of technical reserves.

The changes brought about by the Third Non-Life and Life Insurance Directives of 1992 reflect the Commission's consistent approach to achieving an Internal Market based on a single insurance license (a 'European Passport') permitting insurers to operate on a Community-wide basis through branches/agencies, or the cross-border provision of services.

The First Generation Directives, maintaining host country control over insurance companies, had not succeeded in creating a truly single insurance market, since insurance products were still subject to twelve different supervisory regimes, companies in most countries still being subject to specific authorization requirements for establishment and services business and consumers not being able to shop around and select from the products on offer throughout the Community.
To overcome this the concepts of home country control and a single licence were introduced. The introduction of a system of a single authorization and home country control with a view to creating a high level of protection for the consumer, however, also necessitated further steps, namely the harmonization of Member States' rules on the definition and calculation of technical provisions and on the currency matching, diversification, spread and localisation of the assets representing them.

As regards the assets representing the technical provisions, the Stage II measures lay down co-ordinated rules on their admissibility, diversification, valuation and currency matching requirements.

The requirement that assets be located in the Member State in which business is carried on is deleted to take account of the measures adopted in the field of the liberalisation of capital movements and provisions in the Maastricht Treaty. For the same reason, any requirement that a minimum proportion of assets be invested in specific categories can no longer be maintained.

Phase II measures abolish the prior, systematic notification and approval of policy conditions and tariffs, for authorization purposes, including new products for a company in operation: prior approval is no longer a condition for acquiring a licence or selling insurance products.

Phase II measure equally stipulate that the competent authorities, before granting an authorisation, must be informed of the identity of shareholders and Members, holding a qualified participation in the proposed insurance undertaking, as well as of the amount of such participations. This applies to direct or indirect shareholders or members, irrespective of whether they are natural or legal persons. This procedure enables the competent authority to appraise the suitability of the shareholders and members and, if necessary, to reject any particular group structures as improper, at the moment of the setting-up of the institution.

For information on the annual and consolidated accounts of Insurance undertakings, see the contribution on Accounting.

**STAGE II MEASURES**

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Remaining non-key measures:

1. Legal expenses insurance

In order to co-ordinate national requirements for insurance against legal costs, a Directive 87/344/EEC (OJ L185, 4.7.87) was adopted on 22 June 1987 on the co-ordination of laws, regulations and administrative provisions relating to legal expenses insurance.

The directive mainly obliges an insurance undertaking to provide for a separate contract, or a separate section of a single policy for legal expenses insurance, to have separate management for legal expenses insurance and to entrust the management of claims in respect of legal expenses insurance to an undertaking having a separate legal identity.

In the event of a conflict of interest or a disagreement over settlement of the dispute, the insurer must inform the insured person of his right to choose his lawyer freely and of the possibility of using an arbitration procedure.

2. Credit and surety insurance

To provide additional financial guarantees for credit insurance and to abolish the provisions permitting one Member State, (Germany) to prohibit surety insurance from being combined with other classes of insurance, a Directive 87/343/EEC (OJ L185, 4.7.85) was adopted on 22 June 1987. It provided for the removal of Germany's specialisation requirements and laid down an obligation on Member States to require, of underwriters, additional financial guarantees for credit insurance. This is to be achieved by setting up an equalisation reserve which will offset any technical deficit or above-average claims ratio arising for a particular financial year. Four permitted methods of calculating the equalisation reserve for credit insurance were described in an Annex to the Directive. As far as expert credit insurance operations are concerned the Directive excludes such operations, when carried out for the account of or guaranteed by the State.

3. Motor Insurance Directives

The First Motor Insurance Directive 72/166/EEC (OJ L103, 2.5.72) laid down the principles of the Green Card System as the basis of the EU-Motor Insurance arrangement, and did away with control of Green Cards at EU's internal borders.

The second Motor Insurance Directive 84/5/EEC (OJ L8, 11.1.84) required each Member State to set up or authorise a body (guarantee fund) to compensate the victims of accidents caused by uninsured or unidentified vehicles and harmonised the minimum compensatory amounts (for material damage and physical injury).
The Third Council Directive 90/232/EEC (OJ L129, 19.5.90) of 14 May 1990 filled gaps that still existed in the compulsory insurance coverage of passengers across the Community. It mainly provided that Member States must take the necessary steps to ensure that all compulsory insurance policies covering civil liability in respect of the use of vehicles cover the entire territory of the Community on the basis of a single premium.


It mainly provided that the Member State where services are provided must require the insurance undertaking to become a member of, and participate in the financing of, its national motor insurers' bureau and its national guarantee fund. Furthermore, insurers must appoint a representative in the Member State where services are provided, responsible for collecting information and representing the insurer in relation to persons pursuing claims or seeking redress before the courts or authorities of the State.

4. Tourist Assistance

Directive 84/641/EEC (OJ L339, 27.12.84) inserts tourist assistance cover into the scope of the First Directive. Tourist assistance is defined as assistance provided for persons who get into difficulties while travelling, while away from home or while away from their permanent residence. The Directive was the consequence of the divergent treatment, in the Member States, of tourist assistance cover. For many years the Member States were unable to agree on the precise nature of this activity, in particular, where the assistance was organised by the undertaking itself and the benefit provided by the undertaking consisted of a service in kind, often using its own material and staff rather than the payment of a cash sum.

This disagreement prevented an undertaking, providing assistance cover and having its head office in one Member State, which treated this activity as insurance, from establishing a branch in another Member State where that latter State took the view that this activity was not insurance, but purely an assistance activity. Consequently, it did not consider that the First Non-Life Insurance Directive applied.

The Text adopted amends the First Directive to make clear that the typical type of tourist assistance operation is indeed to be regarded as insurance, and therefore subject to its provisions. A careful line is drawn around the activities covered, in order to ensure that the Directive applies to the assistance which is provided for persons who are away from home and which is not merely of a roadside assistance nature.
5. Community Co-insurance

Directive 78/473/EEC (OJ L151, 7.6.78) adopted in 1978, applies to certain large industrial and commercial risks which by their nature or their size call for the participation of several insurers for their coverage. The Directive limits its scope to Community co-insurance, i.e. insurance operations which satisfy certain conditions as follows:

- the risk must be covered by a single contract at an overall premium, for the same time period and by two or more insurance undertakings;

- the risk must be situated within the Community;

- at least one of the co-insurers participating in the contract should come from a Member State other than that of the leading insurer; and,

- the leading insurer should be authorised in accordance with the conditions laid down in the First Non-Life Co-ordination Directive, i.e. he is treated as if he were the insurer covering the whole risk.

6. Transitional Directives

Two Directives in the fields of Non-Life (88/357/EEC of 22 June 1988 - OJ L172, 4.7.88) and Life (90/619/EEC of 8 November 1990 - OJ L330, 29.11.90) are of transitional importance, bridging the gap between the first Generation Directives, having their focus on facilitating the freedom of establishment for insurance companies, and the third generation Directives which introduce a complete EU insurance system spanning both freedom of establishment and the freedom to provide services.