EUROPEAN COMMISSION

GUIDE

TO THE IMPLEMENTATION OF DIRECTIVES BASED ON NEW APPROACH AND 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 twenty-first century.

The European Union has developed original and innovative instruments to remove the barriers to free circulation of goods. Among these, pride of place is taken by the New Approach to product regulation and the Global Approach to conformity assessment. The common thread between these complementary approaches is that they limit public intervention to what is essential and leave to industry the greatest possible choice in 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 is to manage the marketplace. 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 Directorate-General III (Industry) in close co-operation with other Commission services, with contributions from Member State experts and interest groups. My thanks to all whom have contributed to this enterprise.

Magnus Lemmel
Acting Director General for DG III

IMPORTANT NOTICE

- *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 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 applies also 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. INTRODUCTION

1.1. Concept of New Approach and Global Approach

Free movement of goods is a cornerstone of the Single Market. The mechanisms in place to achieve this aim are based on prevention of new barriers to trade, mutual recognition and technical harmonisation.

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 twelve 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 of the Member States, the European standards organisations to elaborate European standards.

National technical regulations are subject to the provisions of Art. 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 legislation, may only be accepted, if national measures:

- are necessary to satisfy mandatory requirements (such as health, safety, consumer protection, 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.

[1] The Directive 98/34/EC is a codification of the Directive 83/189/EEC and its amendments. The Directive 98/34/EC has been amended by Directive 98/48/EC.
[2] According to the Court of Justice a breach of the obligation to notify renders the technical regulations in question inapplicable to individuals (case C-194/94).

Restrictions to free movement of products, which may be acceptable under Art. 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.[3]

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.

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]

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[3] Originally, a third party assessment was considered necessary where products were not manufactured in compliance with harmonised standards. This has evolved since the first New Approach directives were adopted.

[4] The New Approach has not been applied in sectors where Community legislation was well advanced prior to 1985, or where provisions for finished products and hazards related to such products cannot be laid down. For instance, Community legislation on foodstuffs, chemical products, pharmaceutical products, motor vehicles and tractors does not follow the principles of the New Approach.

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 intercomparison 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, co-operation 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:

- manufacturer’s internal design and production control activities;
- third party type examination combined with manufacturer’s 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, a product may be covered by several directives.

☑ 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.

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[5] Third party approval of product or production quality assurance systems and third party product verification can also be provided for without third party type or design examination.

[6] The standard elements are presented in the order usually followed in the New Approach directives.

Member States are allowed to adopt, in compliance with the Treaty (in particular Art. 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 Art. 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 Art. 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 his 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.

Co-ordination 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.[7]

☑ Withdrawal of the presumption of conformity: section 4.4.

☑ Administrative co-operation: 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,

[7] The co-operation is based on the Council Resolution of 1994 on the development of administrative co-operation in the implementation and enforcement of Community legislation in the internal market.

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 Art. 95 of the EC Treaty, and adopted according to the co-decision procedure provided for in Art. 251 of the EC Treaty.*

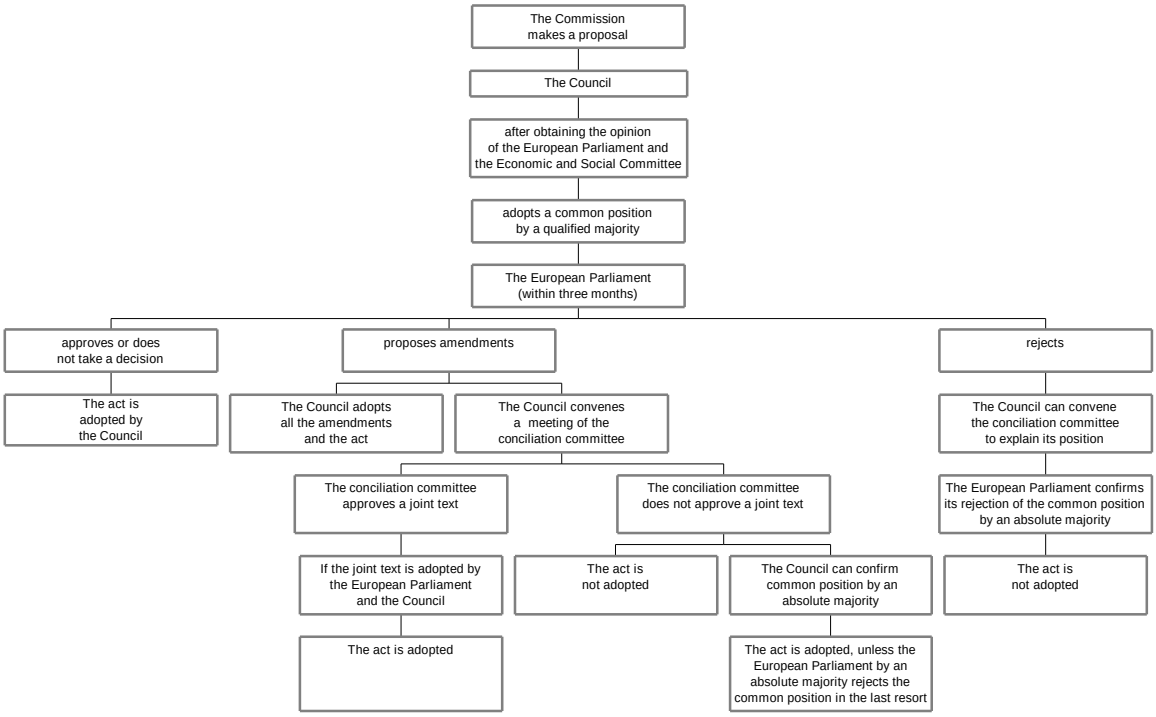
- *Adopted New Approach directives are published in the L series of the Official Journal of the European Communities. Commission proposals for New Approach directives are published in the C series of the Official Journal.*

The legal basis for adopting or modifying New Approach directives is Art. 95 of the EC Treaty. According to Art. 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 Art. 95, take as a basis a high level of protection. Further, Art. 95 requires that a safeguard clause is provided for in appropriate cases.

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 flowchart shows the adoption procedure according to Art. 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.

Table 1/1: Adoption of directives according to Art. 251 of the EC Treaty



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 Art. 138 of the EC Treaty (directives aiming to improve the health and safety of workers, especially, in the working environment).[8]

Directives are, according to Art. 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 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 Art. 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 Art. 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

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[8] As an exception, additional national provisions in areas covered by New Approach directives may be acceptable in accordance with Art. 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.

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[11]

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.

Table 1/2: New Approach directives (= directives providing for the CE marking)

	Directive (as referred to in this Guide)	Number of Directive, *Amendment*	Date of application	End of transitional period
1.	Low voltage equipment[12]	73/23/EEC *93/68/EEC*	19/8/74 *1/1/95*	1/1/97 *1/1/97*
2.	Simple pressure vessels	87/404/EEC *90/488/EEC* *93/68/EEC*	1/7/90 *1/7/91* *1/1/95*	1/7/92 *1/1/97*
3.	Toys	88/378/EEC *93/68/EEC*	1/1/90 *1/1/95*	 *1/1/97*
4.	Construction products	89/106/EEC *93/68/EEC*	27/6/91 *1/1/95*	 *1/1/97*
5.	Electromagnetic compatibility	89/336/EEC *92/31/EEC* *93/68/EEC* *[98/13/EC][13]*	1/1/92 *28/10/92* *1/1/95* *6/11/92*	31/12/95 *1/1/97*
6.	Machinery[14]	98/37/EC *98/79/EC*	1/1/93 *1/1/93* *1/1/95* *1/1/95* *7/6/00*	31/12/94 *31/12/94* *31/12/96* *1/1/97*
7.	Personal protective equipment	89/686/EEC *93/68/EEC* *93/95/EEC* *96/58/EC*	1/7/92 *1/1/95* *29/1/94* *1/1/97*	30/6/95 *1/1/97*
8.	Non-automatic weighing instruments	90/384/EEC *93/68/EEC*	1/1/93 *1/1/95*	31/12/02 *1/1/97*
9.	Active implantable medical devices	90/385/EEC *93/42/EEC* *93/68/EEC*	1/1/93 *1/1/95* *1/1/95*	31/12/94 *14/6/98* *1/1/97*
10.	Gas appliances	90/396/EEC *93/68/EEC*	1/1/92 *1/1/95*	31/12/95 *1/1/97*

[10] Judgement of the Court, case C-178/94.

[11] For a complete presentation of directives referred to in this section, see annex 1.

[12] 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.

[13] This is not a modification of the Directive relating to electromagnetic compatibility, but it has an impact on its application.

[14] This Directive codifies into one single text the 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.

11.	Hot water boilers	92/42/EEC *93/68/EEC*	1/1/94 *1/1/95*	31/12/97 *1/1/97*
12.	Civil explosives	93/15/EEC	1/1/95	31/12/02
13.	Medical devices	93/42/EEC *98/79/EC*	1/1/95 *7/6/00*	14/6/98 *30/6/01*
14.	Potentially explosive atmospheres	94/9/EC	1/3/96	30/6/03
15.	Recreational craft	94/25/EC	16/6/96	16/6/98
16.	Lifts	95/16/EC	1/7/97	30/6/99
17.	Refrigeration appliances	96/57/EC	3/9/99	
18.	Pressure equipment	97/23/EC	29/11/99	29/5/02
19.	Telecommunications terminal equipment[15]	98/13/EC	6/11/92 *1/5/92* *1/1/95*	
20.	In vitro diagnostic medical devices	98/79/EC	7/6/00	7/12/03 7/12/05
21.	Radio and telecommunications terminal equipment[16]	99/5/EC	8/4/00	7/4/00 7/4/01

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

	Directive (as referred to in this Guide)	Number of Directive	Date of Application	End of transitional period
1.	Packaging and packaging waste[17]	94/62/EC	30/6/96	31/12/99
2.	High speed rail system	96/48/EC	8/4/99	
3.	Marine equipment	96/98/EC	1/1/99	

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

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

[15] This Directive codifies into one single text the 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.

[16] This Directive will replace the Directive on telecommunications terminal equipment.

[17] This Directive contains neither a conformity assessment procedure nor a marking regime, which are 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

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 his product is within the scope of one or more directives.*

- *Products that have been subject to important changes may be considered as new products which 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 Art. 296 of the EC Treaty products intended specifically for military purposes.*

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,

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[18] 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.

[19] For placing on the market and putting into service, see section 2.3.

[20] 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 Art. 28 and 30 of the EC Treaty.

[21] See annex 6.

fittings, accessories or systems. It is the responsibility of the manufacturer to verify whether or not his 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 make up the combination, for putting the combination together in such a way that it complies with the provisions of the directives concerned, and for fulfilling all the requirements of the directive in relation to the assembly, the EC declaration of conformity and CE marking. The decision whether a combination of products and parts needs to be considered as one finished product has to be taken by the manufacturer[22]on a case by case basis.

A product, which has been subject to important changes that aim to modify its original performance, purpose or type after it has been put into service, may be considered as a new product. This has to be assessed on a case by case basis and, in particular, in view of the objective of the directive and the type of products covered by the directive in question. Where a rebuilt or modified product is considered as a new product, it must comply with the provisions of the applicable directives when it is placed on the market and put into service. This has to be verified – as deemed necessary according to the risk assessment – by applying the appropriate conformity assessment procedure laid down by the directive in question. In particular, if the risk assessment leads to the conclusion that the nature of the hazard or the level of risk has increased, then the modified product should normally be considered as a new product. 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 county for the repair operations. Such operations are often carried out by replacing a defective or worn out 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 Art. 296 of the EC Treaty

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[22] In some situations the responsibilities of the manufacturer are taken over by another person, see sections 3.1 – 3.3.

[23] For products used at the workplace the employer must take all measures necessary to ensure that work equipment is suitable and safe. For instance, the user of repaired machinery must ensure that it is no less safe than the original. See section 3.6.

[24] See Directives relating to machinery, personal protective equipment, civil explosives, potentially explosive atmospheres, lifts, pressure equipment, and radio and telecommunications terminal equipment.

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). Art. 296(1) of the EC Treaty offers Member States the possibility to exclude from the application of Community legislation products intended for specifically military purposes, insofar the products concerned appear in the list drawn up by the Council according to Art. 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.

The same product or hazard can be covered by two or more directives. 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 possibly applicable directives.[25]

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; or*

  ⇒ *all aspects of safety or categories of risk are not covered by New Approach directives or other Community legislation.*

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

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[25] For instance,

- the Directive relating to low voltage equipment is not applicable to electrical equipment for medical purposes, instead either the Directive relating to active implantable medical devices or medical devices may apply;
- the Directive relating to electromagnetic compatibility is not applicable to products covered by specific Directives that harmonise the protection requirements specified in the Directive on electromagnetic compatibility;
- the Directive relating to personal protective equipment applies in all aspects, where the principal intended purpose of the personal protective equipment is to protect the person using it, whether or not this takes place in a medical environment;
- the Directive relating to lifts is not applicable to lifts connected to machinery and intended exclusively for access to the workplace, instead the Directive relating to machinery applies; and
- marine equipment, which is also within the scope of other directives than the Directive on marine equipment, is excluded from the application of such directives.

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.

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 (art. 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.

2.2.3. 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 objective of New Approach directives is to protect the public interest (for example health and safety of persons, consumer protection, protection of business transactions, environmental protection). Thus, they intend to prevent, as far as possible, the placing on the market and putting into service of unsafe or otherwise non-compliant products. The Directive on product liability (85/374/EEC), which is applicable to all products covered by New Approach directives, provides a powerful incentive to guarantee the safety of products. It is in the interest of 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]

[26] This procedure is described in section 8.5.1.
[27] For product liability, see section 3.7.

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 directive 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 interest 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 Art. 28 and 30 of the EC Treaty), additional national provisions regarding the use of particular product, and 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

[28] Directives relating to toys, low voltage equipment, construction products, civil explosives and refrigeration appliances cover only placing on the market.

[29] Placing on the market has only been defined in very few directives. According to the Directive on toys it covers both sale and distribution free of charge; according to the Directives relating to active implantable medical devices, medical devices and in vitro diagnostic medical devices it means the first making available in return for payment or free of charge of a device, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished; according to the Directive on civil explosives it means the first disposal against payment or free of charge of explosives covered by the Directive, with a view to their distribution and/or use on the Community market; and according to the Directive on lifts it occurs when the installer first makes the lift available for the end user.

with the intention of distribution or use on the Community market.[30] 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 his 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 his 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 his 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

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30 Thus, imports for own use are also considered as being placed on the market at the moment they enter the Community. The responsibility for the compliance of the product in such situations is described in sections 3.1 – 3.3.
Products built for own use are, generally, not considered as being placed on the market. However, concerning the Directive relating to construction products it should be considered that, in order to achieve the objectives of this Directive, construction products manufactured by the constructor himself on site or elsewhere should be regarded as placed on the market although a transfer is not taking place.

31 The distribution chain can also be the commercial chain of the manufacturer or his authorised representative.

32 For authorised representative, see section 3.2.

33 In these situations the person considered as the manufacturer has the sole and ultimate responsibility for the conformity of his product to the applicable directives, and must be able to do so (see section 3.1.1).

34 See Council Regulation (EEC) No 2913/92 establishing the Community customs code. In accordance with this Regulation, non-Community goods placed under a suspensive customs procedure or in a free zone are subject to customs supervision and don't benefit from the free circulation in the internal market. Before benefiting from the free circulation in the internal market, these goods must be declared for release for free circulation that entails application of commercial policy measures, completion of the other formalities laid down in respect of the importation of goods and the charging of any duties legally due.

35 However, in such circumstances a visible sign must clearly indicate that the product in question may not be placed on the market or put into service until it has been made to comply.

- in the stocks of the manufacturer, or his 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 Art. 28 and 30 of the EC Treaty.

2.3.2. Putting into service[37]

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,[36] 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
- which are not placed on the market prior to putting into service (for example products manufactured for own use)[39].

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[36] For market surveillance, see chapter 8.

[37] Putting into service is usually not defined in the directives. However, according to the Directive relating to active implantable medical devices putting into service means making available to the medical profession for implantation, and according to the Directives relating to medical devices and in vitro diagnostic medical devices it means the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose. The Directive on marine equipment uses the expression of placing on board a Community ship instead of putting into service.
The Directives relating to toys, low voltage equipment, construction products, civil explosives and refrigeration appliances do not cover putting into service.

[38] As regards lifts and equivalent products, the putting into service should be considered to take place at the moment when the first use within the Community is possible.

[39] The Directive relating to recreational craft excludes from the field of application boats build for own use, provided that they are not subsequently placed on the Community market during a period of five years.

Member States may not prohibit, restrict or impede the putting into service of products that meet the provisions of the applicable directives.[40] However, Member States are allowed to maintain and adopt, in compliance with the Treaty (in particular Art. 28 and 30 of the EC Treaty), additional national provisions regarding the putting into service, installation or use, and 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.

As an exception concerning the Directive relating to construction product, see footnote 30. As another exception, the Directive on pressure equipment does not cover the assembly of pressure equipment on the site and under the responsibility of the user.

[40] According to the Directive relating to hot-water boilers, products cannot be put into service unless they meet, in addition to the efficiency requirements laid down by the Directive, the national conditions for entry into service. However, such provisions may not prevent the free movement of boilers.
According to the Directive on radio and telecommunications terminal equipment Member States may restrict the putting into service of radio equipment for reasons related to the effective and appropriate use of the radio spectrum, avoidance of harmful interference or matters related to public health.

2.4. Transitional period

- *Most New Approach directives provide for a transitional period.*[41]

- *Member States are obliged to allow on their market, until the end of the transitional period, products designed and manufactured according to their national system. Thus, the manufacture 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 Art. 28 and 30 of the EC Treaty.*[42]

- *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.*[43] *Consequently, only products in compliance with the applicable directive may be placed on the Community market and put into service after the transitional period.*

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.[44] The obligation to maintain the pre-existing rules applies not only to all

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[41] The transitional period is still running for the Directives relating to non-automatic weighing instruments (until 31/12/2002), civil explosives (until 31/12/2002), potentially explosive atmospheres (until 30/6/2003), medical devices (until 30/06/2001 as regards putting into service), lifts (until 30/6/1999), pressure equipment (until 29/5/2002 as regards placing on the market), in vitro diagnostic medical devices (until7/12/2003 as regards placing on the market, and 7/12/2005 as regards putting into service), and radio and telecommunications terminal equipment (until 7/4/00 as regards conformity assessment in accordance with the existing system, and until 7/4/2001 as regards placing on the market and putting into service).

[42] However, where the national regulations to be replaced have transposed existing Community harmonised legislation, all products – whether in accordance with the old or new system – are subject to free movement during the transitional period. For instance, the Directive on radio and telecommunications terminal equipment is replacing the existing Community directive on telecommunications terminal equipment.

[43] For the exception provided for by Art. 28 and 30 of the EC Treaty, see section 2.3.

[44] As an exemption, 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-

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 maintain the existing system and, hence, 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 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, are 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

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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 time 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 these Directives.
For placing on the market and putting into service, see section 2.3.

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]

[46] For the EC declaration of conformity, see section 5.4; for the CE marking, see chapter 7.

3. RESPONSIBILITIES

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 of 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 he may subcontract his tasks. However, he must always retain the overall control and have the necessary competence to take the responsibility for the product.*[47]

The manufacturer is any natural or legal person who is responsible for designing and manufacturing a product with a view of placing it on the Community market under his own name.[48] 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 his 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.

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[47] Where the manufacturer uses finished product, 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, medical devices and in vitro diagnostic medical devices.

[49] For products submitted to directives, see section 2.1.

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 procedure(s) 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 the situations where the manufacturer designs, manufactures, packs and labels the product himself as to the 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 manufacture 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 his product to a third party (usually a notified body) for product testing and certification, or to have his 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 who, 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). Accordingly, he must ensure that the product complies with the applicable directives, and that the appropriate conformity assessment procedure has been carried out.[52]

A product may be put into service without prior placing on the market (such as a product manufactured for own use). In such a case the person who puts the product into service must assume the responsibilities of the manufacturer. Accordingly, he must ensure that the

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[50] See annex 7.

[51] See Directives relating to low voltage equipment, toys, construction products, machinery, non-automatic weighing instruments, active implantable medical devices, gas appliances, medical devices, potentially explosive atmospheres, recreational craft, lifts, pressure equipment, telecommunications terminal equipment, in vitro diagnostic medical devices, and radio and telecommunications terminal equipment. Further, according to the Directive on in vitro diagnostic medical devices, a manufacturer who places devices on the Community market under his own name is obliged to register in the Member State where he has his place of business.

[52] Further, according to the Directives relating to machinery and lifts obligations regarding the conformity assessment procedure fall to any person placing the product on the market in the Community, where neither the manufacturer nor his authorised representative established in the Community or the installer of the lift fulfils these obligations.

product complies with the directive, and that appropriate conformity assessment has been carried out.[53]

New Approach directives do not require the manufacturer to be established in the Community. Thus, the responsibilities of a manufacturer according to the directives are equal whether he is established outside the Community or in a Member State.

3.1.2. The Directives on product liability and general product safety

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 any person 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 what is 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, and 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. 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.[54]

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[53] This is not applicable to products covered by Directives relating to toys, low voltage equipment, civil explosives and refrigeration appliances, since these Directives only cover placing on the market. Further, this is not applicable to recreational craft build for own use, provided that it is not subsequently placed on the Community market during a period of five years, or to craft designed before 1950. As an exception, construction products manufactured for own use should be considered as being placed on the market (see footnote 30).

[54] To a limited extent the Directive on general product safety may be applicable to products covered by New Approach directives (see section 2.2.2).

3.2. Authorised representative

- *The manufacturer may appoint any natural or legal person to act on his behalf as an authorised representative.*[55]

- *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.*

The manufacturer may be based in the Community or elsewhere. In either case, the manufacturer may appoint an authorised representative in the Community to act on his behalf in carrying out certain tasks required in the applicable directives. However, a manufacturer established outside the Community is not obliged to have an authorised representative, although this may present some advantages.[56]

For the purposes of New Approach directives, thus to be able to act on behalf of the manufacturer, the authorised representative must be established inside the Community. Commercial representatives of the manufacturer (such as authorised distributors), whether or not established inside the Community, are not to be confused with the authorised representative in the meaning of New Approach directives.

The delegation of tasks from the manufacturer to the authorised representative must be explicit and should take place in writing, in particular to define the contents of the tasks and the limits of the representative's powers. Depending on the conformity assessment procedure and the directive in question, the authorised representative can, for 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.[57]

The tasks that may be delegated to the authorised representative according to the directives are of an administrative nature. Thus, the manufacturer may neither delegate the measures necessary to ensure that the manufacturing process assures compliance of the products nor the setting up of a technical documentation, unless otherwise provided for. Further, an authorised representative cannot modify the product on his own initiative in order to bring it into line with the applicable directives.

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[55] The authorised representative is usually not defined in the New Approach directives, with the exception of the Directives on medical devices and in vitro diagnostic medical devices.

[56] As an exception, according to the Directives on medical devices (as regards certain types of devices) and in vitro diagnostic medical devices the manufacturer must designate a person who is established in the Community to be responsible for marketing of medical devices, if he does not have a registered place of business in a Member State and he places devices on the Community market under his own name.

[57] See annex 7.

The authorised representative can, at the same time, act as a subcontractor. Accordingly, as a subcontractor he may, for instance, take part in the design and manufacture of the product, on condition that the manufacturer retains the overall control for the product to fulfil his responsibility regarding its compliance with the provisions of the applicable directives.

The authorised representative can also at the same time act as an importer or a person responsible for placing on the market in the meaning of New Approach directives. His responsibilities are extended accordingly.[58]

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 he 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 manufacture that the documents will be made available when requested by the surveillance authority.[59]

The importer neither needs 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.

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[58] See section 3.3.

[59] All directives are not explicit about this obligation. The Decision 93/465/EEC explicitly foresees this obligation for conformity assessment procedures based on modules A, B, C and their variants.

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 establishes 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.[60]

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 about the applicable legal requirements. He should know, for instance, which products must bear the CE marking, what information (for example EC the declaration of conformity) has to accompany the product, what are the language requirements for users' instructions or other accompanying documents, and what is a clear indication of the product being non-compliant. Accordingly, he may not supply products that he knows or should have assumed, on the basis of information in his possession and as a professional, not to be in compliance with the legislation. Further, he should co-operate in actions taken to avoid or minimise these risks.

The distribution conditions (for example transportation or storage) may have an impact on maintaining the compliance with the provisions of the applicable directive. This may, for instance, be the case for measuring instruments and medical devices. Thus, the person in charge of the distribution conditions shall take the necessary measures to protect the

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[60] Where the importer assembles, packs, processes, or labels ready-made products with a view to their being placed on the Community market under his own name, or where he substantially 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 3.1.1).
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 fall to any person placing the product on the market in the Community, where neither the manufacturer nor his authorised representative established in the Community or the installer of the lift fulfils these obligations.

compliance of the product. This is to ensure that the product complies with the essential requirements at the moment of first use within the Community.

The distribution conditions may, in the absence of Community legislation, be regulated to some extent on the national level in accordance with Art. 28 and 30 of the EC Treaty. National legislation which grants to members of a specific profession the exclusive right to distribute certain products is capable, insofar as it restricts sales to certain channels, of affecting the possibilities of marketing imported products. Accordingly, such legislation may constitute a measure having an effect equivalent to a quantitative restriction on imports. However, it can be justified for instance on grounds of the protection of public health, if the measure is appropriate for the purpose and does not go beyond what is necessary to achieve it.[61]

New Approach directives do not foresee that the distributor would take over the responsibilities of the manufacturer. Therefore, he cannot, for instance, be requested to make a copy of the EC declaration of conformity or the technical documentation available, unless he is at the same time the authorised representative established in the Community or the importer (person responsible for placing on the market).[62] Nevertheless, he has an obligation to demonstrate to the national surveillance authority to have acted with due care and ensured that the manufacturer, or his authorised representative in the Community, or the person who provided him with the product has taken the necessary measures required by the applicable directives. The distributor must also be able to identify the manufacturer, his authorised representative in the Community, the importer or the person who has provided him with the product in order to assist the surveillance authority in its efforts to receive the EC declaration of conformity and the necessary parts of the technical documentation.

According to the Directive on general product safety the distributor is defined as any professional in the supply chain whose activity does not affect the safety properties of a product. The Directive requires distributors to act with due care in order to help to ensure compliance with the general safety requirement of the Directive, in particular by not supplying products that they know or should have presumed, on the basis of the information in their possession and as professionals, not to comply with this requirement. In particular, within the limits of their activities, they must participate in monitoring the safety of products placed on the market, especially by passing information on product risks and co-operating in the action taken to avoid these risks.

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[61] See judgement of the Court: case C-271/92.

[62] See sections 3.2 and 3.3. 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).

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.*

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 telecommunications terminal equipment.[63]

Where the directive in question covers putting into service,[64] 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.

3.6. 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 workplace has an impact on the maintenance and use of products covered by New Approach directives that are used at the workplace.*

Many products covered by New Approach directives are used at the workplace. According to directives based on Art. 138 of the EC Treaty,[65] employers have obligations as regards the use of work equipment at the workplace. An employer is considered to be any natural or legal person who has an employment relationship with a worker (that is any person employed by an employer), and has responsibility for the undertaking or establishment.

According to the Directive concerning the minimum safety and health requirements for the use of work equipment by workers at work (89/655/EEC, modification 95/63/EC), the employer must take all measures necessary to ensure that the work equipment (for example machinery and apparatus) made available to the workers is suitable for the work carried out, and may be used by workers without impairment to their safety or health. The employer may only obtain or use work equipment that complies with the provisions of the applicable

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[63] 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.

[64] For putting into service, see section 2.3.2.

[65] For differences between directives based on Art. 95 and 138, see section 1.4.

directives, or, if no other directive is applicable or is so only partially, the minimum requirements laid down in the annex to the Directive 89/655/EEC. The employer must also take the necessary measures to ensure that work equipment is kept at such a level. Further, the employer has an obligation to provide information and training for workers as regards the use of work equipment.

According to the Directive concerning the minimum health and safety requirements for the use of personal protective equipment by workers at workplace (89/656/EEC), such equipment must comply with the relevant Community provisions on design and manufacture with respect to safety and health (that is the New Approach Directive relating to personal protective equipment). Further, the equipment must be appropriate for the risk involved, correspond to existing conditions at the workplace, take into account ergonomic requirements and the worker's state of health, fit the wearer correctly, and be compatible where more than one equipment must be used simultaneously. 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 (90/270/EEC), employers are obliged to perform an analysis of workstation in order to evaluate the safety and health conditions, particularly regarding possible risks to eyesight, physical problems and problems of mental stress. The Directive also lays down the minimum requirements for the display screen and other equipment.

According to the Directive on the introduction of measures to encourage improvements in the safety and health of workers at work (89/391/EEC), 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. Therefore, Member States are allowed to adopt or retain more stringent provisions, as long as they are compatible with the EC Treaty. Further, provision of New Approach directives must be respected and, thus, additional national provisions may neither request a modification 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

- *Any product manufactured or imported into the Community, which causes damage to individuals or private property, is covered by the Directive on product liability. 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 which 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, the Directive applies. The fact that a better product is made afterwards does not render defective 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 putting a trademark). 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 500 ECUs[66] for a single incident. Non-material damages (such as pain and suffering) may be governed by national law. 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 70 million ECU,[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 the damage was caused by this product. 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.

[66] The equivalence in national currency is calculated at the exchange rate of 25 July 1985.

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.

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[67] Accordingly, harmonised standards – although they give a presumption of conformity – do not free from liability, but they may reduce the likelihood of damages. For presumption of conformity, see section 4.3.

[68] According to the Court of Justice (case C-300/95) this refers to an objective state of knowledge, related not only to safety standards existing in a particular sector, but to any high standard the producer is presumed to be aware of and that it was accessible to him. Liability for development risks exists only in two Member States.

4. COMPLIANCE WITH DIRECTIVES[69]

4.1. Essential requirements

- *Essential requirements lay down the necessary elements for protecting the public interest.*
- *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.*

A fundamental principle of 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

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[69] This chapter does not apply to the Directives on refrigeration appliances (the efficiency levels are laid down in the annex 1 to the Directive) and marine equipment (such equipment has to meet the applicable requirements of the international conventions, the relevant resolutions and circulars of the International Maritime Organization (IMO), and the relevant international testing standards instead of essential requirements).

[70] According to the Directive relating to construction products essential requirements are mandatory only when and where they are regulated in national legislation. Further, these essential requirements refer to construction works: Construction products intended for use in construction works may be placed on the market only if they are fit for the intended use, i.e. they have such characteristics that the works in which they are to be incorporated satisfy the essential requirements.

[71] For technical documentation, see section 5.3.

assessment of whether requirements have been met or not is 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 aimed 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]

4.2. 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 of the Member States.*[73]

- *Harmonised standards in the meaning of 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]

Directive 98/34/EC defines European standards as technical specifications adopted by European standards organisations[75] for repeated or continuous application with which compliance is not compulsory. According to the internal rules of these organisations, European standards must be transposed at national level. This transposition means that the European standards in question must be made available as national standards in an identical way, and that all conflicting national standards must be withdrawn in a given period.

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[72] According to the Directive on construction products, essential requirements are given concrete form in interpretative documents. In order to take into account different levels of protection, each essential requirement may give rise to the establishment of classes in the interpretative documents and the technical specifications.
According to the Directive on high-speed rail system each sub-system is covered by a Technical Specification of Interoperability (TSI), which specifies the essential requirements.

[73] For the Directive relating to low voltage equipment no explicit mandate is issued. Instead, CENELEC has a standing mandate for elaborating standards in the framework of this Directive.

[74] Although European standards are considered as harmonised before a 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 procedures.

[75] CEN = European Committee for Standardization, CENELEC = European Committee for Electrotechnical Standardization, ETSI = European Telecommunication Standards Institute.

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,[76] 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 the 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.[77]

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 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 co-operation 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 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 environment, 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

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[76] Exceptionally, harmonisation documents adopted by European standards organisations can also be accepted by the Commission as harmonised standards. The differences between European 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 the document, and by the withdrawal of conflicting national standards. However, it is acceptable to retain or publish a national standard dealing with a subject covered by the harmonisation document, provided that it has technically equivalent contents. In addition, harmonisation documents allow for national divergences under special conditions, which could create some application problems if they were accepted as harmonised standards.
Publicly available specifications, which are adopted by private consortia of companies, or other documents from European standards organisations, are not harmonised standards in the meaning of New Approach.

[77] The term "mandate", although common, is not the only term used in this context. Rather than focusing on the terminology, it is important to consider that standardisation activities must be based on a formal invitation of the Commission, on which Member States were consulted.

[78] The revision of these Guidelines is underway. The basic principles laid down in the Guidelines have been re-enforced by the Council conclusions on efficiency and accountability in European standardisation that were adopted on 18 May 1998.

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 which 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 specification in order to meet all the essential requirements of the directive.

Table 4/1: Standardisation procedure under the New Approach

1.	A mandate is drawn up, following consultation of the Member States.
2.	The mandate is transmitted to European standards organisations.
3.	European standards organisations accept the mandate.[80]
4.	European standards organisations elaborate a (joint) programme.
5.	Technical Committee elaborates a draft standard.
6.	European standards organisations and national standards bodies organise public enquiry.
7.	Technical Committee considers comments.
8.	National standards bodies vote/ European standards organisations ratify.
9.	European standards organisations transmit references to the Commission.
10.	Commission publishes the references.
11.	National standards bodies transpose the European standard.
12.	National authorities publish references of national standards.

[79] Still, the Commission may verify that the terms of the mandate are fulfilled (see section 4.3).
[80] This is without prejudice to their right to refuse a mandate.

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.*[81]

- *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/newapproa/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.*[83]

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.

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[81] As regards the Directive relating to low voltage equipment a harmonised standard provides a presumption of conformity after ratification by CENELEC and publication as a national standard under national procedures. The publication of the references in the Official Journal takes place only for information purposes.
According to the Directives relating to radio and telecommunications terminal equipment, and packaging and packaging waste, conformity with a harmonised standard, whose reference has been published in the Official Journal, confers a presumption of conformity with the corresponding essential requirements.

[82] For further information, see also http://www.NewApproach.org.

[83] The Directive relating to construction products is an exception to this general principle. The Directive on the high-speed rail system requires the application of technical specifications for interoperability. The Directive relating to telecommunications terminal equipment allows that harmonised standards are transformed into common technical regulations, compliance with which is mandatory.

[84] In the case of the Directive on construction products, the presumption of fitness for the intended use.

The application of harmonised standards that give a presumption of conformity remains voluntary.[83] The manufacturer can choose whether or not he refers 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.[85]

According to certain directives, national standards may give a presumption of conformity – as a transitional measure – in so far as there is no harmonised standard covering the same area.[86] Member States may communicate to the Commission the text of those national standards, which they consider to meet the essential requirements. After consulting the Committee under the Directive 98/34/EC and, if provided for, the sectoral Committee, the Commission notifies the Member States whether or not the national standard should enjoy presumption of conformity. If the opinion is positive, Member States are required to publish references of such standards. The reference is also published in the Official Journal. This procedure has not been used so far in order to give full priority to the developing of European standards.

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[85] See Directives relating to simple pressure vessel, toys, electromagnetic compatibility, machinery, lifts and recreational craft.
The lack of harmonised standards may lead to the application of a specific procedure, see the Directives relating to construction products (the European technical approval may be granted to products for which there is neither a harmonised standard, nor a recognised national standard, nor a mandate for a harmonised standard, and to products which differ significantly from harmonised or recognised national standards) and to pressure equipment (the European approval may be granted to materials which are not covered by any harmonised standard and which are intended for repeated use in the manufacture of pressure equipment).

[86] See, for instance, Directives relating to construction products, electromagnetic compatibility and gas appliances.

4.4. Withdrawal of the presumption of conformity

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

New Approach directives contain a clause according to which a harmonised standard can be challenged:[87]

⇒ Where a Member State or the Commission considers that a harmonised standard does not fully meet the essential requirements, the matter shall be brought before the Committee established under the Directive 98/34/EC, and, if provided for, the sectoral Committee, giving reasons for doing so.
⇒ The Committee shall deliver an opinion without delay.
⇒ In the light of the committee's opinion, the Commission shall inform the Member States to 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,[88] 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.

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[87] In addition, the Directive relating to radio and telecommunications terminal equipment provides a possibility for the Commission, in the case of shortcomings of harmonised standards, to publish in the Official Journal guidelines to the interpretation of harmonised standards, or the conditions under which compliance is possible.

[88] Only national standards, which may give a presumption of conformity according to certain directives as a transitional measure before the area is covered by a harmonised standard, are subject to a verification procedure (see section 4.3).

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 standard 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 standards organisations. This takes place on the basis of their own initiative,[89] 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 challenge the contents of the harmonised standard, indicating that it could not 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 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 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 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.

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[89] Under the terms of their internal regulations or rules of procedure, the European standards organisations review their standards – whether or not based on a mandate – at intervals not exceeding five years.

The reference of the revised harmonised standard, the reference of the old harmonised standard, and the date where the presumption of conformity of the old standard finishes are published together in the Official Journal.

5. CONFORMITY ASSESSMENT PROCEDURE

5.1. The modules[90]

- *Conformity assessment is subdivided into modules, which comprise a limited number of different procedures applicable to a widest range of products.*
- *The modules relate to the design phase of products, their production phase or both. The eight basic modules and their eight possible variants can be combined with each other in a variety of ways in order to establish complete conformity assessment procedures.*
- *As a general rule, a product is subject to conformity assessment according to a module during the design as well as the production phase.*
- *Each New Approach directive describes the range and contents of possible conformity assessment procedures, which are considered to give the necessary level of protection. The directives also set out the criteria governing the conditions under which the manufacturer can make his choice, if more than one option is provided for.*

Conformity assessment according to the modules is either based on the intervention of a first party (manufacturer) or a third party (notified body),[91] and relates to the design phase of products, to their production phase or both (see tables 5/1 and 5/3 and picture 5/2). Should a manufacturer subcontract design or production, he still remains responsible for the execution of conformity assessment for both phases.[92]

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 risks involved, the economic infrastructures of the given sector (such as existence or non-existence of third parties), the types and importance of production to ensure a high degree of protection as defined in Art. 95(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 unnecessarily 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 within the same category, or

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[90] This section does not apply to the Directive on construction products, according to which the Commission specifies the conformity assessment procedure for a product, or given family of products, based on methods laid down in the annex to this Directive.

[91] The Directive relating to pressure equipment has introduced user inspectorates, which operate as second party.

[92] For manufacturer's responsibilities, see section 3.1.1.

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.[93]

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 the competitiveness.

[93] According to the Directive on high-speed rail system the conformity assessment procedures are defined in the Technical Specifications of Interoperability, following the modules provided for in the Decision 93/465/EEC.

Table 5/1: Basic modules

A	Internal control of production	Covers internal design and production control. This module does not require a notified body to take action.
B	EC type-examination	Covers the design phase, and must be followed up by a module providing for assessment in the production phase. The EC type-examination certificate is issued by a notified body.
C	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.
D	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.
E	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.
F	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.
G	Unit verification	Covers the design and production phases. Each individual product is examined by a notified body, which issues a certificate of conformity.
H	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.

Picture 5/2: Simplified flowchart of conformity assessment procedures

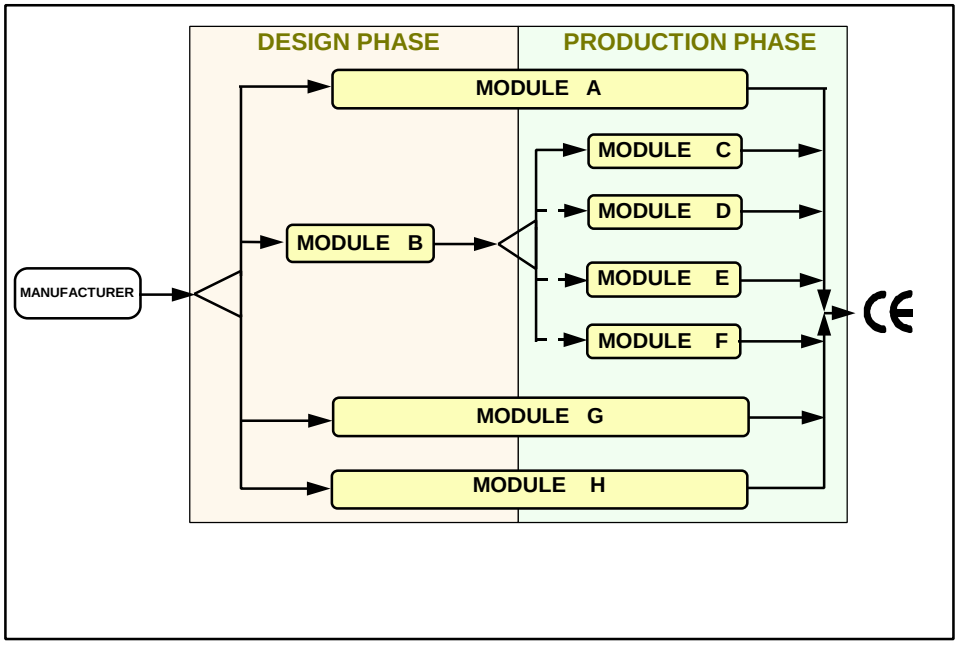

Table 5/3: Variants of basic modules

		Additional elements compared to basic modules
Aa1 and Cbis1	Internal production control, and one or more tests on one or more specific aspect of the finished product	Intervention of a notified body either at design or production stage regarding testing carried out by the manufacturer or on his behalf. The products concerned and the applicable tests are specified in the directive.
Aa2 and Cbis2	Internal production control, and product checks at random intervals	Intervention of a notified body regarding product checks at production stage. The relevant aspects of the checks are specified in the directive.
Dbis	Production quality assurance without use of module B	A technical documentation is required.
Ebis	Product quality assurance without use of module B	A technical documentation is required.
Fbis	Product verification without use of module B	A technical documentation is required.
Hbis	Full quality assurance with design control	A notified body analyses the design of a product or a product and its variants, and issues an EC design examination certificate.

5.2 Application of quality system standards

- *The use of quality systems for the purpose 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 respectively 9003, although it provides a useful means in establishing compliance. The manufacturer is free to apply other quality system models for the purpose of complying with these modules than those based on EN ISO 9000 standards.*

- *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.*

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 fulfil the applicable essential requirements.

A quality system implemented on the basis of the EN ISO 9001, 9002 or 9003[94] standard gives a presumption of conformity with the respective modules with regard to the provisions in the modules that these standards cover, and provided 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

[94] 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. Further, 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 include some additional requirements.

New Approach directives, in particular:

- the quality objectives, quality planning, quality manual and control of documents must fully take onboard 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 fulfilment 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 production process and finished products must identify and use methods, which are either identified in standards or other methods appropriate to ensure that the essential requirements are met; and
- quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, must be suitable to ensure the fulfilment of the applicable essential requirements.

The manufacturer has the responsibility to implement and continuously operate the quality system in such a way that regulatory needs are respected. The notified body must ensure in its assessment, approval and continued surveillance, that this is the case.

Very few directives refer explicitly to the quality system standards.[95] However, a general reference can be found in the Decision 93/465/EEC.

Directives may lay down additional provisions for conformity assessment according to modules D, E, H, and their variants which require that compliance with standards EN ISO 9001, 9002 and 9003 is completed with supplementary elements. This is to take into consideration the specificity of the products for which it is implemented.[96]Technical documentation.

[95] See the Directives relating to telecommunications terminal equipment and lifts.

[96] For example, the quality systems set up according to the Directives relating to active implantable medical devices and medical devices must be supplemented by standard EN 46001, or accordingly by standard EN 46002.

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.[97]

The technical documentation 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.[98] This is the responsibility of the manufacturer, or his 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.[99]

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 and, 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. EC Declaration of conformity

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97 For placing on the market, see section 2.3.1.

98 According to the Directives relating to active implantable medical devices, medical devices and in vitro diagnostic medical devices these documents must be kept for five years. According to the Directive relating to refrigeration appliances the time period is three years. The Directives relating to simple pressure vessels, toys, non-automatic weighing instruments, gas appliances and construction products do not define a time period, but the general rule should be applied also to the technical documentation required according to these Directives.

99 For responsibilities of the manufacturer, his authorised representative, the importer and person responsible for placing on the market, see sections 3.1 – 3.3.

100 See the Directives relating to simple pressure vessels, machinery (for module B), non-automatic weighing instruments, active implantable medical devices, gas appliances, telecommunications terminal equipment, medical devices, potentially explosive atmospheres, lifts (for module B, C, D, G, H), pressure equipment, in vitro diagnostic medical devices, and radio and telecommunications terminal equipment.

5.4. EC Declaration of conformity

- *The manufacturer or his authorised representative established within the Community must draw up an EC declaration of conformity as a part of a 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, his authorised representative, if applicable the notified body, the product, and where appropriate a reference to harmonised standards or other normative documents.*

New Approach directives impose an obligation on the manufacturer, or his 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 his 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.[99]

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 his 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;

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[101] As an exception, the Directive relating to toys does not require an EC declaration of conformity.

[102] According to the Directives relating to active implantable medical devices, medical devices and in vitro diagnostic medical devices the EC declaration must be kept for five years. According to the Directive relating to refrigeration appliances the time period is three years. The Directives relating to simple pressure vessels, machinery, non-automatic weighing instruments, gas appliances and construction products do not define a time period, but the general rule should be applied also to the EC declaration required according to these Directives.

- 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, his 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 his 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 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 system 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 Art. 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, his authorised representative or the distributor. Additionally, a copy of the declaration in the original language should be supplied.

[103] It is not necessary for the signatory to be domiciled in the Community. A manufacturer established outside the Community is entitled to carry out all the certification procedures at his premises and, therefore, to sign the declaration of conformity, unless otherwise provided for in the directive(s).

6. NOTIFIED BODIES

6.1. Principles of notification

- *Notified bodies carry out the task 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 continuously comply with the requirements of the directives and the principles laid down in the 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 follow the practice established by the accreditation organisations.*

- *The EN 45000 series of standards and accreditation are important instruments to help establishing conformity with the requirements of the applicable directive.*

Notified bodies[104] take responsibilities in areas of public interests 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 a body which complies with the requirements laid down in the directives and the Decision 93/465/EEC.

Since notification falls within the discretion of Member States, they are not obliged under Community law to notify all the bodies demonstrating technical competence. Further, Member States are not obliged 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.

[104] Under certain New Approach directives this body is not called 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 apply also to recognised third-party organisations referred to in art. 13 (except section 6.4) and to the user inspectorates referred to in art. 14 (only sections 6.1 and 6.2) of the Directive on pressure equipment.

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 of standards 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.

[105] For the purpose of the Directive on marine equipment notified bodies shall fulfil the requirements of the relevant standards of the EN 45000 series.

[106] European Accreditation (EA) has set up a system of mutual recognition.

Table 6/1: The EN 45000 series of standards relevant for notified bodies

	Certification bodies	Testing laboratories	Inspection bodies
Criteria for accreditation bodies	EN 45010	EN 45002 EN 45003	EN 45010
Accreditation and assessment criteria	EN 45010	EN 45002 EN 45003	EN 45010
Operational criteria	EN 45011 EN 45012 EN 45013	EN 45001	EN 45004

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.[107]

[107] The standard EN 45001 sets out the general requirements a laboratory must meet if it is to be recognised to carry out testing or calibration. To be eligible as a notified body the laboratory must be a third party.
The standard EN 45004 specifies the general criteria for the competence of bodies performing inspection. Inspection involves examination of a product design, product, service, process or plant and determination of their conformity with specific requirements or, on the basis of professional judgement, general requirements. To be eligible as a notified body the inspection body must be a third party (type A).
The standard EN 45011 specifies the general requirements that a third party operating a product certification system must meet. Product certification entails assurance that a product conforms to specified requirements such as standards, regulations, specifications or other normative documents.
Inspection and product certification have a similarity and there is some overlapping in the definitions. Generally, inspection involves direct determination of the conformity with specifications or general requirements of unique, often complex or critical, products or small series of products, whereas product certification primarily involves indirect determination of the conformity of products manufactured in long series.
The standard EN 45012 specifies the general requirements that a third party operating quality system certification must meet. 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.

Table 6/2: Relevant standards of the EN 45000 series for each module

Module	EN 45000 standard(s) applicable
Aa1, Aa2	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)
B	EN 45004 (EN 45001 to be observed for testing required), or EN 45011 (EN 45001 to be observed for testing required)
Cbis1, Cbis2	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)
D, Dbis	EN 45012 (+product related knowledge)
E, Ebis	EN 45012 (+product related knowledge)
F, Fbis	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)
G	EN 45004 (EN 45001 to be observed for testing required), or EN 45011 ((EN 45001 to be observed for testing required)
H	EN 45012 (+product related knowledge)
Hbis	EN 45012 + EN 45004 or EN 45011

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, as the standards, relate to different technical activities. However, for such bodies a complete assessments or re-assessments 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 in 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 secure that the national accreditation bodies are operating on the same basis and according to the same requirements and, thus, providing 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 Journal 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.*

[108] This section does not apply to the body mentioned in art. 8 (2) of the Directive relating to low voltage equipment and to the competent body referred to in art. 10 of the Directive relating to electromagnetic compatibility.

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[109] 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 Journal 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 national level the information concerning all notified bodies (those they notify as well as those notified by other Member States).

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, at its own initiative or after complaint, that a notified body does not comply with the requirements or fulfil 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 Art. 226 of the EC Treaty against the notifying Member State.

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[109] 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.

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

When a notified body ceases to fulfil 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 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 Art. 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.

A withdrawal of the 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.

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 activity, unless liability is assured under the national legislation of the notifying Member State.*
- *Notified bodies shall participate in co-ordination activities.*[110] *They shall also take part directly or be represented in European standardisation, or otherwise ensure that they know the situation of relevant standards.*

Notified bodies must keep their national notifying authorities informed of their activities (for example concerning the conduct of conformity assessment, availability of resources, subcontracting, situations of conflicts of interest), either directly or via an authorised 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 independence and impartiality and integrity is ensured, and they are identifiable as a legal entity to bear rights and obligations.

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[110] For co-ordination of notified bodies, see section 6.6.

[111] 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.

In order to guarantee impartiality, the notified body and its staff has to be free from any commercial, financial and other pressure which 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, his 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 to exchange technical information and guidance between the manufacturer, his authorised representative, a supplier 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, which has sufficient knowledge and experience relating to products and conformity assessment procedure in question, and which is 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 controlling 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

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[112] For the added value in relation with 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.

ensure that no results or other information is disclosed to any other party than the competent authority in question, and to the manufacturer or his 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 activities of the notified body. The manufacturer in particular retains, however, always 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]

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 the area of public interests.*
- *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]

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[114] For product liability, see section 3.7.

[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.

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, but at least 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 his authorised representative regarding the directive in question, apply the conformity assessment procedure without unnecessary burden for the economic operators, and refrain from proposing additional certification or marking that has no added value.[116]

To avoid unnecessary burden 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 to ensure 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.

[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 to ensure 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 transparency and confidence of 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 withdraws or limits 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 subcontractor with the requirements laid down in the relevant directive.

Information on subcontracting activities and on the competence of the subcontractor 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 notified body shall in all cases have a direct private-law contractual link with its subcontractors to ensure the fulfilling of its general responsibilities.[117] Serial subcontracting is prohibited in order to avoid undermining the coherence of the system and the 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. Co-ordination and co-operation

- *A coherent application of the conformity assessment procedures requires a close co-operation 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 co-ordination with Member States, also ensures that co-operation is organised between the notified bodies.*

The co-ordination of Member States is carried out through the sectoral working groups of governmental experts established under the directives.[118] The co-operation of notified bodies takes place under the authority of the relevant working groups.

Co-operation 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 co-operation 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.

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[117] See section 6.3.
[118] See section 1.2.

In recognition of the fact that notified bodies fulfil tasks delegated to them by public authorities they must take part in co-ordination activities organised by the Commission. If a body refuses to co-operate, the notification might 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 of 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 observes 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.

[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 directives providing for the affixing of the CE marking mostly follow the principles of New Approach and Global Approach, but this is in itself irrelevant for the application of the CE marking. In fact, CE marking can be introduced in Community legislation as legal conformity marking if:

⇒ the method of total harmonisation is used, which means that diverging national regulations that cover the same public interests as the directive are prohibited; and
⇒ the directive contains conformity assessment procedures according to the 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 the 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.

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[120] This chapter does not apply to the Directive on high-speed rail system.
[121] For market surveillance, see chapter 8.
[122] Conformity assessment according to the Directive relating to construction products does not follow the Decision 93/465/EEC. However, this Directive provides for the CE marking.
[123] The Directive on marine equipment does not provide for a CE marking, but instead for a special conformity mark to which the guidelines of this chapter generally apply.

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 Directiveon in vitro diagnostic medical devices);
- they are accompanied by a certificate of conformity (as is the case for components referred to in the Directive relating to potentially explosives atmospheres which are intended to be corporated into equipment or protective systems, and fittings referred to in the Directive relating to gas appliances);

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[124] For products submitted to directives, see section 2.1.

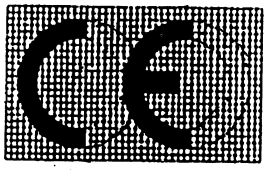
[125] In addition, the Directive on pressure equipment entitles Member States to authorise, on their territory, the placing on the market and the putting into service by users, of pressure equipment or assemblies not bearing the CE marking, but that have been subject to a conformity assessment carried out by a user inspectorate instead of a notified body.

- the product bears the manufacturer's name and an indication of maximum capacity (as is the case for instruments not subject to conformity assessment according to the Directive relating to non-automatic weighing instruments); or
- the product is manufactured in accordance with sound engineering practice (as is the case for certain vessels referred to in the Directives relating to simple pressure vessels and pressure equipment).

During the transitional period of a directive the manufacturer usually has the choice to either meet the requirements of the directive or the relevant national regulations. The option chosen and, hence, the extent of the conformity expression enshrined in the CE marking shall be clarified by the manufacturer in the EC declaration of conformity, and in the documents, notices or instructions accompanying the product.[126]

7.3. Affixing of the CE marking

- *The CE marking must be affixed by the manufacturer, or by his 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 warranted 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 identification number is affixed, under the responsibility of the notified body, by the manufacturer or his authorised representative established in the Community.*

The manufacturer, whether established inside or outside the Community, is the person ultimately responsible for the conformity of the product with the provisions of the directive and the affixing of the CE marking. The manufacturer may appoint an authorised representative established in the Community to act on his behalf. The person responsible for placing the product on the market may, exceptionally, be deemed to have assumed the responsibilities of the manufacturer.[127]

The CE marking may not, in principle, be affixed until the conformity assessment procedure has been completed to ensure that the product complies with all the provisions of the relevant directives. This will usually be at the end of the production phase. This poses no problem if, for example, the CE marking is on a data plate that is not affixed to the product until after the final inspection. However, if the CE marking forms an inseparable part of the

[126] For the transitional period, see section 2.4.
[127] See sections 3.1 – 3.3 .

product, or of a component, for example by stamping or casting, the marking can be affixed at any other stage of the production phase, provided that the conformity of the product is verified as appropriate throughout the production phase.

The CE marking shall be, as a rule, affixed to the product or to its data plate. 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 type 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.[128]

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.[129] It shall also be indelible so that it cannot be removed under normal circumstances without leaving noticeable traces (for example some product standards use a rub test with water and petroleum spirits). However, this does not mean 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.[130] 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 the CE marking is followed by several identification numbers.

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[128] The provisions regarding the affixing of the CE marking vary between directives; in some sectors they are more stringent (see for instance Directives relating to simple pressure vessels, machinery, non-automatic weighing instruments, active implantable medical devices, gas appliances, medical devices, telecommunications terminal equipment, hot-water boilers, recreational craft – as regards boats –, lifts, potentially explosive atmospheres, refrigeration appliances, pressure equipment, in vitro diagnostic medical devices, and radio and telecommunications terminal equipment), and in other sectors more flexible (see for instance Directives relating to low voltage equipment, toys, construction products and electromagnetic compatibility).

[129] According to the Directives relating to machinery, personal protective equipment, active implantable medical devices, medical devices, potentially explosives atmospheres, lifts (as regards safety components), in vitro diagnostic medical devices, and radio and telecommunications terminal equipment the minimum dimension of the CE marking may be waived for small devices. The same applies to the conformity mark provided for in the Directive on marine equipment.

[130] See section 5.1 and annex 7.

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 Cbis1 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 notied body assumes the responsibility:

- for the tests on specific aspects of the product (modules Aa1 and Cbis1 where the notified body intervened during the production phase);
- for product checks (modules Aa2 and Cbis2);
- 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.[131]

7.4. 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.*

[131] For instance, the symbol to indicate that telecommunications terminal equipment is suitable for connection to the public telecommunications network, the energy performance label required for hot-water boilers, the explosion protection symbol required for equipment and protective systems intended for use in potentially explosives atmospheres, or the equipment class identifier required for radio equipment. Some directives also require that the last digits of the year in which the CE marking was affixed is indicated.

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.[132] 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.

[132] The wording used in various New Approach directives varies slightly, but any other interpretation would prevent achieving the purpose of the applicable provisions.

8. MARKET SURVEILLANCE

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.*

Enforcement of Community legislation is an obligation on Member States: Art. 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 provision of the New Approach directives that require Member States to allow free movement of products which 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]

[133] For application of the safeguard clause procedure, see section 8.3.

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 which 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 to allocate 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 co-operation 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 case of non-compliance, to take appropriate action 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, which has 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.

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[134] See art. 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 Art. 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).

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 usually 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: (1) 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, and (2) subsequently, when necessary, they shall take action to establish conformity.*

- *Although market surveillance operations cannot take place during the design and product 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.[138] 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

[137] Directives relating to active implantable medical devices, potentially explosive atmospheres, medical devices and in vitro diagnostic medical devices have provisions on confidentiality.

[138] For placing on the market and putting into service, see section 2.3.

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.[142] Another exception to the principle, that market surveillance can only take place after the manufacturer has taken formal responsibility for his 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-

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[139] See also section 8.2.3.

[140] This is usually not necessary for consumer products that are made available in shops or otherwise on the market. It is more important for products (for example machinery and pressure equipment) that are directly, after being manufactured, installed and put into service at the premises of the client.

[141] For the responsibility to provide information, see sections 3.1. – 3.4 and 6.3.

[142] An explicit provision has been included in the Directive relating to toys (art. 12). However, such a provision is difficult to apply where the manufacturing process takes place outside the Community.

compliance.[143] 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.[144] 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), co-ordination 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 Art. 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, his 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.[145]

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 co-operation. A failure to present the declaration when

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[143] According to the Directive on high-speed rail system each Member State authorises the putting into service of the structural subsystems in their territory. This is a systematic mechanism to monitor the compliance of subsystems and their interoperability constituents.

[144] Member States are obliged, according to Directive on the introduction of measures to encourage improvements in the safety and health of workers at work (89/391/EEC), to ensure adequate controls and supervision.

[145] For responsibilities, see chapter 3; for EC declaration of conformity, see section 5.4; for technical documentation, see section 5.3; for notified bodies' general responsibilities, see section 6.3.

requested by a national surveillance authority may constitute sufficient grounds for doubting the presumption of conformity with the requirements of the directive.[146]

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 need to ensure the health and safety of persons or other public interests foreseen in the directive, 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 the 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 Art. 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-

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[146] This does not apply to products covered by directives that do not provide for the EC declaration of conformity, such as the Directive relating to toys.

[147] As essential technical data is to be considered, in particular: the name and address of the manufacturer; the list of harmonised standards followed or other solutions adopted to satisfy the essential requirements; a description of the product; the operating instructions, if any; and the overall plan of the product, if any. Examples of detailed technical information are test reports, quality manual information, quality control plans and other plans, descriptions of the products and processes and standards applied.

[148] According to annex IV of the Directive relating to low voltage equipment the technical documentation must be kept on Community territory.

ROM), which allows its being 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 to be 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 his 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-compliances 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 a non-compliance should be considered as substantial.

Enforcement of conformity can be achieved by obliging the manufacturer, his authorised representative, or other responsible persons, to take required measures.[149] 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 his authorised representative, to make the product intended to be placed on the market and, if necessary, 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 his 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 subjected.[150]

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[149] For responsibilities, see chapter 3.

[150] See Directives relating to simple pressure vessels, toys, machinery, personal protective equipment, non-automatic weighing instruments, active implantable medical devices, gas appliances, potentially explosive atmospheres, medical devices, recreational craft, lifts, refrigeration appliances, pressure equipment, and in vitro diagnostic medical devices.

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 his 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 his authorised representative has been provided an opportunity to react. However, it should not delay the proceeding, if the manufacturer or his 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, his authorised representative, or other person may consider 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 that 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

[151] An explicit provision to consult has been included in the Directives relating to medical devices and in vitro diagnostic medical devices.

[152] For application of the safeguard clause procedure, see section 8.3; for administrative co-operation, see section 8.6.

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 affixed the CE marking to non-compliant products.[153] 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 can take the form of a general publication or, if the number of persons at risk is limited, it can be directed to individuals. The authority should also consider whether or not it would be necessary to restrict the use of products that have proven to be dangerous.

When a competent authority decides to restrict or prohibit the placing on the market and the putting into service of a product, or to withdraw it from the market, it should also consider - in accordance with the principle of proportionality - whether or not it would be necessary to destroy the product, or ban its export to other Member States, and to require the withdrawal of certificates. Sometimes it is also important to verify whether or not decisions need to be taken for other products which have the same technical features as those subject to market surveillance actions, in order to ensure the high level of protection.

New Approach directives may require the competent authority to take special action regarding non-compliant products. For instance, the directive relating to telecommunications terminal equipment requires Member States to disconnect equipment from the public telecommunication network if it is not used for the intended purpose.

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[153] The Directives relating to low voltage equipment, hot-water boilers, and refrigeration appliances do not explicitly require this. However, it should be considered that this obligation applies to all New Approach directives.

[154] This obligation is based on Art. 10 of the EC Treaty; see case 68/88 from the Court of Justice. Directive on civil explosives requires Member States to determine penalties to be applied for infringement of the provisions adopted in implementation of the Directive, and which must be sufficient to promote compliance with these provisions.

[155] See art. 6 of the Directive on general product safety .

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 – or, according to some directives, otherwise non-compliant – 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,

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[156] Art. 7 of the Directive on general product safety contains a safeguard clause similar to that included in the New Approach directives. The general principles that apply to the safeguard clause under the New Approach directives are, therefore, also applicable to the safeguard clause under the Directive on general product safety.
Directives relating to hot-water boilers and refrigeration appliances do not provide for a safeguard clause. However, the Directive relating refrigeration appliances contains provisions for the exchange of information.

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-conformity has to be established regarding a systematic failure in the design or 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 his authorised representative to take 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.[158]

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 means of 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 a reasonably foreseeable way. There

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[157] However, according to the Directive relating to machinery safety components and according to the Directive relating to medical devices custom-made medical devices may be subject to the safeguard clause procedure, although they may not be CE marked. The same applies to interoperability constituents according to the Directive relating to high-speed rail system. As regards the Directive on marine equipment the safeguard clause is applicable to products that bear the mark of conformity provided for in the Directive.

The Directives relating to low voltage equipment, construction products, active implantable medical devices, and radio and telecommunications terminal equipment do not lay down as a precondition for invoking the safeguard clause that the CE marking is affixed to the product. However, it should be generally considered that also under these Directives the safeguard clause is only applied to products which are considered to comply with all applicable provisions (including the provisions regarding CE marking). The reason for this is that the safeguard clause allows a Member State to challenge a product, which is, basically, subject to free movement.

For corrective action in cases where a non-compliance has been established regarding products that either are CE marked or not, see section 8.2.

[158] For administrative co-operation, see section 8.6.1.

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.[160]

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 his 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.

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[159] Directive on toys requires that toys must be safe when used as intended or in a foreseeable way, bearing in mind the normal behaviour of children.

[160] 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, in vitro diagnostic medical devices, and radio and telecommunications terminal equipment.

[161] 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.

[162] As an exemption, Member States have to inform the other Member States as well as the Commission when invoking the safeguard clause according to the Directive relating low voltage equipment.

[163] The copy is usually sent via the Permanent Representation.

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;
- name and address of manufacturer, his 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;
- the name and number of the notified body that intervened in the conformity assessment procedure, if applicable;
- 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, his authorised representative, or other responsible person, agrees to modify the product in such a way that it complies with the applicable provisions, the Member State should withdraw the safeguard clause notification.

8.3.3. Administering the safeguard clause

The Commission is responsible for administering the safeguard clause at Community level, and for ensuring that it applies to the whole of the Community. To this end, the Commission consults the interested parties to verify whether or not the action that invoked the safeguard clause can be justified. Precautions are necessary during the consultations to protect the confidentiality of the information.[164]

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 (which usually are 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.

[164] A safeguard clause that is notified according to the Directive relating to low voltage equipment is examined only if other Member States raise objection as regards the measure taken.

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 Art. 226 of the EC Treaty.[165]

Conversely, should the Commission see no justification for the national action that invoked the safeguard clause, it will ask that 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 Art. 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 matter to the Court of Justice. In such cases, legal proceedings may be taken at national level by the manufacturer, or other person who considers 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]

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[165] In addition, the Directives on medical devices and in vitro medical devices foresee a possibility to take measures at Community level.

[166] For withdrawal of the presumption of conformity, see section 4.4.

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 covered by any of the directives providing for its affixing 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.

[167] See section 7.4.

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 Art. 226 of the EC Treaty should it consider 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 data-collection 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

[168] For actions to be taken, see section 8.2.2.

[169] According to 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.

and industrial (non-food) products. It is also applicable to consumer products covered by New Approach directives and it is, in particular, important for toys and low voltage products. This is because 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 according to New Approach directives, 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 New Approach directives apply independently from RAPEX. 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.

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[171] As an exception, a vigilance system has been established for medical devices; see section 8.5.2.

[172] See Directives relating to active implantable medical devices, medical devices and in vitro diagnostic medical devices.

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 co-ordinate, 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 necessary measures are taken by the manufacturer 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 system of home and leisure accidents (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.

[173] European Parliament and Council Decision 372/99/EC.

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.

8.6. Administrative co-operation

- *Administrative co-operation 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 co-ordinate administrative co-operation.*
- *National surveillance authorities should make information available on request in a specific case and without prior request, according to mutually agreed principles and mechanisms.*
- *National surveillance authorities should consider if co-ordination of national operations provides a means to increase the efficiency of market surveillance at Community level.*
- *The information exchanged in the framework of administrative co-operation has to be covered by the requirements of professional secrecy.*
- *Administrative co-operation 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.*

8.6.1. Outline for administrative co-operation

The proper application of Community law depends upon smooth administrative co-operation to ensure uniform and efficient enforcement of Community legislation in all Member States. The obligation to co-operate is in accordance with Art. 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 co-operation 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. Co-operation 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, co-operation can be useful for exchanging views and solving practical problems.

Administrative co-operation 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 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, but also 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 New Approach directives is, basically, only applicable to CE marked products, and all non-

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[174] An explicit obligation for administrative co-operation 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 co-operate 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.

consumer products as well as minor non-compliances 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, since 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 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.

Co-operation 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, his authorised representative, or other responsible person is established, needs to be contacted.[176] 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 to which 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 could be provided for. Otherwise the sending authority is entitled to withhold the information.

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[176] For responsibilities, see sections 3.1 – 3.4.

[177] See judgement of the Court, cases 272/80 and 25/88.

Co-ordination 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 correspondent for every sector, which would co-ordinate internally as appropriate;
- agreement about the types of cases for which the communication 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 communicated in each case, including the request for further information;
- accepting the obligation to respond to enquiries within a given time scale;[178]
- 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 co-operation

Committees and working groups

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

Administrative co-operation between national authorities carrying out market surveillance is taking place in the following sectors: low voltage equipment, electromagnetic compatibility (EMC Administrative co-operation), 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 being discussed.

The emergencies committees, set up under the Directive on general product safety, regularly discusses administrative co-operation 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

[178] An information request does not infringe the right of a national authority to take whatever measures are needed to ensure compliance with New Approach directives within its jurisdiction.
[179] See Commission Decision 95/319/EC setting up a Committee of Senior Labour Inspectors.
[180] See Commission Decision 93/72/EEC on the setting-up of an Advisory Committee for co-ordination in the Internal Market field.

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 Commission their respective ministries for certain priority areas of Single Market legislation.[181] The main aim behind this provision is to enable governments to co-operate 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 of enforcing Community legislation relating to the Single Market, to raise awareness of the European dimension, to build mutual confidence between Member State administrations, and to permit cross-fertilisation of ideas.

The Commission decides, on an annual basis, the priority areas of 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;

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[181] See Council Resolution of 8 July 1996 on co-operation between administrations for the enforcement of legislation on the internal market.

[182] See Council Decision 92/481/EEC for the period 1993 – 1997, which has been extended by Council Decision 889/98/EC until the end of 1999.

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 manufacture 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 display certain characteristics which would give rise to a serious doubt as to the existence of a serious and immediate risk to health and safety, or*
  ⇒ *if they find products which 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, on 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 authority 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 doubt 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.

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[183] See section 3.1.
[184] See section 3.2.
[185] See section 3.3.

Regulation (EEC) 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**.**[186]

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:

(a) 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 eleven official Community languages.[187]

(b) 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]

[186] See Decision 93/583/EEC establishing the list of products provided for in art. 8 of Council Regulation (EEC) No 339/93. Other products included in this list are medicinal products for human use, veterinary medicinal products and foodstuffs. For placing on the market and putting into service, see section 2.3.

[187] If the products are declared for customs-approved treatment or use other than release for free circulation, and provided the market surveillance authorities have no objections, the same wording must be added, under the same conditions, to the documents relating to that treatment or use.

(c) 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 are met.

(d) The customs authorities have not been notified of any action taken by the market surveillance authorities.

⇒ In this case the products in question must be released for free circulation, at the latest within three working days from the suspension of release, 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:

(a) 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 art. 9 of the Directive on general product safety.[188]

(b) 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.

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[188] For the application of the Directive on general product safety to products covered by New Approach directives, see section 2.2.2; for the rapid exchange of information on dangers arising from the use of consumer products, see section 8.5.1.

(c) 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 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 co-operation 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. The 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 exactly in 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 co-operation between the Commission and the administration of the EEA EFTA States. The Commission seeks informally 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, a close co-operation 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 the 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 case where a Member State triggers a safeguard clause, consultations between the Commission and the Surveillance Authority are envisaged. The Commission communicates its decision to the EFTA Surveillance Authority, which sends it to the EEA EFTA States for further actions. If an EEA EFTA State does not follow the decision, the Surveillance Authority can initiate an infringement procedure.

9.1.4. Mutual Recognition Agreements and European Conformity Assessment Protocols

The mandate from the Council to the Commission to negotiate Mutual Recognition Agreements and European Conformity Assessment Protocols indicated the objective that 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.[189]

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

[189] See section 9.2 for Mutual Recognition Agreements and 9.3 for European Conformity Assessment Protocols.

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.

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 Community in its relations with third countries endeavours to promote international trade of regulated products, in particular by concluding Mutual Recognition Agreements (MRAs) on the basis of Art. 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 which 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 a 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 requires 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.

MRAs are not based on the necessity to mutually accept other Party's standards or technical regulations, or to consider the legislation of the two Parties as equivalent. However, MRAs

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[190] This is the principal difference with subcontracting that provides only for some of the procedures, such as tests.

[191] According to some MRAs the rule of origin may not be applicable (such as MRAs with USA and Canada).

can pave the way towards a harmonised system of standardisation and certifications of the Parties. Nevertheless, the two legislations are, as a rule, deemed to ensure a comparable level regarding the protection of health, safety, environment or other public interests. Moreover, MRAs increase the transparency of the regulatory systems, since the different systems are shown to the others countries and they have to demonstrate coherence.

As a result of the different conditions established and the interest of third countries and the Community, the Commission has been authorised in 1992 to negotiate with the following countries: United States, Japan, Canada, Australia, New Zealand, Hong Kong, Israel, Singapore, Philippines, Republic of Korea and Switzerland.

At the moment (May 1999), the Commission has finalised negotiations with Australia, New Zealand, United States, Canada, Switzerland and Israel,[192] and is negotiating with Japan. The concluded MRAs all contain commitments for further negotiations.

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, 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 given 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.

[192] The MRA with Israel covers only Good Laboratory Practice.

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 could have confidence.*

- *Technical assistance aims to achieve to the availability of high quality products on the market.*

Technical assistance is a transfer of knowledge and legislation policies, such as New Approach and 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 country in the technical areas.

Technical assistance programmes take place in the fields of institutional co-operation, 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 usually are 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 fulfilment 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 have subsequently been used as a preliminary step towards the possible acceptance of these countries into the European Union.

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.*

The TBT Agreement lays down obligations, which apply to technical regulations and conformity assessment procedures issued either on a national or 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 issue persists, the disagreement may lead to a consultation procedure and, eventually, to a dispute settlement.