

Europa



Business Support Programme

Phare Business Support Programme - SMECA

European standardisation and normalisation and quality management



The European Standardisation System

This training set is designed to provide a general overview of the European Voluntary Standardisation System and its significance for SMEs. It is assumed that the readers are not yet familiar with all the facets of the system, including aspects such as the elimination of barriers to trade, certification and conformity assessment. It is not a most detailed presentation of standardisation but an instrument to help users understand the principles and the outline of the functioning of the system.

References and links are given to detailed documents and sources of information for those interested in further studying the foundations and the implementation of the European Standardisation System.

The training material is divided into four major chapters:

- Standards
Gives definitions, basic principles and benefits of standards
- Standardisation system
Presents the European, International and National bodies and their interrelations
- Elimination of barriers to trade
Deals with policy and the corresponding instruments: Directives, Regulations and the New Approach
- Conformity assessment
Describes the system of Global Approach, Accreditation, Certification, Notified Bodies and CE marking

The layout of the material is schematically given below. Links provided take the reader directly to the relevant page.

The above four chapters describe the main building blocks of the European Standardisation. The standards are of course one of the basic elements.

The Standardisation System is the network of institutions that create standards including the rules of their interrelation.

The chapter on the elimination of barriers to trade presents the European Union directives and regulations that are the other basic element of the European Standardisation. Their function is to guarantee on the one hand the elementary safety and the general public interests with regard to products and services and on the other hand the free movement of products and services within the European Union. The New Approach is the reformed system for adopting directives that prescribe only the essential requirements, in the public interest, of products and services that are free to move in the European Union if they conform to these requirements. The New Approach directives refer to standards that prescribe the exact technical requirements.

The chapter on Conformity Assessment describes the elements of the system of certification of conformity that has been set up under the Global Approach to guarantee that the essential safety and public interest requirements have been met. Once conformity is certified, goods and services can freely move across national borders. The system comprises the elements of accreditation, certification, notification and CE marking.

STANDARDISATION			
STANDARDS	STANDARDISATION SYSTEM	ELIMINATION OF BARRIERS TO TRADE	CONFORMITY ASSESSMENT
Definition	European standardisation system	Elimination of barriers to trade	Conformity
Types of standards	European standards bodies	EU Standardisation and Certification Policy	Accreditation and certification
Principles	CEN SYSTEM	New Approach	Accreditation
Benefits	Internal Regulations	Fundamental principles	Modular approach
Specifications - standards - regulations	International Agreements	General outline	CE-marking
Voluntary / Mandatory character	Work programme	New approach Directives	notified body

1.1 What is a standard?

- ❑ document
- ❑ **established** by consensus
- ❑ approved by a recognised body
- ❑ that provides, for common and repeated use
- ❑ rules, guidelines or characteristics for activities or their results
- ❑ aimed at the achievement of the optimum degree of order in a given context
- ❑ based on the consolidated results of science, technology and experience
- ❑ aimed at the promotion of optimum community benefits

This is the definition of “Standard” as contained in EN 45020:1993 “General terms and their definitions concerning standardisation and related activities (ISO/IEC Guide 2:1991)”.

Consensus is defined in EN 45020 as “general agreement, characterised by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the view of all parties concerned and to reconcile any conflicting argument (*Note: consensus need not imply unanimity.*) (1. 7 of EN 45020).

*The definition in the **Directive 83/189** reads:*

“a technical specification approved by a recognised standardising body for repeated or continuous application, with which compliance is not compulsory”.

*The definition of “standard” in the **WTO Code of Good Practice for Standardisation** reads:*

“Document approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method”

1.2 Types of standards

- ❖ **basic standards**
- ❖ **terminology standards**
- ❖ **testing standards**
- ❖ **product standards**
- ❖ **process standards**
- ❖ **service standards**
- ❖ **interface standards**
- ❖ **standards on data to be provided**

BASIC STANDARD: Standard that has a wide-ranging coverage or contains general provisions for one particular field (5.1)

TERMINOLOGY STANDARD: Standard that is concerned with terms, usually accompanied by their definitions and, sometimes, by explanatory notes, illustrations, examples etc. (5.2)

TESTING STANDARD: Standard that is concerned with test methods, sometimes supplemented with other provisions related to testing, such as sampling, use of statistical methods, sequence of test (5.3)

PRODUCT STANDARD: Standard that specified requirements to be fulfilled by a product or a group of products, to establish its fitness for purpose (5.4)

PROCESS STANDARD: Standard that specifies requirements to be fulfilled by a process, to establish its fitness for purpose (5.5)

SERVICE STANDARD: Standard that specifies requirements to be fulfilled by a service, to establish its fitness for purpose (5.6)

INTERFACE STANDARD: Standard that specifies requirements concerned with the compatibility of products or systems at their points of interconnection (5.7)

STANDARD ON DATA TO BE PROVIDED: Standard that contains a list of characteristics for which values or other data are to be stated for specifying the product, process or service (5.8)

Note: Numbers in brackets indicate the respective paragraph of EN 45020

1.3 Principles of standardisation

- **consensus**
- **openness (involvement of all stakeholders)**
- **transparency**
- **quality of results**
- **coherence**

Consensus See Definitions 1.1 What is a Standard (page 1.1)

INVOLVEMENT OF ALL STAKEHOLDERS: all interested parties must have the right to participate in and contribute to the elaboration of standards.

TRANSPARENCY: already at the initiation phase (standards project, creation of a Technical Committee...) the project is made public (via standards bulletins etc.) or even notified to a defined body (cf. notification procedures according to EU Directive 98/34 or WTO Code of Good Practice for Standardisation).

COHERENCE: Standards define the state of the art; therefore a standards collection shall be a coherent set of standards (the standards should not contradict each other).

Furthermore standards should be

- wanted by the parties concerned and prepared with the voluntary commitment to their use
- concise, clear, unambiguous and user friendly
- able to achieve benefits from their use that are at least commensurate to the cost of producing and maintaining them
- prepared for the widest application consistent with meeting the needs of the interested parties with primacy given to international standardisation

(c.f. also BSI "Standardisation - the principles" 94/01)

1.4 Benefits of standardisation for the various stakeholders

- ✓ **simplification of the growing variety of products and procedures in human life**
- ✓ **variety control and efficient use of materials, energy and human resources**
- ✓ **compatibility and interchangeability communication**
- ✓ **safety, health and protection of life and the environment**
- ✓ **reduction of the degree of market uncertainty**
- ✓ **protection of consumers and community interests**
- ✓ **fitness for purpose**
- ✓ **elimination of trade barriers**

Let us quote Jacques Repussard (“Technical Standards as an Aid to European Integration”, *Revue du Marché commun et de l'Union Européenne*, no 396 mars 1996): “*From the industrial to the social stakes:*

If a technical standard can by itself solve a given problem (by defining for example a coherent system of dimensional co-ordination) a complete collection of thousands of standards dealing with a multitude of products and techniques can exert an important structural effect in the whole area of business which takes up these standards, and it also modulates the relative competitiveness of the industry active in the sector.

The existence of a comprehensive and stable set of technical standards is thus likely to reduce the degree of market uncertainty for companies and to create more transparency in competitive situations; choices for long-term investments are thereby made easier.

The fact that consumers start to behave in a predictable way and to refer to a system of standards recognised by them influences the competitiveness of companies which are competing in the consumer market and this can modify the economic balance in quite a significant way.

There is only one step further to realise that standards can be even more effective and influential if they succeed in taking into account expectations of the whole of society, that is to say that standards resolve the problems of industrial rationalisation in the light of society's expectations.”

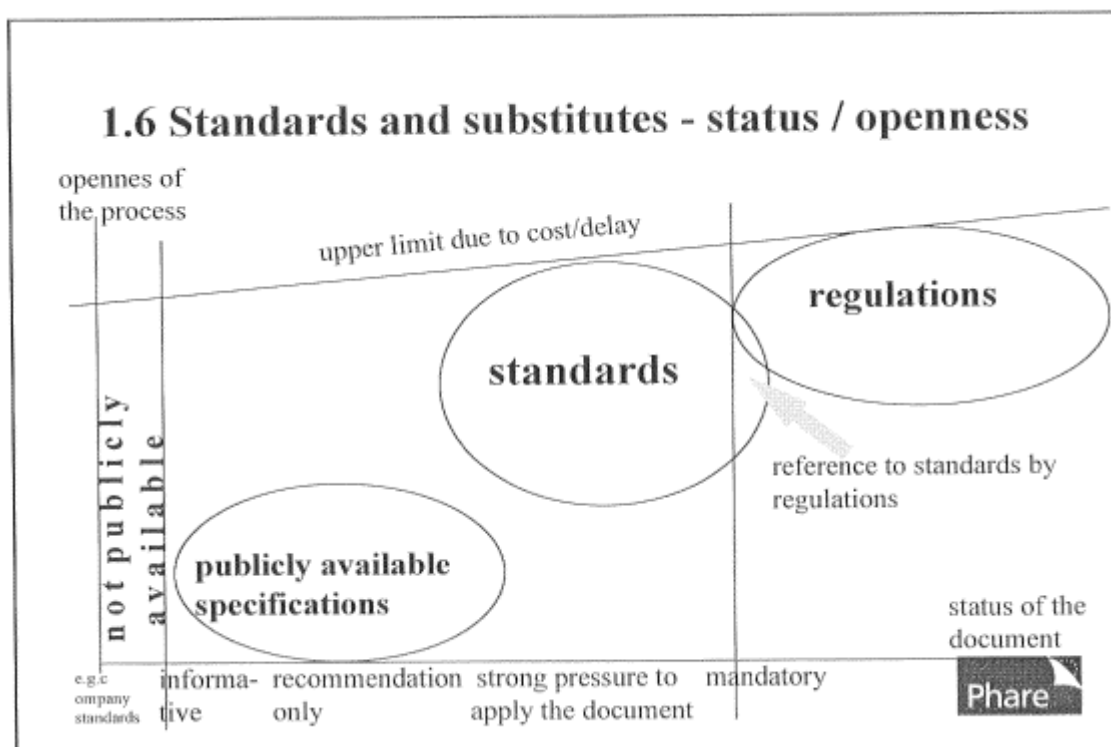
1.5 Specifications - standards - regulations

<u>specifications</u> <u>(publicly available)</u>	<u>standards</u>	<u>regulations</u>
◆ Voluntary	◆voluntary	◆mandatory
◆ Workshop, Consortium Groups.....	◆all stakeholders	◆legislative authority
◆ E.g.: ECMA DAVIC.....	◆e.g. ISO, EN DIN, BS, NF	◆e.g. law, act decree

(Publicly available) specifications are voluntary reference documents that provide rules, guidelines or characteristics for activities or their results. They are elaborated by workshops, consortia or other groups that usually do not comprise all relevant stakeholders. In most cases there are no detailed procedures for their elaboration and maintenance.

Standards are also voluntary reference documents, but the procedures for their elaboration ensure democratic legitimacy (for details cf. [1.1](#) and [1.3](#)).

Regulations are documents providing binding legislative rules. They are adopted by a legislative authority and are mandatory.

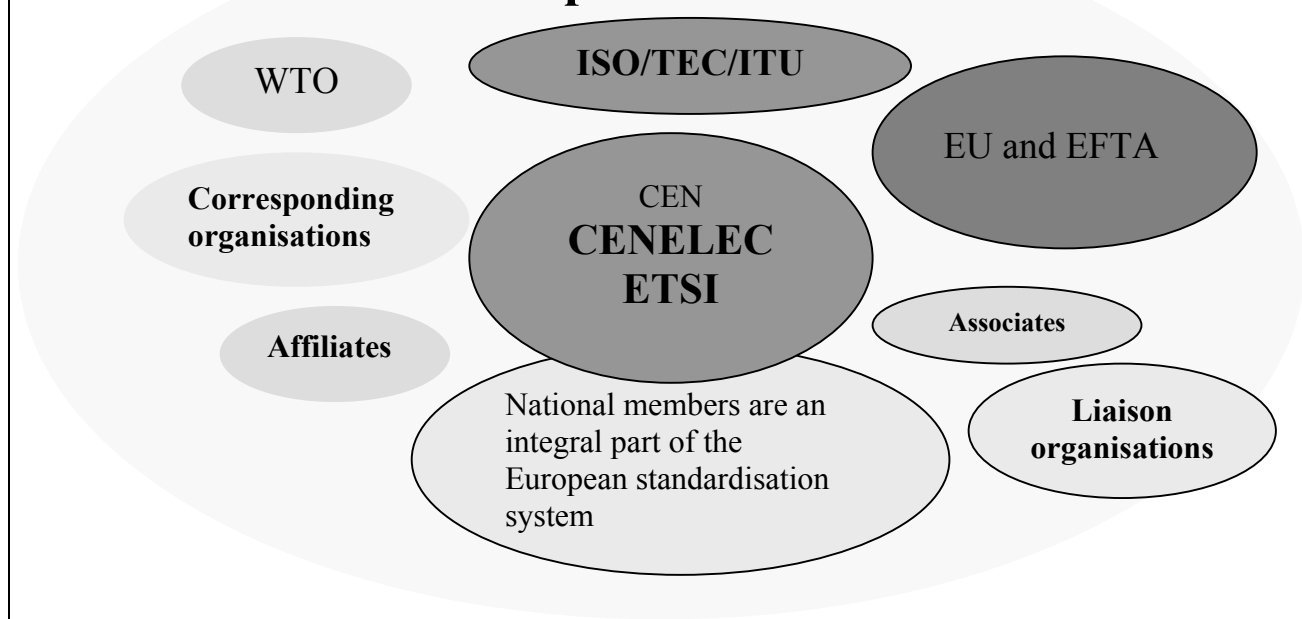


Publicly available specifications, standards and regulations . they are all a solution offered on the ‘technical reference document market’.

The graph represents the respective position of those documents in terms of “status” (from informative to mandatory) and in terms of the openness of the process (from a small group which consists only of a few members and only one interest group to the complete democratic process for regulations).

Reference to standards is made by only quoting the standard or by integrating the full text into the regulation.

2.1 The European standardisation system and its partners



The co-operation with its partners is essential for the European standardisation system. The system is based on the principle of good relationships with other standards bodies: to National Standardisation Bodies (NSBs) in Europe, co-operation is offered on the basis of affiliateship, to NSBs outside Europe co-operation is offered on the basis of the status of corresponding organisation. Close links exist between the European standardisation system and the respective international organisations (cf. also "[VIENNA Agreement](#)" and "[DRESDEN Agreement](#)").

European level organisations participate as liaison organisations or as associates.

At the political level the European standardisation system is a recognised partner of the European Commission, the European Parliament and the EFTA Secretariat.

The WTO Code of Good Practice for the Preparation, Adoption and Application of Standards is recognised by the European standardisation system.

2.2 European standards bodies

- ◆ **CEN** (Comité Européen de Normalisation / European Committee for standardisation)
- ◆ **CENELEC** (Comité Européen de Normalisation Electrotechnique / European Committee for Electrotechnical Standardisation)
- ◆ **ETSI** (European Telecommunications Standards Institute)

CEN is the multisectoral organisation and is active in all fields except the electrotechnical and the telecommunications field.

<http://www.cenorm.be/>

CENELEC is the organisation responsible for standardisation in the electrotechnical area.

<http://www.cenelec.org/>

They have their offices in the rue de Stassart in Brussels. CEN and CENELEC have common regulations for the standardisation work (CEN/CENELEC Internal Regulations) and as far as possible common policies (e.g. for the acceptance of new members, for copyright and sales of European standards and for the operation of a common scheme for the conformity to European standards).

ETSI was established in 1988 in response to the Green Book of the European Commission on the subject of the development of telecommunications in Europe. ETSI is active in the telecommunications field. ETSI has its premises in Sophia Antipolis / France.

<http://www.etsi.org/>

CEN/CENELEC/ETSI have co-ordination structures for general policy (Joint Presidents Group) and technical liaison (Joint Co-ordination Group). They have specific co-operation agreements for the IT area.

2.3 CEN SYSTEM: MEMBERS, ASSOCIATES AND AFFILIATES

19 NATIONAL MEMBERS

the national standards organisations of the 18 EU - and EFTA countries and of the Czech Republic

7 ASSOCIATES

European sector organisations: ANEC, CECIMO, CEFIC, EUCOMED, FIEC, NORMAPME, TUTB

14 AFFILIATES

the national standards organisation of Albania, Bulgaria, Croatia, Cyprus, Estonia, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia, Romania, Turkey

For details <http://www.cenorm.be/boss/supmat/hl000.htm>

2.4 Main elements of the CEN/CENELEC Internal Regulations

- **Standstill**
- **Weighted voting**
- **Implementation**
- **Withdrawal of conflicting standards**

Four elements of the CEN/CENELEC Regulations

<http://www.cenorm.be/boss/supmat/refdoc/ir200.htm>

are key to the elaboration and implementation of European standards:

- **Standstill:**
Standstill is an obligation accepted by the members of CEN/CENELC not to take any action, either during the preparation of an EN or HD or after its approval, which could prejudice the harmonisation intended and, in particular, not to publish a new or revised national standard which is not completely in line with an existing EN or HD.
- **weighted voting:**
The general principle for votes is the simple majority of those voting, but weighted voting applies for the formal approval of an EN, HD or ENV (as well as for the votes on standstill and the approval of B-deviations - cf. CEN-IR-2 paragraph 5.1.4).
- **implementation:**
The CEN/CENELEC members shall implement the European standards as national standards (usually within 6 months after the approval) - for details cli CEN-IR-2 Chapter 5.2.2.
- **withdrawal of conflicting standards:**
Conflicting national standards (= national standards on the same subject as the EN/HD and with requirements such that what complies with the national standard does not comply with the EN/RD or vice versa) have to be withdrawn.

2.5 Relationship between European and International standardisation

CEN and CENELEC have concluded agreements with their respective international partner in order to fix the rules of co-operation.

CEN - ISO: VIENNA Agreement

CENELEC - IEC: DRESDEN Agreement

In order not to “reinvent to wheel” and to ensure coherence with the international level, CEN and CENELEC have concluded agreements with their international partner: in 1991 CEN has concluded the “Vienna Agreement” with ISO

<http://www.cenorm.be/boss/supmat/refdoc/ms002.htm>

CENELEC has concluded the “Lugano Agreement” with IEC (called “Dresden Agreement” in its present version).

<http://www.cenelec.org/Info/about.htm#Co-operation>

The agreements cover mainly exchange of information

- co-operation on drafting standards
- co-operation by transferring work
- adoption of existing international standards
- parallel approval of standards.

2.6 – Assessment/programme phase

→ Requests for standards work (from the private or the public sector)

- from the national level via the CEN/CENELEC member
- from the Commission (or EFTA Secretariat) cf. "mandates"
- from international or European organisations

→ Selection of projects (by BT)

REQUESTS FOR STANDARDS WORK

- of national origin shall be presented to the relevant CEN/CENELEC member, which submits the proposal to the BT
- may also come from a CEN/CENELEC technical body
- may also come from the CEC of EFTA
- may come from international organisations or by European trade, professional, technical or scientific organisations (to the CEN/CS)

The BT decides whether or not a project will be pursued and, if so, how it should be dealt with, in the light of all relevant information.

Duplication of effort between the corresponding international and European standards organisations should be avoided and therefore the Vienna/Dresden Agreements should be applied wherever possible

3.1 Elimination of barriers to trade in Europe

through:

- Articles 30 - 36 Treaty of Rome
- Article 100 Treaty of Rome
- Directive 83/189/EEC
- New approach
- Article 100a Treaty of Rome
- Case law of the European Court of Justice; Cassis de Dijon-judgement

Means for the elimination of barriers to trade

- ‘The Treaty of Rome itself (in its 1957-version) contains two provisions, which can be applied in order to eliminate technical barriers to trade. Articles 30 to 34 prohibit all illegitimate quantitative restrictions on imports as well as measures having equivalent effect between Member States. (The corresponding articles in the Treaty establishing the European Community, “Treaty of Amsterdam” are 28 and 29). In Article 36 (30) though a safeguard clause for the member states is laid down; restrictions on imports or exports are justified if certain vital interests like health or public security would be harmed.
- Article 100 (94) regulates the procedure for the approximation of the legislation of the member states which directly affects the establishment or functioning of a common market.
http://europa.eu.int/eur-lex/en/treaties/dat/ec_cons_treaty_en.pdf
http://europa.eu.int/eur-lex/en/treaties/dat/eu_cons_treaty_en.pdf
- Directive 83/189/EEC is one of the most important instruments for the elimination of barriers to trade. It has been updated and repealed by the Directive 98/34
http://europa.eu.int/eur-lex/en/lif/dat/1998/en_398L0034.html
- New approach is a policy aiming at technical harmonisation.
- Article 100a (95), which was inserted into the Treaty of Rome by the Single European Act, contains a modified and more effective legislative procedure
- What concerns the role of the European Court of Justice and its case law its judgement in the “Cassis de Dijon”- case in 1979 was of great importance for the establishment of a common market. One of its key messages was that any product lawfully produced and marketed in one Member State must be admitted to the market of another Member State. This means that the level of protection in the various countries concerning the various interests (like health, safety etc.) is deemed to be equivalent (principle of equivalence).

3.2 EU Standardisation and Certification Policy

1983-03 Directive 83/189

1985-05 New Approach

1989-12 Global Approach

1990-12 Modular Approach

1992-06 Council resolutions on the role of standardisation in european economy

1993-07 Council Decision on the "modules" and rules for affixing and use of CE marking

Council Directive of 28 March 1983 laying down a procedure for the provision of information in the field of technical Regulation (replaced by Directive 98/34)

Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards (85/C 136/01)

Council Resolution of 21 December 1989 on a global approach to conformity assessment

For details cf. Chapter 4.1

Council Decision of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures, which are intended to be used in the technical harmonisation directives

For details cf. Chapter 4.3

Council Resolution of 18 June 1992 on the role of European standardisation in the European economy

Decision of the EC Council of 22 July 1993 on “modules” and rules for affixing and use of the CE marking

For details cf. Chapter 4.3

3.3 New Approach

OLD Approach

- Directive is very technical and detailed
- time-consuming elaboration

NEW Approach

- Directive only contains the "essential requirements"
- reference to standards

Old approach

From 1970 to 1985 the European Community followed the so-called "old approach" in its policy to combat technical barriers to trade. Harmonisation was achieved by introducing specific instruments in order to meet the individual requirements of each product category. This meant that the directives were highly technical and detailed, which led to an enormous bulk of EC technical regulations. The area of motor vehicles can be given as an example for Directives under the "old approach". As the consultation procedure of Article 100 - which was the basis for these Directives - requires unanimity decision-making in these very specific matters became more difficult and caused delays so that a new solution had to be found.

New approach

Therefore, on 7 May 1985 the Council of the EC adopted a resolution on, a new approach to technical harmonisation and standards" (85/C 136/01). This resolution gave way to a new European policy, which uses standardisation as a means of support to legislation. The technical Directives only contain the "essential requirements". Standards elaborated by competent European standards bodies define the technical specifications, which comply with these essential requirements.

3.4 Fundamental principles of the New Approach

- ⇒ directive limited to the harmonisation of **essential requirements**
- ⇒ **reference to standards**
harmonised standards = technical specifications which comply with the essential requirements
- ⇒ **conformity assessment policy**
products conforming with harmonised standards are presumed to conform with the essential requirements

Within the policy of the new approach the following fundamental principles were introduced:

- essential requirements:
Directives based on Article 100 (94) shall be limited to the harmonisation of "essential requirements" connected with safety and other requirements like consumer and environment protection with which the products have to conform when put on the market. This means that these new Directives do not contain all technical details anymore. The introduction of Article 100a (co-operation procedure) by the Single European Act of course speeded up the procedure of technical harmonisation as Council decisions by qualified majority were introduced.
- reference to standards:
Organisations competent in the area of standardisation are entrusted to draw up harmonised standards. These standards define the technical specifications, which comply with the essential requirements established by the new approach Directives while at the same time taking into account the current stage of technology. In this way standardisation contributes to ensuring free movement of goods and therefore to the functioning of the internal market.

(In order to avoid terminological confusions it has to be stated that the term "harmonised standard" as created by the EC within the concept of the new approach does not conform with the term "harmonised standard" as laid down by the ISO/IEC Guide no.2. In the latter case "harmonised standards" are defined as "standards on the same subject approved by different standardising bodies, that establish interchangeability of products, processes and services, or mutual understanding of the test results or information provided according to these standards")
- conformity assessment policy:

Although the harmonised standards remain voluntary, national authorities are obliged to recognise that products manufactured in conformity with harmonised standards are presumed to conform to the essential requirements of the Directive. The reference to these harmonised standards -which are transposed into national standards - is published in part C of the Official Journal of the European Communities. These standards are European standards as the task of elaborating harmonised standards has been entrusted to CEN, CENELEC and ETSI for their respective working areas.

3.5 General outline of a new approach Directive

- Free movement clause
 - free movement of goods complying with the Directive
- Proof of conformity
 - conformity to harmonised standards
 - CEN, CENELEC, and ETSI: competent bodies for the elaboration of harmonised standards
 - no conformity to harmonised standards
 - absence of harmonised standards
- Management of the lists of standards
 - Procedure applied if Commission or member state is not "satisfied" with the harmonised standard
- Safeguard clause
 - Conditions under which a member state can take measures to protect vital interests
- Means of attestation of conformity
 - modules a means of conformity assessment
- Standing Committee
 - "manages" the new approach Directive in question
- Definitions of the tasks and operation of the Standing Committee

1 Free movement clause:

Under this clause the Member States are obliged to accept the free movement of goods which comply with the provisions of the Directive.

2 Proof of conformity:

Three different conditions are covered by this clause:

a) conformity to harmonised standards:

Member States have to presume conformity with the clause for placing goods on the market and the essential safety requirements of the relevant Directive when the product has met one of the means of attestation (see 8 below) given in the relevant Directive. In this declaration is then stated that the product is in conformity with the national standard transposing the harmonised European

standard.

The references of the harmonised European standards have to be published in the Official Journal of the European Communities (C Series) and the standards have to be transposed into national standards.

Harmonised standards have to be adopted by a European standardisation body competent in relation to the scope of the relevant Directive. CEN, CENELEC and ETSI are considered to be competent bodies in this field (cf. Co-operation Agreement signed with the European Commission on 13 November 1984). The obligation of transposition into national standards and the withdrawal of diverging national standards is laid down in the Internal Regulations (part 2) of CEN and CENELEC concerning standards work. The Member States themselves have to publish references of those national standards which transpose harmonised European standards.

Harmonised standards may be any type of European document adopted by a European standardisation body, whether it is an EN or a HD.

b) no conformity to harmonised standards:

If a product does not conform to all or part of a harmonised standard, the Directives provide for special methods of conformity assessment.

c) absence of harmonised standards:

If no harmonised standards are available the conformity of the products to the essential safety requirements can be confirmed and attested by a third party chosen amongst the “Notified Bodies”. These are organisations notified by the Member States to the European Commission. (see chapter [4.5](#))

3 Management of the lists of standards:

If the Commission or a Member State considers that a harmonised standard, as submitted by CEN, CENELEC and ETSI does not fulfil the above mentioned points 2 and 3, an appeal procedure in the course of which the Commission sets measures, in the light of the opinion of the Standing Committee, is set into force. A new or revised mandate could be given as an example for a possible measure.

4 Safeguard clause:

This fundamentally important article enables the Member States to take all necessary measures to protect vital interests as described in Article 36 of the Treaty of Rome (as interpreted by the case law of the EC Court of Justice). If the product concerned is accompanied by one of the means of conformity laid down in the Directive the Member State is obliged to inform the Commission on the measures taken. The Commission then decides whether the measure taken was justified or not.

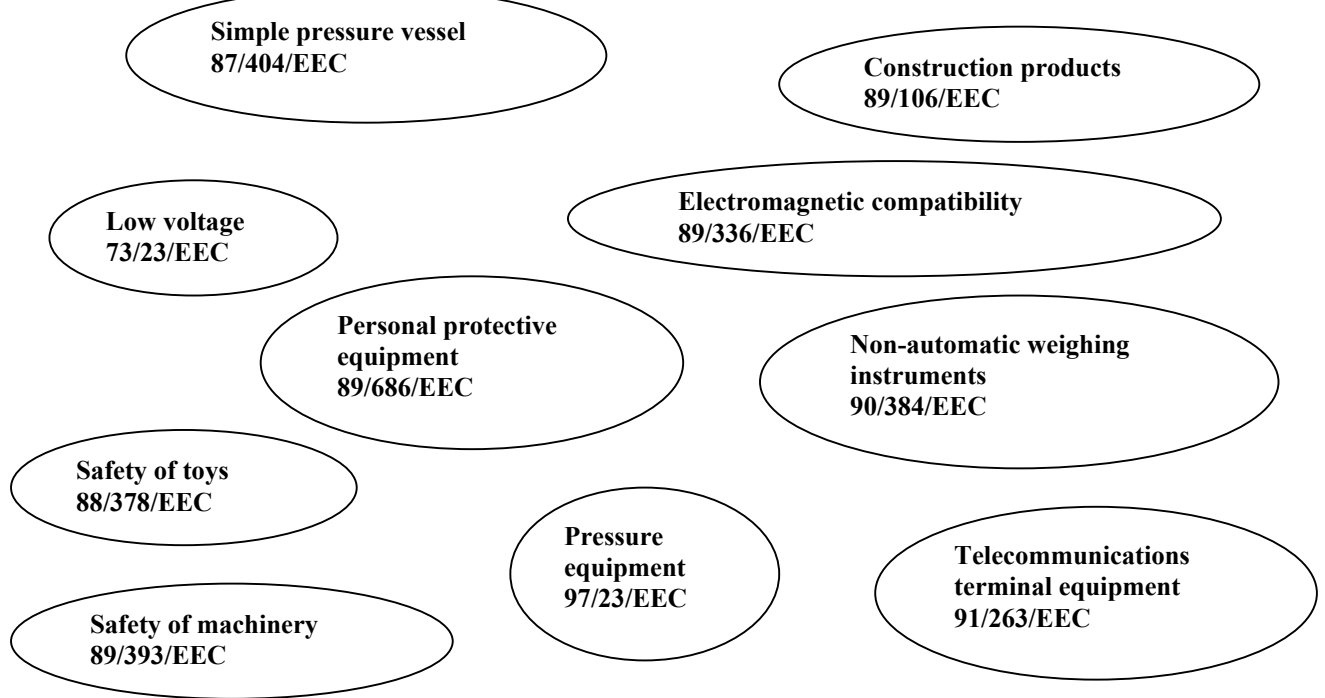
5 Means of attestation of conformity:

In this area the Council Resolution of 7 May 1985 was clarified by the Resolution of 21 December 1989 on a global approach to conformity assessment (90/C 10/01), the Decision

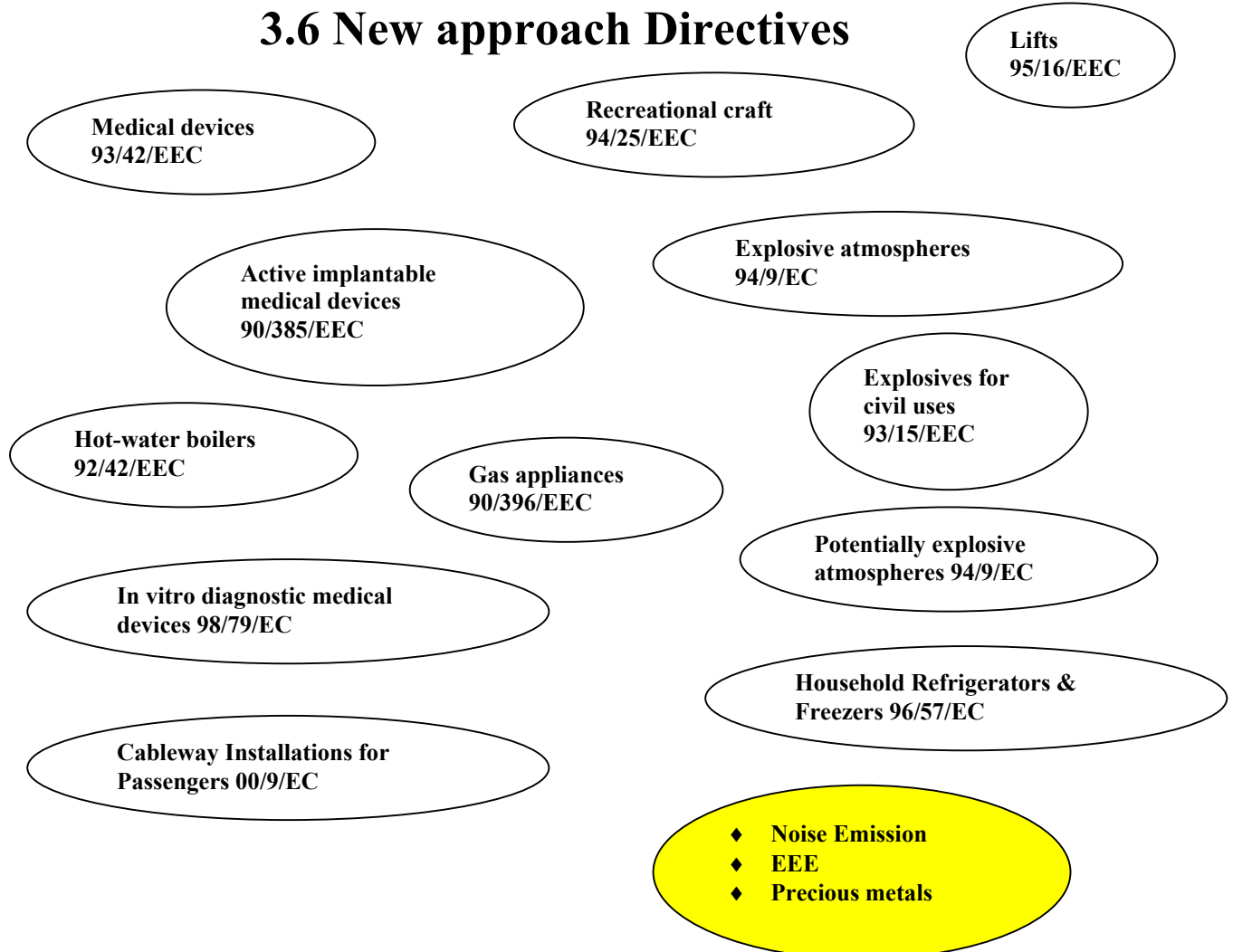
90/683/EEC concerning the modules that has been since replaced by its update 93/465/EEC

http://europa.eu.int/eur-lex/en/lif/dat/1993/en_393D0465.html

Manufacturers are offered several methods (modules) for attesting that their products conform to the requirements of the Directive. Decision 93/465/EEC contains the modules for conformity assessment. The procedures in the single Directives may only depart from these modules if specific circumstances of the area of the Directive concerned warrant this. This means that under specific conditions the Directive may stipulate a single means of conformity assessment. This, for example, is the case with the construction products Directive where certification of conformity is only possible if based on harmonised technical specifications.



3.6 New approach Directives



New approach directives:

- Low voltage equipment (73/23/EEC)
http://europa.eu.int/eur-lex/en/lif/dat/1973/en_373L0023.html
- Simple pressure vessels (87/404/EEC)
http://europa.eu.int/eur-lex/en/lif/dat/1987/en_387L0404.html
- Safety of toys (88/378/EEC)
http://europa.eu.int/eur-lex/en/lif/dat/1988/en_388L0378.html
- Electromagnetic compatibility (89/336/EEC)
http://europa.eu.int/eur-lex/en/lif/dat/1989/en_389L0336.html
- Construction products (89/106/EEC)
http://europa.eu.int/eur-lex/en/lif/dat/1989/en_389L0106.html
- Safety of machinery (98/37 EC replacing 8 9/3 92/EEC)
http://europa.eu.int/eur-lex/en/lif/dat/1998/en_398L0037.html
- Lifts (95/16/EC)
http://europa.eu.int/eur-lex/en/lif/dat/1995/en_395L0016.html
- Personal protective equipment (89/686/EEC)
http://europa.eu.int/eur-lex/en/lif/dat/1989/en_389L0686.html
- Non-automatic weighing instruments (90/384/EEC)
http://europa.eu.int/eur-lex/en/lif/dat/1990/en_390L0384.html
- Medical devices (93/42/EEC)
http://europa.eu.int/eur-lex/en/lif/dat/1993/en_393L0042.html
- Active implantable medical devices (90/385/EEC)
http://europa.eu.int/eur-lex/en/lif/dat/1993/en_393L0042.html
- Gas appliances (90/396/EEC)
http://europa.eu.int/eur-lex/en/lif/dat/1990/en_390L0396.html
- New hot-water boilers fired with liquid or gaseous fuels (92/42/EEC)
http://www.europa.eu.int/eur-lex/en/lif/dat/1992/en_392L0042.html
- Explosives for civil uses (93/15/EEC)
http://www.europa.eu.int/eur-lex/en/lif/dat/1993/en_393L0015.html
- Equipment and protective systems in potentially explosive atmospheres (94/9/EC)
http://www.europa.eu.int/eur-lex/en/lif/dat/1994/en_394L0009.html
- Recreational craft (94/25/EC)
http://www.europa.eu.int/eur-lex/en/lif/dat/1994/en_394L0025.html
- Telecommunications terminal equipment (99/5/EEC)
http://europa.eu.int/eur-lex/en/lif/dat/1999/en_399L0005.html

- Pressure equipment (97/23/EC)
http://europa.eu.int/eur-lex/en/lif/dat/1997/en_397L0023.html
- Potentially explosive atmospheres (94/9/EC)
http://europa.eu.int/eur-lex/en/lif/dat/1994/en_394L0009.html
- In vitro diagnostic medical devices (98/79/EC)
http://europa.eu.int/eur-lex/en/lif/dat/1998/en_398L0079.html
 - Energy Efficiency: Household Refrigerators & Freezers
http://europa.eu.int/eur-lex/en/lif/dat/1996/en_396L0057.html
- Cableway Installations for Passengers
http://europa.eu.int/eur-lex/en/lif/dat/2000/en_300L0009.html
- Packaging and Packaging Waste
http://europa.eu.int/eur-lex/en/lif/dat/1994/en_394L0062.html

4 Conformity with Directives and standards

4.1. Accreditation and certification in Europe)

4.2. Global Approach

4.3. Modular Approach

4.4. CE marking

4.5. Notified bodies

4.1 Accreditation and certification in Europe

- **Accreditation** = procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks
- **Certification** = procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements
- **Testing** = carrying out of tests (= technical operations in order to determine characteristics of a product, process or service according to a specified procedure)
- **Inspection** = evaluation for conformity by measuring, observing, testing or gauging the relevant characteristics of the product, process or service

Accreditation and certification in Europe

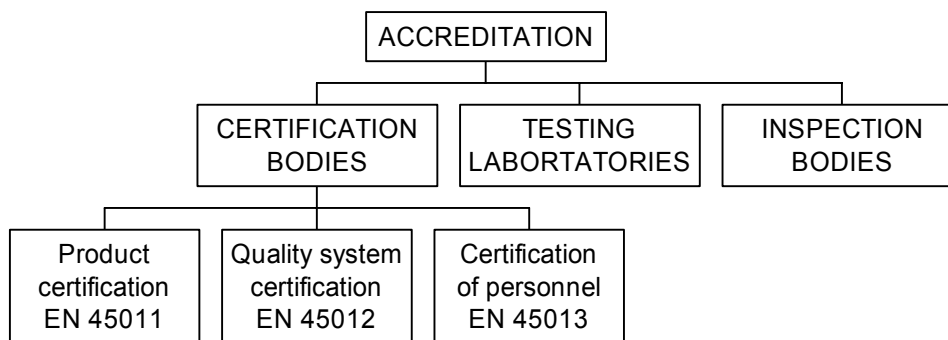
Before going deeper into the topic of conformity assessment in Europe a few terms have to be explained.

The definitions given above are taken from EN 45020 “General terms and their definitions concerning standardisation and related activities”.

Other terms used in this field...

- certification system = system that has its own rules of procedure and management for carrying out certification of conformity (includes rules for testing and inspection). It may be operated on a national, regional or international level.
- certification scheme = certification system related to specified products, processes or services to which the same standards and the same procedure apply
- certificate of conformity = document indicating that a product, process or service is in conformity with a specific standard or other normative document
- mark of conformity = protected mark applied under the rules of a certification system indicating that the relevant product, process or service is in conformity with a specific standard or other normative document

4.2 Accreditation



If an authoritative body gives formal recognition that a body (or person) is competent to carry out certification, inspection and testing tasks then this body is referred to as accredited for these tasks.

- certification bodies = bodies that conduct certifications of conformity
- inspection bodies = bodies that perform inspection tasks
- testing laboratories = laboratories that perform tests

In EN 45000 series general criteria for testing laboratories, inspection bodies and certification bodies are laid down.

For example:

- EN 45011 General criteria for certification bodies operating product certification
- EN 45012 General criteria for certification bodies operating quality system certification
- EN 45013 General criteria for certification bodies operating certification of personnel

4.3 Modular approach

- **modular approach specifies global approach in the regulatory sphere (conformity with new approach Directives)**
 - **Council Decisions on modules (90/683/EEC) -modular approach**
- ⇒ **modules: basis of conformity assessment procedure**
- ⇒ **broad choice between modules for manufacturers -but:**
- ➡ **complexity and stringency of modules depends on risks associated with the specific products**

Modular approach

The global approach was specified by the modular approach for the assessment of conformity with the new approach Directives. A conformity assessment procedure in the framework of the new approach Directives is necessary for the public authorities to ensure that products placed on the EU market conform to the essential requirements of the Directive(s) concerned.

The Council Decision of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonisation Directives (90/683/EEC .L 3 80/90) (it has been updated and repealed by Council Decision 93/465) introduces the concept of the modular approach. Concerning the new approach Directives the conformity assessment procedure is subdivided into modules (A-H) which relate to either the design or the production phases of the products or to both of them.

As the EU favours a free-market economy a broad choice between the modules must be left to the manufacturer. The Community legislator can choose between the different modules described. The complexity and stringency of the modules to be applied varies according to the risks associated with the product, i.e. for toys a less stringent procedure will be sufficient, but for implantable medical devices more stringent methods of control will be necessary. This means that the type of the product, the risks involved, the circumstances of the sector concerned are all factors relevant for the appropriateness of certain modules for a specific Directive.

The modules range from internal production control combined with a declaration of conformity (module A) to very stringent modules like H where a notified body (cf. 5.4) is involved in the certification procedure of a quality management system.

4.3 Modules

Design	Production
A	Internal production control by manufacturer
B	EC-Type examination
	C Conformity to type
	D Production quality assurance EN ISO 9002
	E Product quality assurance EN ISO 9003
	F Verification of products
	G Verification on per-item base
	H Complete quality assurance EN ISO 9001

Modules

- Module A internal production control (manufacturer only)
- Module Aa Module A but in addition intervention of a notified body
- Module B type examination (intervention of a notified body)
- Module C conformity to type (intervention of a notified body) ‘Module D production quality assurance EN ISO 9002 (intervention of a notified body)
- Module E product quality assurance EN ISO 9003 (intervention of a notified body)
- Module F product verification (intervention of a notified body) ‘Module G unit verification (intervention of a notified body)
- Module H full quality assurance EN ISO 9001 (intervention of a notified body)

EN ISO 9000 series: methods of quality assurance (a new version **ISO 9000 - 2000** was published in December 2000)

The EN ISO 9000 series is recommended both in the regulatory as well as in the non-regulatory sphere.

EN ISO 9001 Quality systems - Model for quality assurance in design, development, production, installation and servicing

EN ISO 9002 Quality systems - Model for quality assurance in production, installation and servicing

EN ISO 9003 Quality systems - Model for quality assurance in final inspection and test

4.4 The CE-marking

- **Decision 93/465/EEC - application and use of the CE-marking**
- **Directive 93/68/EEC - amending all new approach Directives already adopted with regard to the CE-marking**

CE-marking

In 1993 the global approach to conformity assessment was extended by the Council Decision 93/465/EEC which supplemented the “modules” Decision (90/683/EEC) by establishing common rules for the application and use of the CE-marking in the framework of the new approach Directives. In this respect the existing new approach Directives were modified by the Directive 93/68/EEC (the term “CE-mark” was replaced by “CE-marking”).

The CE-marking

- ➡ indicates that the product is authorised to be placed freely on the EU market
- ➡ is affixed on the product or its packaging by the manufacturer or his authorised agent
- ➡ certifies that the product conforms to the provisions of the Directive(s) concerned
- ➡ does not specify the modules applied
- ➡ is accompanied by a code identifying the notified body involved in the production control phase
- ➡ does not exclude the affixing of marks indicating conformity to national or European standards

Implications of the CE-marking

If the CE-marking is affixed on a product this product is authorised to be placed freely on the market of the European Union.

The CE-marking is affixed on the product concerned itself or on the packaging by the manufacturer or his authorised agent. It does not have any fixed colour.

The CE-marking certifies conformity with all provisions (the essential requirements relating to health, safety etc. but also obligations of the Directives apart from the essential requirements) of the new approach Directives concerned. This means that if several Directives providing for the CE-marking apply to one and the same product, the application of the CE-marking indicates conformity with all applicable Directives.

The CE-marking does not specify the modules on the basis of which the conformity assessment procedure has been established.

If a notified body is involved in the production control phase, the CE-marking is accompanied by a code identifying the notified body (code = serial number assigned by the European Commission after notification of the body by a Member State).

The CE-marking does not prohibit the application of other marks (e.g. marks indicating conformity to national or European standards) provided such marks are not liable to cause confusion with the CE-marking. The affixing for any other marking liable to deceive third parties as to the meaning and form of the CE-marking must be prohibited.

4.5 A notified body...

- ⇒ ...is a body notified by a Member State to the European Commission
- ⇒ ...is authorised for conformity assessment and certification procedures with respect to the new approach Directives
 - certification
 - inspection
 - testing
- ⇒ list of notified bodies: cf. OJ C of the EC

What is a notified body?

A notified body is a body notified by a member state to the European Commission which is authorised by the national authorities for carrying out conformity assessment tasks in the field of testing, certification and inspection with respect to one or more new approach Directives.

A list of the bodies notified is published and updated in part C of the Official Journal (OJ) of the European Communities by the European Commission.

Designation criteria for notified bodies

◆ requirements for the designation of a notified body according to the respective annex of the new approach Directive (impartiality, professional competence etc.) or

◆ conformity of the body to EN 45000

◆ subcontracting possible under certain conditions

Criteria for the designation of notified bodies

The new approach Directives contain annexes regulating the criteria for the designation of notified bodies. All bodies, notified by the Member States for certification, testing and surveillance tasks, under the specific new approach Directive, have to fulfil these requirements.

Impartiality of the staff of the body with respect to design, construction, marketing or maintenance of the product concerned, professional integrity and competence, professional secrecy as well as a liability insurance belong to these requirements.

However, if a body can prove conformity with EN 45000 series by submitting an accreditation certificate or other documentary evidence it is presumed to conform to the requirements of the Directive.

Subcontracting is possible under certain conditions even if the subcontractor is located in a third (i.e. a non-EU) country.

- competence of the subcontractor has to be in conformity with EN 45000 series or the requirements of the specific Directive on notified bodies
- notified body must be able to exercise effective responsibility for the work carried out by the subcontractor
- Member State of the notified body has to ensure effective control of the compliance with the requirements