Guide to the implementation of directives based on the New Approach and the Global Approach
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European Commission
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Cataloguing data can be found at the end of this publication.

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Guide to the implementation of directives based on the New Approach and the Global Approach

FOREWORD

The single market is one of the great achievements of our time. This economic space, where goods, services, capital and labour can circulate freely, provides a foundation for prosperity in the European Union as we move towards the 21st century.

The European Union has developed original and innovative instruments to remove the barriers to free circulation of goods. Among these, the New Approach to product regulation and the Global Approach to conformity assessment take pride of place. The common thread between these complementary approaches is that they limit public intervention to what is essential and leave business and industry the greatest possible choice on how to meet their public obligations. Since 1987 some 20 directives, adopted on the basis of the New Approach and the Global Approach, have progressively come into force. The operation of any innovative system inevitably raises questions. A first Guide, intended to answer some of these, was published in 1994. This has now been updated and rewritten, on the basis of experience.

We hope that this Guide will be helpful to those who want to do business in the single market and that it will assist those whose job it is to manage the market place. It will be an invaluable aid to the candidate countries of central and eastern Europe in taking over the New Approach and the Global Approach and the directives adopted following them. We dare to hope that it will also contribute to better understanding of these methods in other countries and may even lead them to adopt similar principles.

A Guide can, at best, only draw out the meaning, significance and practical consequences of the directives to which it refers. It cannot replace a legal text, or change what the legislator has decided. However, it can elucidate the legal text by bringing to bear knowledge of the usage of the European Union and the provisions of the European Community Treaty and its derived law, including the case law of the European Court of Justice. The European Commission is uniquely well placed to do this. It has consulted widely in preparing the Guide and all opinions have been carefully considered. The Guide has been discussed with the Senior Officials Group on Standardisation and Conformity Assessment Policy, who agreed to its publication. As far as possible, it reflects a broad consensus. While this does not mean that it is the last word on anything, it certainly means that it represents an authoritative expression of opinion.

This Guide has been drawn up by the Directorate-General for Enterprise in close cooperation with other Commission services, with contributions from Member State experts and interest groups. My thanks to all who have contributed to this enterprise.

Magnus Lemmel
Acting Director-General
Directorate-General for Enterprise
September 1999
This Guide is intended to contribute to better understanding of directives based on the New Approach and the Global Approach, and to their more uniform and coherent application across different sectors and throughout the single market.

It is addressed to the Member States. It is also intended to be a manual for others who need to be informed of the provisions designed to ensure the free circulation of CE marked products as well as a high level of protection throughout the Community (such as trade associations, consumer associations, standards bodies, manufacturers, importers, distributors, conformity assessment bodies, trade unions).

It reflects the state of the art. Therefore, the guidance offered may be subject to modifications in the future.

Only the text of the directive is authentic in law. Accordingly, the text of the directive is applicable where there are differences between the provisions of a directive and the contents of this Guide. In particular, these differences are due to slightly divergent provisions in the individual directives, which cannot be fully described in this Guide.

The focus of this Guide is on the New Approach and the Global Approach. However, products covered by directives based on the principles of the New Approach and the Global Approach may also be subject to other provisions of Community law, which are not presented in this Guide.

The guidance offered to the Member States in this Guide also applies to Iceland, Liechtenstein and Norway as signatories of the Agreement on the European Economic Area (EEA). References to the Community or the single market are, accordingly, to be understood as referring to the EEA, or to the EEA market.
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1.1. Concept of the New Approach and the Global Approach

New barriers to trade, which result from the adoption of diverging national technical standards and regulations, can be prevented through a procedure laid down by Directive 98/34/EC (1). Member States are obliged to notify draft technical regulations and standards to the Commission and to the other Member States (2). During a standstill period these may not be adopted, which leaves the Commission and the other Member States the possibility to react. In the absence of reactions within the initial standstill period of three months, the draft technical regulations may then be adopted. Otherwise, where objections are raised, a further three months standstill is imposed. The standstill period is 12 months where there is a proposal for a directive. However, the standstill period does not apply where, for urgent reasons, a Member State is obliged to introduce technical regulations in a very short space of time in order to protect public health or safety, animals or plants. Directive 98/34/EC also gives the Commission the possibility of inviting, after consultation with the Member States, the European standards organisations to elaborate European standards.

National technical regulations are subject to the provisions of Articles 28 and 30 of the Treaty establishing the European Community (the EC Treaty), which prohibit quantitative restrictions or measures having equivalent effect. Case law of the European Court of Justice, especially case 120/78 (the 'Cassis de Dijon' case), provides the key elements for mutual recognition. The effect of this case law is as follows.

- Products legally manufactured or marketed in one country should in principle move freely throughout the Community, where such products meet equivalent levels of protection to those imposed by the Member State of exportation and where they are marketed in the territory of the exporting country.
- In the absence of Community measures, Member States are free to legislate on their territory.
- Barriers to trade, which result from differences between national legislations, may only be accepted, if national measures:
  - are necessary to satisfy mandatory requirements (such as health, safety, consumer protection and environmental protection);
  - serve a legitimate purpose justifying the breach of the principle of free movement of goods; and
  - can be justified with regard to the legitimate purpose and are proportionate with the aims.

Restrictions to free movement of products, which may be acceptable under Articles 28 and 30 of the EC Treaty, can only be avoided or eliminated through technical harmonisation on Community level. This harmonisation was, at first, rather slow for two reasons. First, the legislation became highly technical, as it had the objective of meeting the individual requirements of each product category. Second, the adoption of technical harmonisation directives was based on unanimity in the Council.

The creation of a single market by 31 December 1992 could not have been achieved without a new regulatory technique that set down only the general essential requirements, reduced the control of public authorities prior to a product being placed on the market, and integrated quality assurance and other modern conformity assessment techniques. Moreover, the decision-making procedure needed to be adapted in order to facilitate the adoption of technical harmonisation directives by a qualified majority in the Council.

A new regulatory technique and strategy was laid down by the Council Resolution of 1985 on the New Approach to technical harmonisation and standardisation, which established the following principles.

- Legislative harmonisation is limited to essential requirements that products placed on the Community market must meet, if they are to benefit from free movement within the Community.
- The technical specifications of products meeting the essential requirements set out in the directives are laid down in harmonised standards.
- Application of harmonised or other standards remains voluntary, and the manufacturer may always apply other technical specifications to meet the requirements.
- Products manufactured in compliance with harmonised standards benefit from a presumption of conformity with the corresponding essential requirements (1).

The operation of the New Approach requires that the standards offer a guaranteed level of protection with regard to the essential requirements established by the directives, and that the national authorities carry out their responsibilities for the protection of safety or other interests covered by the directive. Further, a safeguard clause procedure is necessary to allow the possibility of contesting the conformity of a product, or failures or shortcomings of harmonised standards.

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Since the New Approach calls for essential requirements to be harmonised and made mandatory by directives, this approach is appropriate only where it is genuinely possible to distinguish between essential requirements and technical specifications. Further, a wide range of products has to be sufficiently homogenous, or a horizontal hazard identifiable, to allow common essential requirements. The product area or hazard concerned must also be suitable for standardisation (4).

In addition to the principles of the New Approach, conditions for reliable conformity assessment are necessary. The key elements in this respect are the building of confidence through competence and transparency, and the setting up of a comprehensive policy and framework for conformity assessment. The Council Resolution of 1989 on the Global Approach to certification and testing states the following guiding principles for Community policy on conformity assessment.

A consistent approach is developed in Community legislation by devising modules for the various phases of conformity assessment procedures, and by laying down criteria for the use of these procedures, for the designation of bodies operating these procedures, and for the use of the CE marking.

The use of European standards relating to quality assurance (EN ISO 9000 series), and to the requirements to be fulfilled by conformity assessment bodies operating quality assurance (EN 45000 series) is generalised.

Setting up of accreditation systems and the use of inter-comparison techniques are promoted in Member States and at Community level.

Mutual recognition agreements concerning testing and certification in the non-regulatory sphere are promoted.

The differences of existing quality infrastructures (such as calibration and metrology systems, testing laboratories, certification and inspection bodies, and accreditation bodies) between Member States and between industrial sectors are minimised by programmes.

International trade between the Community and third countries is promoted by means of mutual recognition agreements, cooperation and technical assistance programmes.

The New Approach entailed refining conformity assessment in such a way as to allow the Community legislator to evaluate the consequences of the utilisation of different conformity assessment mechanisms. The objective was to provide flexibility of conformity assessment over the entire manufacturing process in order for it to be adapted to the needs of each individual operation. The Global Approach introduced a modular approach, which subdivided conformity assessment into a number of operations (modules). These modules differ according to the stage of development of the product (for example design, prototype, full production), the type of assessment involved (for example documentary checks, type approval, quality assurance), and the person carrying out the assessment (the manufacturer or a third party).

The Global Approach was completed by Council Decision 90/683/EEC, which was replaced and brought up to date by Decision 93/465/EEC. These decisions lay down general guidelines and detailed procedures for conformity assessment that are to be used in New Approach directives. Thus, conformity assessment is based on:

- manufacturers’ internal design and production control activities;
- third party type examination combined with manufacturers’ internal production control activities;
- third party type or design examination combined with third party approval of product or production quality assurance systems, or third party product verification (5);
- third party unit verification of design and production; or
- third party approval of full quality assurance systems.

In addition to laying down guidelines for the use of conformity assessment procedures in technical harmonisation directives, Decision 93/465/EEC harmonises the rules for the affixing and use of the CE marking.

1.2. Standard elements of New Approach directives (6)

- New Approach directives are based on the following principles.
  - Harmonisation is limited to essential requirements.
  - Only products fulfilling the essential requirements may be placed on the market and put into service.
  - Harmonised standards, the reference numbers of which have been published in the Official Journal and which have been transposed into national standards, are presumed to conform to the corresponding essential requirements.
  - Application of harmonised standards or other technical specifications remains voluntary, and manufacturers are free to choose any technical solution that provides compliance with the essential requirements.
  - Manufacturers may choose between different conformity assessment procedures provided for in the applicable directive.

Scope

The scope defines the range of products covered by the directive, or the nature of hazards the directive is intended...
to avert. It usually covers hazards related to a product or to a phenomenon. Accordingly, several directives may apply to the same product.

**Scope of New Approach directives:** Chapter 2.

**Placing on the market and putting into service**

Member States are obliged to take the necessary measures to ensure that products are placed on the market and put into service only if they do not endanger the safety and health of persons, or other public interests covered by the directive, when properly installed, maintained and used for the intended purposes. This entails an obligation for market surveillance on the part of the Member States.

Member States are allowed to adopt, in compliance with the Treaty (in particular Articles 28 and 30 of the EC Treaty), additional national provisions to protect, in particular, workers, consumers or the environment. However, these provisions may neither require modifications of the product nor influence the conditions for its placing on the market.

**Placing on the market and putting into service:** Section 2.3.

**Market surveillance:** Chapter 8

**Essential requirements**

Essential requirements are set out in the annexes to the directives, and include all that is necessary to achieve the objective of the directive. Products may be placed on the market and put into service only if they are in compliance with the essential requirements.

New Approach directives are generally designed to cover all hazards related to the public interest that the directive intends to protect. Thus, compliance with Community legislation often requires simultaneous application of several New Approach directives and, possibly, other Community legislation. Further, some elements may have been left outside the scope of applicable Community legislation. This allows Member States to draw up national legislation in accordance with Articles 28 and 30 of the EC Treaty.

**Compliance with directives:** Chapter 4.

**Free movement**

Member States must presume that products bearing the CE marking comply with all the provisions of the applicable directives providing for its affixing. Accordingly, Member States may not prohibit, restrict or impede the placing on the market and putting into service in their territory of products bearing the CE marking, unless the provisions relating to CE marking are incorrectly applied.

As an exception, Member States may prohibit, restrict or impede the free movement of products bearing CE marking - in accordance with Articles 28 and 30 of the EC Treaty - because of a hazard that is not covered by the applicable directives.

**Placing on the market and putting into service:** Section 2.3.

**CE marking:** Chapter 7.

**Presumption of conformity**

Products that comply with national standards transposing harmonised standards, the reference numbers of which have been published in the Official Journal of the European Communities, are presumed to comply with the corresponding essential requirements. Where the manufacturer has not applied, or has only partially applied, such a standard, the measures taken and their adequacy must be documented in order to comply with the essential requirements.

**Compliance with directives:** Chapter 4.

**Safeguard clause**

Member States are obliged to take all appropriate measures to prohibit or restrict the placing on the market of products bearing the CE marking or to withdraw them from the market, if these products might compromise the safety and health of individuals or other public interests covered by the applicable directives, when the products are used for their intended purpose. Further, Member States must inform the Commission when they take such a measure. Where the Commission considers the national measure justified, it informs all Member States who must take appropriate action in view of their general obligation to enforce Community legislation.

**Market surveillance:** Chapter 8.

**Safeguard clause procedure:** Section 8.3.

**Conformity assessment**

Before placing a product on the Community market, the manufacturer must subject the product to a conformity assessment procedure provided for in the applicable directive, with the view to affixing the CE marking.

**Conformity assessment procedure:** Chapter 5.

**Notified bodies**

Third party conformity assessment is carried out by notified bodies, which have been designated by the Member States among bodies that fulfil the requirements laid down in the directive and that are established on their territory.

**Notified bodies:** Chapter 6.

**CE marking**

Products in compliance with all provisions of the applicable directives providing for the CE marking must bear this marking. Thus, the CE marking is, in particular, an indication that the products comply with the essential requirements of applicable directives and that the products have been subject to a conformity assessment procedure provided for in the directives. Further, Member States are obliged to take appropriate measures to protect the CE marking.

**CE marking:** Chapter 7.

**Protection of CE marking:** Section 8.4.
After receiving a Commission proposal, the Council requests an opinion from the Parliament and the Economic and Social Committee before reaching its common position on the proposal. Once the common position has been reached, it is transmitted to the Parliament, which may accept, reject or propose amendments during this second reading. The Commission re-examines its proposal in the light of Parliament's amendments, and returns the proposal to the Council, which takes a final decision within three months. If necessary, problems are referred to a conciliation committee of Council and Parliament, in which the Commission participates as a moderator. The flow chart in Table 1.1 shows the adoption procedure according to Article 251 of the EC Treaty, and the alternatives at the different phases.

Withdrawal of the presumption of conformity: Section 4.4.
Administrative cooperation: Section 8.6.
Transposition and transitional provisions
Member States are required to transpose the provisions of the directives into their national legislation. They must also inform the Commission of the measures taken.
Member States must permit the placing on the market of products that comply with regulations in force in their territory at the date of application of the directive in question, until the date as set up by the directive. Under certain restrictions, such products must also be permitted to be put into service beyond that date.
Transposition of New Approach directives: Section 1.4.
Transitional period: Section 2.4.

1.3 Adoption of New Approach directives

- New Approach directives are based on Article 95 of the EC Treaty, and adopted according to the co-decision procedure provided for in Article 251 of the EC Treaty.

The legal basis for adopting or modifying New Approach directives is Article 95 of the EC Treaty. According to Article 251 of the EC Treaty, the Commission initiates the legislative procedure by making a proposal to the Council and to the European Parliament. Such Commission proposals concerning health, safety, environmental protection and consumer protection should, according to Article 95 take as a basis a high level of protection. Further, Article 95 requires that a safeguard clause is provided for in appropriate cases.

Coordination of implementation
Where a Member State or the Commission considers that a harmonised standard does not fully meet the essential requirements of a directive, the matter will be brought to the attention of the committee set up by the Directive 98/34/EC (Committee on Technical Standards and Regulations). The Commission, taking into account the Committee’s opinion, notifies the Member States whether or not the standard should be withdrawn from the list published in the Official Journal of the European Communities.

Many New Approach directives provide for a standing committee to assist the Commission, delivering its opinion on draft measures to implement the provisions of the relevant directive and examining matters relating to the implementation and practical application of the directive. Further, regular meetings to discuss technical implementation issues take place in working groups, which are composed of representatives appointed by Member States and interest groups (for example notified bodies, standards organisations, manufacturers, distributors, consumer organisations and trade unions), and chaired by the Commission (1).

Administrative cooperation: Section 8.6.
Transposition and transitional provisions
Member States are required to transpose the provisions of the directives into their national legislation. They must also inform the Commission of the measures taken.
Member States must permit the placing on the market of products that comply with regulations in force in their territory at the date of application of the directive in question, until the date as set up by the directive. Under certain restrictions, such products must also be permitted to be put into service beyond that date.
Transposition of New Approach directives: Section 1.4.
Transitional period: Section 2.4.

After receiving a Commission proposal, the Council requests an opinion from the Parliament and the Economic and Social Committee before reaching its common position on the proposal. Once the common position has been reached, it is transmitted to the Parliament, which may accept, reject or propose amendments during this second reading. The Commission re-examines its proposal in the light of Parliament’s amendments, and returns the proposal to the Council, which takes a final decision within three months. If necessary, problems are referred to a conciliation committee of Council and Parliament, in which the Commission participates as a moderator. The flow chart in Table 1.1 shows the adoption procedure according to Article 251 of the EC Treaty, and the alternatives at the different phases.

Up to the adoption of the common position, discussion is based on the Commission’s proposal. While the Commission can modify its proposal at any time, for example in the light of the opinion of the Parliament, the Council can only diverge from the Commission’s proposal by unanimity.

Notes:
(1) The cooperation is based on the Council Resolution of 1994 on the development of administrative cooperation in the implementation and enforcement of Community legislation in the internal market.
11

Table 1/1 • Adoption of directives according to Article 251 of the EC Treaty •

<table>
<thead>
<tr>
<th>Action</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Commission makes a proposal</td>
<td>The act is adopted by the Council</td>
</tr>
<tr>
<td>The Council proposes amendments.</td>
<td>The Council can convene the conciliation committee to explain its position.</td>
</tr>
<tr>
<td>The Council adopts all the amendments and the act.</td>
<td>The Council can confirm the common position by an absolute majority.</td>
</tr>
<tr>
<td>The conciliation committee approves a joint text.</td>
<td>The act is adopted.</td>
</tr>
<tr>
<td>The conciliation committee does not approve a joint text.</td>
<td>The act is not adopted.</td>
</tr>
<tr>
<td>The European Parliament confirms its rejection of the common position by an absolute majority.</td>
<td>The act is not adopted.</td>
</tr>
<tr>
<td>The European Parliament confirms its rejection of the common position by an absolute majority.</td>
<td>The act is not adopted.</td>
</tr>
</tbody>
</table>

1.4. Transposition of New Approach directives

- New Approach directives are total harmonisation directives: the provisions of these directives supersede all corresponding national provisions.
- New Approach directives are addressed to the Member States, which have an obligation to transpose them into their national legislation as appropriate.
- National laws, regulations or administrative provisions, which transpose the directive, shall contain a reference to the directive in question or shall be accompanied by such a reference on the occasion of their official publication.
- National laws, regulations or administrative provisions, which are adopted and published in order to transpose a directive, must be communicated to the Commission.

New Approach directives approximate the laws of Member States in order to remove barriers to trade. Since New Approach directives are total harmonisation directives, Member States must repeal all contradictory national legislation. Further, Member States are, as a general rule, not allowed to maintain or introduce more stringent measures than foreseen in the directive, as is the case for directives adopted according to Article 138 of the EC Treaty (directives aiming to improve the health and safety of workers, especially, in the working environment). (9)

Directives are, according to Article 249 of the EC Treaty, binding on the Member States as to the result to be achieved, but the choice of form and method is their own. Case law of the European Court of Justice has clarified the contents of this obligation and the possible measures to be taken where a non-compliance can be established (9).

It is up to the Member States to decide which measures should be adopted and published in order to comply with a directive. However, Member States must take appropriate implementing measures to transpose the directive in a way that fully meets the

(*) As an exception, additional national provisions in areas covered by New Approach directives may be acceptable in accordance with Articles 28 and 30 of the EC Treaty (see Section 1.2).

(9) Judgement of the Court: cases C-102/79, C-30/81, C-34/81, C-102/79, C-29/84, C-178/84, C-179/84, C-188/84, C-190/84, C-392/93, C-46/93, C-48/93 and C-66/95.
requirements of clarity and certainty in legal situations, which directives seek for the benefit of traders established in other Member States. This may not necessarily require legislative action in each case as regards all the provisions of a directive.

Failure to take measures, or the correct measures, to transpose a directive in order to achieve the results it prescribes, within the period laid down for that purpose, constitutes a breach of Community law. According to Article 226 of the EC Treaty, the Commission may take action against a Member State, which has failed to fulfil an obligation under the Treaty. Further, according to Article 228, Member States are required to take necessary measures to comply with the judgement of the Court of Justice.

Member States are obliged to make reparation for damages that result from breaching Community law. This obligation exists where three conditions are fulfilled: the rule of law infringed is intended to confer rights on individuals; the breach is sufficiently serious; and there is a direct causal link between the breach of the obligation resting on the Member State and the damage sustained by the injured party. Failure to take any of the necessary measures to transpose a directive within the period laid down by the directive will amount to a sufficiently serious breach (10).

**1.5. New Approach directives**

In this Guide the New Approach directives are defined as directives that provide for the CE marking. In addition there are certain directives that follow the principles of the New Approach or the Global Approach, but which do not provide for the CE marking.

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<table>
<thead>
<tr>
<th>Directive (as referred to in this Guide)</th>
<th>Number of Directive, Amendment</th>
<th>Date of application</th>
<th>End of transitional period</th>
</tr>
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<tbody>
<tr>
<td>1. Low voltage equipment (12)</td>
<td>73/23/EEC, 93/68/EEC</td>
<td>19/8/74, 1/1/95</td>
<td>1/1/97, 1/1/97</td>
</tr>
<tr>
<td>2. Simple pressure vessels</td>
<td>87/404/EEC, 90/488/EEC, 93/68/EEC</td>
<td>1/7/90, 1/7/91, 1/1/95</td>
<td>1/7/92, 1/7/92, 1/1/97</td>
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<tr>
<td>3. Toys</td>
<td>88/378/EEC, 93/68/EEC</td>
<td>1/1/90, 1/1/95</td>
<td>1/1/97, 1/1/97</td>
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<td>5. Electromagnetic compatibility</td>
<td>89/336/EEC, 92/31/EEC, 93/68/EEC (98/13/EC)</td>
<td>1/1/92, 28/10/92, 6/11/92</td>
<td>31/12/95, 1/1/97</td>
</tr>
<tr>
<td>6. Machinery (14)</td>
<td>98/37/EC</td>
<td>1/1/93, 1/1/95, 1/1/95</td>
<td>31/12/94, 31/12/94, 1/1/97</td>
</tr>
<tr>
<td>7. Personal protective equipment</td>
<td>89/686/EEC, 93/68/EEC, 93/95/EEC, 96/58/EC</td>
<td>1/7/92, 1/1/95, 29/1/94, 1/1/97</td>
<td>30/6/95, 1/1/97</td>
</tr>
<tr>
<td>8. Non-automatic weighing instruments</td>
<td>90/384/EEC</td>
<td>1/1/93, 1/1/95</td>
<td>31/12/02, 1/1/97</td>
</tr>
<tr>
<td>10. Gas appliances</td>
<td>90/396/EEC, 93/68/EEC</td>
<td>1/1/92, 1/1/95, 1/1/95</td>
<td>31/12/95, 1/1/97</td>
</tr>
<tr>
<td>11. Hot water boilers</td>
<td>92/42/EEC, 93/68/EEC</td>
<td>1/1/94, 1/1/95</td>
<td>31/12/97, 1/1/97</td>
</tr>
<tr>
<td>12. Civil explosives</td>
<td>93/15/EEC, 93/42/EEC, 98/79/EC</td>
<td>1/1/93, 1/1/95, 7/6/00</td>
<td>31/12/02, 14/6/98, 30/6/01</td>
</tr>
<tr>
<td>13. Medical devices</td>
<td>98/79/EC</td>
<td>1/1/95, 7/6/00</td>
<td>31/12/02, 14/6/98, 30/6/01</td>
</tr>
</tbody>
</table>

(98/13/EC) (13) 6/11/92

# Table 1/2 • New Approach directives (directives providing for the CE marking) •

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(1) Judgement of the Court, case C-178/94.
(2) For a complete presentation of directives referred to in this section, see Annex 1.
(3) This Directive, drawn up in 1973 before the concept of New Approach and Global Approach was established, was, to some extent, aligned in 1993 with other New Approach directives.
(4) This Directive codifies into one single text Directive 89/392/EEC, as modified by Directives 91/368/EEC, 93/44/EEC and 93/68/EEC. The date of application is based on the original Directives.
### Table 1/2 • New Approach directives (directives providing for the CE marking) • (continued)

<table>
<thead>
<tr>
<th>Directive (as referred to in this Guide)</th>
<th>Number of Directive, Amendment</th>
<th>Date of application</th>
<th>End of transitional application period</th>
</tr>
</thead>
<tbody>
<tr>
<td>14. Potentially explosive atmospheres</td>
<td>94/9/EC</td>
<td>1/3/96</td>
<td>30/6/03</td>
</tr>
<tr>
<td>15. Recreational craft</td>
<td>94/25/EC</td>
<td>15/6/96</td>
<td>16/6/98</td>
</tr>
<tr>
<td>16. Lifts</td>
<td>95/16/EC</td>
<td>1/7/97</td>
<td>30/6/99</td>
</tr>
<tr>
<td>18. Pressure equipment</td>
<td>97/23/EC</td>
<td>29/11/99</td>
<td>29/5/02</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. In vitro diagnostic medical devices</td>
<td>98/79/EC</td>
<td>7/6/00</td>
<td>7/12/03</td>
</tr>
</tbody>
</table>

### Table 1/3 • Directives based on the principles of the New Approach or the Global Approach, but which do not provide for the CE marking •

<table>
<thead>
<tr>
<th>Directive (as referred to in this Guide)</th>
<th>Number of Directive</th>
<th>Date of application</th>
<th>End of transitional period</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Packaging and packaging waste (17)</td>
<td>94/62/EC</td>
<td>30/6/96</td>
<td>31/12/99</td>
</tr>
<tr>
<td>3. Marine equipment</td>
<td>96/98/EC</td>
<td>1/1/99</td>
<td></td>
</tr>
</tbody>
</table>

### Table 1/4 • Proposals for directives based on the principles of the New Approach or the Global Approach •

<table>
<thead>
<tr>
<th>Draft Directive</th>
<th>Number of proposal, Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Articles of precious metal</td>
<td>COM/93/322 final, COM/94/267 final</td>
</tr>
<tr>
<td>2. Cableway installations designed to carry passengers</td>
<td>COM/93/646 final</td>
</tr>
<tr>
<td>3. Marking of packaging</td>
<td>COM/96/191 final</td>
</tr>
<tr>
<td>4. Noise emission</td>
<td>COM/98/46 final</td>
</tr>
</tbody>
</table>

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*This Directive codifies into one single text Directive 91/263/EEC, as modified by Directive 93/68/EEC, and the supplementary Directive 93/97/EEC. The date of application is based on the original Directives.*

*This Directive will replace the Directive on telecommunications terminal equipment.*

*This Directive contains neither a conformity assessment procedure nor a marking regime, which were foreseen in the proposal for a directive on marking of packaging (COM/96/191 final). Thus, only Chapter 4 of the Guide is relevant for the Directive on packaging and packaging waste.*
2. Scope of New Approach directives

New Approach directives apply to products which are intended to be placed (or put into service) on the Community market (19). Usually such products are ready for use, or require only adjustments that can be performed in view of their intended use. Further, the directives apply only when the product is placed (and put into service) on the Community market for the first time. Consequently, the directives apply also to used and second-hand products imported from a third country when they enter the Community market for the first time, but not to such products already on the Community market (20). This applies even to used and second-hand products imported from a third country that were manufactured before the directive became applicable.

The concept of product varies between New Approach directives (21). The objects submitted to the directive are referred to, for instance, as products, equipment, apparatus, devices, appliances, instruments, material, assemblies, components or safety components, units, fittings, accessories or systems. It is the responsibility of the manufacturer to verify whether or not the product is within the scope of a directive (22).

A combination of products and parts, which each comply with applicable directives, does not always have to comply as a whole. However, in some cases, a combination of different products and parts designed or put together by the same person is considered as one finished product which, as such, has to comply with the directive. In particular, the manufacturer of the combination is responsible for selecting suitable products to meet the requirements of a third country where such products will be placed on the market and put into service outside the Community, where free movement of used and second-hand products takes place according to Articles 28 and 30 of the EC Treaty, products intended specifically for military purposes.

2.1. Products submitted to directives

- New Approach directives apply to products which are intended to be placed (or put into service) on the Community market for the first time. Consequently, the directives apply to new products manufactured in the Member States, and to new, as well as used and second-hand, products imported from third countries (18).
- The concept of product varies between New Approach directives, and it is the responsibility of the manufacturer to verify whether or not the product is within the scope of one or more directives.
- Products that have been subject to important changes may be considered as new products that have to comply with the provisions of the applicable directives when placed on the Community market and put into service. This has to be assessed on a case-by-case basis, unless otherwise provided for.
- Products, which have been repaired without changing the original performance, purpose or type, are not subject to conformity assessment according to the New Approach directives.
- Products specially or exclusively intended for military or police purposes are explicitly excluded from the scope of certain New Approach directives. For the other directives, Member States may, under certain conditions, exclude from their field of application according to Article 296 of the EC Treaty, products intended specifically for military purposes.

(20) Nothing in this Guide is intended to prevent or prohibit the manufacture of products to meet the requirements of a third country where such products will be placed on the market and put into service outside the Community.

(21) For placing on the market and putting into service, see Section 2.3.

(22) In this context the Community should be considered to mean the present Member States, where free movement of used and second-hand products takes place according to Articles 28 and 30 of the EC Treaty.

(23) See Annex 6. In some situations the responsibilities of the manufacturer are taken over by another person, see Sections 3.1 - 3.3.
The person who carries out important changes to the product is responsible for verifying whether or not it should be considered as a new product.

Products which have been repaired (for example following a defect), without changing the original performance, purpose or type, are not to be considered as new products according to New Approach directives. Thus, such products need not undergo conformity assessment, whether or not the original product was placed on the market before or after the directive entered into force. This applies even if the product has been temporarily exported to a third country for the repair operations. Such operations are often carried out by replacing a defective or worn item by a spare part, which either is identical, or at least similar, to the original spare part (for example modifications may have taken place due to technical progress, or discontinued production of the old part). Thus, maintenance operations are basically excluded from the scope of the directives. However, at the design stage of the product the intended use and maintenance must be taken into account (23).

Some New Approach directives explicitly exclude products that are specially or exclusively intended for military or police purposes (24). For other directives Article 296 of the EC Treaty may be taken into consideration, unless the product according to its definition cannot be used for military purposes (such as toys, recreational craft and refrigeration appliances). Article 296(1) of the EC Treaty offers Member States the possibility of excluding from the application of Community legislation products intended for specifically military purposes, insofar as the products concerned appear in the list drawn up by the Council according to Article 296(2), and provided such exclusion may not have an adverse effect on the competition conditions in the Community market concerning products that are not specifically intended for military purposes.

### 2.2. Simultaneous application of directives

#### 2.2.1. New Approach directives

- Essential requirements set up by New Approach directives may overlap or complement each other, depending on the hazards covered by these requirements that are related to the product in question.
- The placing on the market and putting into service can only take place when the product complies with the provisions of all applicable directives, and when the conformity assessment has been carried out in accordance with all applicable directives.
- Where the same product or hazard is covered by two or more directives, the application of other directives can sometimes be excluded following an approach that includes a risk analysis of the product with a view to intended use as defined by the manufacturer.

New Approach directives cover a wide range of products and hazards, which both overlap and complement each other. As a result several directives may have to be taken into consideration for one product, since the placing on the market and putting into service can only take place when the product complies with all applicable provisions.

Hazards covered by the essential requirements of the directives concern different aspects that in many cases complement each other (for example the Directives relating to electromagnetic compatibility and pressure equipment cover phenomena not covered by the Directives relating to low-voltage equipment or machinery). This calls for a joint application of the directives. Accordingly, the product has to be designed and manufactured in accordance with all applicable directives, as well as to undergo the conformity assessment procedures according to all applicable directives, unless otherwise provided for.

Certain directives make a direct reference to the application of other directives (for example the Directive relating to lifts refers to the Directives relating to machinery, and the Directive relating to telecommunications terminal equipment to the Directive relating to low voltage equipment). Although such a reference has not been included in a number of directives, the general principle of simultaneous application still applies where the essential requirements of the directives are complementary to each other.

Two or more directives can cover the same product or hazard. In such a case, the application of other directives is often limited by excluding certain products from the field of application of the other directives, or by giving preference to the more specific directive. This usually requires a risk analysis of the product, or sometimes an analysis of the intended purpose of the product, which then determines the applicable directive. In specifying the hazards related to a product, the manufacturer may be assisted by the risk assessment performed by the standards bodies in relation to harmonised standards for the product in question. Taking into account the dominant hazards of the product this risk analysis may lead to the publication of such standards under only one of the possibly applicable directives (23).
The Directive on general product safety (92/59/EEC) aims to ensure that consumer products placed on the market do not present a risk under conditions of use that are normal or can be reasonably foreseen. It requires producers to place only safe products on the market, and to inform about risks. It also obliges Member States to survey products on the market, and to inform the Commission about actions taken through either a safeguard clause procedure or the information system for serious and immediate risks. The Directive on general product safety covers new, used and reconditioned products intended for consumers or likely to be used by consumers, supplied in the course of commercial activity. According to this definition, products within the scope of several New Approach directives are to be considered as consumer products (such as toys, recreational craft, refrigeration appliances, and to certain extent electrical equipment, gas appliances, machinery, personal protective equipment and pressure equipment).

The Directive on general product safety is applicable insofar as there are no specific provisions in rules of Community law governing all the safety aspects of the products concerned. Further, where specific rules of Community law contain provisions governing only certain aspects of product safety or categories of risk for the product concerned, these provisions are applicable to the products in question with regard to the relevant safety aspects or risks. This rule gives priority to the application of New Approach directives for all aspects of product safety and categories of risk they cover. Further, for products covered by New Approach directives the objective has been to cover all foreseeable risks, if necessary by means of simultaneous application of these directives and other relevant provisions of Community legislation.

The Directive on general product safety applies to consumer products supplied in the course of commercial activity, provided that:
- the product is not covered by New Approach directives or other Community legislation;
- not all aspects of safety or categories of risk are covered by New Approach directives or other Community legislation.

Consumer products outside the field of application of New Approach directives and other Community legislation (for example products not complying with the definition laid down by the directive in question, used and second-hand products that were originally placed on the Community market before the directive entered into force, and repaired products) come under the Directive on general product safety, where they are supplied in the course of commercial activity.

New Approach directives do not contain any system for rapid exchange of information between market surveillance authorities in emergency situations, with the exception of the vigilance system included in the directives relating to different types of medical devices. Therefore, the provisions concerning the procedure for rapid exchange of information on dangers, and the subsequent action at Community level are applicable to consumer products covered by New Approach directives (26).

The Directive on general product safety contains detailed provisions on market surveillance (Articles 5 and 6). These provisions are not directly applicable in sectors covered by New Approach directives, but they provide a model for obligations and powers that are necessary for carrying out market surveillance, in particular as regards consumer products.

2.2.2. New Approach directives and the Directive on general product safety

The Directive on general product safety applies to consumer products supplied in the course of commercial activity, provided that:
- the product is not covered by New Approach directives or other Community legislation;
- not all aspects of safety or categories of risk are covered by New Approach directives or other Community legislation.

2.2.3. New Approach directives and the Directive on product liability

The Directive on product liability is applicable to all products covered by New Approach directives.

The manufacturer, the importer and the distributor to supply safe products in order to avoid the costs that liability places on them for defective products causing damages to individual or property. Consequently, New Approach directives and the Directive on product liability are complementary elements in ensuring an adequate level of protection (27).
2.3. Placing on the market and putting into service

- Placing on the market is the initial action of making a product available for the first time on the Community market, with a view to distribution or use in the Community. Making available can be either for payment or free of charge.

- Putting into service takes place at the moment of first use within the Community by the end user. However, the need to ensure, in the framework of market surveillance, that products are in compliance with the provisions of the directives when being put into service is limited.

- A product must comply with the applicable New Approach directives when it is placed on the Community market for the first time and put into service (28).

- Member States are obliged:
  - not to prohibit, restrict or impede the placing on the market and putting into service of products that comply with the applicable New Approach directives; and
  - to take any measures necessary to ensure that products are placed on the market and put into service only if they do not endanger the safety and health of persons, or other interests not covered by the applicable directives, when correctly constructed, installed, maintained, and used in accordance with their purpose.

2.3.1. Placing on the market (29)

New Approach directives are designed to ensure free movement of products that comply with the high level of protection laid down in the applicable directives. Therefore, Member States may not prohibit, restrict or impede the placing on the market of such products. However, Member States are allowed to maintain or adopt, in compliance with the Treaty (in particular Articles 28 and 30 of the EC Treaty), additional national provisions regarding the use of particular products which are intended for the protection of workers or other users, or the environment. Such national provisions may neither require modifications of a product manufactured in accordance with the provisions of the applicable directives, nor influence the conditions for its placing on the Community market.

A product is placed on the Community market when it is made available for the first time. This is considered to take place when a product is transferred from the stage of manufacture with the intention of distribution or use on the Community market (29). Moreover, the concept of placing on the market refers to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series.

The transfer of the product takes place either from the manufacturer, or the manufacturer’s authorised representative in the Community, to the importer established in the Community or to the person responsible for distributing the product on the Community market (31). The transfer may also take place directly from the manufacturer, or authorised representative in the Community, to the final consumer or user.

The product is considered to be transferred either when the physical hand-over or the transfer of ownership has taken place. This transfer can be for payment or free of charge, and it can be based on any type of legal instrument. Thus, a transfer of a product is considered to have taken place, for instance, in the circumstances of sale, loan, hire, leasing and gift.

Placing on the market is considered not to take place where a product is:

- transferred from the manufacturer in a third country to an authorised representative in the Community whom the manufacturer has engaged to ensure that the product complies with the directive (32);
- transferred to a manufacturer for further measures (for example assembling, packaging, processing or labelling) (33);
- not (yet) granted release for free circulation by customs, or has been placed under another customs procedure (for example transit, warehousing or temporary importation), or is in a free zone (34);
- manufactured in a Member State with a view to exporting it to a third country;
- displayed at trade fairs, exhibitions or demonstrations (35); or
- in the stocks of the manufacturer, or the authorised representative established in the Community, where the product is not yet made available, unless otherwise provided for in the applicable directives.

A product offered in a catalogue or by means of electronic commerce is deemed not to have been placed on the Community market until it is actually made available for the first time. In order to respect the rules and principles aiming to prohibit misleading advertising, a non-compliance of a product intended for the Community market should be clearly indicated.

Products must be in compliance with the applicable New Approach directives, and other Community legislation, when they are placed on the market. Accordingly, new products manufactured in the Community and all products imported from third countries – whether new or used – must meet the provisions of the applicable directives when made available for the first time on the Community market. Member States have an obligation to ensure this in the framework of market surveillance (36). Used products, which are on the Community market, are subject to free movement according to the principles laid down by Articles 28 and 30 of the EC Treaty.
2.3.2. Putting into service (\(^{27}\))

Putting into service takes place at the moment of first use within the Community by the end user (\(^{38}\)). Where the product is put into service at the workplace, the employer is to be considered as the end user.

Products must comply with the provisions of the applicable New Approach directives and other Community legislation when they are put into service. However, the need to verify the compliance of products, and – if applicable – that they are correctly installed, maintained and used for the intended purpose, should be limited, in the framework of market surveillance (\(^{39}\)), to products:

- which can only be used after an assembly, an installation or other manipulation has been carried out;
- whose compliance can be influenced by the distribution conditions (for example storage, transport); or

The aim of the transitional period is to allow manufacturers and notified bodies to adjust gradually to the conformity assessment procedures and the essential requirements set up by the new directive, and, thus, to avert the risk of blocking production. Further, manufacturers, importers and distributors need to be given time to exercise any rights they have acquired under the rules predating the new directive, for example to sell their stocks of products manufactured in line with the national rules in force before the directive. Finally, the transitional period provides for extra time for the adoption of harmonised standards, even though this is not, in principle, a precondition for the application of New Approach directives.

In line with the objectives of the transitional period, Member States are obliged to maintain their national system as an option until the end of the transitional period, unless otherwise provided for (\(^{40}\)). The obligation to maintain the pre-existing rules applies not only to all mandatory provisions in force in each Member State, but also to all national specifications applied voluntarily by manufacturers. Consequently, Member States with no regulations, in the strict sense, must refrain from legislation. Further, the national standards bodies are obliged to make available, throughout the transitional period, copies of national standards applied under the existing national system.

Each directive providing for a transitional period sets the date for freezing the national system in force. Generally, this is the date on which the directive enters into force, but sometimes it is the date on which the directive is adopted.

During the transitional period Member States, may make no changes to the system in question which would modify product requirements or the conformity assessment procedure or which would otherwise have an effect on acquired rights. However, Member States are allowed to carry out changes in cases of force majeure. For example, technical progress or exceptional circumstances may reveal that the system in force fails to satisfy a legitimate requirement and that this shortcoming creates risks, which the Member State was unable to prevent by amending the rules in force in good time. Such amendments have to be notified at the draft stage, as required by Directive 98/34/EC, so that the Commission and other Member States may not prohibit, restrict or impede the putting into service of products that meet the provisions of the applicable directives (\(^{41}\)). However, Member States are allowed to maintain and adopt, in compliance with the Treaty (in particular Articles 28 and 30 of the EC Treaty), additional national provisions regarding the putting into service, installation or use, of products which are intended for the protection of workers or other users, or other products. Such national provisions may not require modifications of a product manufactured in accordance with the provisions of the applicable directives.

2.4. Transitional period

- Most New Approach directives provide for a transitional period (\(^{42}\)).
- Member States are obliged to allow on their markets, until the end of the transitional period, products designed and manufactured according to their national system. Thus, the manufacturer has the choice, throughout the transitional period, either to apply the national system or the directive.
- During the transitional period, products conforming to all applicable directives may be placed on the Community market and put into service in any Member State. Products manufactured in line with national regulations or with non-mandatory technical specifications move freely according to the principles laid down by Articles 28 and 30 of the EC Treaty (\(^{43}\)).
- At the end of the transitional period, the directive applies to the exclusion of any national rules covering the same products or the same essential requirements (\(^{44}\)). Consequently, only products in compliance with the applicable directive may be placed on the Community market and put into service after the transitional period.
States may have an opportunity to submit comments on the proposed amendment.

At the end of the transitional period, Member States are obliged to terminate the national systems kept in force until then, for example to repeal the relevant regulations. As a result, the national measures implementing the new directive will be the only mandatory rules in force for the products or risks concerned in every Member State. Consequently, products may no longer be manufactured according to type approvals or other certificates issued under the system to be repealed.

After the transitional period, products manufactured before or during this period, in line with the system to be repealed, may no longer be placed on the Community market. In accordance with the safety or other objectives of the new directive, a product – which is placed on the market before the end of the transitional period – should be allowed to be put into service after that date if it was ready for use when placed on the market. Otherwise, it may only be put into service after that date if it fully complies with the provisions of the directive (45).

According to the general rule, CE marking is an indication that products, which are subject to several directives providing for its affixing, conform to the provisions of all these directives. However, where one or more of these directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking is an indication of conformity only to the directives applied by the manufacturer. Consequently, during a transitional period, the CE marking does not necessarily indicate that the product conforms to all applicable directives providing for its affixing. Therefore, the documents, notices or instructions required by the directives, and accompanying the product, must indicate clearly the directives applied by the manufacturer, where at least one of the applicable directives contains a transitional period when the product is manufactured. Information concerning the directives applied must also be given in the EC declaration of conformity (46).
3. Responsibilities

The manufacturer is any natural or legal person who is responsible for designing and manufacturing a product with a view to placing it on the Community market with his own name (49). The responsibilities of the manufacturer apply also to any natural or legal person who assembles, packs, processes, or labels ready-made products with a view to their being placed on the Community market under his own name. Further, the responsibility of the manufacturer is placed on any person who changes the intended use of a product in such a way that different essential requirements will become applicable, or substantially modifies or re-builds a product (thus creating a new product), with a view to placing it on the Community market (49).

The manufacturer may design and manufacture the product himself. As an alternative, he may have it designed, manufactured, assembled, packed, processed or labelled with a view to placing it on the Community market under his own name, and thus presenting himself as a manufacturer. Where subcontracting takes place, the manufacturer must retain the overall control for the product and ensure that he receives all the information that is necessary to fulfil his responsibilities according to the New Approach directives. The manufacturer who subcontracts some or all of his activities may in no circumstances discharge himself from his responsibilities, for example to an authorised representative, a distributor, a retailer, a wholesaler, a user or a subcontractor.

The manufacturer has sole and ultimate responsibility for the conformity of the product to the applicable directives, whether he designed and manufactured the product himself or is considered as a manufacturer because the product is placed on the market under his name.

He is responsible:
- for designing and manufacturing the product in accordance with essential requirements laid down by the directive(s); and
- for carrying out conformity assessment in accordance with the procedures laid down by the directive(s).

The manufacturer is obliged to understand both the design and construction of the product to be able to take the responsibility for the product being in compliance with all provisions of the relevant New Approach directives. This applies equally to situations where the manufacturer designs, manufactures, packs and labels the product himself, as to situations where some or all of these operations are carried out by a subcontractor.

As regards conformity assessment, the manufacturer’s responsibility depends on the procedure applied (50). As a general rule, the manufacturer must take all measures necessary to ensure that the manufacturing process assures compliance of the products, to affix the CE marking to the product, to establish a technical documentation and to draw up the EC declaration of conformity. Depending on the directive, the manufacturer may be required to submit the product to a third party (usually a notified body) for product testing and certification, or to have the quality system certified by a notified body. In addition, several directives set up complementary obligations (such as the requirement to accompany the product with specified information).

Directives usually require that the manufacturer is identified on the product, for example on a marking on the product or the accompanying documentation (51). However, sometimes it is not possible to identify the person, in reality, was in charge of designing and manufacturing the product. Unless otherwise provided for, this does not reduce the responsibilities of the person who placed the product on the Community market (for example any natural or legal person who imports a new or used product from a third country and places it on the Community market).

3.1. Manufacturer

3.1.1. New Approach directives
- A manufacturer, in the meaning of New Approach, is the person who is responsible for designing and manufacturing a product with a view to placing it on the Community market on his own behalf.
- The manufacturer has an obligation to ensure that a product intended to be placed on the Community market is designed and manufactured, and its conformity assessed, to the essential requirements in accordance with the provisions of the applicable New Approach directives.
- The manufacturer may use finished products, ready-made parts or components, or may subcontract these tasks. However, he must always retain the overall control and have the necessary competence to take the responsibility for the product (57).
Community directive on telecommunications terminal equipment.

(44) As an exception, the Directive relating to gas appliances imposes no obligation on the Member States, but stipulates that they may permit the placing on their markets of products complying with the pre-existing rules during the transitional period. As another exception, the Directive on radio and telecommunications terminal equipment replaces the existing system at the beginning of the transitional period, although products in compliance with it may be placed on the market and put into service during a transitional period of one year.

(45) Since the Directive on civil explosives covers only placing on the market and since the Directive on pressure equipment sets no limit for the putting into service, products covered by these Directives can be put into service at any time without being subject to further conditions according to the Directives. For placing on the market and putting into service, see Section 2.3.

(46) For the EC declaration of conformity, see Section 5.4; for the CE marking, see Chapter 7.

(47) Where the manufacturer uses finished products, ready-made parts or components subject to a New Approach directive as such, the responsibility for these lies with their original manufacturer.

(48) The manufacturer is not defined in the New Approach directives, with the exception of the Directives relating to active implantable medical devices.

The concept of manufacturer according to New Approach is different from that according to the Directives on product liability and general product safety.

Legal or administrative action may take place against anyone in the supply or distribution chain who can be considered responsible for a non-compliant product. This may, in particular, be the case when the manufacturer is established outside the Community. According to the Directive on product liability, the concept of manufacturer covers more and different persons compared to those considered under the New Approach directives. The definition of manufacturer (producer) and his liability according to the Directive on product liability is described in Section 3.7.

According to the Directive on general product safety, a producer is the manufacturer of the product when he is established in the Community. Any other person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product, is also the producer. A producer is also the manufacturer’s representative when the manufacturer is not established in the Community or if there is no representative established in the Community, the importer. Other professionals in the supply chain are producers insofar as their activities may affect the safety properties of a product on the market.

The Directive on general product safety requires manufacturers to place only safe products on the market. They are obliged, within the limits of their respective activities, to provide consumers with the relevant information to enable them to assess the risks inherent in a product, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks. They are also obliged to adopt measures commensurate with the characteristics of the product in order to be informed of possible risks, and to take appropriate action including, if necessary, withdrawing the product from the market.

3.2. Authorised representative

- The manufacturer may appoint any natural or legal person to act on his behalf as an authorised representative (35).
- For the purposes of New Approach directives the authorised representative must be established inside the Community.
- The authorised representative is explicitly designated by the manufacturer, and he may be addressed by the authorities of the Member States instead of the manufacturer with regard to the latter’s obligations under the New Approach directive in question.
- The manufacturer remains generally responsible for actions carried out by an authorised representative on his behalf.

instance, be appointed to ensure and declare that the product complies with the requirements, to affix the CE marking and the notified body’s number to the product, to draw up and sign the EC declaration of conformity, or to keep the declaration and the technical documentation at the disposal of national surveillance authorities (35).

The tasks that may be delegated to the authorised representative according to the directives are of an
3.3. Importer/person responsible for placing on the market

An importer (a person responsible for placing on the market) in the meaning of New Approach directives is any natural or legal person established in the Community who places a product from a third country on the Community market.

The importer must ensure that he is able to provide the market surveillance authority with the necessary information regarding the product, where the manufacturer is not established in the Community, and has no authorised representative in the Community.

The natural or legal person who imports a product into the Community may, in some situations, be considered as the person who must assume the responsibilities placed on the manufacturer according to the applicable New Approach directives.

The importer established in the Community who places a product from a third country on the Community market has a limited, but defined responsibility under the New Approach directives. In some directives the importer is referred to as the person responsible for placing on the market.

According to New Approach directives, the importer (person responsible for placing on the market) must be able to provide the surveillance authority with a copy of the EC declaration of conformity, and make the technical documentation available. This responsibility is placed on the importer (person responsible for placing on the market) only where the manufacturer is not established in the Community, and has no authorised representative in the Community. Thus, the importer (person responsible for placing on the market) should require formal assurance in writing from the manufacturer that the documents will be made available when requested by the surveillance authority.

The importer needs neither a mandate from the manufacturer, nor a preferential relationship with the manufacturer like the authorised representative. However, the importer must ensure, in order to fulfil his responsibilities, that a contact with the manufacturer can be established.

The importer may wish to carry out administrative tasks on behalf of the manufacturer. In such a case, he has to be explicitly designated by the manufacturer in order to become an authorised representative, provided that he is established in the Community.

In some situations the person referred to as an importer shall be able to assume the responsibilities of the manufacturer. Thus, he shall ensure that the product complies with the essential requirements and that the appropriate conformity assessment procedure has been applied.

3.4. Distributor

Provisions regarding distribution are in general not included in New Approach directives.

A distributor is to be considered as any natural or legal person in the supply chain who takes subsequent commercial actions after the product has been placed on the Community market.

The distributor shall act with due care in order not to place clearly non-compliant products on the Community market. He shall also be capable of demonstrating this to the national surveillance authority.

Retailers, wholesalers and other distributors in the supply chain do not need to have a preferential relationship with the manufacturer like the authorised representative. They may take commercial actions on behalf of the manufacturer or on their own behalf after the product has been made available on the Community market.

The distributor should act with due care and have a basic knowledge of the applicable legal requirements. He should know, for instance, which products must bear the CE marking, what information (for example EC declaration of conformity) has to
that it is not subsequently placed on the Community market during a period of five years, or to craft conformity assessment during a period where he substantially

Some products can only be used after an assembly, an installation or other manipulation has been carried out. This may, for instance, be the case for machinery, personal protective equipment, measuring instruments, gas appliances and telecommunication terminal equipment.

Where the directive in question covers putting into service, and where an assembly, an installation or other manipulations may have an impact on maintaining the compliance of the product, the person responsible for such manipulations must ensure that they do not cause a non-compliance with the essential requirements. This is to ensure that the product complies with the provision of the applicable directives at the moment of first use within the Community.

3.5. Assembler and installer

- The installer and assembler of a product, which is already placed on the market, should take necessary measures to ensure that it still complies with the essential requirements at the moment of first use within the Community. This applies to products where the directive in question covers putting into service, and where such manipulations may have an impact on the compliance of the product.
3.6. User (employer)

- New Approach directives do not lay down obligations for users, apart from those related to putting into service.
- Community legislation concerning the health and safety of the workplace has an impact on the maintenance and use of products covered by New Approach directives that are used at the workplace.

The employer is required, before choosing the personal protective equipment, to assess that it satisfies the requirements. According to the Directive on the minimum safety and health requirements for work with display screen equipment, workers have a general responsibility to take care, as far as possible, of their own safety and health and that of other persons affected by their acts at work. In accordance with the training and the instructions given by their employer they must, for instance, make correct use of machinery, apparatus, and other means of production, and the personal protective equipment.

Directives 89/391/EEC, 89/655/EEC, 89/656/EEC and 90/270/EEC lay down minimum requirements. Thereafter, Member States are allowed to adopt or retain more stringent provisions, as long as they are compatible with the EC Treaty. The provisions of New Approach directives must be respected and, thus, additional national provisions may neither modify a product of a product within the scope of a New Approach directive, nor influence the conditions of the placing on the market of such products.

3.7. Product liability

- The Directive on product liability covers any product manufactured or imported into the Community, which causes damage to individuals or private property. Thus, the Directive applies also to products that fall within the scope of a New Approach directive.
- The Directive on product liability establishes a strict liability regime on manufacturers and importers in the Community.

The Directive on product liability covers all movables and electricity, as well as raw materials and components of final products. Services as such are excluded from the scope at present. Secondly, the Directive applies only to defective products, that is products not providing the safety that a person is entitled to expect. The fact that a product is not fit for the use expected is not enough. Only if a product lacks safety, modifies or changes the intended use of the product, he may be considered as the manufacturer in the meaning of the New Approach (see Section 3.11).

The responsibilities of the importer (person responsible for placing on the market) have been explicitly extended under the Directives relating to machinery and lifts, according to which the obligations regarding the conformity assessment procedure fail to any person placing the product on the market in the Community, where neither the manufacturer, his authorised representative established in the Community nor the installer of the lift fulfills these obligations. (61) See Judgement of the Court: case C-271/92.

Further, where the directive explicitly requires that the product is accompanied by the EC declaration of conformity, the distributor should ensure that this is the case (see Section 5.4).

(62) According to the Directives relating to lifts and pressure equipment the assembler is considered to be the manufacturer, and accordingly must take over the responsibilities of the manufacturer. Further, the Directive on medical devices contains a particular procedure for putting together devices bearing the CE marking in order to place them on the market as a system or procedure pack.

(63) For putting into service, see Section 2.3.2.

(64) For putting into service, see Section 2.3.2.

(65) For differences between directives based on Articles 95 and 138, see
does the Directive apply. The fact that a better product is made afterwards does not render defective the older models.

Liability, the responsibility to pay for damages, is placed on a producer. A producer is either a manufacturer of a finished product or a component part of a finished product, producer of any raw material, or any person who presents himself as a manufacturer (for example by affixing a trade-mark). Importers placing products on the Community market from third countries are all considered to be producers according to the Directive on product liability. If the producer cannot be identified, each supplier of the product becomes liable, unless he informs the injured person within a reasonable time of the identity of the producer, or of the person who supplied him with the product. When several persons are liable for the same damage, they are all liable jointly and severally.

The producer must compensate for damages caused by the defective product to individuals (death, personal injury) and private property (goods for private use). However, the Directive does not cover any damage to property under EUR 500 (66) for a single incident. National law may govern non-material damages (such as pain and suffering). The Directive does not cover the destruction of the defective product itself and, therefore, there is no obligation to compensate for it under the Directive on product liability. This is without prejudice to national law.

The Directive on product liability allows Member States to set up a financial ceiling for serial accidents fixed at EUR 70 million (66) as a minimum. However, most Member States have not used this possibility.

The producer is not automatically liable for damages caused by the defective product to individuals (death, personal injury) and private property (goods for private use). However, the Directive does not cover any damage to property under EUR 500 (66) for a single incident. National law may govern non-material damages (such as pain and suffering). The Directive does not cover the destruction of the defective product itself and, therefore, there is no obligation to compensate for it under the Directive on product liability. This is without prejudice to national law.

The Directive on product liability allows Member States to set up a financial ceiling for serial accidents fixed at EUR 70 million (66) as a minimum. However, most Member States have not used this possibility.

The producer is not automatically liable for damages caused by the product. The injured person, whether or not he is the buyer or user of the defective product, must claim his rights to obtain compensation. The victim will be paid only if he proves that he has suffered damage, the product was defective, and this product caused the damage. If the injured person contributes to the damage, the producer's liability may be reduced or even disallowed. However, the victim does not need to prove that the producer was negligent, because the Directive on product liability is based on the principle of liability without fault of the producer. Thus, the producer will not be exonerated even if he proves he was not negligent, if an act or omission of a third person contributes to the damage caused, if he has applied standards, or if his product has been tested.

The producer will not have to pay, if he proves:
- he did not place the product on the market (for example the product was stolen);
- the product was not defective when he placed it on the market (thus he proves that the defect was caused subsequently);
- the product was not manufactured to be sold;
- the defect was caused due to compliance with mandatory regulations issued by the public authorities (which excludes national, European and international standards) (67);
- the state of scientific and technical knowledge at the time when the product was put on the market could not as such enable the existence of the defect to be discovered (the development risks defence) (68); or,
- where he is a subcontractor, that the defect was due either to the design of the finished product or to defective instructions given to him by the producer of the finished product.

Ten years after the product is placed on the market, the producer ceases to be liable, unless legal action is pending. Further, the victim must file an action within three years after the damage, the defect and the identity of the producer were known. No waivers of liability in relation to the injured person may be agreed.

The Directive on product liability does not require Member States to repeal any other legislation on liability. In this respect, the Directive's regime is added to the existing national rules on liability. It is up to victim to choose on what grounds to file the action.
4. Compliance with directives (69)

A fundamental principle of the New Approach is to limit legislative harmonisation to the essential requirements that are of public interest. These requirements deal in particular with the protection of health and safety of users (usually consumers and workers) and sometimes cover other fundamental requirements (for example protection of property or the environment).

Essential requirements are designed to provide and ensure a high level of protection. They either arise from certain hazards associated with the product (for example physical and mechanical resistance, flammability, chemical, electrical or biological properties, hygiene, radioactivity, accuracy), or refer to the product or its performance (for example provisions regarding materials, design, construction, manufacturing process, instructions drawn up by the manufacturer), or lay down the principal protection objective (for example by means of an illustrative list). Often they are a combination of these. As a result, several directives may be applicable to a given product at the same time, since essential requirements of different directives need to be applied simultaneously in order to cover all relevant public interests.

Essential requirements must be applied as a function of the hazard inherent to a given product. Therefore, manufacturers need to carry out risk analysis to determine the essential requirement applicable to the product. This analysis should be documented and included in the technical documentation (71).

Essential requirements define the results to be attained, or the hazards to be dealt with, but do not specify or predict the technical solutions for doing so. This flexibility allows manufacturers to choose the way to meet the requirements. It allows also that, for instance, the materials and product design may be adapted to technological progress. Accordingly, New Approach directives do not necessitate regular adaptation to technical progress, since assessment of whether requirements have been met or not are based on the state of technical know-how at a given moment.

The essential requirements are set out in annexes to the directives. Although no detailed manufacturing specifications are included in the essential requirements, the degree of detailed wording differs between directives. The wording is intended to be precise enough to create, on transposition into national legislation, legally binding obligations that can be enforced, and to facilitate the setting up of mandates by the Commission to the European standards organisations in order to produce harmonised standards. They are also formulated as to enable the assessment of conformity with those requirements, even in the absence of harmonised standards or in case the manufacturer chooses not to apply them (72).

4.1. Essential requirements

Essential requirements are mandatory. Only products complying with essential requirements may be placed on the market and put into service (70).

Essential requirements must be applied as a function of the hazards inherent to a given product.

4.2. Harmonised standards

Harmonised standards are European standards, which are adopted by European standards organisations, prepared in accordance with the General Guidelines agreed between the Commission and the European standards organisations, and follow a mandate issued by the Commission after consultation with the Member States (73).

Harmonised standards in the meaning of the New Approach are deemed to exist when the European standards organisations formally present to the Commission the European standards elaborated or identified in conformity with the mandate (74).
which specifies the essential requirements. (76) Although European standards are considered as harmonised before publication of the references in the Official Journal, it is this publication that gives presumption of conformity to the essential requirements of the directive in question (see Section 4.3). However, according to the Directive relating to low voltage equipment a standard is considered as harmonised after it has been drawn up by common agreement between the bodies notified by the Member States in accordance with the procedure laid down in the Directive, and published under national or Community procedures. (77) CEN (European Committee for Standardisation); Cenelec (European Committee for Electrotechnical Standardisation); ETSI (European Telecommunication Standards Institute). (78) Exceptionally, harmonisation documents adopted by European standards organisations can also be accepted by the Community as harmonised standards. The differences between European and national standards and harmonisation documents essentially relate to the degree of obligation on the part of the national members. Harmonisation documents must be implemented at national level, at least by public notification of the title and number of

Harmonised standards are not a specific category amongst European standards. The terminology used in New Approach directives is a legal qualification of technical specifications existing as European standards (79), but to which a special meaning has been given by these directives. Harmonised standards maintain their status of voluntary application in the field of New Approach directives.

The Commission formally requests the European standards organisations to present European standards by issuing a mandate. Prior to this the Commission consults the Committee established under Directive 98/34/EC, and, in some cases, the sectoral Committee set up under the directive in question. Reaching consensus within the Committee under Directive 98/34/EC implies wide consultation of sectoral authorities at national level. Thus, the mandate provides a strong indication of the expectations of public authorities (79).

The European standards organisations will formally take a position on a mandate from the Commission in conformity with their internal regulations. Acceptance of the mandate and the subsequent working programme of these organisations initiate the standstill period as provided for in their internal regulations and in Directive 98/34/EC.

The elaboration and adoption of harmonised standards is based on the General Guidelines for cooperation between the European standards organisations and the Commission signed on 13 November 1984. These orientations contain series of principles and commitments concerning standardisation, such as the participation of all interested parties (for example manufacturers, consumer associations and trade unions), the role of public authorities, the quality of standards and a uniform application of standards throughout the Community (78).

The European standards organisations are responsible for identifying and elaborating harmonised standards in the meaning of the New Approach and for presenting a list of adopted harmonised standards to the Commission. The technical contents of such standards are under the entire responsibility of the European standards organisations. Once public authorities have agreed on a mandate, the search for technical solutions should in principle be left to the interested parties. In certain areas, such as the environment and health and safety, the participation of public authorities on a technical level is important in the standardisation process. However, New Approach directives do not foresee a procedure under which public authorities would verify or approve either at Community or national level the contents of harmonised standards, which have been adopted with the procedural guarantees of the standardisation process (79). The dialogue between standards bodies and authorities and, when appropriate, their participation in the standardisation process should, nevertheless, help to ensure that the terms of the mandate are correctly understood and public concerns are properly taken into account in the process.

The European standards organisations are not obliged to present newly developed standards as harmonised standards. They may also identify existing standards that they judge, after examination and possible revision, to meet the terms of the mandate, or modify existing standards in order to meet those terms. In the same way, they may identify international or national standards and adopt them as European standards, and present them to the Commission as harmonised standards.

A harmonised standard must match the essential requirements of the relevant directive. A European standard may contain provisions relating not only to essential requirements but also to other provisions. In such a case, these provisions should be clearly distinguished from those covering the essential requirements. Further, a harmonised standard does not necessarily cover all essential requirements. This would oblige the manufacturer to use other relevant technical specifications in order to meet all the essential requirements of the directive.

Table 4/1 • Standardisation procedure under the New Approach

<table>
<thead>
<tr>
<th>No.</th>
<th>Step in the Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>A mandate is drawn up, following consultation with the Member States.</td>
</tr>
<tr>
<td>2.</td>
<td>The mandate is transmitted to European standards organisations.</td>
</tr>
<tr>
<td>3.</td>
<td>European standards organisations accept the mandate (75).</td>
</tr>
<tr>
<td>4.</td>
<td>European standards organisations elaborate a joint programme.</td>
</tr>
<tr>
<td>5.</td>
<td>The technical committee elaborates a draft standard.</td>
</tr>
<tr>
<td>6.</td>
<td>European standards organisations and national standards bodies organise a public enquiry.</td>
</tr>
<tr>
<td>7.</td>
<td>The technical committee considers comments.</td>
</tr>
<tr>
<td>9.</td>
<td>European standards organisations transmit references to the Commission.</td>
</tr>
<tr>
<td>10.</td>
<td>The Commission publishes the references.</td>
</tr>
</tbody>
</table>
Harmonised standards provide a presumption of conformity with the essential requirements (84), if their reference has been published in the Official Journal and if they have been transposed at national level. However, it is not necessary that transposition takes place in all Member States before the presumption of conformity becomes effective. Since European standards have to be transposed in a uniform way, a manufacturer may choose any of the corresponding national standards.

The objective of publishing the reference in the Official Journal is to set the earliest date for the presumption of conformity to take effect. Before the Commission publishes the reference, it may verify that the terms of the mandate are fulfilled. When it considers that a standard does not meet the terms of the mandate, it will either not publish the reference of this standard, or it will limit publication of the reference to parts of this standard. In such cases, the condition for a harmonised standard to produce a presumption of conformity is not met, or it is only met for the part that the published references cover.

The application of harmonised standards that give a presumption of conformity remains voluntary (83). The manufacturer can choose whether or not to refer to harmonised standards. However, if the manufacturer chooses not to follow a harmonised standard, he has the obligation to prove that his products are in conformity with essential requirements by the use of other means of his own choice (for example by means of any existing technical specifications). If the manufacturer applies only a part of a harmonised standard or the applicable harmonised standard does not cover all the essential requirements, the presumption of conformity exists only to the extent the standard corresponds to the essential requirements.

Compliance with harmonised standards will, according to certain directives, determine the applicable conformity assessment procedure, which sometimes opens the possibility for conformity assessment without the intervention of a third party or for a larger choice of procedures (83).

### 4.3. Presumption of conformity

- Conformity with a national standard that transposes a harmonised standard, whose reference has been published, confers a presumption of conformity with the essential requirements of the applicable New Approach directive that is covered by such a standard (84).
- References (such as titles, identification numbers) of harmonised standards are published in the Official Journal for the directive in question. An updated list of references for each directive can be found at the following Internet address: http://europa.eu.int/comm/dg03/directs/dg3b/newappro/eurstd/harmstds/index.html (82).
- Member States must publish the reference of the national standard that transposes a harmonised standard. It is useful to indicate in the publication the link with the legislation in question.
- The application of harmonised standards, which give a presumption of conformity, remains voluntary in the field of New Approach directives. Thus, the product may be manufactured directly on the basis of the essential requirements (84).

### 4.4. Withdrawal of the presumption of conformity

- The Commission withdraws the presumption of conformity, if it has been established that the harmonised standard does not fully meet the essential requirements.

In the light of the committee’s opinion, the Commission shall inform the Member States who shall take necessary measures.
If, according to the opinion taken by the Committee, the harmonised standard is not in full compliance with the essential requirements, the Commission and the Member States must withdraw the references to this standard from the published information.

The procedure to challenge a standard and its outcome does not affect its existence as a harmonised standard. It may only lead to the withdrawal of its reference published by the Commission and by the Member States. This signifies that the harmonised standard in question no longer gives presumption of conformity with the essential requirements.

The fact that the Commission or the Member States can challenge a harmonised standard, instead of conducting an approval procedure prior to the publication of its reference (\(^\text{84}\)), indicates that a systematic verification of the technical contents of harmonised standards is not provided for. Only in cases where a standard, after it has been challenged, is found not to satisfy the essential requirements or to present shortcomings, may its reference be withdrawn.

### 4.5. Revision of harmonised standards

- The principles concerning the mandate and the adoption of harmonised standards, their availability, and the presumption of conformity to the essential requirements apply also to the revised version of harmonised standards.
- During the transitional period, both the old and the revised standards give presumption of conformity, provided that the conditions for this are met by both standards.

The formal decision to revise a standard is, in principle, taken by the European standard organisations. This takes place on the basis of their own initiative (\(^\text{85}\)), or following a request from the Commission directly or, indirectly, based on an initiative of a Member State. The need for revision can result from the changes of the scope of the directive (such as an extension of the scope to other products or a modification of the essential requirements), from the fact that the Commission or a Member State challenges the contents of the harmonised standard, indicating that it could no longer give presumption of conformity with the essential requirements, or as a result of technological development.

When a harmonised standard is revised, the revision must be covered by a mandate to maintain the possibility of giving presumption of conformity. Unless the contrary can be deduced from the original mandate, the terms and conditions of the original mandate apply also for the revision of the harmonised standard. This does not exclude the possibility of a new mandate, in particular where the revision is related to shortcomings with respect to the essential requirements.

To give presumption of conformity, the revised standard must satisfy the general conditions according to the New Approach: the standard is based on a mandate, it is presented by the relevant European standards organisation to the Commission, its reference is published by the Commission in the Official Journal, and it is transposed as a national standard.

Following its internal regulations, the relevant European standard organisation lays down the date of publication at the national level of the revised harmonised standard, and the date of withdrawal of the old standard. The transitional period is normally the time period between these two dates. During this transitional period both harmonised standards give presumption of conformity, provided that the conditions for this are met. After this transitional period, only the revised harmonised standard gives a presumption of conformity.

The Commission may consider that, for safety or other reasons, the old version of the harmonised standard must cease giving a presumption of conformity before its date of withdrawal, set by the European standards organisation in question. In such cases, the Commission fixes an earlier date after which the standard will no longer give a presumption of conformity, and publishes this information in the Official Journal. If circumstances allow, the Commission consults the Member States prior to taking a decision to reduce the period during which the standard gives a presumption of conformity.

The reference of the revised harmonised standard, the reference of the old harmonised standard, and the date when the presumption of conformity of the old standard finishes are published together in the Official Journal.
Conformity assessment according to the modules is either based on the intervention of a first party (manufacturer) or a third party (notified body) (81), and relates to the design phase of products, to their production phase or both (see Tables 5/1 to 5/3). Should a manufacturer subcontract design or production, he still remains responsible for the execution of conformity assessment for both phases (82).

The modules give the legislator, in relation to the type of products and hazards involved, the means to set up the appropriate procedures for manufacturers to demonstrate product conformity against the provisions of the directive. In setting the range of possible modules, directives take into consideration, according to the principle of proportionality in particular, such issues as the type of products, the nature of the risks involved, the economic infrastructures of the given sector (such as the existence or non-existence of third parties), the types and importance of production to ensure a high degree of protection as defined in Article 9S(3) of the EC Treaty. Additionally, the conformity assessment procedures under a specific directive must provide in an equivalent way, although the procedures are not identical, sufficient confidence as regards the conformity of products to the relevant essential requirements. The principle of proportionality also requires that the directives should not include unnecessary procedures, which are too onerous relative to the objectives, in particular as laid down in the essential requirements. The factors that have been taken into account when setting the range of possible procedures are described in the directives.

New Approach directives establish different procedures, according to the categories of products covered, by either leaving manufacturers no choice or by giving them the freedom of choice within the same category of products. Alternatively, the directives can also establish, for all the products covered by the scope, a range of procedures from which the manufacturer shall choose. Further, each New Approach directive determines the contents of the applicable conformity assessment procedure, which may differ from the models set up by the modules (81).

Providing a choice under a New Approach directive between two or more conformity assessment procedures for the same product may, for instance, be justified, where different certification infrastructures have developed in the Member States as a result of different legislation. Still, the Member States must transpose into their national legislation all the conformity assessment procedures established under a directive and they must guarantee the free movement of all products, which have been subject to a conformity assessment procedure according to the directive in question. The choice of modules may also be justified where a product is subject to the provisions of more than one directive. In such cases the objective is to provide the manufacturer with a common procedure contained in all the relevant directives or at least with compatible procedures. Finally, a choice may also be justified on the basis of the infrastructure of the branch of industry concerned, to enable manufacturers to choose the most suitable and economic procedure.

Certain directives provide for the possibility of using procedures based on quality assurance techniques. In these cases the manufacturer also usually has recourse to a procedure or a combination of procedures not using such techniques, except where compliance with the requirements demands the exclusive application of a certain procedure.
Modules based on quality assurance techniques derived from the EN ISO 9000 series of standards establish a link between the regulated and non-regulated sectors. This should help the manufacturers to meet simultaneously the obligations based on directives and client needs. Further, under certain conditions it allows manufacturers to benefit from their investment in quality systems. It contributes also to the development of the quality chain (from the quality of products to the quality of companies themselves), and promotes awareness of the importance of quality management strategies for improving competitiveness.

Table 5/1 • Basic modules •

<table>
<thead>
<tr>
<th>Module</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Internal control of production covers internal design and production control. This module does not require a notified body to take action.</td>
</tr>
<tr>
<td>B</td>
<td>EC type-examination covers the design phase, and must be followed up by a module providing assessment in the production phase. The EC type-examination certificate is issued by a notified body.</td>
</tr>
<tr>
<td>C</td>
<td>Conformity to type covers the production phase and follows module B. Provides for conformity with the type as described in the EC type-examination certificate issued according to module B. This module does not require a notified body to take action.</td>
</tr>
<tr>
<td>D</td>
<td>Production quality assurance covers the production phase and follows module B. Derives from quality assurance standard EN ISO 9002, with the intervention of a notified body responsible for approving and controlling the quality system for production, final product inspection and testing set up by the manufacturer.</td>
</tr>
<tr>
<td>E</td>
<td>Product quality assurance covers the production phase and follows module B. Derives from quality assurance standard EN ISO 9003, with the intervention of a notified body responsible for approving and controlling the quality system for final product inspection and testing set up by the manufacturer.</td>
</tr>
<tr>
<td>F</td>
<td>Product verification covers the production phase and follows module B. A notified body controls conformity to the type as described in the EC type-examination certificate issued according to module B, and issues a certificate of conformity.</td>
</tr>
<tr>
<td>G</td>
<td>Unit verification covers the design and production phases. Each individual product is examined by a notified body, which issues a certificate of conformity.</td>
</tr>
<tr>
<td>H</td>
<td>Full quality assurance covers the design and production phases. Derives from quality assurance standard EN ISO 9001, with the intervention of a notified body responsible for approving and controlling the quality system for design, manufacture, final product inspection and testing set up by the manufacturer.</td>
</tr>
</tbody>
</table>

Table 5/2 • Simplified flow chart of conformity assessment procedures •

[Diagram of conformity assessment procedures]
Conformity assessment procedure

3.3 EN ISO 9001, EN ISO 9002 and EN ISO 9003 of 1994 replaced the 1987 versions of the standards, i.e. EN 29001, EN 29002 and EN 29003. A revision of the ISO 9000 series of standards is underway to integrate the standards ISO 9001, ISO 9002 and ISO 9003 into the standard ISO 9001. The structure and contents of the revised standard will be different and will include some additional requirements.

Table 5/3 • Variants of basic modules •

<table>
<thead>
<tr>
<th>Additional elements compared to basic modules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aa1 and Cbis1 Internal production control, and one or more tests on one or more specific aspect of the finished product</td>
</tr>
<tr>
<td>Aa2 and Cbis2 Internal production control, and product checks at random intervals</td>
</tr>
<tr>
<td>Dbis Production quality assurance without use of module B</td>
</tr>
<tr>
<td>Ebis Product quality assurance without use of module B</td>
</tr>
<tr>
<td>Fbis Product verification without use of module B</td>
</tr>
<tr>
<td>Hbis Full quality assurance with design control</td>
</tr>
</tbody>
</table>

The modules based on quality assurance techniques (modules D, E, H and their variants) describe the elements a manufacturer must implement in his organisation in order to demonstrate that the product fulfils the essential requirements of the applicable directive. This means that a manufacturer is given the possibility of using an approved quality system for the purpose of demonstrating compliance with regulatory requirements, thus having the capability to design (if applicable), manufacture and supply products that fulfill the applicable essential requirements.

A quality system implemented on the basis of the EN ISO 9001, 9002 or 9003 (***) standard gives a presumption of conformity with the respective modules with regard to the provisions in the modules that these standards cover, and provided that the quality system enables the manufacturer to demonstrate that the products fulfil the essential requirements of the directive in question. This means that the manufacturer must specifically address regulatory needs when implementing and applying a quality system for the purpose of the New Approach directives, in particular:

- the quality objectives, quality planning, quality manual and control of documents must fully take on board the objective of delivering products that conform to the essential requirements;
- the manufacturer must identify and document the essential requirements that are relevant for the product and the harmonised standards to be used or other technical solutions that will ensure fulfillment of the essential requirements;
- the identified standards or other technical solutions must be used as design input, and as verification that design output ensures that the essential requirements will be met;
- the measures taken by the organisation to control production must ensure that the products conform to the identified safety requirements;
- the organisation in its measurement and control of the

5.2. Application of quality system standards

- The use of quality systems for the purpose of conformity assessment procedures in the directives is described in modules D, E and H and their variants.
- Compliance with standards EN ISO 9001, 9002 and 9003 gives a presumption of conformity with the corresponding quality assurance modules as regards the provisions covered by the standard in question, provided that the quality system takes into consideration — as necessary — the specific requirements of the products for which they are implemented.
- Compliance with modules D, E, H and their variants does not require a certified quality system according to standards EN ISO 9001, 9002 or 9003, although it provides a useful means of establishing compliance. The manufacturer is free to apply other quality system models than those based on EN ISO 9000 standards for the purpose of complying with these modules.
- For the purpose of complying with the applicable directives the manufacturer shall ensure that the quality system is implemented and applied in such a way that it ensures the full application of the essential requirements in question.
5.3. Technical documentation

- The manufacturer must draw up a technical file (technical documentation).
- The technical documentation is intended to provide information on the design, manufacture and operation of the product.

New Approach directives oblige the manufacturer to draw up technical documentation containing information to demonstrate the conformity of the product to the applicable requirements. This documentation may be part of the quality system documentation where the directive provides for a conformity assessment procedure based on a quality system (modules D, E, H and their variants). This obligation begins when the product is placed on the market, whatever its geographical origin is (96). The technical documentation must be kept for at least 10 years from the last date of manufacture of the product, unless the directive expressly provides for any other duration (97). This is the responsibility of the manufacturer or the authorised representative established within the Community. In some cases the importer or the person placing the product on the Community market must take on this responsibility (98).

The contents of the technical documentation are laid down, directive by directive, in accordance with the products concerned. As a rule, the documentation should cover the design, manufacture and operation of the product. The details included in the documentation depend on the nature of the product and on what is considered as necessary, from the technical point of view, for demonstrating the conformity of the product to the essential requirements of the relevant directive or, if the harmonised standards have been applied, to these instead by indicating the essential requirements covered by the standards.

Several directives require that the technical documentation is written in an official language of the Member State where the procedures are to be carried out, or in which the notified body is established, or in a language accepted by it (100). In order to carry out the conformity assessment procedures requiring third-party verification in a proper way, the documentation should always be in a language understood by the notified body, even if this has not been explicitly mentioned in all New Approach directives.

5.4. EC declaration of conformity

- The manufacturer or the authorised representative established within the Community must draw up an EC declaration of conformity as part of the conformity assessment procedure provided for in the New Approach directives.
- The EC declaration of conformity should contain all relevant information to identify the directives according to which it is issued, as well as the manufacturer, the authorised representative, the notified body if applicable, the product, and where appropriate a reference to harmonised standards or other normative documents.

New Approach directives impose an obligation on the manufacturer, or the authorised representative established within the Community, to draw up an EC declaration of conformity when the product is placed on the market. Depending on the procedure, the EC declaration of conformity must either ensure that the product satisfies the essential requirements of the applicable directives, or that the product is in conformity with the type for which a type-examination certificate has been issued and satisfies the essential requirements of the applicable directives (101).

The EC declaration of conformity must be kept for at least ten years from the last date of manufacture of the product, unless the directive expressly provides for any other duration (102). This is the responsibility of the manufacturer or the authorised representative.
established within the Community. In some cases the importer or the person responsible for placing on the market must take on this responsibility (109).

The contents of the EC declaration of conformity are laid down, directive by directive, in accordance with the products concerned. The standard EN 45014 has been drawn up with the objective of providing the general criteria for the declaration of conformity, and it can also be used as a guidance document in view of New Approach directives. According to the standard the declaration may take the form of a document, a label or equivalent, and should contain sufficient information to enable all products covered by it to be traced back to it.

As a minimum the following information should be provided:

- the name and address of the manufacturer or the authorised representative issuing the declaration;
- the identification of the product (name, type or model number, and any relevant supplementary information, such as lot, batch or serial number, sources and numbers of items);
- all relevant provisions complied with;
- the referenced standards or other normative documents (such as national technical standards and specifications) in a precise, complete and clearly defined way;
- all supplementary information that may be required (for example grade, category), if applicable;
- the date of issue of the declaration;
- signature and title or an equivalent marking of authorised person (103); and
- the statement that the declaration is issued under the sole responsibility of the manufacturer and, if applicable, the authorised representative.

Other useful information to be included in the EC declaration of conformity is the name, address and identification number of the notified body when it has been involved in the conformity assessment procedure, as well as the name and address of the person who keeps the technical documentation.

Where several New Approach directives apply to a product, the manufacturer or the authorised representative can, basically, merge all the declarations into a single document. However, this is not possible if the directive provides for a specific form of the EC declaration of conformity (such as the Directive relating to personal protective equipment). Consequently, the EC declaration should also provide information on whether or not it covers only one directive. In such a case the declaration should include a reference to other directives in order to verify whether the manufacturer has followed all the Community legislation, or which legislation has been chosen during the transitional period.

The EC declaration of conformity must be made available to the surveillance authority immediately upon request. Moreover, Directives relating to machinery, gas appliances, potentially explosive atmospheres, recreational craft, lifts and high-speed rail systems require that products are accompanied by the EC declaration of conformity.

The EC declaration of conformity must be drawn up in one of the official languages of the Community. If the Community directives contain no further provisions concerning the language of the declaration, the requirements of the Member States to use a specific language must be assessed according to Articles 28 and 30 of the EC Treaty on a case by case basis. However, for products, which are required to be accompanied by the declaration of conformity, it has to be in the official language of the country of use. In these situations a translation should be provided by the manufacturer, the authorised representative or the distributor. Additionally, a copy of the declaration in the original language should be supplied.
6. Notified bodies

6.1 Principles of notification

- Notified bodies carry out the tasks pertaining to the conformity assessment procedures referred to in the applicable New Approach directives when a third party is required.
- Member States are responsible for their notification. They may choose the bodies they notify from the bodies under their jurisdiction which comply with the requirements of the directives and the principles laid down in Decision 93/465/EEC.
- The assessment of the body seeking notification determines if it is technically competent and capable of carrying out the conformity assessment procedures in question, and if it can demonstrate the necessary level of independence, impartiality and integrity. Further, the competence of the notified body should be subject to surveillance, which is carried out at regular intervals and follows the practice established by the accreditation organisations.
- The EN 45000 series of standards and accreditation are important instruments to help in establishing conformity with the requirements of the applicable directive.

Notified bodies (104) take responsibilities in areas of public interest and, therefore, should remain answerable to the competent national authorities. To be eligible a body must be a legal entity established on the territory of the Member State and, thus, come under its jurisdiction. Otherwise, Member States remain free to decide whether or not to notify bodies in respect of each procedure to be applied according to a specific directive. Even so, they cannot prohibit the placing on the market of products which have been subject to one of the conformity assessment procedures set up by a directive and which a body notified by another Member State has certified. This is due to the fact that Member States have an obligation to transpose each conformity assessment procedure established in the directive into their national legislation.

Member States take the final responsibility for the competence of the notified bodies vis-à-vis the other Member States and the Community institutions. Therefore, they must verify the competence of the bodies seeking notification. This shall be based on the criteria laid down in the applicable directive in conjunction with essential requirements and the conformity assessment procedure in question. In general, the competence criteria set out in the directives cover:
- availability of personnel and equipment;
- independence and impartiality in relation to those directly or indirectly concerned with the product (such as the designer, the manufacturer, the manufacturer’s authorised representative, the supplier, the assembler, the installer, the user);
- technical competence of personnel that is relevant to the products and conformity assessment procedure in question;
- maintenance of professional secrecy and integrity; and
- subscription to civil liability insurance, unless that liability is covered by the state under national law.

The assessment of the body seeking notification will determine if the body fulfils the requirements. Accreditation according to the EN 45000 series is a support to the technical part of notification and, although it is not a requirement, it remains an important and privileged instrument for evaluating the competence, impartiality and integrity of the bodies to be notified (105). Further, accreditation should be considered by national notifying authorities as the most favoured technical basis for the assessment in order to reduce differences in the criteria applied for notification. It falls within the discretion of the notifying Member State to decide whether or not assessment carried out by a competent accreditation body established in another Member State is taken into consideration (106).

The EN 45000 series cover different types of conformity assessment bodies (certification bodies, testing laboratories, inspection bodies and accreditation bodies). It is irrelevant whether the body calls itself a laboratory, a certification body or an inspection body as long as it carries out the tasks in the conformity assessment procedure and has technical ability to do so in an independent and impartial way.

(104) Under certain New Approach directives this body is not notified a notified body, but for example an inspection body (Directives relating to simple pressure vessels and construction products), a testing laboratory and a certification body (Directive relating to construction products), or an approved body (Directive relating to toys). Competent bodies under the Directive on electromagnetic compatibility have a similar purpose to that of the notified bodies and, thus, the same principles that apply to notified bodies are applicable to these bodies. Further, most of the principles described in this Chapter also apply to recognised third-party organisations referred to in Article 13 (except Section 6.4) and to the user inspectorates referred to in Article 14 (only Sections 6.1 and 6.2) of the Directive on pressure equipment.

(105) For the purpose of the Directive on marine equipment, notified bodies shall fulfill the requirements of the relevant standards of the EN 45000 series.

(106) European Accreditation (EA) has set up a system of mutual recognition.
The EN 45000 standards consist, in general terms, of a part dealing with the organisation and management of the body, and a part dealing with the technical requirements relating to the operation of the body. The standards must be seen as an integral whole, since both parts are needed to ensure the reliability and capability of the operations of the conformity assessment bodies. For the assessment of competence of bodies seeking notification the essential standards are EN 45001, 45004, EN 45011 and EN 45012 (\(^{[207]}\)).

<table>
<thead>
<tr>
<th>Module</th>
<th>EN 45000 standard(s) applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aa1, Aa2</td>
<td>EN 45001 (+ ability to evaluate and decide on conformity), or EN 45004 (EN 45001 to be observed for testing required), or EN 45011 (EN 45001 to be observed for testing required)</td>
</tr>
<tr>
<td>B</td>
<td>EN 45004 (EN 45001 to be observed for testing required), or EN 45011 (EN 45001 to be observed for testing required)</td>
</tr>
<tr>
<td>Cbis1, Cbis2</td>
<td>EN 45001 (+ ability to evaluate and decide on conformity), or EN 45004 (EN 45001 to be observed for testing required), or EN 45011 (EN 45001 to be observed for testing required)</td>
</tr>
<tr>
<td>D, Dbis</td>
<td>EN 45012 (+ product related knowledge)</td>
</tr>
<tr>
<td>E, Ebis</td>
<td>EN 45012 (+ product related knowledge)</td>
</tr>
<tr>
<td>F, Fbis</td>
<td>EN 45001 (+ ability to evaluate and decide on conformity), or EN 45004 (EN 45001 to be observed for testing required), or EN 45011 (EN 45001 to be observed for testing required)</td>
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<tr>
<td>G</td>
<td>EN 45004 (EN 45001 to be observed for testing required), or EN 45011 (EN 45001 to be observed for testing required)</td>
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<td>H</td>
<td>EN 45012 (+ product related knowledge)</td>
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<td>Hbis</td>
<td>EN 45012 + EN 45004 or EN 45011</td>
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The determination of the technological knowledge and experience of the body seeking notification, and its capability to carry out assessment and verification with regard to specific technical specifications or general objectives or performance requirements in accordance with the directive in question is essential.

Conformity to the relevant standard of the EN 45000 series on the part of the notified body constitutes an element of presumption of conformity to the requirements of the directive, but is not always in itself sufficient without demonstration of technical capability within the scope of the directives. If the assessment of competence according to the relevant standard of the EN 45000 series is to give a presumption of conformity, the criteria in the specific EN 45000 standards must relate to the specific tasks to be performed according to the directive. Consequently, elements such as knowledge of the products and conformity assessment procedures in question, technology involved, and voluntary nature of standards must be considered. The request for product related knowledge is, in particular, important for conformity assessment procedures that involve a quality system (modules D, E, H and their variants), because the quality system must ensure that the product in question meets the requirements of the applicable directive.

Where a notified body operates conformity assessment according to different modules, it may lead to the need to apply several of the EN 45000 standards. This is evident since the modules, like the standards, relate to different
technical activities. However, for such bodies a complete assessment or re-assessment according to each applicable standard is not necessary as regards the management requirements, since the main objective is always to ensure consistency and reliability. Thus, the overall management requirements could be considered as a common element among the EN 45000 standards, even if these requirements are formulated differently. For the technical competence (such as equipment, training and qualification of personnel) assessment on the basis of each relevant standard should be carried out.

In order to build and maintain confidence between the Member States concerning the assessment of notified bodies, it is essential not only to apply the same assessment criteria. It is also important that the bodies performing the assessment of notified bodies have the capability to do so, can demonstrate an equivalent competence and operate according to the same criteria. Such requirements are laid down in EN 45003 and EN 45010. Most of the national accreditation bodies of the Member States fulfil and operate according to the requirements of these standards, and have put into place peer evaluation schemes in order to attain mutual recognition of the accreditation results. The peer evaluation schemes should ensure that the national accreditation bodies are operating on the same basis and according to the same requirements and, thus, provide confidence that the bodies they accredit or assess operate according to the same rules, criteria and level of competence.

Member States are responsible for ensuring that notified bodies maintain their competence at all times and are capable of carrying out the work for which they are notified. It is up to the Member States to choose the means and methods for this. However, the practice concerning surveillance and re-assessment developed by the accreditation bodies should be followed. Member States may also decide to notify a body for a limited period of time, and to renew the notification subsequently.

The Commission does not check or have checked the technical competence of notified bodies. However, Member States having notified bodies unable to prove their conformity with the EN 45000 series may be requested to provide the Commission and other Member States with the appropriate supporting documents on the basis of which notification was carried out.

6.2. Notification procedure and withdrawal of notification (108)

- Notification is an act to inform the Commission and the other Member States that a body, which fulfils the requirements, has been designated to carry out conformity assessment according to a directive.
- The Commission publishes a list of notified bodies in the Official J ournal of the European Communities for information purposes. The list is constantly updated and can be obtained directly from the Commission services.
- Withdrawal of notification takes place when the notified body ceases to fulfil the requirements or its obligations. Withdrawal is the responsibility of the notifying Member State. It can also be the end result of an infringement procedure.

6.2.1. Notification procedure

Member States are free to notify a body at any time after the directive has been adopted. To put the transitional periods provided for in the directives to effective use so that certificates may be granted as from the date of first application, Member States should consider the possibility of ensuring a mechanism by which to notify bodies before formal transposition. In such a case notified bodies are not, however, entitled to issue certificates before the directive is in force.

Notification requires that the Commission has allocated an identification number to the body. Each body receives a single number irrespective of the number of directives for which it is notified. Allocation of the number is a purely administrative act designed to ensure the consistent management of the lists of notified bodies, and it does not confer rights or commit the Commission in any way.

Member States should designate their bodies within three months of the number being allocated. Once this deadline has expired the Commission can take back the number allocated to the body.

Official notification of a body takes place when all the information required (205) and the identification number allocated beforehand to each body is sent — normally by the national administration responsible for the implementation and management of the directive in question — via the Permanent Representation to the Commission (Secretariat-General) and to the other Member States (via their Permanent Representations). The notification takes effect after it has been sent to the Commission and the other Member States.

The Commission ensures that a consolidated list of notified bodies is regularly kept up to date. The Commission has this list published for information purposes in the Official J ournal of the European Communities (C series). Amendments or reductions of the scope, modifications of the validity of the notification and reduction or cancellation of the notification will likewise be published in the same form. The Member States should also publish at the

Quality system certification involves the assessment, determination of conformity against quality system standard and within a certain scope of activity and surveillance of the supplier's quality system.

(205) This section does not apply to the body mentioned in Article 8 (2) of the Directive relating to low voltage equipment or to the competent body referred to in Article 10 of the Directive relating to electromagnetic compatibility.

(108) The notification will comprise the names and addresses of the establishments (operational units) concerned, with details of the product range covered and qualification criteria used by the individual notifications as well as a clear indication of the conformity assessment procedures for which the bodies are notified. Should notification be limited in time by the notifying authorities, the duration of the notification will also be indicated.
6.2.2. Withdrawal of notification

The Commission and the Member States have the responsibility to act when doubt arises about the competence of a notified body, either at the moment of notification or thereafter. Should the Commission consider, on its own initiative or after complaint, that a notified body does not comply with the requirements or fulfill its responsibilities, it will inform the national notifying authority and ask for appropriate documented evidence concerning the basis for the notification or the maintenance of the competence of the body. Should a Member State not provide such information, the Commission may bring this to the attention of the other Member States for discussion or initiate the procedure under Article 226 of the EC Treaty against the notifying Member State.

Apart from presenting a complaint to the Commission, Member States may have recourse to the procedure laid down in Article 227 of the EC Treaty, if they dispute that a body notified by another Member State fulfills the requirements or its obligations properly.

When a notified body ceases to fulfill the requirements or its obligations, the Member State has to withdraw or, if appropriate, suspend the notification after immediately contacting the body in question. The Member State must also have this information published, and inform the Commission and the other Member States following a procedure similar to that of the notification. The body in question should have the possibility to appeal against such a decision. Whether this appeal postpones the de-notification or not depends on the national legislation.

The national authority in question is solely entitled to withdraw notification. The Commission can only withdraw a notified body from the consolidated list when the notifying authority of a Member State itself withdraws its notification or when, at the end of an infringement procedure under Article 226 or 227 of the EC Treaty, the Court declares a Member State to be in infringement of a given directive and, consequently, declares a notification to be invalid.

The withdrawal of a notification does not affect certificates issued by the notified body until such time as demonstration can be made that the certificates should be withdrawn. Where a Member State withdraws its notification, it shall take appropriate steps to ensure that another notified body processes files of the body concerned in order to ensure continuity.

Notified bodies must keep their national notifying authorities informed of their activities (for example concerning the conduct of conformity assessments, availability of resources, subcontracting, situations of conflicts of interest), either directly or via an authorized body (for example the accreditation body). They must also be prepared to provide to their notifying authorities all information concerning the proper implementation of the conditions under which they were notified, either at the request of their notifying authorities or of the Commission.

Notified bodies have generally an obligation to inform the other notified bodies and the national surveillance authority about all certificates suspended or withdrawn and, on request, about certificates issued or refused. They shall also provide the surveillance authority and, according to some directives, also the competent authorities of other Member States, with relevant information for the purpose of market surveillance [111]. Further, notified bodies shall provide the Commission services responsible for administering a safeguard clause necessary information related to the product or the conformity assessment upon request.

Notified bodies are and must remain third parties independent of their clients and other interested parties. The legal status of bodies seeking notification, whether they are private or State-owned, is irrelevant as long as their 6.3. General responsibilities of notified bodies

- Notified bodies shall provide relevant information to their notifying authority, the market surveillance authorities and other notified bodies.
- Notified bodies shall operate in a competent, non-discriminatory, transparent, neutral, independent and impartial manner.
- Notified bodies shall employ the necessary personnel, which has sufficient and relevant knowledge and experience to carry out conformity assessment in accordance with the directive in question.
- Notified bodies shall make adequate arrangements to ensure confidentiality of the information obtained in the course of conformity assessment.
- Notified bodies shall be adequately insured to cover their professional activities, unless liability is assured under the national legislation of the notifying Member State.
- Notified bodies shall participate in coordination activities [110]. They shall also take part directly or be represented in European standardization, or otherwise ensure that they know the situation of relevant standards.

[111] For coordination of notified bodies, see Section 6.6.
[110] However, notified bodies are not responsible for providing the EC declaration of conformity or the technical documentation. See Sections 3.1 – 3.3, 5.3 and 5.4.
independence, impartiality and integrity are ensured, and they are identifiable as a legal entity to bear rights and obligations.

In order to guarantee impartiality, the notified body and its staff has to be free from any commercial, financial and other pressure that might influence their judgement. The body also has to implement procedures to ensure that its work cannot be influenced from outside. The structure of the body shall safeguard impartiality, especially if the body has other activities than those as a notified body. Further, the body shall have policies and procedures that distinguish between the tasks carried out as a notified body and any other activity in which the body is engaged, making this distinction clear to their customers. Accordingly, marketing material should not give any impression that assessment or other activities carried out by the body are linked with tasks described in the applicable directives.

Notified bodies should not offer or provide additional services, unless they have an added value for the product \((112)\). They should also ensure that their activities outside the scope of the New Approach directives do not compromise or diminish confidence in their competence, objectivity, impartiality or operational integrity as notified bodies. To safeguard objectivity, impartiality and operational integrity the body and its staff (whether directly employed or subcontracted) responsible for the activities carried out as a notified body may, for instance, neither be the manufacturer, the authorised representative, a supplier or their commercial competitor, nor offer or provide (or have offered or provided) consultancy or advice to any of these parties as regards the design, construction, marketing or maintenance of the products in question. However, this does not preclude the possibility of exchanging technical information and guidance between the manufacturer, the authorised representative, suppliers and the notified body.

To safeguard impartiality it is important to make a clear distinction between conformity assessment and market surveillance. Therefore, it is to be considered - as a general rule - as inappropriate for notified bodies to be responsible for market surveillance \((113)\).

Notified bodies shall have documented procedures for the identification, review and resolution of all cases where conflict of interest is suspected or proven. The notified body should also require all staff acting on its behalf to declare any potential conflict of interest.

Notified bodies shall have under their control the necessary personnel, who have sufficient knowledge and experience relating to the products and conformity assessment procedure in question, and who are subject to appropriate training. In particular, knowledge and experience should relate to relevant regulatory requirements and enforcement policies, European and international standardisation activities, relevant technologies, production methods and verification procedures, and normal conditions of use of the product in question. The body shall be in a position to manage, control and be responsible for the performance of all its resources and maintain comprehensive records concerning the suitability of all the staff it uses in particular areas, whether they are employees, employed on contract or provided by external bodies.

Notified bodies shall make adequate arrangements to ensure confidentiality of the information obtained in the course of conformity assessment. These arrangements must ensure that no results or other information is disclosed to any other party than the competent authority in question, and to the manufacturer or the authorised representative.

Notified bodies shall be adequately insured to cover their professional activity according to New Approach directives, unless liability is assured under the national legislation of the notifying Member State. The scope and overall financial value of liability insurance must correspond to the level of activity of the notified body. The manufacturer in particular retains, however, the overall responsibility for the conformity of the product with all the requirements of the applicable directives, even if some stages of the conformity assessment are carried out under the responsibility of a notified body \((114)\).

\((112)\) For the added value in relation to the CE marking, see Section 7.4. However, notified bodies may offer any type of certification and markings where the products are intended for the markets of third countries, for example in the context of Mutual Recognition Agreements (see Section 9.2).

\((113)\) See Section 8.1.

\((114)\) For product liability, see Section 3.7.
6.4. Notified bodies and conformity assessment

- The primary task of a notified body is to provide services for conformity assessment on the conditions set out in the directives. This is a service to the manufacturers in an area of public interest.
- Notified bodies are free to offer their conformity assessment services, within their scope of notification, to any economic operator established either inside or outside the Community. They may carry out these activities also on the territory of other Member States or of third countries.
- Manufacturers are free to choose any notified body that has been designated to carry out the conformity assessment procedure in question according to the applicable directive.

Notified bodies are designated to assess the conformity with the essential requirements, and to ensure consistent technical application of these requirements according to the relevant procedures in the directives concerned. The notified bodies must have appropriate facilities that enable them to carry out technical and administrative tasks related to conformity assessment. They must also apply appropriate procedures of quality control in relation to such services provided.

The conformity assessment procedures have been divided into a set of separate modules, which cannot be further subdivided without putting into question the coherence of the system and the responsibilities which should lie with the manufacturer and, where applicable, the notified bodies. This means that a notified body must be capable of taking the responsibility and have the competence to carry out the conformity assessment according to a complete module or for several complete modules. Consequently, the body cannot be notified for part of a module. For instance, as regards the module Hbis a body may not be notified to deal with the design phase only. Further, a body notified for modules D, E, H or their variants must be capable of taking the responsibility not only for the aspects of the quality systems involved but also for product-related requirements. In either case the notified body may subcontract some of the operations (115).

A notified body wishing to offer services according to several conformity assessment procedures must fulfil the relevant requirements for the respective tasks, and this has to be assessed according to the requirements for each different procedure in question. However, since the scope of most New Approach directives can be relatively wide and heterogeneous, a notified body need not be qualified to cover all products falling within its scope, just a defined range of products within its scope.

Notified bodies shall have appropriate structures and procedures to ensure that the conduct of conformity assessment and the issuing of certificates are subject to a review process. Relevant procedures must, in particular, cover obligations and responsibilities in relation to suspension and withdrawal of certificates, requests addressed to the manufacturer to take corrective measures, and reporting to the competent authority.

Apart from carrying out certain responsibilities in the field of public interest, notified bodies must regard themselves as rendering services to industry. Thus, they should provide relevant information to the manufacturer and the

authorized representative regarding the directive in question, apply the conformity assessment procedure without unnecessary burdens for the economic operators, and refrain from proposing additional certification or marking that has no added value (116).

To avoid unnecessary burdens for economic operators, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessing conformity to the directives. Further, a quality system approved by a notified body or an accredited certification body should be taken into account when the same or any other notified body is carrying out conformity assessment according to modules D, E, H, or their variants, either for the same or another product category. In such cases, however, the notified body should check that the certificate covers the applicable provisions of the directive. It should also consider whether or not it is necessary to require appropriate supplementary audits specifically relating to the (new) product category, although there is often no need to fully duplicate the quality system approval as such.

Although the notified body must be established on the territory of the notifying Member States, it may have activities or personnel outside the Member State, or even outside the Community. Certificates are, however, always issued by and in the name of the notified body. Since the notified body always has to carry out its assessment functions within the jurisdiction of the designating Member State, it shall inform the notifying authority, which must be capable of ensuring the monitoring of the total body as it has to take the responsibility for its operations. If monitoring is not considered possible, the notifying authority should withdraw or limit the scope of the notification as deemed necessary.

(115) For the modules, see Section 5.1; for subcontracting, see Section 6.5; and for notified bodies’ tasks according to the conformity assessment procedures, see Annex 7.
(116) For the added value in relation with the CE marking, see Section 7.4.
6.5. Notified bodies and subcontracting

- A notified body can have part of its work carried out by another body on the basis of established and regularly monitored competence.
- The body subcontracted by the notified body must be technically competent, and display independence and objectivity according to the same criteria and under the same conditions as the notified body. However, notification is not necessary. The Member State that has notified the body, which subcontracts part of its work, must be capable of ensuring effective monitoring of the competence of the body subcontracted by the notified body.
- A further condition for subcontracting is that the conformity assessment procedure can be subdivided into technical operations and assessment operations, and that the methodology used to carry out the technical operations is sufficiently precise. The body subcontracted by the notified body must, nevertheless, carry out substantial and coherent parts of these technical operations.
- Subcontracting must be based on a contract, which makes it possible to ensure the transparency of and have confidence in the notified body’s operations.
- A subcontracting notified body remains responsible for all the activities covered by the notification. Subcontracting does not entail the delegation of powers or responsibilities. Certificates are always issued in the name and under the responsibility of the notified body.
- The conditions for subcontracting apply to any subcontractor whether or not established within the Community.

The bodies acting as subcontractors for the notified bodies need not be notified as such. Nevertheless, the notified body must inform the Member State concerned of its intention to subcontract certain work. Consequently, the Member State may decide that it cannot take the overall responsibility as a notifying authority for such an arrangement, and withdraw or limit the scope of the notification. The notified body shall keep a register of all its subcontracting activities, and update it systematically.

The notified body shall ensure that its subcontractors have the necessary competence and that they maintain this competence, for example by carrying out regular evaluations and by keeping itself regularly informed of the details regarding the performance of their tasks. The notified body must also be able to provide proof of the compliance of its subcontractors with the requirements laid down in the relevant directive.

Information on subcontracting activities and on the competence of the subcontractors shall be available for the notifying authority so that it can take necessary action, and for communication without delay to the Commission and the other Member States on request. Compliance with the EN 45000 series of standards entails a presumption of conformity with most of the requirements, as is the case with the notified body itself.

A notified body can subcontract strictly limited technical tasks (such as tests and examinations), as long as these can be defined as substantial and coherent parts of the technical operation. The notified body cannot under any circumstances subcontract all of its activities, as that would make the notification meaningless. Notified bodies may for example subcontract tests while continuing to assess their results and, in particular, to validate the test report in order to evaluate whether the requirements of the directive are met. Similarly, subcontracting is possible in the field of certification of quality systems by using external persons as auditors, provided that the notified body carries out the evaluation of the audit results.

The subcontracted work must be carried out according to pre-established technical specifications setting out a detailed procedure based on objective criteria to guarantee total transparency. Where the body subcontracted by the notified body is involved in the assessment of conformity to standards, these must be used if they lay down the procedures. If this body is involved in the assessment of conformity to essential requirements, the procedure followed by the notified body itself or a procedure deemed by the notified body to be equivalent to that must be used.

The subcontracted work shall in all cases have a direct private-law contractual link with its subcontractors to ensure the fulfilment of its general responsibilities (117). Serial subcontracting is prohibited in order to avoid undermining the coherence of the system and confidence in it.

The notified body remains entirely responsible for the work carried out for it by the subcontractor. It can have its notification withdrawn for any reason connected with its subcontractor.
6.6. Coordination and cooperation

- A coherent application of the conformity assessment procedures requires close cooperation between the notified bodies, the Member States and the European Commission.
- The Commission supports the Member States in their efforts to establish coherence between the notifying authorities regarding, in particular, the assessment of the competence of the bodies to be notified, the application of notification procedures and the surveillance of notified bodies.
- The Commission, in coordination with Member States, also ensures that cooperation is organised between the notified bodies.

The coordination of Member States is carried out through the sectoral working groups of governmental experts established under the directives (118). The cooperation of notified bodies takes place under the authority of the relevant working groups.

Cooperation of notified bodies is established for each New Approach directive, by usually making use of existing structures. Each group has a technical secretariat and a president. The cooperation is limited to technical problems relating to conformity assessment in order to ensure a uniform application of the technical provisions of the New Approach directives.

In recognition of the fact that notified bodies fulfil tasks delegated to them by public authorities they must take part in coordination activities organised by the Commission. If a body refuses to cooperate, the notification may be withdrawn. However, the notified bodies are not obliged to participate in meetings at European level, if they keep themselves informed of, and apply as general guidance, the administrative decisions and documents produced by their group. The relevant working documents, meeting reports, recommendations and guidelines elaborated by the sectoral and intersectoral groups of notified bodies or their subgroups will be circulated to all notified bodies forming part of those groups, whether they have taken part in the meetings or not.

The groups of notified bodies are composed of representatives of notified bodies (119). To achieve a higher degree of efficiency in their work the groups can set up subgroups with a restricted number of participants to discuss specific technical questions. The Commission is represented in the groups. Governmental experts and representatives of the authorities directly responsible for the effective implementation of the directives can participate as observers in the groups. The European standards organisations (CEN, Cenelec and ETSI) will be represented in the groups when such issues arise. The groups will also invite relevant European federations or representatives of other interested parties as observers. Where the groups of notified bodies have to treat subjects of a confidential nature, the participation in meetings will be restricted as deemed necessary.

(118) See Section 1.2.
(119) Should the number of notified bodies per directive become excessive, the Commission can request the Member States to put in place a proper mechanism for their representation.
7. CE marking (120)

7.1. Principles of CE marking

- The CE marking symbolises the conformity of the product with the applicable Community requirements imposed on the manufacturer.
- The CE marking affixed to products is a declaration by the person responsible that:
  - the product conforms to all applicable Community provisions, and
  - the appropriate conformity assessment procedures have been completed.

CE marking symbolises conformity to all the obligations incumbent on manufacturers for the product by virtue of the Community directives providing for its affixing. When affixed to products it is a declaration by the natural or legal person having affixed or been responsible for the affixing of CE marking that the product conforms to all applicable provisions, and that it has been subject to the appropriate conformity assessment procedures. Hence, Member States are not allowed to restrict the placing on the market and putting into service of CE marked products, unless such measures can be justified on the basis of evidence of the non-compliance of the product (121).

- The directive contains conformity assessment procedures according to Decision 93/465/EEC (122).

As a general rule, all New Approach directives provide for the affixing of the CE marking. In duly justified cases a total harmonisation directive that follows Decision 93/465/EEC may provide for a different marking instead of the CE marking (123).

Since all products covered by New Approach directives bear CE marking, this marking is not intended to serve commercial purposes. Neither is the CE marking a mark of origin, as it does not indicate that the product was manufactured in the Community.

7.2. Products to be CE marked

- The CE marking is mandatory and must be affixed before any product subject to it is placed on the market and put into service, save where specific directives require otherwise.
- Where products are subject to several directives, which all provide for the affixing of the CE marking, the marking indicates that the products are presumed to conform to the provisions of all these directives.
- A product may not be CE marked, unless it is covered by a directive providing for its affixing.

The obligation to affix the CE marking extends to all products within the scope of directives providing for its affixing, and which are intended for the Community market (124). Thus, the CE marking must be affixed:
- to all new products, whether manufactured in the Member States or in third countries;
- to used and second-hand products imported from third countries; and
- to substantially modified products that are subject to directives as new products.

Directives may exclude the application of the CE marking on certain products, even if the directive otherwise applies to the product. As a general rule, such products are subject to free circulation (125), if:
- they are accompanied by a declaration of conformity (as is the case for safety components referred to in the Directive on machinery and partly completed boats referred to in the Directive on recreational craft);
- they are accompanied by a declaration of compliance (as is the case for products playing a minor part with respect to the health and safety listed in accordance with the Directive on construction products);
- they are accompanied by a statement (as is the case for custom-made medical devices and devices intended for clinical investigations referred to in the Directives on active implantable medical devices and medical devices, and devices intended for performance evaluation referred to in the Directive on in vitro diagnostic medical devices);
73. Affixing of the CE marking

- The CE marking must be affixed by the manufacturer, or by the authorised representative established within the Community.
- The CE marking must take the form below. If the CE marking is reduced or enlarged the proportions must be respected.

- The CE marking must be affixed visibly, legibly and indelibly to the product or to its data plate. However, where this is not possible or not arranged on account of the nature of the product, it must be affixed to the packaging, if any, and to the accompanying documents, where the directive concerned provides for such documents.
- Where a notified body is involved in the production control phase according to the applicable directives, its identification number must follow the CE marking. The manufacturer or the authorised representative established in the Community affixes the identification number, under the responsibility of the notified body.

The CE marking must be affixed by the manufacturer, or by the authorised representative established within the Community, according to the applicable directives, its identification number must follow the CE marking. The manufacturer or the authorised representative established in the Community affixes the identification number, under the responsibility of the notified body.

The CE marking symbolises conformity to essential public interests covered by the directives in question. Therefore, it is to be considered as essential information to Member States’ authorities as well as other relevant parties (for example distributors, consumers and other users). Accordingly, the requirement for visibility means that the CE marking must be easily accessible for all parties. It could, for instance, be affixed on the back or underside of a product. A minimum height of 5 mm is required to ensure that it is legible. In addition, it can be affixed, for instance, to the packaging or to the accompanying documents. However, it may exceptionally be moved from the product or its data plate if this rule cannot be followed. This would be justified where affixing it to the product was impossible (for example on certain types of explosives), or not possible under reasonable technical or economic conditions, or where the minimum dimensions could not be respected, or it could not be ensured that the CE marking was visibly, legibly and indelibly affixed. In such cases, the CE marking has to be affixed to the packaging, if it exists, and to the accompanying document, where the directive concerned provides for such documents. The CE marking on the product may neither be omitted nor be moved to the packaging or accompanying documents on purely aesthetic grounds.

The CE marking symbolises conformity to essential public interests covered by the directives in question. Therefore, it is to be considered as essential information to Member States’ authorities as well as other relevant parties (for example distributors, consumers and other users). Accordingly, the requirement for visibility means that the CE marking must be easily accessible for all parties. It could, for instance, be affixed on the back or underside of a product. A minimum height of 5 mm is required to ensure that it is legible. It shall also
CE marking was affixed and protective systems symbol to indicate that the CE marking must form an integral part of the product. 

A notified body may be involved in the design phase, the production phase, or both, depending on the conformity assessment procedures applied. The CE marking shall only be followed by the identification number of the notified body if it is involved in the production phase. Thus, the identification number of a notified body involved in conformity assessment according to module B does not follow the CE marking. Sometimes several notified bodies are involved in the production phase, which is possible where more than one directive is applicable. In these situations several identification numbers follow the CE marking. 

Thus, the CE marking may appear on products either: 

- without an identification number, which means that a notified body did not intervene in the production phase (module A, modules Aa1 and Cb1 where the notified body only intervened during the design phase, and the combination of modules B and C); or 
- with an identification number, which means that the notified body assumes the responsibility:

- for the tests on specific aspects of the product (modules Aa1 and Cb1 where the notified body intervened during the production phase); 
- for product checks (modules Aa2 and Cb2); 
- for the examinations and tests carried out to assess the conformity of the product during the production control phase (modules F, Fbis and G); or 
- for the assessment of production, product quality assurance or full quality assurance (modules D, E, H and their variants).

The CE marking and the identification number of the notified body do not necessarily have to be affixed within the Community. They may be affixed in a third country, for example if the product is manufactured there and the notified body carried out conformity assessment in accordance with the directive in that country. The CE marking and the identification number can also be affixed separately, as long as they remain combined. 

The CE marking consists exclusively of the letters 'CE' followed by the identification numbers of any notified body involved in the production phase. Pictograms or other marks indicating, for instance, the category of use are, according to some New Approach directives, complementary to the CE marking but do not form part of it.

74. CE marking and other marks

- CE marking is the only marking which symbolises conformity to all the obligations incumbent on manufacturers for the product as required by the applicable directives providing for its affixing. Member States shall refrain from introducing any reference to another conformity marking into their national regulations, which would signify conformity with objectives that relate to the CE marking. 
- A product may bear additional markings and marks, provided that they:
  - fulfil a different function from that of the CE marking, 
  - are not liable to cause confusion with it, and 
  - do not reduce its legibility and visibility.

The CE marking replaces all mandatory conformity markings having the same meaning, which existed before harmonisation took place. Such national conformity markings are incompatible with CE marking and would constitute an infringement of the applicable New Approach directives. When transposing the directives, Member States shall incorporate the CE marking in their national regulations and administrative procedures. They shall also refrain from introducing any other conformity marking into their national legislation that has the same meaning as the CE marking.

 Owners of trademarks similar to the CE marking, that were acquired before the introduction of the CE marking, will be protected against expropriation since such marks will, as a rule, not be liable to deceive market surveillance authorities, distributors, users, consumers or other third parties. 

In view of the objectives of technical harmonisation, markings and marks additional to the CE marking need to fulfil a different function from that of the CE marking. Thus, they should provide an added value in signifying conformity with objectives that are different from those to which the CE marking relates (for example environmental aspects not covered by applicable directives).

The affixing of legal marking (such as a protected trademark of a manufacturer), or of acceptable certification and other marks additional to the CE marking, is allowed to the extent that such markings or marks do not create confusion with the CE marking, and that they do not reduce the legibility and visibility of the CE marking. This confusion may either refer to the meaning or form of the CE marking. Whether or not a marking or mark is confusing should be decided from the point of view of all relevant parties likely to come into contact with it.
8. Market surveillance

Enforcement of Community legislation is an obligation on Member States: Article 10 of the EC Treaty requires Member States to take all appropriate measures to ensure fulfilment of their obligation arising out of the Treaty. Market surveillance is an essential tool for enforcing New Approach directives, in particular by taking measures to check that products meet requirements of the applicable directives, that action is taken to bring non-compliant products into compliance, and that sanctions are applied when necessary.

A high level of protection is envisaged in the New Approach directives. This requires Member States to take all necessary measures to ensure that products may be placed on the market and put into service only if they do not endanger the safety and health of persons, or other interests covered by the applicable New Approach directives, when correctly constructed, installed and maintained, and used in accordance with their purpose. This implies an obligation for Member States to organise and carry out market surveillance, in a way that is effective and sufficiently extensive to discover non-compliant products. This is to protect not only the interests of consumers, workers and other users, but also the interests of economic operators from unfair competition.

The obligation for market surveillance is complementary to the provisions of the New Approach directives that require Member States to allow free movement of products that are in compliance with the requirements. This obligation also corresponds to the right of Member States to challenge, under the safeguard clause, the free movement of substantially non-compliant products (133).

The Directive relating to toys lays down provisions for the market surveillance authority, and obliges the Member States to send to a report the Commission every three years (134). Other New Approach directives do not contain special provisions on how market surveillance should be organised and carried out in Member States. The Directive on general product safety has a more detailed description of the obligation of Member States to organise market surveillance and to adopt appropriate surveillance tools. This Directive is not applicable to products that are covered by specific rules of Community law based on total harmonisation containing provisions on all safety aspects, such as New Approach directives. However, it can be used as a reference for market surveillance carried out in the field of New Approach directives, especially regarding consumer products.

Market surveillance is the responsibility of public authorities (135). This is, in particular, to guarantee the impartiality of market surveillance operations. Each Member State can decide upon the market surveillance infrastructure, for example there is no limitation on the allocation of responsibilities between authorities on a functional or geographical basis as long as surveillance is efficient and covers the whole territory (136). As a result, the legal and administrative market surveillance infrastructures differ from one Member State to another. This requires, in particular, that efficient administrative cooperation between competent national authorities is in place so that an equivalent level of protection can be ensured throughout the Community, in spite of the competence for market surveillance being limited to each Member State's territory.

Market surveillance authorities should have the necessary resources and powers to conduct their surveillance activities. This is to monitor products placed on the market and, in cases of non-compliance, to take appropriate action

8.1 Principles of market surveillance

- Market surveillance is an essential tool for the enforcement of New Approach directives.
- The purpose of market surveillance is to ensure that the provisions of applicable directives are complied with across the Community. Citizens are entitled to an equivalent level of protection throughout the single market, regardless of the origin of the product. Further, market surveillance is important for the interest of economic operators, because it helps to eliminate unfair competition.
- Member States must nominate or establish authorities to be responsible for market surveillance. These authorities need to have the necessary resources and powers for their surveillance activities, ensure technical competence and professional integrity of their personnel, and act in an independent and non-discriminatory way respecting the principle of proportionality.
- Notified bodies should, basically, be excluded from the responsibility of market surveillance activities. This is to avoid conflicts of interest.

(133) For application of the safeguard clause procedure, see Section 8.3.
(134) See Article 12 of the Directive relating to toys, according to which Member States are required to ensure that sample checks are carried out on toys to verify their conformity with the directive. The surveillance authority must be entitled to obtain access to places of manufacture or storage, to receive information, and to select a sample and take it away for examination and testing.
(135) The Directive on general product safety requires Member States to establish or nominate market surveillance authorities.
(136) According to Article 249 of the EC Treaty the choice of form and method of implementing the directives lies with the Member States (see also Section 1.4).
to enforce conformity. As regards personnel resources, the authority needs to have, or have access to, a sufficient number of suitably qualified and experienced staff, with the necessary professional integrity. To guarantee the quality of the test data, the testing facility used by the authority should comply with the relevant criteria of the EN 45001 standard. The authority should also be independent, and carry out its operations in an impartial and non-discriminatory way. Further, the authority should carry out market surveillance respecting the principle of proportionality, for example action must be in accordance with the degree of risk or non-compliance and the impact on the free circulation of products may not be more than is necessary for achieving the objectives of market surveillance.

The surveillance authority may subcontract technical tasks (such as testing or inspection) to another body, provided that it retains the responsibility for its decisions, and provided there is no conflict of interest between the other body’s conformity assessment activities and its surveillance tasks. In doing so the authority should exercise great care to ensure that the impartiality of the advice it receives is beyond reproach. The responsibility for any decision to be taken on the basis of such advice shall reside in the surveillance authority.

As a general rule, it is inappropriate for notified bodies to be responsible for market surveillance. In order to avoid a conflict of interest it is necessary to make a clear distinction between conformity assessment (which takes place before the product is placed on the market) and market surveillance (which takes place after the product has been placed on the market). As an exception, where a notified body and a market surveillance authority come under the same superior authority in a Member State, the lines of responsibility should be so organised that there is no conflict of interest between these activities.

New Approach directives include certain provisions that require Member States to inform the Commission or the other Member States, but they usually say nothing on the confidentiality or transparency of information obtained during market surveillance operations (137). Consequently, rules on confidentiality are based on the national legal systems, and therefore vary between Member States. However, information on activities underway that concern individual economic operators should generally be considered as confidential. An exception to this may be justified where the health and safety of consumers is subject to serious and immediate danger.

8.2. Market surveillance activities

Market surveillance involves two main stages:

- National surveillance authorities shall monitor that products placed on the market comply with the provisions of the applicable national legislation transposing the New Approach directives;
- Subsequently, when necessary, they shall take action to establish conformity.

Although market surveillance operations cannot take place during the design and production stages, efficient enforcement usually requires that surveillance authorities act in collaboration with manufacturers and suppliers in order to prevent the placing on the market of non-compliant products.

8.2.1. Monitoring of products placed on the market

The objective of monitoring products placed on the market is to verify that they comply with applicable directives at the moment when placed on the market and, if relevant, when put into service.

The EC declaration of conformity and the technical documentation provide the surveillance authority with necessary information about the product.

Market surveillance authorities must monitor products placed on the market. The aim is to find out whether or not a product complies with the applicable provisions at the moment when placed on the market and, if relevant, when put into service (134). Basically, market surveillance cannot take place during the design and production stages, that is before the manufacturer has taken formal responsibility for the conformity of the products, usually by affixing the CE marking. However, this does not exclude collaboration between the surveillance authority and the manufacturers and suppliers (139).

For market surveillance to be efficient, resources should be concentrated where risks are likely to be higher or non-compliance more frequent, or where a particular interest can be identified. Statistics and risk assessment procedures can be used for this purpose. To be able to monitor products placed on the market, surveillance authorities shall have the power, competence and resources:

- To regularly visit commercial, industrial and storage premises;
- To regularly visit, if appropriate, work places and other premises where products are put into service (140);
- To organise random and spot checks;
- To take samples of products, and to subject them to examination and testing; and
- To require all necessary information (141).
Although market surveillance cannot, basically, take place during the design and production stages, the surveillance authority may make a check on the production premises after a non-compliance has been discovered to verify whether or not a constant error can be established. Other exceptions to the principle that market surveillance can only take place after the manufacturer has taken formal responsibility for the products are trade fairs, exhibitions and demonstrations. Most New Approach directives allow the showing of non-compliant products under such circumstances, provided that a visible sign clearly indicates that the products may not be marketed or put into service until they have been made to comply, and that adequate measures are taken during demonstrations, where appropriate, to ensure the protection of persons. Market surveillance authorities must monitor that this obligation is respected.

Market surveillance should cover all applicable provisions of the directives in question. To a certain extent formal checks are sufficient, for example regarding the CE marking and its affixing, the availability of the EC declaration of conformity, the information accompanying the product and the correct choice of conformity assessment procedures. More profound checks are necessary to verify the material conformity of the product, for example regarding the correct application of the conformity assessment procedure, the compliance with the essential requirements, and the contents of the EC declaration of conformity. In practice, individual market surveillance operations can focus on certain aspects of the requirements.

Besides market surveillance operations, that have as their explicit object the verification of products placed on the market, other public mechanisms exist that, although not directly designed for that aim, can nevertheless have as a consequence the uncovering of non-compliance. Labour inspectorates that check safety at the workplace, for example, can discover that the design or construction of a machine, or personal protective equipment bearing the CE marking, is not in conformity with the applicable requirement. Consequently, they may take measures that affect the placing on the market of a product and, thus, carry out market surveillance, or they may contact the market surveillance authority that may take the necessary measures. Information on the compliance of a product at the moment when it was placed on the market can also be obtained during in-use inspections, or by analysing the factors that caused an accident. Complaints from consumers or other users about the product, or from manufacturers or distributors about unfair competition can also provide information for market surveillance purposes.

Monitoring of products placed on the market may be divided between several authorities on the national level, for example functionally or geographically. Where the same products are subject to control by more than one authority (for example customs and a sectoral authority, or local authorities), coordination between services within a Member State is necessary.

Voluntary initiatives, such as product certification or application of a quality system, cannot be put on the same footing as surveillance activities carried out by an authority. Still, they can contribute to the elimination of risks. However, market surveillance authorities must be impartial, in the light of Article 28 of the EC Treaty, regarding all voluntary marks, labels and arrangements, and they may only be taken into consideration, in a transparent and non-discriminatory way, for the risk assessment. Accordingly, products may not be excluded from market surveillance operations even if they have been subject to voluntary certification or other voluntary initiatives.

New Approach directives provide for two different tools that enable surveillance authorities to receive information on the product: the EC declaration of conformity and the technical documentation. These must be made available by the manufacturer, the authorised representative established within the Community, or under certain circumstances by the importer or person responsible for placing on the market. Other natural or legal persons, such as notified bodies, distributors, retailers, suppliers or subcontractors, cannot be obliged to make these available. However, they can assist the surveillance authority in obtaining them. Further, the surveillance authority may request the notified body to provide information on the conduct of conformity assessment for the product in question.

The EC declaration of conformity must be made available for the market surveillance authority immediately upon request. Therefore, it should be kept inside the Community. It can be made available for surveillance purposes in each of the Member States, for instance, by means of administrative cooperation. A failure to present the declaration when requested by a national surveillance authority may constitute sufficient grounds for doubting the presumption of conformity with the requirements of the directive.

The technical documentation must be made available to the surveillance authority within a period of time commensurate with its importance and the risk in question, but the authority cannot request it systematically. In general, it can be requested only during random checks made for market surveillance purposes, or when there are grounds for a concern that a product does not offer the level of protection required in all respects. Initially the surveillance authority may be provided with only a summary of the technical documentation. The essential technical data, if it has been drawn up, with reasonable time allowed for transmission. More detailed information (for example certificates and decisions from the notified body) can, nevertheless, be requested in cases of serious doubt about the conformity of the product to the Community regulations. The full technical documentation should be requested only where clearly necessary, and not, for example, when only a detail has to be checked. This request has to be evaluated in accordance with the principle of proportionality and, thus, taking into account the importance of the products in question. Further, the surveillance authority may request the notified body to provide information on the conduct of conformity assessment for the product in question.

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Market surveillance
account the need to ensure the health and safety of persons or other public interests foreseen in the directives, as well as to protect the economic operators from unnecessary burden. Further, failure to present the documentation in response to a duly substantiated request by a national surveillance authority, within an acceptable delay, may constitute sufficient grounds for doubting the presumption of conformity with the requirements of the directive (147).

A national authority may request a translation of the technical documentation and the EC declaration of conformity into its official language. However, it should avoid doing so if they, especially the detailed technical information of the documentation, are available in a language that can be understood by the national authority in question. If the authority considers a translation necessary, it must clearly define the part of the documentation to be translated and allow reasonable time for this to take place. No further conditions may be imposed on the translation, such as a requirement of a translator accredited or recognised by the public authorities. The request for a translation must be assessed on the basis of Article 28 of the EC Treaty on a case by case basis, taking into consideration the proportionality of the demands.

It must be possible to make the technical documentation available in the Community. However, it need not be kept inside the Community, unless otherwise provided for in the applicable directives (148). The requirement for making it available does not mean that the person who bears this responsibility must be in possession of it, as long as he is capable of stating where it can be found and of presenting it on request from the national authority. The name and address of the person in possession of the documentation need not be expressly mentioned on the product or on its packaging, unless otherwise specified. Further, the technical documentation can be kept in any format (for example as a hard copy or CD-ROM), which allows it to be made available within a period of time commensurate with its importance and the risk in question.

Member States must ensure that everyone receiving information about the contents of the technical documentation during market surveillance is bound to secrecy according to principles laid down in the national legislation.

8.2.2. Corrective actions

- Before any action is taken, the party concerned must be notified and — unless the matter is urgent — given the possibility of being consulted.
- The corrective action depends on the level of non-compliance, which has to be established on a case by case basis, and it has to be in accordance with the principle of proportionality:
  - first, the manufacturer, or the authorised representative, should be obliged to make the product comply with the provisions and to remedy the infringement;
  - ultimately, where other measures have failed or they are not considered as sufficient, all appropriate measures shall be taken to restrict or prohibit the placing on the market and putting into service of the product in question, and to ensure that it is withdrawn from the market.

Competent national authorities must take action to enforce conformity, when they discover that a product is not in compliance with the provisions of the applicable directives.

The corrective action depends on the degree of non-compliance and, thus, must be in accordance with the principle of proportionality. However, the difference between non-substantial and substantial non-compliance is not always clear, and must be decided on a case by case basis.

The incorrect affixing of the CE marking as regards, for instance, the design, size, visibility, indelibility or legibility, can usually be considered as a non-substantial non-compliance. Examples of typically non-substantial non-compliance could also be the situations where other conformity markings provided for in the directive are incorrectly affixed, or where the EC declaration of conformity cannot be provided for immediately or it does not accompany the product when this is mandatory, or the requirement to accompany other information provided for in the directive(s) is complied with insufficiently, or, where applicable, the identification number of the notified body has not been affixed to the CE marking.

Non-conformity to essential requirements must usually be considered as a substantial non-compliance, because this may, for instance, present a potential or actual risk to the health and safety of citizens. However, non-conformity to a harmonised standard is not, as such, sufficient evidence of non-conformity to essential requirements, but indicates that further investigations may be necessary.

Depending on the circumstances, it may be considered either as a non-substantial or substantial non-compliance, if a product is not CE marked when it should be according to the applicable directives, or a product is CE marked when it should not be. It needs to be taken into account that the application of a directive, and accordingly the requirement to affix the CE marking, can sometimes prove to be difficult. On the other hand, if a product covered by a New Approach directive is not CE marked, it is an indication that the product does not comply with the essential requirements or the...
conformity assessment procedure has not been applied and, consequently, the product may, for instance, endanger the health and safety of persons. Such non-compliance should be considered as substantial.

Enforcement of conformity can be achieved by obliging the manufacturer, the authorised representative, or other responsible persons, to take required measures (144). Corrective action can also take place if the necessary measures are taken (for example the product is modified or withdrawn from the market), either as a result of consultations carried out by the surveillance authority or as a result of formal or informal warnings. In all cases the surveillance authority must establish accompanying measures to ensure that conformity is enforced.

Action taken against non-substantial non-compliance can be on two levels.

- First, the surveillance authority should oblige the manufacturer, or the authorised representative, to make the product intended to be placed on the market and, if necessary, to modify the product already on the market, comply with the provisions and to remedy the infringement.
- Secondly, if no result can be achieved, the competent authority shall, ultimately, take a further step to restrict or prohibit the placing on the market of the product and, if necessary, to ensure that it is also withdrawn from the market.

In case of substantial non-compliance the competent authority has to take appropriate measures, following the principle of proportionality, to enforce conformity.

- The authority shall, ultimately, restrict or prohibit the placing on the market and the putting into service of the product and ensure that it is withdrawn from the market, if no other measures are sufficient to maintain the high level of protection envisaged in the directives. This usually invokes the safeguard clause.
- Action to prohibit or restrict the placing on the market may first be temporary to allow the surveillance authority to obtain sufficient evidence about the danger or other substantial non-compliance of the product.

Any decision taken by national authorities to restrict or prohibit the placing on the market, or the putting into service, or to withdraw products from the market must state the exact grounds on which it is based. The party concerned - in particular, the manufacturer, or the authorised representative established in the Community - shall be notified. They shall also be informed about remedies available under the national law in force in the Member State in question, and of the time limits to which such remedies are subject (150).

Unless the matter is urgent (for example the product presents a serious and immediate danger to the health and safety of persons), the manufacturer, or the authorised representative established in the Community, should have an opportunity to be consulted in advance, before the competent authority takes action to restrict the free circulation of products. In practice, it should be considered as sufficient when the manufacturer or the authorised representative has been provided with an opportunity to react. However, it should not delay the proceeding, if the manufacturer or the authorised representative remains passive (151).

The decision to restrict the free movement of a CE marked product in case of substantial non-compliance usually invokes the safeguard clause procedure. This procedure is aimed to enable the Commission to keep an overview of such measures and to consider whether or not they are justified. In addition, the exchange of information between national surveillance authorities on corrective actions taken, whether or not based on substantial non-compliance, should take place, where this is considered appropriate and necessary, and where the need for confidentiality as well as transparency can be respected (152).

A manufacturer, the authorised representative, or other person may consider himself to have suffered a loss as a result of an inappropriate national measure that restricted the free movement of a product. In such a case he could be entitled to claim damages under the jurisdiction of the State which initiated the procedure and in accordance with the laws of that State. For instance, an opinion taken by the Commission, at the end of a safeguard clause procedure, where the national measure is considered as non-justified, may raise the question whether or not a liability case for incorrect implementation of Community law could take place.

8.2.3. Complementary activities

- Efficient enforcement of directives usually requires that, in addition to market surveillance operations described in Sections 8.2.1 and 8.2.2, surveillance authorities should:
  - act in collaboration with manufacturers and suppliers;
  - take appropriate action against the person who has affixed the CE marking to a non-compliant product, and against those who are responsible for the non-compliance of the product; and
  - have the possibility to warn persons who might be at risk, to destroy dangerous products and ban their export, to prohibit the use of such products, and to require the withdrawal of certificates.

Surveillance authorities should not limit their activities to monitoring products placed on the market, and to taking the necessary corrective actions. Informal contacts and other collaboration between the authority and the manufacturers and suppliers may help in preventing the placing
on the market of non-compliant products. For instance, the authority can provide general advice and guidance to the economic operators on the application of the directives. Further, the authority should also consider the possibilities of raising the awareness of consumers and other users, for example on issues relevant to their health and safety.

New Approach directives require that action is taken against persons who affix the CE marking to non-compliant products (155). Action should, as well, be taken against the manufacturer (or other person) responsible for placing a non-compliant product on the market. These actions can, for instance, consist of warnings or legal proceedings. Actions must also be considered against the notified body. If it was involved in the conformity assessment procedure that had, as a result, non-compliant products. In such cases, the competence of the notified body may need to be assessed as well.

Since New Approach directives do not specify any penalty, Member States remain free to choose the sanctions to be used when infringements take place. These penalties must be analogous to those applicable to infringements of national law of a similar nature and importance. In addition, these penalties must be effective, proportionate and dissuasive (154).

Usually some products from the same product series will have already been sold or even put into use after the non-compliance has been discovered. In these cases, it is important to ensure that persons who might be exposed to a risk from a product are informed. This should basically be considered as a responsibility of the manufacturer or the distributor, in particular as regards consumer products (155). The warning may take the form of a general publica-

8.3. Safeguard clause procedure

- New Approach directives include a form of safeguard clause, which obliges Member States to restrict or forbid the placing on the market and the putting into service of dangerous products, or to have them withdrawn from the market (156).
- As a general rule, this safeguard clause procedure is restricted to products which are:
  - covered by New Approach directives;
  - CE marked; and
  - ascertained by the Member State to present a substantial hazard, even if the products are correctly constructed, installed and maintained, and used according to their intended purpose.
- This safeguard clause procedure shall be applied to national measures which:
  - restrict or forbid the placing on the market of a product, or have a product withdrawn from the market;
  - relate to all products belonging to the same batch or series; and
  - have binding legal effects.
- The Member State must notify the Commission immediately after taking action that invokes the safeguard clause. The necessary information and evidence to justify the action must accompany the notification.
- If the Commission considers the national action to be justified, it informs the other Member States. They are required to take the necessary measures on their territory.

8.3.1. Conditions for invoking the safeguard clause

The safeguard clause is designed to allow the Commission to analyse the justification of national measures restricting the free movement of CE marked products (products presumed to comply with requirements). Secondly, it provides a means to inform all national surveillance authorities about dangerous products, and, accordingly, to have the necessary restrictions extended to all Member States so as to ensure an equivalent level of protection throughout the Community.

The safeguard clause shall be applied to products that...
fall within the scope of a New Approach directive and bear the CE marking provided by such a directive. Consequently, the safeguard clause cannot be applied to products that are not CE marked in accordance with the directive providing for the safeguard procedure in question (157).

For the safeguard clause to be applicable, the non-compliance has to be established regarding a systematic failure in the design of a whole series of products manufactured, however limited the series. For an isolated error, limited to the territory of the Member State that has discovered the non-compliance, there is no need to invoke the safeguard clause, since there is no need to take action on Community level.

The application of the safeguard clause requires that the competent national authority decides to restrict or forbid the placing on the market and, possibly, the putting into service of the product, or has it withdrawn from the market. The contents of the decision should relate to all products belonging to the same batch or series. It must also have binding legal effect: it is followed by sanctions, if not respected, and can be subject to an appeals procedure. Court decisions, which restrict the free movement of CE marked product within the scope of the relevant directive(s), do not invoke the safeguard clause. However, where administrative proceedings initiated by the surveillance authority must be, according to the national law, confirmed by a court, such court decisions are not excluded from the safeguard clause procedure.

Conformity can be enforced if the national authority requests the manufacturer or the authorised representative to take the necessary measures, or if the product is modified or voluntarily withdrawn from the market. Unless a formal decision is taken in these cases, to prohibit or restrict the placing on the market of the product or to have it withdrawn from the market, the safeguard clause procedure is not invoked. Thus, a direct exchange of information between market surveillance authorities may be necessary (159).

The findings that justify the national measure are established either by the market surveillance authority on its own initiative, or based on information received from a third party (such as consumers, competitors, consumer organisations, labour inspectorates). Further, the national measure must be based on evidence (for example tests or examinations) that constitutes sufficient proof of errors in the product design or the manufacture to indicate a foreseeable potential or actual danger or other substantial non-compliance, even when the products are correctly constructed, installed, maintained and used in accordance with their intended purpose or in a reasonably foreseeable way. There is a grey zone between correct and incorrect maintenance and use, and it can be considered that, to a certain extent, products should be safe, even if maintained and used with their intended purpose in an incorrect way that can reasonably be expected (159). In evaluating this, the data supplied by the manufacturer on the labelling, in the instructions, in the user's manual or in promotion materials are to be taken into consideration (161).

The reason for invoking the safeguard clause may result, for instance, from differences or failures in the application of essential requirements, incorrect application of harmonised standards or shortcomings in them. The surveillance authority can add or specify other motives (for example failure to comply with good engineering practice) when invoking the safeguard clause, provided that they are directly linked with these three reasons.

Where non-compliance with harmonised standards that give a presumption of conformity is established, the manufacturer, or the authorised representative in the Community, must be requested to provide evidence about compliance with essential requirements. The decision of the competent authority to take corrective action must always be based on an established non-compliance with the essential requirements invoking the application of the safeguard clause.

8.3.2. Notification to the Commission

As soon as a competent national authority restricts or forbids the free movement of a product in such way that the safeguard clause is invoked, the Member State must immediately notify the Commission indicating the reasons and justification for the decision (161). At this stage, the Commission does not distribute the information it has received.

The safeguard clause does not include an obligation to inform the other Member States (162). In several sectors Member States tend to send a copy of their notification to other Member States (163). Member States that have received such a notification from another Member State should decide if action is necessary, and take into account that such action must be justified.

To reduce the time taken to process the file by the Commission, the notification should include:
- a reference to the directive(s), and in particular to the essential requirements, against which the non-compliance has been established;
- the name and address of the manufacturer, the authorised representative, and in addition - if necessary - the name and address of the importer or other person responsible for placing the product on the Community market;
- a copy of the declaration of conformity;
- information on the procedure which was used by the authority to verify the compliance of the product; and
- a comprehensive assessment and evidence to justify the measure (for example harmonised standards or other technical specifications used by the authority, the test reports and identification of the testing laboratory).

Where the manufacturer, the authorised representative, or other responsible person, agrees to modify the product...
must be safe when used as intended or in a foreseeable way, bearing in mind the normal behaviour of children. (164) The manufacturer is explicitly required to supply data according to the Directives relating to low voltage equipment, simple pressure vessels, toys (only for certain toys), machinery, personal protective equipment, active implantable medical devices, gas appliances, medical devices, potentially explosive atmospheres, recreational craft, lifts, pressure equipment, industrial diagnostic medical devices, and radio and telecommunications terminal equipment. (165) The official notification usually takes place via the Permanent Representation with a copy sent to the Commission department responsible for managing the directive in question. (166) As an exemption, the manufacturer may also decide to publish this opinion. Consequently, the Commission may also decide to publish this opinion. Where the Commission considers in its consultation to protect the confidentiality of the information (164). The Commission is responsible for administering the safeguard clause, to the manufacturer and, if appropriate, to the authorised representative or other person who is responsible for placing the product on the Community market. Also, in this case, the Commission will consider initiating the infringement procedure provided for by Article 226 of the EC Treaty, on the basis of the Member State not complying with the principle of free movement of goods. This procedure may cause the Commission to take the case to the Court of Justice. In such cases, legal proceedings may be taken at national level by the manufacturer, or other person who considers himself to have suffered damage, in order to obtain compensation for the damage that resulted from a national measure not in compliance with Community law.

The action to be taken is decided case by case. After the Commission departments responsible for managing the directive have been informed, they will, as a general rule, first contact the Member State and the national surveillance authority which invoked the procedure, and the manufacturers concerned or their authorised representative. The Commission may also contact the other Member States most directly concerned by the case in question (usually the Member States where the manufacturer or notified body is established), and the notified bodies (or other third parties) involved in the conformity assessment procedure.

If the Commission considers it necessary, it may — in collaboration with the Member State(s) concerned — seek the opinion of other adequately qualified, impartial bodies or experts capable of providing further information directly relevant to the subject (such as other surveillance authorities, other notified bodies, scientific committees of the Commission, standards organisations, conformity assessment bodies, organisations representing industry, distributors or consumers, trade unions, research institutes or scientific experts). Although these consultations can be relatively wide, the urgency of the problem is taken into account and the procedure is kept as short as possible.

At the end of the consultation procedure, the Commission takes an opinion on the justification of the national measure that restricted or prohibited the free movement of products.

Where the Commission considers in its opinion that the action is justified, it informs the Member State concerned and the other Member States immediately. The Commission may also decide to publish this opinion. Consequently, Member States have an obligation to take appropriate action, with a view to the opinion of the Commission, to ensure a similar level of protection throughout the Community. This requirement is based on the general obligation of Member States for market surveillance and for enforcement of Community legislation. If a Member State refuses to follow the position taken by the Commission, the Commission will consider initiating the procedure provided for by Article 226 of the EC Treaty (165).

8.3.3. Administering the safeguard clause

The action to be taken is decided case by case. After the Commission departments responsible for managing the directive have been informed, they will, as a general rule, first contact the Member State and the national surveillance authority which invoked the procedure, and the manufacturers concerned or their authorised representative. The Commission may also contact the other Member States most directly concerned by the case in question (usually the Member States where the manufacturer or notified body is established), and the notified bodies (or other third parties) involved in the conformity assessment procedure.

If the Commission considers it necessary, it may — in collaboration with the Member State(s) concerned — seek the opinion of other adequately qualified, impartial bodies or experts capable of providing further information directly relevant to the subject (such as other surveillance authorities, other notified bodies, scientific committees of the Commission, standards organisations, conformity assessment bodies, organisations representing industry, distributors or consumers, trade unions, research institutes or scientific experts). Although these consultations can be relatively wide, the urgency of the problem is taken into account and the procedure is kept as short as possible.

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Conversely, should the Commission see no justification for the national action that invoked the safeguard clause, it will ask the Member State to withdraw its action and take immediate appropriate steps to re-establish the free movement of the products in question on its territory. This opinion is addressed to the Member State that invoked the safeguard clause, to the manufacturer and, if appropriate, to the authorised representative or other person who is responsible for placing the product on the Community market. Also, in this case, the Commission will consider initiating the infringement procedure provided for by Article 226 of the EC Treaty, on the basis of the Member State not complying with the principle of free movement of goods. This procedure may cause the Commission to take the case to the Court of Justice. In such cases, legal proceedings may be taken at national level by the manufacturer, or other person who considers himself to have suffered damage, in order to obtain compensation for the damage that resulted from a national measure not in compliance with Community law.

If the safeguard clause is invoked because of a shortcoming in a harmonised standard that gives a presumption of conformity, the Commission, after consulting the interested parties, will submit the case to the Committee set up by Directive 98/34/EC and, if provided for, the sectoral committees (166).

Whether the action taken by the Member State is considered justified or not, in either case, the Commission keeps the Member States informed of the progress and the results of the procedure.

8.4. Protection of CE marking

- Market surveillance authorities must check that the affixing and use of the CE marking is correct, and that the principles regarding additional markings and marks are respected.
- Where necessary, the authority has to take appropriate corrective action to protect the CE marking.
- A Member State must notify to the Commission and to the other Member States when it decides to restrict free movement due to incorrect affixing of the CE marking, or when it takes action against those who are responsible for a non-compliant product bearing the CE marking.

Member States must provide in their national legislation for appropriate measures both to prevent the abuse and misuse of CE marking, and to redress the situation if such abuse or misuse takes place.

The affixing of the CE marking to a product that is not validated by Directive 98/34/EC is considered to be deceiving because consumers or users, for instance, are likely to get the impression that the
product in question satisfies certain Community safety provisions. Competent authorities must, therefore, have at their disposal legal instruments that enable them to act where the deceptive use of the CE marking is evident. Action must be taken to enforce conformity, and against those responsible for a non-compliant product bearing the CE marking.

The affixing of marking and marks in addition to the CE marking is subject to certain restrictions (167). The surveillance authority shall take the necessary measures to ensure that these principles are respected and, where necessary, take appropriate action.

The action to be taken by market surveillance authorities shall be decided on a case by case basis according to the principle of proportionality (168).

A Member State must inform the Commission and the other Member States of its decision to restrict free movement due to incorrect affixing of the CE marking, and of its action against the person who has affixed the CE marking to a non-compliant product (169). It is then up to the other Member States to decide whether or not similar action is necessary. No detailed evidence to justify the action is necessary, and no consultations regarding the national measures, as envisaged for the safeguard clause, take place. However, the Commission can take action under Article 226 of the EC Treaty should it consider it necessary.

8.5. Information exchange systems

A rapid information exchange system has been set up by the Directive on general product safety to handle emergency situations caused by consumer products that present a serious and immediate danger.

A vigilance system applies for medical devices. This system requires that a national surveillance authority notifies to the Commission and to the other Member States serious performance defects, inadequate marking or instructions that can result in, or have resulted in, the death of patients or users, or a serious deterioration in their health.

Information on injuries, particularly those resulting from home and leisure accidents, for example, caused by or involving products, is available in the Community injury database and information-exchange system.

8.5.1. Consumer products: rapid exchange of information

The Directive on general product safety provides a legal basis for an information exchange system for emergency situations. This system for the rapid exchange of information on dangers arising from the use of consumer products (RAPEX) (170) is a general and horizontal early warning and monitoring system. It is designed for handling urgent situations caused by new, used or repaired products that present a serious and immediate risk to the health and safety of consumers. Its essential aim is to provide information in order to allow authorities of all Member States to take immediate and appropriate action when a serious risk arising from a product has been detected.

RAPEX applies to all products intended for consumers, or likely to be used by consumers, which, used under normal or reasonably foreseeable conditions, present, for any reason, an immediate and serious risk to the health and safety of consumers. It covers both foodstuffs and industrial (non-food) products. It is also applicable to consumer products covered by the New Approach directives and it is, in particular, important for toys and low voltage products. This is because the New Approach directives do not provide for such a procedure (171).

RAPEX works according to the detailed procedures laid down in the annex to the Directive on general product safety. As soon as a serious and immediate risk is detected, the national authority must consult, insofar as possible and appropriate, the producer or distributor of the product concerned. The authority should try to obtain the maximum of information on the products and the nature of the danger, without compromising the need for rapidity.

A Member State shall inform the Commission when it adopts, or decides to adopt, emergency measures to prevent, restrict or impose specific conditions on the possible marketing or use of consumer products presenting a serious and immediate risk. A further condition for invoking RAPEX is that the effects of the risk can go beyond the territory of the Member State concerned. Member States are not required, as is the case under the safeguard clause procedure, to provide evidence to justify the national measure. The Commission verifies that the information complies with the provisions of the Directive on general product safety, and will pass it to the other Member States.

Where RAPEX has been applied, the Commission, after consulting the Member States and at the request of at least one of them, may adopt a decision requiring Member States to take temporary measures. This is to ensure the protection of health and safety of consumers and the proper functioning of the single market.

The safeguard clause procedures under the New Approach directives apply independently from RAPEX.

(167) See Section 7.4.
(168) For actions to be taken see Section 8.2.2.
(169) According to the New Approach directives, the provision on CE marking usually contains an obligation to inform the Commission and other Member States by referring to the provision on the safeguard clause procedure. However, regarding measures taken due to unduly affixed CE marking, the safeguard clause procedure should not be applied as such but only to the extent relating to information exchange.
(170) The system is also known under the names of REIS and SERI.
(171) As an exception, a vigilance system has been established for medical devices; see Section 8.5.2.
Accordingly, RAPEX does not necessarily have to come into play before the safeguard clause procedure is applied. However, the safeguard clause procedure has to be applied, in addition to RAPEX, when the Member State takes a decision to permanently prohibit or restrict the free movement of CE marked products on the basis of a danger or other serious risk presented by the product.

8.5.2. Medical devices: vigilance system

Risks posed by medical devices have necessitated a comprehensive monitoring system whereby all serious product incidents will be reported \(^{(172)}\). The medical devices vigilance system applies to all incidents which might lead to, or might have led to, the death of a patient or a user, or to a serious deterioration in their state of health, and which result from:

- any malfunction or deterioration in the characteristics or performance of a device;
- any inadequacy in the labelling or the instructions for use; or
- any technical or medical reason in relation to the characteristics or performance of a device, and which leads the manufacturer to systematically recall all devices of the same type.

The manufacturer is responsible for activating the vigilance system and must, accordingly, inform the surveillance authority about incidents that invoke it. After the notification, the manufacturer is obliged to make investigations, send a report to the surveillance authority and consider, in collaboration with the authority, what action should be taken.

The manufacturer's notification is followed by an assessment carried out by the surveillance authority, if possible together with the manufacturer. After the assessment, the authority must immediately inform the Commission, and the other Member States, of the incidents for which relevant measures have been taken or are contemplated. The Commission may then take any steps to coordinate, facilitate and support measures taken by the national surveillance authorities when dealing with the same type of incidents, or, if necessary, take measures at Community level (for example envisaging the re-classification of the device).

A databank containing, among other information, data obtained in accordance with the vigilance system will be set up and made accessible to the competent authorities.

The vigilance system is different from the safeguard clause procedure, since it requires notification even if the manufacturer takes the necessary measures on a voluntary basis. Nevertheless, when applying the vigilance system the surveillance authority is also obliged to adopt a restrictive measure vis-à-vis non-compliant CE marked products, if the conditions for invoking the safeguard clause apply and, accordingly, notify this measure following the safeguard clause procedure. However, the vigilance system does not necessarily have to come into play before the safeguard clause procedure is applied.

8.5.3. Community injury data-collection and information exchange system

The Community action programme on injury prevention within the framework for action in the field of public health aims to contribute to public health activities which seek to reduce the incidence of injuries, particularly injuries caused by home and leisure accidents \(^{(173)}\). For this purpose the programme promotes:

- the epidemiological monitoring of injuries by means of a Community system for the collection of data and the exchange of information on injuries based on strengthening and improving on the achievements of the European home and leisure accident surveillance system (Ehlass); and
- information exchanges on the use of those data to contribute to the definition of priorities and better prevention strategies.

The data is collected from hospitals and other appropriate establishments and services within the Member States, and by means of surveys. The collection and transmission of data to the information system is carried out under the responsibility of the Member States, which have an obligation to ensure the reliability of sources.

The setting up of an on-line telematic tool for sharing and transferring data is underway. This will facilitate direct exchanges of information between national administrations, Commission and international organisations.

The programme is also open to participation by the associated countries of central and eastern Europe, and by Cyprus and Malta.

8.5.4. Other information exchange systems at Community level

The safeguard clause procedure, under the New Approach directives, provides a means to exchange information, although its primary objective is to verify whether or not the national measure can be justified and, if this is the case, to resolve the problem at Community level. In addition, the New Approach directives oblige Member States to inform the Commission, and the other Member States, when free circulation is restricted due to incorrect affixing of the CE marking, or action has been taken against those who are responsible for a non-compliant product bearing the CE marking.
8.1. Outline for administrative cooperation

The proper application of Community law depends upon smooth administrative cooperation to ensure uniform and efficient enforcement of Community legislation in all Member States. The obligation to cooperate is in accordance with Article 10 of the EC Treaty, which states that Member States must take all appropriate measures to fulfil their obligations (174).

Although technical harmonisation has created a single market, where products move over national borders, market surveillance is carried out on a national basis. Administrative cooperation mechanisms between national surveillance authorities, therefore, need to be developed to increase the efficiency of surveillance, to minimise the effect of different surveillance practices and to reduce the overlapping of national surveillance operations. Cooperation between market surveillance authorities can also spread good surveillance practice and techniques across the Community, as national authorities can compare their methods with those of other authorities, for example in the framework of comparisons and joint surveys or study visits. In addition, cooperation can be useful for exchanging views and solving practical problems.

Administrative cooperation calls for mutual trust and transparency between national surveillance authorities. Member States and the Commission need to be informed about the way enforcement of New Approach directives, in particular market surveillance of products covered by the New Approach, is organised throughout the single market. This includes information about national authorities in charge of market surveillance for the different product sectors, and about national market surveillance mechanisms to clarify how monitoring of products placed on the market takes place and what corrective actions and other activities the surveillance authority is entitled to use. Transparency is also necessary regarding the national rules on confidentiality.

For the achievement of effective market surveillance in the Community, it is important that national surveillance authorities assist each other. On request, a national authority should make information available and provide other assistance. Without prior request, a national authority may consider sending to the other national authorities all relevant information concerning operations that constitute, or are likely to constitute, breaches of New Approach directives, which may have an impact on the territory of other Member States. In addition, the national authorities should communicate to the Commission any information they consider relevant, spontaneously or in response to a reasoned request from the Commission. The Commission may then communicate this information to the other national authorities when considered necessary.

Information exchange has been set up in Community legislation to a limited extent, mainly where a risk of a serious danger is present (175). For instance, the safeguard clause of the New Approach directives is, basically, only applicable to CE marked products, and all non-consumer products as well as minor non-compliance are excluded from the application of the rapid information exchange system according to the Directive on general product safety. In some circumstances, the existing information exchange systems are not quick enough as regards the potential or actual risk. For example, the safeguard clause requires consultation and an opinion taken by the Commission that justifies the national measure before the information is forwarded to other Member States. In cases where the mechanisms provided for are insufficient, the need to exchange information should be considered, with a view to assuring confidentiality. To keep exchange of information manageable, it should be limited to findings where the non-compliance is considered as substantial or where it is otherwise considered as essential to keep surveillance authorities in different Member States informed.

8.6. Administrative cooperation

- Administrative cooperation is an obligation of Member States. National surveillance authorities and the Commission must provide mutual assistance to ensure proper and uniform application of New Approach directives.
- Member States need to communicate to the Commission and the other Member States a list of surveillance authorities, which they have designated as contact points to coordinate administrative cooperation.
- National surveillance authorities should make information available spontaneously or on request, according to mutually agreed principles and mechanisms.
- National surveillance authorities should consider if coordination of national operations provides a means to increase the efficiency of market surveillance at Community level.
- The information exchanged in the framework of administrative cooperation has to be covered by the requirements of professional secrecy.
- Administrative cooperation regarding the enforcement of New Approach directives is organised in the standing committees established under the directives, and in the horizontal group of Senior Officials for Standardisation and Conformity Assessment Policy.

(174) An explicit obligation for administrative cooperation is laid down in the Directives relating to pressure equipment and in vitro diagnostic medical devices. Member States are required to take appropriate measures in order to encourage/ensure that the authorities responsible for implementing the Directive cooperate with each other, and provide each other (and the Commission) with information in order to assist the functioning of the Directive.

(175) See Sections 8.3 — 8.5.
Cooperation and mutual assistance are, in particular, necessary to ensure that action can be taken against all those who are responsible for a non-compliant product being placed on the market. In such cases the authority of the Member State, where the manufacturer, the authorised representative, or other responsible person is established, needs to be contacted (179). This is to obtain information from these economic operators, for example to require the EC declaration of conformity or some specified details from the technical documentation, or to request information concerning the distribution chain. The Member State under whose jurisdiction the notified body operates needs to be contacted as well. When a national authority acts due to information it has received from another national body, it should report back to this authority on the outcome of the action.

Moreover, market surveillance would be more efficient, on the Community level, if the national surveillance authorities could agree on how to allocate their resources in such a way that a maximum number of different product types could be covered in each sector. To avoid duplication of product tests, or other investigations for market surveillance purposes, national authorities should build up a mechanism to exchange a summary report of these tests. National surveillance authorities should also consider whether or not there is special need to carry out technical analyses or laboratory tests when another surveillance authority has already done so, and the results are available to those authorities or may at their request be placed at their disposal (177). It might also be useful to exchange results of periodic inspections on equipment in service, to the extent that they provide information on the compliance of products when they were placed on the market.

Information exchanged between national surveillance authorities has to be covered by professional secrecy, according to principles of the national legal system in question, and it has to enjoy the protection extended to similar information under national law. Where a Member States has rules permitting free access by persons to information held by surveillance authorities, this fact must be revealed at the time of the request to another surveillance authority, or during the exchange of information if no such request occurs. If the sending authority indicates that the information involves matters of professional or commercial secrecy, the receiving authority should ensure that this can be provided for. Otherwise the sending authority is entitled to withhold the information.

Coordination and exchange of information between national surveillance authorities need to be agreed by the parties involved and taking into account the needs of the sector concerned. The following principles could be taken into consideration, where appropriate:

- appointing a national communication point or correspon-
dent for every sector, which would coordinate internally as appropriate;
- agreement about the types of cases for which the commu-
nication of surveillance information would serve a useful purpose;
- developing a common approach to issues such as the classification of risks and hazards and their coding;
- identification of the details which should be communicat-
ed in each case, including the request for further informa-
tion;
- accepting the obligation to respond to enquiries within a
given time scale (179);
- transmitting information (requests and responses), as simply as possible, by e-mail, or through a telematic system operated by the Commission or an external body, and by using standard multi-language forms;
- taking advantage of up-to-date data recording techniques so that enquiries can be easily undertaken; and
- treating the information received in complete confidence.

8.6.2. Infrastructures for administrative cooperation

Committees and working groups

Cooperation between national administrations takes place in working groups set up under the New Approach directives. Discussions mainly focus on interpretation issues, but questions related to market surveillance and administrative cooperation are also dealt with.

Administrative cooperation between national authorities carrying out market surveillance is taking place in the following sectors: low voltage equipment, electromagnetic compatibility (EMC administrative cooperation), machinery (Machex) (179), medical devices (in particular regarding the vigilance system), telecommunications terminal equipment, recreational craft, and consumer products (Prosafe, the product safety forum of Europe).

The group of Senior Officials for Standardisation and Conformity Assessment Policy is a horizontal committee where, for instance, general questions related to the implementation and enforcement of New Approach directives, such as horizontal aspects of market surveillance, are discussed.

The emergencies committees, set up under the Directive on general product safety, regularly discusses administrative cooperation issues of general interest.

The Internal Market Advisory Committee (IMAC) (180) advises the Commission on all aspects concerned with the functioning of the single market. The committee facilitates exchange of information between the Commission and the Member States. The committee does not intervene if other appropriate mechanisms are in place, but it can deal with situations that do not come within the scope of existing mechanisms.

Data on national enforcement structures

Member States have been required to notify to the Com-
mission their respective ministries for certain priority areas of single market legislation (181). The main aim behind this provision is to enable governments to cooperate with each other to enforce legislation, mainly through exchange of information, such as data about dangerous products, inspections and tests carried out in another Member State, approvals, licensing and audits. This resolution also requires the Member States to notify contact points for enterprises and for citizens, which will be available to help to solve problems related to the exercise of rights granted to them under single market rules.

The Commission also maintains a database of contact points within Member States’ administrations for the purpose of facilitating contact with the administrations of other Member States. This database is a directory of all officials, in the Member States and the Commission, who have responsibility for the different single market legislative measures. It is planned to make the database available on-line on the Europa web site. Thereby it will become directly accessible to the officials concerned. However, it does not give direct information on the national authorities responsible for carrying out market surveillance in the field of New Approach directives.

A complementary framework document describing national enforcement structures and procedures has been produced. The main purpose of the document is to assist Member States and the Commission in understanding the national means of enforcement.

Karolus programme

The Karolus programme (182) provides for the exchange between Member States’ officials who are engaged in the enforcement of Community legislation to complete the single market. The programme has been opened to the participation of central and eastern European countries, the EEA EFTA States and Cyprus.

The objectives of the programme are to develop a convergent approach to enforcing Community legislation relating to the single market, to raise awareness of the European dimension, to build mutual confidence between Member States’ administrations, and to permit cross-fertilisation of ideas.

The Commission decides, on an annual basis, the priority areas for the Karolus programme. These have included conformity testing and market supervision, and in particular the following sectors: toys; personal protective equipment; low voltage electrical equipment, electromagnetic compatibility; equipment and protective systems intended for use in potentially explosive atmospheres; medical devices; gas appliances; pressure vessels; chemicals; civil explosives; machinery; motor vehicles; recreational craft; and different quality control instruments.

8.7 Products imported from third countries

- A manufacturer established in a third country is responsible, in the same way as a manufacturer established in a Member State, for designing and manufacturing a product in accordance with all applicable New Approach directives and for carrying out the required conformity assessment procedure, where the product is intended to be placed or put into service on the Community market (183).
- The manufacturer may appoint an authorised representative established in the Community to act on his behalf (184).
- Where the manufacturer is not established in the Community and has no authorised representative in the Community, the importer or person responsible for placing the product on the Community market may become responsible to some extent (185).
- Customs authorities shall, in the case of products imported from third countries, suspend the release of goods:
  - if they find products that exhibit certain characteristics which would give rise to a serious concern as to the existence of a serious and immediate risk to health and safety; or
  - if they find products that are not accompanied by a document or marked in accordance with applicable rules on product safety.
- As regards products covered by New Approach directives, the attention of customs authorities must be drawn, in particular, to the CE marking of toys.
- Customs authorities and market surveillance authorities must keep each other informed, and take appropriate action based on the information received.

Regulation (EEC) No 339/93 on checks for conformity with the rules on product safety in the case of products imported from third countries requires the customs authorities to be closely involved in the market surveillance operations and information systems provided for under Community and national rules, in cases relating to products from third countries.

Customs authorities are, in particular, requested to suspend the release of goods that display certain characteristics which would give rise to a serious concern as to the existence of a serious and immediate risk to health and
safety under normal and foreseeable conditions of use. The same applies where customs authorities find that a document required to accompany the products is missing, or that products do not bear conformity marking or labelling required under Community or national rules on product safety.

Regulation (EEC) No 339/93 applies to products imported from third countries, whether or not covered by New Approach directives. As regards products covered by New Approach directives, customs authorities must be particularly vigilant in checking that toys are CE marked, where these can be considered as finished products that are presented in a manner (packaging, marking, labelling) indicating that they are to be placed on the market without further processing.

Customs authorities must notify their decisions to suspend release of a product to the market surveillance authorities, which in turn must be in a position to take appropriate action. Four hypotheses must be distinguished as from the moment of the notification.

1. The products in question present a serious and immediate risk to health or safety.
   - In this case the market surveillance authorities must take measures to prohibit the placing on the market in accordance with the applicable Community or national rules, and request the customs authorities to mark the commercial invoice accompanying the product, and any other relevant accompanying document, with the words ‘Dangerous product — release for free circulation not authorised — Regulation (EEC) No 339/93’ in one of the 11 official Community languages (187).
   - The products in question do not comply with Community or national rules on product safety.
   - In this case the market surveillance authorities must take appropriate measures, if necessary prohibiting the placing on the market under the rules in question. In cases where placing on the market is prohibited, they must ask the customs authorities to mark the commercial invoice accompanying the products, and any other relevant accompanying document, with ‘Product not in conformity — release for free circulation not authorised — Regulation (EEC) No 339/93’ in one of the eleven official Community languages (187).
   - The products in question do not present a serious and immediate risk and cannot be considered as not conforming to the rules applicable to product safety.
   - In this case the products must be released for free circulation, provided that all the other conditions and formalities regarding release for free circulation have been met.

   By virtue of several community acts — including Regulation (EEC) No 339/93 and the Directive on general product safety — the surveillance authorities have an obligation to notify the customs authorities of their findings, which concern products imported from third countries. The following three situations may be possible.

   1. Products imported from third countries intended for consumers or likely to be used by them present a serious and immediate risk to health and safety according to the Directive on general product safety.
   - In this case the system for the rapid exchange of information on dangers arising from the use of consumer products according to the Directive on general product safety applies to consumer products covered by New Approach directives or other Community legislation. As a consequence, market surveillance authorities in all Member States are informed, and they may in turn inform the national customs authorities about products imported from third countries, which display characteristics giving rise to a serious doubt as to the existence of a serious and immediate risk to health and safety. This information is of particular importance for customs authorities where it involves measures banning or withdrawing from the market products imported from third countries, based on a Commission decision taken in accordance with Article 9 of the Directive on general product safety (188).
   - Products imported from third countries are not accompanied by documents, or bear no conformity marking or labelling as provided for by Community or national rules on product safety.
   - In this case the market surveillance authorities must inform the customs authorities in order to draw their attention to the existence of such products falling under the scope of Regulation (EEC) No 339/93.
   - Products imported from third countries, which present a risk to health or safety that is not serious and immediate, and are subject to measures prohibiting or restricting their placing on the market, or imposing their withdrawal from the market.
   - In this case the Member State taking these measures must notify them to the Commission according to the safeguard clause procedure under the New Approach directives, provided that the conditions for triggering such a clause are met. Where the product is intended for consumers or likely to be used by consumers, the safeguard clause under the Directive on general product safety applies, unless the product is covered by Community legislation providing for a safeguard clause (such as the New Approach directives). In such cases, it is necessary to inform customs authorities.

   For the purposes of applying Regulation (EEC) No 339/93, the provisions of Council Regulation (EC)
No 515/97 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure correct application of the law on customs and agricultural matters are applicable as appropriate. This is the case, in particular, where the endorsement 'Dangerous product — release for free circulation not authorised — Regulation (EEC) No 339/93' or 'Product not in conformity — release for free circulation not authorised — Regulation (EEC) No 339/93' are added to the commercial invoice and to any other relevant document accompanying products imported from third countries.
9. External aspects

9.1. Agreement on the European Economic Area

The Agreement on the European Economic Area is established between the European Community and Iceland, Liechtenstein and Norway. The Agreement extends the single market to these three EFTA States.

9.1.1. Basic elements of the Agreement

The Agreement on the European Economic Area, in force since 1 January 1994, covers all New Approach directives, and other Community legislation and acquis relevant to the free circulation of products. Hence, it extends the single market to the so-called EEA EFTA States: Iceland, Liechtenstein and Norway.

The objective of the EEA Agreement is to establish a dynamic and homogeneous European Economic Area, based on common rules and equal conditions of competition. The Agreement is amended on a continuous basis through decisions of the EEA Joint Committee following changes in relevant Community legislation. To arrive at and maintain a uniform interpretation and application of the Agreement an EFTA Court and an EFTA Surveillance Authority have been established.

Rights conferred and obligations imposed upon the Member States, or their public entities, undertakings, or individuals in relation to each other, are, according to the EEA Agreement, understood to be conferred or imposed in the same way also upon the EEA EFTA States. This ensures that the EEA EFTA States, and their economic operators, are subject to the same rights and obligations as their counterparts in the Community. For instance, the New Approach directives are applied in exactly the same way in the EEA EFTA States as in the Member States — although the administrative procedures concerning notification bodies and the safeguard clause are modified. Therefore, all guidance applicable to the Member States according to this Guide applies also to the EEA EFTA States.

For the purpose of the EEA Agreement references to the Community or the common market in the EU/EEA acts are understood to be references to the territories of the Contracting Parties. Accordingly, a product is not only placed on the Community market, but on the EEA market.

The EEA Agreement ensures a close cooperation between the Commission and the administration of the EEA EFTA States. The Commission seeks informal advice from experts of these States in the same way as it seeks advice from experts of the Member States. As regards the committees assisting the Commission in its work, close cooperation has been established. The EEA Council meets biannually, and the EEA Joint Parliamentary Committee and the EEA Consultative Committee regularly.

9.1.2. Notification of bodies

Procedures for notification of conformity assessment bodies from the EEA EFTA States have been established based on provisions of the EEA Agreement. The request for allocation of an identification number is first presented to the EFTA Secretariat, applying the same notification form as in the Community. The Secretariat verifies its formal correctness and transmits the application to the Commission with a request for an identification number (or for an extension of the use of the identification number to new directives/tasks). The Commission allocates the number and communicates it via the Secretariat to the notifying country. After this the EEA EFTA State makes a formal notification to the other EEA EFTA States, the EFTA Surveillance Authority and the Secretariat. The Surveillance Authority examines the notification and informs the Commission, which keeps an updated list of notified bodies from the Member States and the EEA EFTA States, and publishes it in the Official Journal.

When a notified body ceases to fulfil the requirements or its obligations, the EEA EFTA State has the responsibility to withdraw the notification. The Member State must also publish this information, and inform the other EEA EFTA States, the EFTA Surveillance Authority and the Secretariat. The Surveillance Authority informs the Commission about the withdrawal, which will then update the list of notified bodies.

9.1.3. Safeguard clause procedure

The EFTA Surveillance Authority is responsible for the examination of the safeguard clause notifications from the EEA EFTA States. The Authority consults all parties concerned and exchanges information with the Commission on the proceedings of the case. The Authority transmits its decision to the EEA EFTA States and the Commission for further actions. If an EEA EFTA State does not follow the decision, the Surveillance Authority can initiate an infringement procedure.

In cases where a Member State triggers a safeguard
Mutual recognition agreements and European conformity assessment protocols

The Community in its relations with third countries endeavours to promote international trade in regulated products, in particular by concluding mutual recognition agreements (MRAs) on the basis of Article 133 of the EC Treaty.

MRAs are designed so that each party shall accept the reports, certificates and marks that are in accordance with its own legislation. These are drawn up and issued by bodies that the other party has designated under the MRA for assessing conformity in the field(s) covered by the MRA. This can be achieved, because MRAs include all the conformity assessment requirements of the parties necessary to obtain full market access (190), and the products are evaluated in the country of production against the regulatory requirements of the other party.

MRAs cover the entire territory of the parties in order to guarantee, in particular in States with a federal structure, the full free movement of products certified to be in conformity. As a general rule, MRAs are limited to products that have their origin on the territory of either party (191).

MRAs apply to one or more categories of products or sectors falling within the regulated field (they are covered by New Approach or other Community technical harmonisation directives in force) and, in certain cases, by non-harmonised national law. In principle MRAs should cover all the industrial products for which the regulations of at least one of the parties require third party conformity assessment.

MRAs comprise a framework agreement and sectorial annexes. The framework agreement lays down the essential principles of a traditional agreement. Sectorial annexes specify, in particular, the scope and coverage, regulatory requirements, the list of designated conformity assessment bodies, the procedures and authorities responsible for designating these bodies and, if applicable, transitional periods. More sectorial annexes can be added successively.

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9.2. Mutual recognition agreements

- Mutual recognition agreements are established between the Community and the government of third countries, which are on a comparable level of technical development and have a compatible approach concerning conformity assessment.
- These agreements are based on the mutual acceptance of certificates, marks of conformity and test reports issued by the conformity assessment bodies of either party in conformity with the legislation of the other party.

The third countries concerned will conclude with the EEA EFTA States parallel agreements and protocols equivalent to those to be concluded with the Community, and which will, possibly, have the same date for entry into force (193). The system of parallel agreements and protocols formally grants the third country concerned the same market access throughout the European Economic Area for products covered by the mutual recognition agreements or European conformity assessment protocols. As to the practical implementation of these agreements and protocols, common sessions of the Joint Committee meetings with the third country concerned will be arranged.

(190) See Section 9.2 for mutual recognition agreements and Section 9.3 for European conformity assessment protocols.
(191) This is the principal difference with subcontracting that provides only for some of the procedures, such as tests.
(192) According to some MRAs the rule of origin may not be applicable (such as MRAs with the USA and Canada).
(193) The MRA with Israel covers only good laboratory practice.
9.3. European conformity assessment protocols

- The European conformity assessment protocols are intended to be established between the European Community and the governments of the applicant countries of central and eastern Europe (Hungary, Poland, the Czech Republic, Slovenia, Estonia, Romania, Bulgaria, Slovakia, Latvia and Lithuania).
- The objective of the European conformity assessment protocols is to support the progressive alignment of the applicant countries with the Community acquis and the facilitation of trade and market access.

The central and eastern European countries, which have signed an association agreement with the Community committing them to align their legislation with the Community acquis, and which at the same time are applying for membership of the European Union, have a special status. This has provided the opportunity of designing a specific model of mutual recognition agreements for those countries. These are called European Conformity Assessment Protocols (ECAP or PECA).

The ECAPs should cover the products submitted to Community legislation, and should include all procedures required to verify the conformity of products to this legislation. They comprise a framework protocol and sectorial annexes. The framework protocol adopts the essential principles concerning mutual recognition of products, based on the principle of the adoption of the acquis. Sectorial annexes are added successively.

The ECAPs should be seen as a support for the alignment process, and as an instrument of the pre-accession strategy. At the same time they are a means to facilitate trade between the Member States and the applicant countries, to support the progressive extension of the single market to these countries, and to promote health and safety. The determining factor for an ECAP is the capacity of the applicant countries to specifically implement the parts of the Community acquis that are adopted in the protocol. Since ECAPs are based on alignment to Community rules, products assessed according to Community legislation in a Member State or an applicant country can be placed on the Community market and on the market of the applicant country.

In order to ensure the development in terms of reciprocal openness of markets until the accession of the applicant countries, the ECAPs are based on the conditions necessary for the adoption and implementation of the Community acquis as follows:
- progressive alignment of framework laws;
- progressive alignment of sectorial laws with the New Approach directives and other directives;
- development of technical infrastructures in order to ensure that the technical competence of the bodies involved in the conformity assessment procedures is at the level required by the European Union;
- setting up the necessary structures for the correct enforcement of the acquis; and
- taking into account the need of the applicant countries to define the procedures and means for correctly carrying out market surveillance.

As part of the pre-accession strategy, the Commission supports the applicant countries through technical assistance programmes in aligning their legislation with Community legislation. This aid is frequently completed by bilateral assistance from Member States.

9.4. Technical assistance

- Technical assistance is the basis for creating a homogeneous, transparent and credible technical environment in which the public authorities, economic operators and users can have confidence.
- Technical assistance aims to achieve the availability of high quality products on the market.

Technical assistance is a transfer of knowledge and legislation policies, such as the New Approach and the Global Approach, but also a transfer of European best practice. It enables European experience to be shared with partners from non-member countries in all areas, with the objective of lifting barriers to trade as a result of increased compatibility or harmonisation on the international level, and increasing investment from the Member States to recipient countries and vice versa. Successful implementation should benefit both parties in this way. The main aims of technical assistance, therefore, are to increase trade relationships and investment opportunities, improve the quality of goods on the domestic market, help the recipient countries develop their own infrastructure and to reinforce the human capacity of the countries in the technical areas.

Technical assistance programmes take place in the fields of institutional cooperation, standardisation, metrology, certification, accreditation, quality management and quality assurance. These programmes are intended for countries that are not on a comparable level with the Member States in these fields. Since some partner countries have reached a stage of economic and industrial development where basic infrastructures are in
place, assistance may be targeted towards areas such as improving the regulatory regime for specific sectors, or refining the infrastructure necessary for ECAPs or MRAs to be concluded.

Technical assistance programmes can be regionally or nationally oriented. There have been a number of national programmes, which are usually very wide in scope, covering all aspects of technical assistance. Nevertheless, there is no single model for technical assistance as every country is at a different stage of development and seeks the fulfillment of different objectives. The Commission too has different priorities in each case, for example where technical assistance is used as part of the accession strategy. The PRAQ programmes (the Regional Programmes on Quality Assurance and other related fields) are examples of regional assistance. At the beginning they provided the European Union with information about the central and eastern Europe countries, but they have subsequently been used as a preliminary step towards the possible acceptance of these countries into the European Union.

The TBT Agreement lays down obligations, which apply to technical regulations and conformity assessment procedures issued either on a national or a regional basis. A Code of Good Practice for the preparation, adoption and application of standards has been annexed to the TBT Agreement. WTO Members are invited to ensure that standards bodies accept and comply with it. WTO Members are also encouraged, within the limits of their resources, to actively participate in the work of international standardisation bodies, and to negotiate mutual recognition agreements on conformity assessment.

Draft technical legislation deviating from international standards and having a significant effect on trade must be published and notified via the WTO Secretariat to the other members, who can make comments and, if necessary, request discussions. Following these discussions, if a technical barrier to trade persists, the disagreement may lead to a consultation procedure and, eventually, to a dispute settlement.

9.5. WTO Agreement on Technical Barriers to Trade

- The WTO Agreement on Technical Barriers to Trade (the TBT Agreement) is a market access instrument, using a variety of measures that help to prevent and eliminate technical barriers to trade caused by technical regulations, voluntary standards and conformity assessment procedures.
### Community legislation referred to in the Guide

<table>
<thead>
<tr>
<th>I</th>
<th>New Approach directives (i.e. directives providing for the CE marking)</th>
<th>Number of Directive amendment</th>
<th>Reference in the OJ EC amendment (corrigendum)</th>
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### I New Approach directives

(i.e. directives providing for the CE marking)

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### II Directives based on the principles of the New Approach or the Global Approach, but which do not provide for the CE marking

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<th>Number</th>
<th>Directive</th>
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### III Proposals for directives based on the principles of the New Approach or the Global Approach

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<td>IV</td>
<td>Other Community directives, regulations and decisions referred to in the Guide</td>
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<td>7.</td>
<td>Council Decision of 22 September 1992 on the adoption of an action plan for the exchange between Member State administrations of national officials who are engaged in the implementation of Community legislation required to achieve the internal market</td>
<td>92/481/EEC</td>
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<td>10.</td>
<td>Council Decision of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives</td>
<td>93/465/EEC</td>
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<tr>
<td>14.</td>
<td>Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters</td>
<td>515/97</td>
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### IV Other Community directives, regulations and decisions referred to in the Guide

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<th>Number of document amended</th>
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Annex 2

Additional information concerning certain Articles of the Treaty establishing the European Community (the EC Treaty)

A. The previous numbers of Articles of the EC Treaty referred to in the Guide

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B. The text of certain Articles of the EC Treaty

Art. 10  Member States shall take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Treaty or resulting from action taken by the institutions of the Community. They shall facilitate the achievement of the Community's tasks. They shall abstain from any measure which could jeopardise the attainment of the objectives of this Treaty.

Art. 28  Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.

Art. 30  The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

Art. 95  1. By way of derogation from Article 94 and save where otherwise provided in this Treaty, the following provisions shall apply for the achievement of the objectives set out in Article 14. The Council shall, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

4. If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

5. Moreover, without prejudice to paragraph 4, if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether...
or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.

When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.

8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.

9. By way of derogation from the procedure laid down in Articles 226 and 227, the Commission and any Member State may bring the matter directly before the Court of Justice if it considers that another Member State is making improper use of the powers provided for in this Article.

10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 30, provisional measures subject to a Community control procedure.

Art. 226

If the Commission considers that a Member State has failed to fulfil an obligation under this Treaty, it shall deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations.

If the State concerned does not comply with the opinion within the period laid down by the Commission, the latter may bring the matter before the Court of Justice.

Art. 227

A Member State which considers that another Member State has failed to fulfil an obligation under this Treaty may bring the matter before the Court of Justice.

Before a Member State brings an action against another Member State for an alleged infringement of an obligation under this Treaty, it shall bring the matter before the Commission.

The Commission shall deliver a reasoned opinion after each of the States concerned has been given the opportunity to submit its own case and its observations on the other party's case both orally and in writing.

If the Commission has not delivered an opinion within three months of the date on which the matter was brought before it, the absence of such opinion shall not prevent the matter from being brought before the Court of Justice.

Art. 228

1. If the Court of Justice finds that a Member State has failed to fulfil an obligation under this Treaty, the State shall be required to take the necessary measures to comply with the judgment of the Court of Justice.

2. If the Commission considers that the Member State concerned has not taken such measures it shall, after giving that State the opportunity to submit its observations, issue a reasoned opinion specifying the points on which the Member State concerned has not complied with the judgment of the Court of Justice.

If the Member State concerned fails to take the necessary measures to comply with the Court's judgment within the time-limit laid down by the Commission, the latter may bring the case before the Court of Justice. In so doing it shall specify the amount of the lump sum or penalty payment to be paid by the Member State concerned which it considers appropriate in the circumstances.

If the Court of Justice finds that the Member State concerned has not complied with its judgment it may impose a lump sum or penalty payment on it.

This procedure shall be without prejudice to Article 227.

Art. 249

In order to carry out their tasks and in accordance with the provisions of this Treaty, the European Parliament acting jointly with the Council, the Council and the Commission shall make regulations and issue directives, take decisions, make recommendations or deliver opinions.

A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States.

A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.

A decision shall be binding in its entirety upon those to whom it is addressed. Recommendations and opinions shall have no binding force.
Art. 251

1. Where reference is made in this Treaty to this Article for the adoption of an act, the following procedure shall apply.

2. The Commission shall submit a proposal to the European Parliament and the Council. The Council, acting by a qualified majority after obtaining the opinion of the European Parliament,
   — if it approves all the amendments contained in the European Parliament's opinion, may adopt the proposed act thus amended;
   — if the European Parliament does not propose any amendments, may adopt the proposed act;
   — shall otherwise adopt a common position and communicate it to the European Parliament. The Council shall inform the European Parliament fully of the reasons which led it to adopt its common position. The Commission shall inform the European Parliament fully of its position. If, within three months of such communication, the European Parliament:
     (a) approves the common position or has not taken a decision, the act in question shall be deemed to have been adopted in accordance with that common position;
     (b) rejects, by an absolute majority of its component members, the common position, the proposed act shall be deemed not to have been adopted;
     (c) proposes amendments to the common position by an absolute majority of its component members, the amended text shall be forwarded to the Council and to the Commission, which shall deliver an opinion on those amendments.

3. If, within three months of the matter being referred to it, the Council, acting by a qualified majority, approves all the amendments of the European Parliament, the act in question shall be deemed to have been adopted in the form of the common position thus amended; however, the Council shall act unanimously on the amendments on which the Commission has delivered a negative opinion. If the Council does not approve all the amendments, the President of the Council, in agreement with the President of the European Parliament, shall within six weeks convene a meeting of the Conciliation Committee.

4. The Conciliation Committee, which shall be composed of the members of the Council or their representatives and an equal number of representatives of the European Parliament, shall have the task of reaching agreement on a joint text, by a qualified majority of the members of the Council or their representatives and by a majority of the representatives of the European Parliament. The Commission shall take part in the Conciliation Committee's proceedings and shall take all the necessary initiatives with a view to reconciling the positions of the European Parliament and the Council. In fulfilling this task, the Conciliation Committee shall address the common position on the basis of the amendments proposed by the European Parliament.

5. If, within six weeks of its being convened, the Conciliation Committee approves a joint text, the European Parliament, acting by an absolute majority of the votes cast, and the Council, acting by a qualified majority, shall each have a period of six weeks from that approval in which to adopt the act in question in accordance with the joint text. If either of the two institutions fails to approve the proposed act within that period, it shall be deemed not to have been adopted.

6. If the Conciliation Committee does not approve a joint text, the proposed act shall be deemed not to have been adopted.

7. The periods of three months and six weeks referred to in this Article shall be extended by a maximum of one month and two weeks respectively at the initiative of the European Parliament or the Council.
## Annex 3

### Additional guidance documents

<table>
<thead>
<tr>
<th>Number</th>
<th>Documents related to New Approach directive</th>
<th>Number Date Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
<td>The designation of approved bodies in the field of the construction products Directive</td>
<td>Guidance paper A 11/95 EN</td>
</tr>
<tr>
<td>4.</td>
<td>The definition of factory production control in technical specifications for construction products</td>
<td>Guidance paper B 5/95 EN</td>
</tr>
<tr>
<td>5.</td>
<td>The treatment of kits and systems under the construction products Directive</td>
<td>Guidance paper C 2/97 EN</td>
</tr>
<tr>
<td>6.</td>
<td>CE marking under the construction products Directive</td>
<td>Guidance paper D 12/98 EN</td>
</tr>
<tr>
<td>12.</td>
<td>Guidelines on a medical devices vigilance system</td>
<td>Meddev 2.12/1 - Rev. 3 3/98 EN</td>
</tr>
</tbody>
</table>
### II Draft Documents related to Language

#### New Approach directives

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Draft guidance paper on the treatment of dangerous substances under the construction products Directive</td>
<td>EN</td>
</tr>
<tr>
<td>2.</td>
<td>Draft guidance paper on levels and classes in the construction products Directive</td>
<td>EN</td>
</tr>
<tr>
<td>3.</td>
<td>Draft guidance paper on transitional arrangements under the construction products Directive</td>
<td>EN</td>
</tr>
<tr>
<td>4.</td>
<td>Draft guidance paper related to pressure equipment</td>
<td>EN</td>
</tr>
</tbody>
</table>

#### Global Approach in general

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Draft guidance paper on the treatment of dangerous substances under the construction products Directive</td>
<td>EN</td>
</tr>
<tr>
<td>2.</td>
<td>Draft guidance paper on levels and classes in the construction products Directive</td>
<td>EN</td>
</tr>
<tr>
<td>3.</td>
<td>Draft guidance paper on transitional arrangements under the construction products Directive</td>
<td>EN</td>
</tr>
<tr>
<td>4.</td>
<td>Draft guidance paper related to pressure equipment</td>
<td>EN</td>
</tr>
</tbody>
</table>

### III Documents related to the New Approach or the Global Approach

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Reference in the OJ EC</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.</td>
<td>Opinion of the Economic and Social Committee on the Communication from the Commission to the Council on the proposal for a Council Decision concerning the modules for various phases of the conformity assessment procedures which are intended to be used in the technical harmonisation directives</td>
<td>OJ C 112 of 07/03/90</td>
</tr>
<tr>
<td>5.</td>
<td>Opinion of the Economic and Social Committee on the Communication from the Commission to the Council on a Global Approach to Certification and Testing</td>
<td>OJ C 112 of 07/03/90</td>
</tr>
<tr>
<td>6.</td>
<td>Council Resolution of 16 June 1994 on the development of administrative cooperation in the implementation and enforcement of Community legislation in the internal market</td>
<td>OJ C 179 of 01/07/94</td>
</tr>
<tr>
<td>7.</td>
<td>Council Resolution of 8 July 1996 on cooperation between administrations for the enforcement of legislation on the internal market</td>
<td>OJ C 224 of 01/08/1996</td>
</tr>
</tbody>
</table>

### IV Certif documents related to the New Approach or the Global Approach

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Number</th>
<th>Date</th>
<th>Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Methods of coordinating the procedures governing the notification and management of notified bodies</td>
<td>Certif. 93/1 Rev. 3</td>
<td></td>
<td>DE, EN, FR</td>
</tr>
<tr>
<td>2.</td>
<td>Framework for coordination and cooperation between notified bodies, Member States and the European Commission under the Community harmonisation directives based on the New Approach and the Global Approach</td>
<td>Certif. 94/6 Rev. 6</td>
<td>20/02/98</td>
<td>EN, FR</td>
</tr>
<tr>
<td>3.</td>
<td>Specifications concerning the assessment and supervision of systems applying to conformity assessment bodies with a view to their designation under the mutual recognition agreements between the European Union (EU) and certain non-member countries</td>
<td>Certif. 96/1 Rev. 6</td>
<td>26/06/96</td>
<td>DE, EN, FR</td>
</tr>
<tr>
<td>4.</td>
<td>Procedure for designation of conformity assessment bodies (CAB) under mutual recognition agreements (MRAs) with non-member countries</td>
<td>Certif. 96/3 Rev. 4</td>
<td>6/10/98</td>
<td>EN, FR</td>
</tr>
</tbody>
</table>
### IV Certif documents related to the New Approach or the Global Approach

<table>
<thead>
<tr>
<th>Number Date Language</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Various factors to be taken into account in order to clarify the meaning of CE marking Certif. 96/4 5/11/96 DE, EN, FR</td>
</tr>
<tr>
<td>6. Code of conduct for the functioning of the system of notified bodies Certif. 97/1 Rev. 3 17/7/98 DE, EN, FR</td>
</tr>
<tr>
<td>7. Accreditation and the Community’s policy in the field of conformity assessment Certif. 97/4 Rev. 2 15/12/97 DE, EN, FR</td>
</tr>
<tr>
<td>8. The EN 45000 series of standards and the conformity assessment procedures of the Global Approach Certif. 97/5 Rev. 1 24/3/98 DE, EN, FR</td>
</tr>
<tr>
<td>9. Conformity marking and market surveillance Certif. 98/2 30/1/98 DE, EN, FR</td>
</tr>
<tr>
<td>10. The EN 45000 standards, accreditation and notification of notified bodies Certif. 98/4 25/3/98 DE, EN, FR</td>
</tr>
<tr>
<td>11. State of play on accreditation and the EN 45000 standard Certif. 98/5 11/5/98 EN</td>
</tr>
<tr>
<td>12. List of presidents and technical secretariats for notified body groups Certif. 98/6 1/9/98 FR</td>
</tr>
<tr>
<td>13. Implementation of mutual recognition agreements on conformity assessment (MRA) and protocols on European conformity assessment (PECA) Certif. 98/7 24/7/98 DE, EN, FR</td>
</tr>
</tbody>
</table>

### V Other relevant documents

<table>
<thead>
<tr>
<th>Number Date Language</th>
</tr>
</thead>
</table>
Annex 4

Commission contact points

I  New Approach directives                      Contact                  Fax number (32-2) 29- ...
    DG  Unit  Enterpr.  G3  66273
12. Civil explosives (93/15/EEC) Enterpr. E3  50281
15. Recreational craft (94/25/EC) Enterpr. E6  67014
16. Lifts (95/16/EC) Enterpr. G3  66273
17. Refrigeration appliances (96/57/EC) Energy C1  66283

II  Directives based on the principles of the New Approach or the Global Approach, but which do not provide for the CE marking
    Contact                  Fax number (32-2) 29- ...
    DG  Unit  Enterpr.  Environ.  E3  91068
1. Packaging and packaging waste (94/62/EC) Enterpr. E6  56851
# Guide to the implementation of directives based on the New Approach and the Global Approach

## III Proposals for directives based on the principles of the New Approach or the Global Approach

<table>
<thead>
<tr>
<th>Proposal</th>
<th>Contact</th>
<th>Unit</th>
<th>Fax number</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Articles of precious metal (COM/93/322 final, amendment COM/94/267 final)</td>
<td>DG 1.1</td>
<td>G4</td>
<td>66273</td>
<td></td>
</tr>
<tr>
<td>2. Cableway installations designed to carry passengers (COM/93/646 final)</td>
<td>DG 1.2</td>
<td>E6</td>
<td>56851</td>
<td></td>
</tr>
<tr>
<td>3. Marking of packaging (COM/96/191 final)</td>
<td>DG 1.3</td>
<td>E1</td>
<td>91925</td>
<td></td>
</tr>
<tr>
<td>4. Noise emissions (COM/98/46 final)</td>
<td>DG 1.4</td>
<td>E3</td>
<td>69554</td>
<td></td>
</tr>
</tbody>
</table>

## IV Other Community legislation referred to in the Guide

<table>
<thead>
<tr>
<th>Legislation</th>
<th>Contact</th>
<th>Unit</th>
<th>Fax number</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Directive on product liability (85/374/EEC)</td>
<td>DG 3.1</td>
<td>D1</td>
<td>93088</td>
<td></td>
</tr>
<tr>
<td>2. Directive on general product safety (92/59/EEC)</td>
<td>DG 3.2</td>
<td>A4</td>
<td>91858</td>
<td></td>
</tr>
<tr>
<td>3. Decision concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking (93/465/EEC)</td>
<td>DG 3.3</td>
<td>G1</td>
<td>53877</td>
<td></td>
</tr>
<tr>
<td>4. Regulation concerning checks on products imported from third countries (EEC No 339/93)</td>
<td>DG 3.4</td>
<td>D2</td>
<td>54351</td>
<td></td>
</tr>
<tr>
<td>7. Directive on the procedure for the provision of information in the field of technical standards and regulations (98/34/EC, amendment 98/48/EC)</td>
<td>DG 3.7</td>
<td>G2</td>
<td>91675</td>
<td></td>
</tr>
<tr>
<td>- As regards the part on standards</td>
<td>DG 3.7</td>
<td>F2</td>
<td>60851</td>
<td></td>
</tr>
</tbody>
</table>

## V Horizontal issues related to New Approach directives

<table>
<thead>
<tr>
<th>Issue</th>
<th>Contact</th>
<th>Unit</th>
<th>Fax number</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Conformity assessment procedures, notified bodies (also updated lists of notified bodies), CE marking, market surveillance</td>
<td>DG 5.1</td>
<td>G1</td>
<td>53877</td>
<td></td>
</tr>
<tr>
<td>2. Standardisation</td>
<td>DG 5.2</td>
<td>G2</td>
<td>91675</td>
<td></td>
</tr>
</tbody>
</table>
Annex 5

Useful web addresses

**DG III Documents and publications:**  
http://europa.eu.int/comm/dg03/public.htm

**References to harmonised standards in the context of New Approach directives:**  
http://europa.eu.int/comm/dg03/directs/dg3b/newapproa/eurstd/harmstds/index.html  
(also access via http://www.NewApproach.org)

**New Approach standardisation in the European internal market —**  
how to access European standards and standards activities on the web:  

**One stop Internet shop for business**  

**Directive 98/13/EC**  
http://forum.europa.eu.int/Public/irc/dg3/tcam/info/data/inforce.html

**Directive 99/5/EC**  
http://forum.europa.eu.int/Public/irc/dg3/tcam/info/data/welcome.html
Annex 6

Products submitted to New Approach directives

Each directive defines the products that are within its scope. This annex is not an exhaustive list of all products covered by the directive in question, and does not take into account that several directives exclude certain products from the field of application although they comply with the product definition used in the directive.

<table>
<thead>
<tr>
<th>New Approach directive</th>
<th>Products that are as a general rule covered by the directive in question</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Low voltage equipment</td>
<td>Electrical equipment designed for use with a voltage rating of between 50 and 1000 volts for alternating current and between 75 and 1500 volts for direct current</td>
</tr>
<tr>
<td>2. Simple pressure vessels</td>
<td>Welded vessels manufactured in series, subjected to an internal gauge pressure greater than 0.5 bar, intended to contain air or nitrogen, and not intended to be fired</td>
</tr>
<tr>
<td>3. Toys</td>
<td>Products or material designed or clearly intended for use in play by children of less than 14 years of age</td>
</tr>
<tr>
<td>4. Construction products</td>
<td>Products which are produced for incorporation in a permanent manner in construction works (i.e. building and civil engineering works)</td>
</tr>
<tr>
<td>5. Electromagnetic compatibility</td>
<td>Apparatus i.e. all electrical and electronic appliances together with equipment and installations containing electrical and/or electronic components which are liable to cause electromagnetic disturbance or the performance of which is liable to be affected by such disturbance</td>
</tr>
<tr>
<td>6. Machinery</td>
<td>Machinery i.e. an assembly of linked parts or components at least one of which moves, with the appropriate actuators, control and power circuits, etc.; joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material; i.e. an assembly of machines which, in order to achieve the same end, are arranged and controlled to function as an integral whole; i.e. interchangeable equipment modifying the function of a machine, and the purpose of which is to be assembled with a machine or a series of different machines or with a tractor by the operator himself in so far as this equipment is not a spare part or a tool</td>
</tr>
<tr>
<td></td>
<td>Safety components placed on the market separately to fulfil a safety function when in use and the failure or malfunctioning of which endangers the safety or health of exposed persons, provided that the component is not an interchangeable equipment</td>
</tr>
<tr>
<td>7. Personal protective equipment</td>
<td>Devices or appliances designed to be worn or held by an individual for protection against one or more health and safety hazards</td>
</tr>
<tr>
<td></td>
<td>Units of several devices or appliances which have been integrally combined by the manufacturer for the protection of an individual against one or more potentially simultaneous risks</td>
</tr>
<tr>
<td></td>
<td>Protective devices or appliances combined, separably or inseparably, with personal non-protective equipment worn or held by an individual for the execution of a specific activity</td>
</tr>
<tr>
<td></td>
<td>Interchangeable components essential to the satisfactory functioning of the personal protective equipment, and used exclusively for such equipment</td>
</tr>
<tr>
<td>New Approach directive</td>
<td>Products that are as a general rule covered by the directive in question</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>8. Active implantable medical devices</td>
<td>Instruments, apparatus, appliances, material or other article, whether used alone or in combination (including any accessories or software necessary for its proper application)</td>
</tr>
<tr>
<td>9. Non-automatic weighing instruments</td>
<td>Measuring instruments</td>
</tr>
<tr>
<td>10. Gas appliances</td>
<td>Appliances</td>
</tr>
<tr>
<td>11. Hot-water boilers</td>
<td>Combined boiler-body units</td>
</tr>
<tr>
<td>12. Civil explosives</td>
<td>Materials and articles</td>
</tr>
<tr>
<td>13. Medical devices</td>
<td>Instrument, apparatus, appliances, materials or other article, whether used alone or in combination (including the software necessary for its proper application)</td>
</tr>
<tr>
<td>14. Potentially explosive atmospheres</td>
<td>Equipment</td>
</tr>
</tbody>
</table>

- **Active implantable medical devices**: Instruments, apparatus, appliances, material or other article, whether used alone or in combination (including any accessories or software necessary for its proper application) which are intended by the manufacturer to be used for human beings for certain defined purposes (e.g. diagnosis, prevention, monitoring, treatment of disease); which rely for their functioning on an external source of power; which are intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice; and which are intended to remain after the procedure.

- **Non-automatic weighing instruments**: Measuring instruments which are serving to determine the mass of a body by using the action of gravity on that body, or to determine other mass related magnitudes, quantities, parameters or characteristics; and which require the intervention of an operator during weighing.

- **Gas appliances**: Appliances i.e. appliances burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or washing and having, where applicable, a normal water temperature not exceeding 105 °C; or forced draught burners and heating bodies to be equipped with such burners.

- **Hot-water boilers**: Combined boiler-body units with a rated output of no less than 4 kW and no more than 400 kW; which are fired with liquid or gaseous fuels and which are designed to transmit to water the heat released from burning.

- **Civil explosives**: Materials and articles considered to be explosives in the United Nations recommendations on the transport of dangerous goods and falling within Class 1 of those recommendations.

- **Medical devices**: Instrument, apparatus, appliances, materials or other article, whether used alone or in combination (including the software necessary for its proper application) which are intended by the manufacturer to be used for human beings for certain defined purposes (e.g. diagnosis, prevention, monitoring, treatment of disease); and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means. Accessories i.e. an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

- **Potentially explosive atmospheres**: Equipment i.e. machines, apparatus, fixed or mobile devices, control components (i.e. items essential to the safe functioning of equipment and protective system, without autonomous function) and instrumentation thereof; and detection or prevention systems intended for use in potentially explosive atmospheres (i.e. atmospheres that could become explosive due to local and operational conditions), and intended, separately or jointly, for the generation, transfer, storage, measurement, control and conversion of energy for the processing of material, and capable of causing an explosion through their own potential sources of ignition.
<table>
<thead>
<tr>
<th>New Approach directive</th>
<th>Products that are as a general rule covered by the directive in question</th>
</tr>
</thead>
<tbody>
<tr>
<td>15. Recreational craft</td>
<td>Protective systems: i.e. design units intended for use in potentially explosive atmospheres; intended to halt incipient explosions immediately and/or to limit the effective range of explosion flames and explosion pressures; and separately placed on the market for use as autonomous systems.</td>
</tr>
<tr>
<td></td>
<td>Safety devices, controlling devices and regulating devices: intended for use outside potentially explosive atmospheres, but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion from 2.5m to 24m hull length, measured according to the appropriate harmonised standards; and intended for sports and leisure purposes.</td>
</tr>
<tr>
<td>16. Lifts</td>
<td>Boats: i.e. boats consisting of a hull and/or components referred to in Annex II of the Directive when separate and when installed.</td>
</tr>
<tr>
<td></td>
<td>Partly completed boats:</td>
</tr>
<tr>
<td></td>
<td>Components:</td>
</tr>
<tr>
<td></td>
<td>Protective systems:</td>
</tr>
<tr>
<td></td>
<td>Safety devices, controlling devices and regulating devices:</td>
</tr>
<tr>
<td></td>
<td>Protective systems:</td>
</tr>
<tr>
<td></td>
<td>Safety devices, controlling devices and regulating devices:</td>
</tr>
<tr>
<td>17. Refrigeration appliances</td>
<td>Electric mains-operated refrigerators, Frozen food storage cabinets, Food freezers, Combinations of these</td>
</tr>
<tr>
<td>18. Pressure equipment</td>
<td>Vessels*: i.e. housings designed and built to contain fluids under pressure including their direct attachments up to the coupling point connecting it to other equipment.</td>
</tr>
<tr>
<td></td>
<td>Piping*: i.e. piping components intended for the transport of fluids, when connected together for integration into a pressure system.</td>
</tr>
<tr>
<td></td>
<td>Safety accessories*: i.e. devices designed to protect pressure equipment against the allowable limits being exceeded.</td>
</tr>
<tr>
<td></td>
<td>Pressure accessories*: i.e. devices with an operational function and having pressure-bearing housings.</td>
</tr>
<tr>
<td></td>
<td>Assemblies*: i.e. several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole*.</td>
</tr>
<tr>
<td>19. Telecommunications terminal equipment</td>
<td>Equipment: intended to be connected to the public telecommunications network in order to transmit, process or receive data capable of being used either for transmission only, or for transmission and reception, or for reception only, of radio-communications signals by means of satellites or other space-based systems.</td>
</tr>
<tr>
<td>20. In vitro diagnostic medical devices</td>
<td>Instruments, apparatus, appliances, materials or other articles, whether used alone or in combination (including the software necessary for its proper application): which are intended by the manufacturer to be used for human beings for certain defined purposes (e.g. diagnosis, prevention, monitoring, treatment or alleviation of disease); and which do not achieve their principal intended action in or on the human body by pharmacological, immunological or metabolic means; and which are reagent, a reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens derived from the human body for the purpose of providing information.</td>
</tr>
</tbody>
</table>

* provided that the maximum allowable pressure is greater than 0.5 bar
## Annex 6

### I New Approach directive

<table>
<thead>
<tr>
<th>Products that are as a general rule covered by the directive in question</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> Packaging and packaging waste</td>
</tr>
<tr>
<td><strong>2.</strong> High-speed rail system</td>
</tr>
<tr>
<td><strong>3.</strong> Marine equipment</td>
</tr>
</tbody>
</table>

### II Directive based on the principles of the New Approach or the Global Approach

<table>
<thead>
<tr>
<th>Products that are as a general rule covered by the directive in question</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>21.</strong> Radio and telecommunications terminal equipment</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
Annex 7

Contents of conformity assessment procedures

Council Decision 93/465/EEC lays down the modules for conformity assessment, which are further defined in each directive. This annex is intended to give an overview of the tasks that are to be carried out under the responsibility of the manufacturer and the notified body, and the tasks that the manufacturer can delegate to the authorised representative. However, there are differences between the conformity assessment procedures adopted by the directives, which are not taken into account in this general presentation. Furthermore, the tasks to be carried out by the importer or the person responsible for placing on the market are described in Section 3.3. of the Guide.

<table>
<thead>
<tr>
<th>Module</th>
<th>Manufacturer</th>
<th>Manufacturer or the authorised representative</th>
<th>Notified body</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>• establishes a technical documentation as regards the design, manufacture and operation of the product • takes all measures necessary to ensure that the manufacturing process assures compliance of the products with the technical documentation and with the applicable requirements (i.e. operates a quality system)</td>
<td>• ensures and declares that the products concerned satisfy the requirements • affixes the CE marking to each product • draws up a declaration of conformity • keeps a copy of the declaration of conformity and the technical documentation at the disposal of the surveillance authorities</td>
<td>• supervises the tests carried out by the manufacturer • supervises the affixing of its identification number, where it was involved in conformity assessment during the production stage • keeps a record of relevant information • communicates to the other notified bodies relevant information (on request)</td>
</tr>
<tr>
<td>Aa1</td>
<td>In addition to the responsibilities as in module A: • carries out, or has carried out on his behalf, one or more tests for each product manufactured • chooses a notified body on whose responsibility the tests are carried out</td>
<td>In addition to the responsibilities as in module A: • affixes the notified body's identification number to follow the CE marking, if the notified body intervened during the production stage</td>
<td>• carries out or has carried out product checks at random intervals, and for this purpose takes samples of final products • supervises the affixing of its identification number • keeps a record of relevant information • communicates to the other notified bodies relevant information (on request)</td>
</tr>
<tr>
<td>Aa2</td>
<td>As in module A: • applies for product checks at random intervals</td>
<td>In addition to the responsibilities as in module A: • affixes the notified body's identification number to follow the CE marking</td>
<td>• ascertains, by performing or having performed examinations and tests, that the specimen(s) meets the applicable provisions and is manufactured in accordance with the technical documentation • issues an EC type-examination certificate • keeps a copy of the certificate and a record of other relevant technical information • communicates to the other notified bodies the relevant information concerning the EC type-examination certificates (on request)</td>
</tr>
<tr>
<td>B</td>
<td>• establishes a technical documentation as regards the design, manufacture and operation of the product</td>
<td>• applies for the EC type-examination • places at the disposal of the notified body one (or more) specimen(s), which is (are) representative of the production envisaged • informs the notified body of all the modifications to the approved product • keeps the technical documentation, including a copy of the EC type-examination certificate, at the disposal of the surveillance authorities</td>
<td>• ascertains, by performing or having performed examinations and tests, that the specimen(s) meets the applicable provisions and is manufactured in accordance with the technical documentation • issues an EC type-examination certificate • keeps a copy of the certificate and a record of other relevant technical information • communicates to the other notified bodies the relevant information concerning the EC type-examination certificates (on request)</td>
</tr>
<tr>
<td>Module</td>
<td>Manufacturer</td>
<td>Manufacturer or the authorised representative</td>
<td>Notified body</td>
</tr>
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</tbody>
</table>
| C      | • takes all measures necessary to ensure that the manufacturing process assures compliance of the products with the type as described in the EC type-examination certificate and with the applicable requirements (i.e. operates a quality system, which includes establishing the necessary documentation) | • ensures and declares that the products concerned are in conformity with the EC type-examination certificate and satisfy the applicable requirements  
• affixes the CE marking to each product  
• draws up a declaration of conformity  
• keeps relevant technical information and a copy of the declaration of conformity at the disposal of the surveillance authorities |   |
| Cbis1  | As in modules C and Aa1 | As in modules C and Aa1 | As in module Aa1 |
| Cbis2  | As in modules C and Aa2 | As in modules C and Aa2 | As in module Aa2 |
| D      | • operates an approved quality system for production, final product inspection and testing, which includes the drawing up of a technical documentation (i.e. relevant information for the product category envisaged, documentation concerning the quality system and its updating, technical documentation of the approved type, a copy of the EC type-examination certificate, and the decisions and reports from the notified body)  
• applies for the assessment of the quality system for the products concerned  
• ensures and declares that the products concerned are in accordance with the EC type-examination certificate and satisfy the applicable requirements  
• undertakes to fulfil the obligations arising out of the approved quality system and upholds it so that it remains adequate and efficient  
• supports the action carried out by the notified body for surveillance purpose  
• keeps at the disposal of the surveillance authority the documentation concerning the quality system, details of any updating of the quality system, the decisions and reports of the notified body | • affixes the CE marking to each product  
• affixes the notified body's identification number to follow the CE marking  
• draws up a declaration of conformity  
• informs the notified body of any intended updating of the quality system  
• keeps a copy of the declaration of conformity at the disposal of the surveillance authorities | • assesses the quality system to determine whether it satisfies the applicable requirements, and accordingly takes a decision  
• supervises the affixing of its identification number  
• carries out surveillance of the manufacturer by means of periodic and unexpected visits  
• keeps a record of relevant technical information  
• communicates to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn (on request) |   |
### Guide to the implementation of directives based on the New Approach and the Global Approach

<table>
<thead>
<tr>
<th>Module</th>
<th>Manufacturer</th>
<th>Manufacturer or the authorised representative</th>
<th>Notified body</th>
</tr>
</thead>
</table>
| **Dbis** | • establishes a technical documentation as regards the design, manufacture and operation of the product  
• operates an approved quality system for production, final product inspection and testing, which includes the drawing up of a technical documentation (i.e. relevant information for the product category envisaged, documentation concerning the quality system and its updating, and the decisions and reports from the notified body)  
• applies for the assessment of the quality system for the products concerned  
• ensures and declares that the products concerned satisfy the requirements  
• undertakes to fulfil the obligations arising out of the approved quality system and upholds it so that it remains adequate and efficient  
• supports the action carried out by the notified body for surveillance purpose  
• keeps at the disposal of the surveillance authority the documentation concerning the quality system, details of any updating of the quality system, the decisions and reports of the notified body | As in module D | As in module D |

| **E** | As in module D, but operates an approved quality system for final product inspection and testing | As in module D | As in module D |

| **Ebis** | As in module Dbis, but operates an approved quality system for final product inspection and testing | As in module D | As in module D |

| **F** | • takes all measures necessary to ensure that the manufacturing process assures conformity of the products with the type as described in the EC type-examination certificate and with the applicable requirements (i.e. operates a quality system, which includes establishing the necessary documentation)  
Where the statistical verification is used:  
• presents the products in the form of homogeneous lots and takes all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced  
• applies for certification of conformity  
• checks and attests that the products are in conformity with the type as described in the EC type-examination certificate and satisfy the applicable requirements  
• affixes the CE marking to each product  
• affixes the notified body's identification number to follow the CE marking  
• draws up a declaration of conformity  
• keeps relevant technical information (e.g. the notified body's certificate of conformity) and a copy of the declaration of conformity at the disposal of the surveillance authorities | • carries out the appropriate examinations and tests in order to check the conformity of the product with the applicable requirements either by examination and testing of every product, or by examination and testing of products on a statistical basis  
• supervises the affixing of its identification number  
• draws up a certificate of conformity relating to the tests carried out  
• if a lot is rejected, takes appropriate measures to prevent the putting on the market of that lot  
• keeps a record of relevant technical information  
• communicates to the other notified bodies relevant information (on request) | | |
<table>
<thead>
<tr>
<th>Module</th>
<th>Manufacturer</th>
<th>Manufacturer or the authorised representative</th>
<th>Notified body</th>
</tr>
</thead>
</table>
| Fbis   | • establishes a technical documentation as regards the design, manufacture and operation of the product  
• takes all measures necessary to ensure that the manufacturing process assures conformity of the products with the applicable requirements (i.e. operates a quality system)  
Where the statistical verification is used:  
• presents the products in the form of homogeneous lots and takes all measures necessary in order that the manufacturing process assures the homogeneity of each lot produced  
• applies for certification of conformity  
• affixes the CE marking to each product  
• affixes the notified body’s identification number to follow the CE marking  
• draws up a declaration of conformity  
• keeps a copy of the declaration of conformity, the technical documentation and the notified body’s certificate of conformity at the disposal of the surveillance authorities | • checks and attests that the products satisfy the applicable requirements  
• affixes the CE marking to each product  
• affixes the notified body’s identification number to follow the CE marking  
• draws up a declaration of conformity  
• keeps a copy of the declaration of conformity, the technical documentation and the notified body’s certificate of conformity at the disposal of the surveillance authorities | As in module F |
| G      | • establishes a technical documentation as regards the design, manufacture and operation of the product  
• ensures and declares that the product concerned conforms to the applicable requirements | • applies for certification of conformity  
• affixes the CE marking to each product  
• affixes the notified body’s identification number to follow the CE marking  
• draws up a declaration of conformity  
• keeps a copy of the declaration of conformity and the technical documentation at the disposal of the surveillance authorities | As in module D |
| H      | • operates an approved quality system for design, manufacture, final product inspection and testing, which includes the drawing up of a technical documentation (i.e. relevant information for the design, the product category envisaged, documentation concerning the quality system and its updating, and the decisions and reports from a notified body)  
• applies for the assessment of the quality system for the products concerned  
• ensures and declares that the products concerned satisfy the applicable requirements  
• undertakes to fulfil the obligations arising out of the approved quality system and upholds it so that it remains adequate and efficient  
• supports the action carried out by the notified body for surveillance purpose  
• keeps at the disposal of the surveillance authority the documentation concerning the quality system, details of any updating of the quality system, the decisions and reports of the notified body | • applies for certification of conformity  
• affixes the CE marking to each product  
• affixes the notified body’s identification number to follow the CE marking  
• draws up a declaration of conformity  
• keeps a copy of the declaration of conformity and the technical documentation at the disposal of the surveillance authorities | As in module D |
<table>
<thead>
<tr>
<th>Module</th>
<th>Manufacturer</th>
<th>Manufacturer or the authorised representative</th>
<th>Notified body</th>
</tr>
</thead>
</table>
| Hbis   | In addition to responsibilities as in module H:  
• applies for examination of the design  
• informs the notified body of any modification to the approved design | As in module D | In addition to responsibilities as in module D:  
• examines the application  
• issues an EC design examination certificate, if the design meets the applicable provisions  
• keeps a record of the EC design examination certificates and the EC design approvals  
• communicates to the other notified bodies relevant information concerning the EC design examination certificates and the EC design approvals (on request) |
# Annex 8

Flow chart presentation of conformity assessment procedures as provided for by the directives

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<thead>
<tr>
<th>I</th>
<th>New Approach directives</th>
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</thead>
<tbody>
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<td>Low voltage equipment (73/23/EEC, amendment 93/68/EEC)</td>
</tr>
<tr>
<td>3</td>
<td>Toys (88/378/EEC, amendment 93/68/EEC)</td>
</tr>
<tr>
<td>5</td>
<td>Machinery (98/37/EC, amendment 98/79/EC)</td>
</tr>
<tr>
<td>6</td>
<td>Personal protective equipment (89/686/EEC, amendments 93/68/EEC, 93/95/EEC and 96/58/EC)</td>
</tr>
<tr>
<td>7</td>
<td>Non-automatic weighing instruments (90/384/EEC, amendment 93/68/EEC)</td>
</tr>
<tr>
<td>8</td>
<td>Active implantable medical devices (90/385/EEC, amendments 93/42/EEC and 93/68/EEC)</td>
</tr>
<tr>
<td>9</td>
<td>Gas appliances (90/396/EEC, amendment 93/68/EEC)</td>
</tr>
<tr>
<td>10</td>
<td>Hot water boilers (92/42/EEC, amendment 93/68/EEC)</td>
</tr>
<tr>
<td>11</td>
<td>Civil explosives (93/15/EEC)</td>
</tr>
<tr>
<td>12</td>
<td>Medical devices (93/42/EEC, amendment 98/79/EC)</td>
</tr>
<tr>
<td>13</td>
<td>Potentially explosive atmospheres (94/9/EC)</td>
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<tr>
<td>14</td>
<td>Recreational craft (94/25/EC)</td>
</tr>
<tr>
<td>15</td>
<td>Lifts (95/16/EC)</td>
</tr>
<tr>
<td>16</td>
<td>Refrigeration appliances (96/57/EC)</td>
</tr>
<tr>
<td>17</td>
<td>Pressure equipment (97/23/EC)</td>
</tr>
<tr>
<td>18</td>
<td>Telecommunications terminal equipment (98/13/EC)</td>
</tr>
<tr>
<td>19</td>
<td>In vitro diagnostic medical devices (98/79/EC)</td>
</tr>
<tr>
<td>20</td>
<td>Radio and telecommunications terminal equipment (99/5/EC)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>II</th>
<th>Directive based on the principles of the Global Approach, but which does not provide for the CE marking</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>Marine equipment (96/98/EC)</td>
</tr>
</tbody>
</table>
1. Flow chart for the conformity assessment procedures provided for in Directive 73/23/EEC on electrical equipment designed for use within certain voltage limits.

NB: In the event of a challenge the manufacturer may submit a 'report by a notified body' on the conformity of the equipment with the safety objectives (Article 8.2).
Annex 8

(*) These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.

2. Flow chart for the conformity assessment procedures provided for in Directive 87/404/EEC on simple pressure vessels

MANUFACTURER

Function of value PS. V (Art. 3.2 & 8.1)

Yes

Compliance with standards

PS. V > 50 bar.L

EC type examination (Art. 10)

MODULE B (*)

Value of PS. V

PS. V > 3000 bar.L

Certification of file adequacy by NB

MODULE A+ (*)

No or partial

PS. V < 300 bar.L

Manufacture in accordance with sound engineering practice (Art. 3.2)

No CE marking

EC verification (Art. 11)

NB verifies and certifies SPV conformity. Manufacturers declare the conformity.

MODULE F (*)

Value of PS. V

PS. V < 3000 bar.L

Manufacturers choice

MODULE C bis 2+

EC conformity declaration by manufacturers, plus EC surveillance by NB if PS. V > 200 bar.L (Art. 12).

*: These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.
3. Flow chart for the conformity assessment procedures provided for in Directive 88/378/EEC on the safety of toys

MANUFACTURER

Compliance with standards

Yes

Manufacturer keeps technical file or technical report, ensuring conformity of production to standard (Art. 8)
MODULE A (*)

Non-compliance, in whole or in part

EC type-examination (Art. 10)
MODULE B (*)

Manufacturer confirms conformity of production with type and keeps technical file or technical reports, inspection (Art. 8, 2)
MODULE C (*)

(*) These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.
These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.
(* ) These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.
6. Flow chart for the conformity assessment procedures provided for in Directive 89/686/EEC on personal protective equipment (PPE)

- **MANUFACTURER**
  - Technical file (Annex III)
    - Type of product
      - Simple design PPE (Art. 8.3)
        - EC type-examination (Art. 10)
          - MODULE B (*)
      - Other equipment
    - Complex design PPE (Art. 8.4a)
      - Manufacturer's choice
        - EC declaration of conformity to essential requirements (Art. 12)
          - MODULE A (*)
      - Other equipment
        - EC declaration of conformity to type (Art. 12)
          - MODULE C (*)
        - EC declaration of conformity (EC final product quality system (Art. 11A))
          - NB carries out product checks
          - MODULE C bis2 (*)
        - EC declaration of conformity (EC production quality system (Art. 11B))
          - NB assesses and monitors the manufacturer's quality system
          - MODULE D (*)

(*) These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.
These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.
Annex 8

These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.

8. Flow chart for the conformity assessment procedures provided for in Directive 90/385/EEC on active implantable medical devices

- **MANUFACTURER**
  - Type of product
    - Art. 9
  - All other devices
    - Manufacturer's choice
      - EC declaration of conformity (complete quality assurance system + product design file (Annex 2))
        - NB issues an EC design examination certificate (Annex 2, para. 4)
        - NB assesses and monitors the manufacturer's quality system
          - MODULE Hbis (*)
      - EC type-examination (Annex 3)
        - MODULE B (*)
    - EC declaration of conformity to type (production quality assurance (Annex 5))
      - NB assesses and monitors the manufacturer's quality system
        - MODULE D (*)
  - Custom made devices and devices for clinical investigations
    - Manufacturer's choice
      - EC declaration of conformity (Annex 6) + technical file
      - No CE marking

(*) These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.

(*) These procedures were approved before the adoption of Council Decision 90/683/EEC (as amended by Decision 93/465/EEC) on conformity assessment procedures (modules). Their provisions may therefore not be identical to those of the modules.

(*) Fittings don't bear CE marking, but they are accompanied by a certificate.
10. Flow chart for the conformity assessment procedures provided for in Directive 92/42/EEC on efficiency requirements for new hot water boilers fired with liquid or gaseous fuel

Manufacturers' choice

- Gas-fired boilers are submitted to conformity assessment procedures provided for in Directive 92/42/EEC, appliances burning gaseous fuels (Art. 7(2))
- EC conformity declaration with type (Annex IV).
- NB carries out spot checks on appliances.

- Gas-fired boilers
- Liquid-fired boilers, series production

MODULE B

- EC type-examination (Annex III)
- MODULE B

MANUFACTURER

Type of production

- Liquid-fired boilers, series production
- Manufacturer’s choice

MODULE Cbis2

- EC conformity declaration with type (production quality assurance, Annex IV)
- NB assesses and monitors manufacturer’s quality system

MODULE D

- EC conformity declaration with type (production quality assurance, Annex IV)
- NB assesses and monitors manufacturer’s quality system

MODULE E

Note: the Directive provides in Article 6 for a label system awarding the boilers energy performances.
11. Flow chart for the conformity assessment procedures provided for in Directive 93/15/EEC on explosives for civil uses

- Manufacturer's choice
  - EC type examination (Annex II.1)
    - MODULE B
  - Manufacturer's choice
    - EC unit verification (Annex II.6)
      - NB verifies and certifies that the appliance meets the directive requirements
      - Technical file (Annex IV) is made available to the NB
      - MODULE G
    - Conformity to type (Annex II.2)
      - NB carries out products checks at random intervals.
      - MODULE C
    - Production quality assurance (Annex II.3)
      - NB assesses and monitors the manufacturer's quality system
      - MODULE D
    - Production quality assurance (Annex II.4)
      - NB assesses and monitors the manufacturer's quality system
      - MODULE E
    - Product verification (Annex II.5)
      - NB verifies and certifies that products conform with the type
      - MODULE F

12.1 Flow chart for the conformity assessment procedures provided for in Directive 93/42/EEC on medical devices

MANUFACTURER

Type of product

Product class I

Product class II B

Product class II B

EC declaration of conformity (Annex VII) + technical file

MODULE A

EC declaration of conformity (Annex VII) + technical file

MODULE B

Manu- facturer's choice

Full quality assurance system (Annex II)

NB assesses and monitors the manufacturer's quality system

EC design verification by NB (Annex II.4) not applicable

MODULE D

MANUFACTURER

Type of product

Product class I

Product class II B

Product class II B

EC type-examination (Annex II)

MODULE B

Manu- facturer's choice

EC verification (Annex IV)

NB verifies and certifies that products conform with the technical file

MODULE F

(*) Third party assessment relates to (a) obtention of sterile devices, (b) metrological aspects.

(*) Third party assessment relates to (a) obtention of sterile devices, (b) metrological aspects.

to Chart 2

EC verification (Annex IV)

NB verifies and certifies that products conform with the technical file

MODULE F

Production quality assurance (Annex V)

NB assesses and monitors the manufacturer's quality system

MODULE D

Production quality assurance (Annex V)

NB assesses and monitors the manufacturer's quality system

MODULE D

(*) Third party assessment relates to (a) obtention of sterile devices, (b) metrological aspects.
12.2 Flow chart for the conformity assessment procedures provided for in Directive 93/42/EEC on medical devices (cont.)

- **Product class III**
  - EC type-examination (Annex III)
  - **MODULE B**
  - Manufacturer's choice
  - **MODULE D**
  - Production Quality Assurance (Annex V)
    - NB assesses and monitors the manufacturer's quality system. Manufacturer declares that products conform with the type
  - **MODULE E**
  - Full quality assurance system (Annex II)
    - NB assesses and monitors the manufacturer's quality system. NB verifies and certifies the design conformity
  - **MODULE F**
    - EC verification (Annex IV)
      - NB verifies and certifies that products conform with the technical file

- **No additive CE marking**
- **No CE marking**
- **No complementary CE marking**

- **Sterile devices**
  - Manufacturer's choice
  - **MODULE F**
    - EC verification (Annex IV)
      - NB verifies and certifies that products conform with the type
  - **MODULE D**
    - Production quality assurance (Annex V)
      - NB assesses and monitors the manufacturer's quality system
  - **MODULE E**
    - Product quality assurance (Annex VI)
      - NB assesses and monitors the manufacturer's quality system

- **Devices for clinical investigations and custom-made devices**
  - Statement concerning devices for special purposes (Annex VIII)
    - The manufacturer declares that products conform with essential requirements
  - **MODULE E**
    - EC verification (Annex IV)
      - NB verifies and certifies the design conformity
  - **MODULE F**
    - Production Quality Assurance (Annex V)
      - NB assesses and monitors the manufacturer's quality system. Manufacturer declares that products conform with the type
  - **MODULE D**
    - Full quality assurance system (Annex II)
      - NB assesses and monitors the manufacturer's quality system. NB verifies and certifies the design conformity

- **Medical devices, bearing the CE marking, marketed as systems or procedure packs (Art. 12)**
  - Manufacturer declaration according to Art. 12.2
  - **MODULE F**
    - EC verification (Annex IV)
      - NB verifies and certifies that products conform with the type
  - **MODULE D**
    - Production quality assurance (Annex V)
      - NB assesses and monitors the manufacturer's quality system
  - **MODULE E**
    - Product quality assurance (Annex VI)
      - NB assesses and monitors the manufacturer's quality system
13. Flow chart for the conformity assessment procedures provided for in Directive 94/9/EC on equipment and protective systems intended for use in potential explosive atmospheres

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(*) All referred procedures shall be applied in respect of components, with the exception of the affixing of the CE marking (Art. 8.3).

(**) Manufacturer may follow the 'internal control of production' (Annex VIII) procedure with regard to the safety aspects referred to in point 1.2.7 of Annex II to the Directive.

---

(1) No CE marking for components
14. Flow chart for the conformity assessment procedures provided for in Directive 94/25/EC on recreational craft

- **Boat design categories A and B**
  - Hull length
    - Hull < 12 m
    - 12 m < hull < 24 m
  - Components in Annex II
  - Boat design category C
  - Hull length
    - 2.5 m < hull < 12 m
    - 2.5 m < hull < 24 m

- **MANUFACTURER**
  - Type of product
  - Internal production control plus test (Annex VI)
    - Manufacturer's choice
  - EC type-examination (Annex VI)
    - Manufacturer's choice
  - Comply with standards

- **MODULE Aa**
  - Internal production control (Annex V)
    - Internal production control plus tests (Annex VI)
      - Product verification (Annex X)
        - Manufacturer declares that products conform with the type
          - Production quality assurance (Annex IX)
            - Full quality assurance (Annex XII)
              - Unit verification (Annex XI)
                - Manufacturer verifies and certifies that the products meet the directive requirements

- **MODULE B**
  - Internal production control plus test (Annex VI)
  - Production quality assurance (Annex VIII)

- **MODULE C**
  - Internal production control plus test (Annex X)
  - Production quality assurance (Annex VIII)

- **MODULE D**
  - Internal production control plus test (Annex VI)
  - Product verification (Annex X)

- **MODULE E**
  - Internal production control plus test (Annex VI)
  - Internal production control plus test (Annex X)

- **MODULE F**
  - Internal production control plus test (Annex X)
  - Product verification (Annex X)

- **MODULE G**
  - Internal production control plus test (Annex X)
  - Product verification (Annex X)

- **MODULE H**
  - Internal production control plus test (Annex X)
  - Product verification (Annex X)

(1) Partly completed boats are not CE marketed. All products must be accompanied by the EC declaration of conformity.
Flow chart for the conformity assessment procedures provided for in Directive 95/16/EC on lifts

1. Installer's choice
   - Lift designed in accordance with a lift having undergone EC type-examination (Annex V)
   - Lift designed in accordance with a model lift having undergone EC type-examination (Annex V)
   - Lift designed in accordance with a lift for which a full quality assurance system (Annex XIII) was implemented, supplemented by a design examination in case it does not wholly comply with the harmonised standards

2. Manufacturer's choice
   - EC type-examination (Annex V) MODULE B
   - Product quality assurance (Annex XII) MODULE C
   - Full quality assurance (Annex IX) MODULE E
   - Production quality assurance (Annex XIV) MODULE D

3. Final inspection (Annex VI)
   - NB verifies and certifies that lifts meet Directive requirements
   - Installer draws up a declaration of conformity

4. Unit verification (Annex X)
   - NB verifies and certifies that lifts meet the Directive requirements
   - Installer draws up a declaration of conformity

5. Full quality assurance (Annex XI) MODULE H
   - NB inspects the design where it is not entirely in accordance with harmonised standards

6. Conformity to type with random checking (Annex XI)
   - NB carries out product checks at random intervals
   - Manufacturer draws up a declaration of conformity

7. Conformity to type (Annex XII)
   - NB assesses and monitors the installer's quality system
   - Installer draws up a declaration of conformity

8. Final inspection (Annex VI)
   - NB verifies and certifies that lifts meet Directive requirements
   - Installer draws up a declaration of conformity

9. Product quality assurance (Annex XII)
   - NB assesses and monitors the installer's quality system
   - Installer draws up a declaration of conformity

10. Full quality assurance (Annex IX)
    - NB assesses and monitors the installer's quality system
    - Installer draws up a declaration of conformity

11. Production quality assurance (Annex XIV)
    - NB assesses and monitors the installer's quality system
    - Installer draws up a declaration of conformity

12. Conformity to type (Annex XI)
    - NB carries out product checks at random intervals
    - Manufacturer draws up a declaration of conformity

13. Conformity to type (Annex XII)
    - NB assesses and monitors the installer's quality system
    - Installer draws up a declaration of conformity

14. Final inspection (Annex VI)
    - NB verifies and certifies that lifts meet Directive requirements
    - Installer draws up a declaration of conformity
16. Flow chart for the conformity assessment procedures provided for in Directive 96/57/EC on refrigeration appliances
### 17. Directive 97/23/EC concerning pressure equipment

**Type of equipment**

<table>
<thead>
<tr>
<th>Vessels</th>
<th>Pressure accessories (1)</th>
<th>Piping</th>
<th>Pressure accessories (7)</th>
</tr>
</thead>
</table>

**Fluid to be contained**

<table>
<thead>
<tr>
<th>(Art. 9)</th>
<th>gaseous</th>
<th>liquid</th>
<th>Steam or superheated water</th>
<th>gaseous</th>
<th>liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>d ('d)</td>
<td>nd ('nd)</td>
<td>d</td>
<td>nd</td>
<td>d</td>
<td>nd</td>
</tr>
</tbody>
</table>

**Annex II:

- Tables**

<table>
<thead>
<tr>
<th>specific categories as a function of PS, V or DN</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Category</th>
<th>Applicable procedures</th>
<th>CE marking</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEP (Sound engineering practice)</td>
<td>See Article 3.3</td>
<td>No</td>
</tr>
<tr>
<td>I</td>
<td>A; A1; D1; E1; B1-D1; B1+F; B+H; B+H1; H; B+D; B+F; G; H1</td>
<td>Yes</td>
</tr>
<tr>
<td>II</td>
<td>A1; D1; E1; B1-D1; B1+F; B+H; B+H1; H; B+D; B+F; G; H1</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>B1-D1; B1+F; B+H; B+H1; H; B+D; B+F; G; H1</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>B+D; B+F; G; H1</td>
<td></td>
</tr>
</tbody>
</table>

(1) If classified on the basis of PS and V. See Annex II, point 3.
(2) If classified on the basis of PS and DN. See Annex II, point 3.
(3) 'd' means dangerous fluid. See Article 9.2.1.
(4) 'n-d' means non-dangerous fluid. See Article 9.2.2.
(5) Within an assembly, CE marking need not be affixed to each individual item of pressure equipment.

### In general:

- Category IV

### For specific equipment:

- Category of equipment to be protected

### Assemblies

- 'Global procedure' (Art. 10.2)

(a) Each item making up the assembly:
- according to its category;
(b) Integration of items:
- according to the highest category of equipment not considering safety accessories;
(c) Protection of assembly:
- highest category of equipment to be protected.
NB: For specific equipment elements the manufacturer of satellite earth station equipment may use the internal production control procedure (Module A, Annex IX) as an alternative to the above conformity assessment procedures.

MANUFACTURER

Device covered by Annex II

Referred to in list B of Annex II

Referred to in list A of Annex II

Intended for performance evaluation

Procedure according to Annex VIII

Manufacturer's choice

EC declaration of conformity/full quality assurance + design examination + verification of manufactured products (Annex V)

MODULE H/plus

EC type-examination (Annex V)

MODULE B

EC declaration of conformity/full quality assurance (Annex IV, except points 4 and 6)

MODULE H

EC type-examination (Annex V)

MODULE B

Manufacturer's choice

EC declaration of conformity/full quality assurance/verification of manufactured products (Annex IV)

MODULE D +

EC verification (Annex V)

MODULE F

EC declaration of conformity/production quality assurance (Annex IV, except point 5)

MODULE D

Statement drawn up by the manufacturer
19.2. Flow chart for the conformity assessment procedures provided for in Directive 98/79/EC on in vitro diagnostic medical devices (cont.)

From Chart 1

- Intended for self testing
  - Yes: Manufacturer's choice
  - No: Intended for performance evaluation

- Procedure according to Annex VIII
  - Statement drawn up by the manufacturer

EC declaration of conformity + examination of design (Annex III)

MODULE A +
At the choice of the manufacturer, compliance with the essential requirements may be demonstrated, as an alternative, using the procedures of the Directives relating to low voltage equipment and electromagnetic compatibility respectively, where the apparatus is within the scope of these Directives (see Tables 1 and 4).
21. Flow chart for the conformity assessment procedures provided for in Directive 96/98/EC on marine equipment

MANUFACTURER

- Produced individually or in small quantities and not in series or in mass
  - Yes: Manufacturer's choice
    - Unit verification (Annex B)
      - MODULE G
    - Full quality assurance and design examination (Annex B)
      - MODULE Hbis
  - No: Manufacturer's choice
    - EC type-examination (Annex B)
      - MODULE B
    - Conformity to type (Annex B)
      - MODULE C
    - Production quality assurance (Annex B)
      - MODULE D
    - Product quality assurance (Annex B)
      - MODULE E
    - Product verification (Annex B)
      - MODULE F
European Commission

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