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Preface

In order to meet the requirements and to be of help to the business organizations in our country, the National Chamber of Skilled Crafts (NCSC), the Regional Craft Chamber - Sofia (RCC) and the Balkan office of SME Support became part of a consortium whose purpose is to acquaint the business representing organizations with the *acquis communautaire* and its implementation in the national economies.

As partners in the Consortium NCSC, RCC-Sofia and the Balkan Bureau are taking part in a project that joins the efforts of experts from Germany, Bulgaria, Romania, Croatia, Turkey, Slovenia, Luxemburg and Denmark.

The purpose of the project is to strengthen the capacity of the business representative organizations in Bulgaria, Romania, Croatia and Turkey by deepening their competency in various aspects of the "*acquis communautaire*" which will enable them to be as helpful as possible to their members by providing up-to-date information, analysis and consultation in the alignment of their national legislations to the Community legislation.

The project activities include:

- Holding several international and national conferences
- Training of experts from the 4 organizations
- Publishing and distributing of three "Manuals", dedicated to the key issues of the conferences:
 - Food Quality and Product Safety
 - Standards and Certification
 - Environment Protection.

The second international conference under the project was held from 8th to 10th September 2008 in Zagreb, Croatia on "Standards and Certification". This manual is dedicated to the same subject and covers reports and presentations of Bulgarian, Romanian, Croatian and Turkish experts from the member countries of the project consortium.

Project summary

Familiarisation of Business Representative Organisations with the Community acquis and its implementation in the national economies

Programme: Business Support Programme for Bulgaria, Romania, Croatia and Turkey

Duration: 01/2008 - 06/2009

European Partners:

- German Confederation of Skilled Crafts (ZDH)
- SEQUA gGmbH
- Luxembourg Chamber of Trades
- Confederation of Danish Industries
- Ost-West-GmbH - Koblenz Chamber of Skilled Crafts and Small Businesses
- Chamber of Crafts of Slovenia

Local Partners:

- National Union of Handicraft and Production Co-operatives of Romania
- National Chamber of Skilled Crafts of Bulgaria
- Croatian Chamber of Skilled Crafts
- Regional Craft Chamber Sofia
- Antalya Union of Tradesmen and Craftsmen

Project Targets

The overall objective is to strengthen the capacities of Business Representative Organisations (BROs) in Bulgaria, Romania, Croatia and Turkey by having gained knowledge on different acquis-topics.

The specific objective is to fully familiarise selected BROs with relevant acquis-topics and to disseminate the gained knowledge and the implications of the relevant acquis for the member companies nation wide.

Results targeted

1. Key expertise in the acquis-subjects "environmental protection", "food quality and product safety", "standards and certification" is transferred to staff of Bulgarian, Romanian, Croatian and Turkish BMOs.
2. Nine Key resource persons of Balkan BMOs are capable to use their network in order to pread the knowledge on specific acquis-topics among members and regional BMOs.
3. Three thematic support groups are set-up and offer consultancy services.
4. Two national conferences in each Balkan country have been implemented.
5. 1200 SME-guides about acquis-topics are published and distributed to national BMOs and companies.

Measures planned

- Transferring expertise in the above-mentioned acquis-subjects via three international conferences.
- Assisting partner BROs in providing acquainted knowledge to other BROs and private businesses via six national conferences.
- Contributing to the compilation and distribution of "SME Guides".
- Setting up three consultative "thematic support groups".

Impact for the region / country, sustainability

The action foreseen in the project is of great importance to the needs of the target countries.

Bulgaria and Romania have to fully comply with the *acquis* to end safeguard measures. At present they have not completed the implementation of the *acquis* regarding food quality and product safety yet. The purpose of setting high standards in this sector is to provide EU citizens with high quality food products and to prevent the spreading of communicable diseases such as swine fever.

To completely understand the impact of those measures, one has to remember that the agricultural sector still contributes an important share to GDP in both countries, with 13.6% in Bulgaria and 10.1% in Romania which are presently not in a position to use all opportunities of EU accession.

Croatia and Turkey on the other hand, need to implement and enforce the *acquis* in order to become full members of the EU. Complying with *acquis* provisions on environmental protection is of great importance to Turkey, with damages to nature becoming more and more expensive to remediate the longer one waits. Croatia as well is trading mostly with EU member countries, thus making the adherence to EU standards and certification extremely relevant for all business purposes.

Furthermore, the action foreseen in the project is of great importance to the target groups. Lacking the necessary technical expertise with regard to the *acquis* hinders the development of economic operators. BROs need more training and capacity building in order to deliver relevant services to their member companies. Through the project they will acquire the necessary instruments, knowledge and especially access to established networks within the EU to transfer relevant information to their member companies who in turn will be better prepared to use the opportunities of the EU market.

Relevance of the project to the country/ region and background information

The integration into the European Union is without doubt the most challenging political and economic project of the four target countries Bulgaria, Rumania, Croatia and Turkey. Although Bulgaria and Rumania have already entered the European Union, they are still in a process of adjustment and transformation in order to comply with all relevant EU regulations. Although the EU is a political project which covers far more than simply economics, the economic dimension of the integration process is of great impact for the daily living conditions of the populations and their macroeconomic well-being.

At present all four countries are still facing similar challenges of complying with the EU *acquis* that have direct impact on economic activities. This project will address some of these challenges in concrete areas:

- food quality and product safety
- environmental protection
- standards and certification, e.g. the protection from unfair commercial practises

The project will try to contribute to the solutions of concrete problems which companies in the target countries are facing due to a lack of knowledge or an inadequate application of *acquis* regulations. The project will address each of these issues in a target country where there is a special interest in solving them. Furthermore, the solutions developed will be transferred into the other country via the partner network. The set-up of a consortium of Business Membership Organisations (BMOs) guarantees close cooperation at European level and the link to thousands of companies at national level.

CONFERENCE REPORTS

GENERAL PRINCIPLES OF FREE MOVEMENT IN THE INTERNAL MARKET

Annette Dragsdahl, Senior Adviser, Confederation of Danish Industry

I. The internal market - goals and challenges

The foundation stone for the internal market was already laid down in the Treaty of Rome in 1957. Six Member States agreed to set up one common market on the basis of the free movement of goods, persons, services and capital. This was the beginning of the end to tariff barriers, quota restrictions and complicated procedures for import and export between the members of the EU.

The goal was - and is - open markets with a free flow of goods, services and capital and in which the inhabitants can move around without restrictions. In 1968 a customs union was introduced, but the development up through the 1970s did not show the anticipated increase in European trade. For this reason, a new vision was created and concrete initiatives were taken to create an internal market as of 1 January 1993.

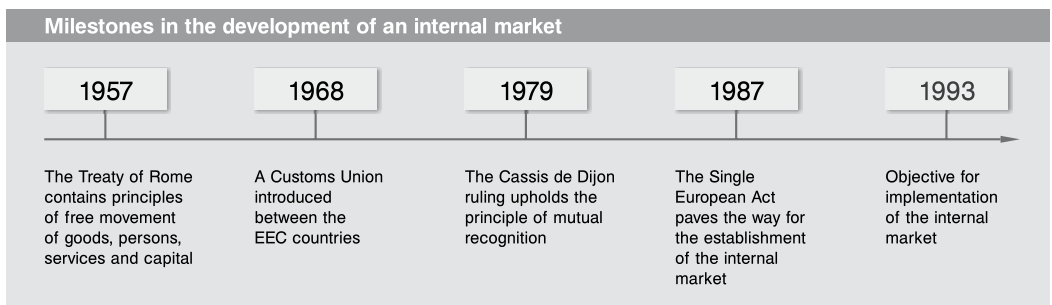


Figure 1. Milestones of the internal market

Time has shown that the creation of the internal market is an on-going process that needs constant political attention and specific action. New technological developments, such as e.g. the Internet allowing for e-commerce; increased awareness of the need to protect the environment as well as the health and safety of persons and animals; the shift from manufacturing to services; globalisation and the enlargement of the EU, are all developments that challenge the functioning of the internal market.

II. The toolbox to ensure free movement

The internal market is the cornerstone of Europe's competitiveness. Therefore a toolbox with different instruments has been created to ensure its well-functioning.

Common EU-rules are established in areas of trans-national concern, i.e. where the overall goal cannot be reached through national initiatives alone. This also means that in areas that are not subject to common EU legislation, Member States can have national rules for products and services, provided that they are notified to the Commission, cf. directive 98/34.

Legislative instruments

- Harmonisation
- Regulations (directly applicable)
- Old and New Approach directives (to be transposed)
- Minimum harmonisation directives (to be transposed)
- Principle of mutual recognition (EC Treaty art. 28 + 30)
- Notification of national technical requirements (cf. 98/34 directive; TRIS-database)

Non-legislative instruments

- Standardisation
- Codes of conduct
- Voluntary industry agreements

Problem prevention and solving

- Commission infringement cases against Member States
- ECJ judgements
- Cross-border cooperation between Member States (interpretation and coordination)
- SOLVIT

Legislative instruments:

Harmonisation

Common rules can be established in the form of 'regulations'. A regulation is directly applicable in the Member States. This instrument will probably be used more frequently in future as different interpretations and changes during transposition will then be avoided.

"Directives" need to be transposed in each Member State in order to be applicable in the Member State.

"Old Approach" directives are very detailed directives, setting the specific requirements to products, such as food and cars.

In order to speed up the process of establishing a real internal market with common rules, the 'New Approach' was introduced at the end of the 1980'ies. Directives under the New Approach are characterised by defining the 'essential requirements' only, whereas the details are agreed upon in harmonised standards. The standards are developed by the European Standardisation organisations CEN, CENELEC and ETSI, and published in the Official Journal of the EU (see section III for more information on the New Approach).

Minimum harmonisation directives allow Member States to set more strict requirements than those specified in the directives. Such directives are especially found in the area of environmental legislation.

Principle of mutual recognition

The principle of mutual recognition derives from case-law of the Court of Justice of the European Communities, based on article 28 of the Treaty. Mutual recognition applies to products which are not subject to Community harmonisation legislation, or to aspects of products falling outside the scope of such legislation.

15-20% of all products fall under the principle of mutual principle (examples are: bicycles, textiles, furniture, and jewellery).

According to this principle, a Member State may not prohibit the sale on its territory of products which are lawfully marketed in another Member State, even where those products were manufactured in accordance with technical rules which are different from those to which domestic products are subject. The only exceptions to that principle are restrictions which are justified on the grounds set out in Article 30 of the Treaty (e.g. public order and health protection), or on the basis of other overriding reasons of

public interest. Furthermore national technical requirements must be proportionate to the aim pursued (see more on procedures under the New Legislative Framework, section IV).

Notification of national technical requirements

According to the Directive 98/34 Member States shall communicate to the Commission any draft technical regulation as well as a justification why it is found necessary. The Commission shall then immediately notify the other Member States of the draft. This makes it possible for the Commission and the other Member States to comment on the draft if they find aspects which may hinder trade. Possible national standards shall also be notified to the Commission and the European Standards Associations.

The EFTA countries as well as Turkey have partly been included into this notification procedure.

A database called TRIS - the Technical Regulations Information System (ec.europa.eu/enterprise/tris/public_info) has been established. Companies (and other interested parties) can search for concrete notifications, classed in specific categories, depending on their aim and the area of activity concerned. In principle notified drafts are translated into all Community languages. It should be noted that the above mentioned principle of mutual recognition applies, even if there are national rules (see section IV).

There are about 600 - 700 notifications on national regulations every year.

Non-legislative instruments

Standardisation

European standardisation is to a large extent replacing legislation. There are about 20 000 European standards, of which more than half are similar to the international standards.

As a general principle, the use of standards is voluntary, but there are exceptions (e.g. for construction materials). In the case of directives under the New Approach, the application of standards gives presumption of conformity with the requirements of the applicable directives.

Codes of conduct and voluntary industry agreements

- are used as a kind of 'soft law' in cases where the overall objectives can be met without legislation.

Problem prevention and solving

Commission infringement cases against Member States and ECJ judgements

EU Member States have primary responsibility for the correct and timely application of EU Treaties and legislation. The Commission works in close partnership with Member States to manage the application of the law.

As guardian of the Treaties, the Commission has been given the authority and responsibility to ensure respect for Community law, verifying that Member States respect Treaty rules and Community legislation. Where the Commission considers that Internal market rules are not properly applied, it may open infringement proceedings against a Member State. The infringement procedure provides for a dialogue between the Commission and the Member State concerned. If this does not bring the desired result, the Commission can bring the matter before the European Court of Justice. Only the Court of Justice can rule definitively that a breach of Community law has occurred. From the Internal Market Scoreboard of July 2008 published by the Commission, it appears that as of 30 April 2008 there were 1298 open cases.

Cross-border cooperation between Member States

In order to ensure uniform transposition, implementation and enforcement of Community law close cooperation between Member States is encouraged and a new regulation (765/2008) on market surveillance sets clear obligations in that respect (see section IV). Cross-border cooperation helps build trust between Member States which is a must for a smooth operation of the internal market.

SOLVIT

is an on-line problem solving network in which EU Member States work together to solve in a pragmatic way problems which arise from the misapplication of internal market law by public authorities. It is a more informal way than complaining via the European Commission.

There is a SOLVIT Centre in every EU Member State (as well as in Norway, Iceland and Liechtenstein). The Centres can help with handling complaints from both individual citizens and businesses. SOLVIT has been operational since July 2002.

When a case is submitted to SOLVIT, the local SOLVIT Centre (known as the 'Home' SOLVIT Centre) will first check the details of the application to make sure that it does indeed concern the misapplication of internal market rules and that all the necessary information is available. This means that before raising a case a company will need to have documentation indicating the applicable rules which may have been broken (e.g. concrete sector directive or general principles such as the principle of mutual recognition). The 'Home' SOLVIT Centre will then enter the case into the database system and contact the SOLVIT Centre in the other Member State where the problem has occurred (known as the 'Lead' SOLVIT Centre). (See figure 2).

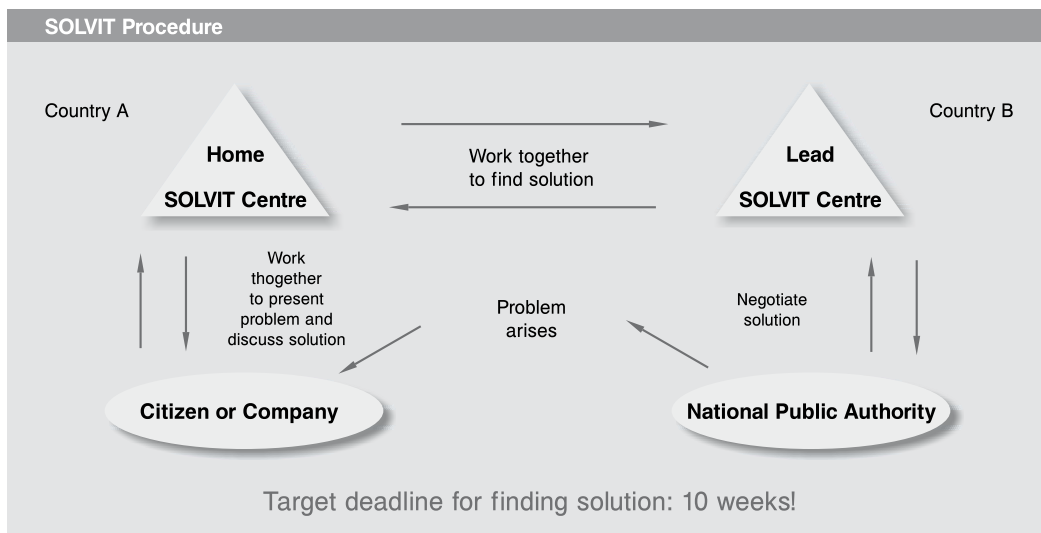


Figure 2. SOLVIT Procedure

The good thing about SOLVIT is that it is informal and thus offers a possible quick solution to the problem. The Lead SOLVIT Centre should thus confirm within a week whether or not it will take on the case. The target deadline for finding a solution to the problem is 10 weeks. This is not always possible, however, but the Home SOLVIT Centre will keep the company informed of progress and the proposed solution.

If a problem goes unresolved, or the company considers that the proposed solution is unacceptable, it can still pursue legal action through a national court or lodge a formal complaint with the European Commission.

Statistics show that 73% of cases raised are solved through the SOLVIT Centres. See europa.eu.int/solvit/ where appropriate forms for submitting a case can be found.

III. The New Approach and the Global Approach

To eliminate technical barriers within the internal market harmonisation of technical legislation is needed. For highly technical legislation this is a very lengthy procedure, as it has to meet the individual requirements of each product category. Therefore, in order to create a single market, in 1985 a new regulatory technique was established, called "The New Approach".

A New Approach directive deals with whole economic sectors or product areas. Examples of New Approach directives are: the Machinery Directive; the Low Voltage Directive; The Toy Safety Directive, and the Medical Device Directive. It defines the essential requirements for the product, covering health, safety and in some cases the environment. The technical details are covered by European harmonised standards. The use of such standards gives presumption of conformity with the requirements of the directive. The directive also specifies which module should be used for conformity assessment. According to the New Approach the control of public authorities prior to a product being placed on the market is reduced. The reduced pre-market control is balanced by increased post-market control by market surveillance authorities.

More information and a guideline on the New Approach can be found on the Commission website: www.ec.europa.eu/enterprise/newapproach. See also the list of directives and follow the shortcut to standards on the website: www.newapproach.org. By a legislative package, called the New Legislative Framework, this approach was updated and improved in July 2008 (see section IV).

The 'Global Approach' defines the different modules which may be used for conformity assessment, as specified in the applicable directive. The modules relate to the design phase of products, their production phase or both. As a general rule, a product is subject to conformity assessment according to a module during the design as well as the production phase. The different modules involve a third party (called Notified Body) to different degrees, from no involvement in Module A - with internal design control - over type approval to full quality assurance.

In 21 out of 25 directives under the New Approach CE-marking is required.

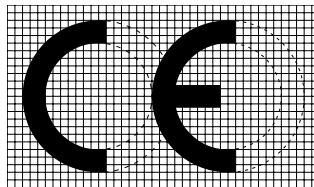


Figure 3: CE-marking

CE-marking shall mean a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing (as defined in the Regulation 765/2008).

The CE marking is mandatory (when required by the applicable directive) and must be affixed before any product subject to it is placed on the market and put into service. 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 (this is e.g. relevant for furniture or textiles which are not to be CE-marked).

CE-marking procedure

The CE-marking involves several functions in the company. Before affixing the CE-marking the manufacturer must follow the below procedure:

1. Specify applicable directives.
2. Define appropriate standards (harmonised, if any).
3. Determine applicable essential requirements.
4. Carry out a risk assessment (eliminate or reduce risks as far as possible, take the necessary protective measures in relation to risks that cannot be eliminated, and inform users of residual risks, if any).
5. Fulfil conformity assessment procedure according to the requirements of the applicable directive.
6. Establish the technical documentation which shall make it possible to assess the product's conformity to the relevant requirements, and shall include the risk assessment.
7. Elaborate the instructions for use, handling, maintenance etc.
8. Draw up an EC declaration of conformity.
9. Affix the CE-marking.

IV. The New Legislative Framework

25 years after the introduction of the New Approach, a need was felt to update and improve some aspects of the approach. The revision process resulted in the so-called New Legislative Framework which applies to the free movement of goods. It was finally approved on 9 July 2008.

The objective of the framework is that it shall lead to more safe products on the market, i.e. better consumer protection, as well as to a better level playing field for companies. It shall also lead to a strengthening of the CE-marking which will be a Community registered trade mark.

The framework consists of three instruments:

Regulation on accreditation, CE-marking and market surveillance (765/2008) - in force as of 1 January 2010

- Accreditation is part of an overall system, including conformity assessment and market surveillance, designed to assess and ensure conformity with the applicable requirements. The particular value of accreditation lies in the fact that it provides an authoritative statement of the technical competence of bodies whose task is to ensure conformity with the applicable requirements. It provides for a legislative framework for accreditation, both in the mandatory and the voluntary field, and includes the provision to have one accreditation body only in each country to avoid competition. The aim is to make mutual recognition of accreditation function in practice and thus avoid multiple accreditation. Therefore the regulation also specifies requirements to ensure a high level of competence and to safeguard the objectivity and impartiality of its activities.
- The CE-marking and the general principles for its affixing are now defined in this regulation. It makes the principles immediately applicable and strengthens its future use as the only marking of conformity indicating that a product is in conformity with Community harmonisation legislation.
- The regulation also provides a framework for the market surveillance of all products covered by Community harmonisation legislation in order to ensure that those products fulfil the regulatory requirements. It obliges Member States (including customs authorities) to set up efficient control systems and to cooperate across borders. Member States are required to draw up either a general market surveillance programme or sector specific programmes, and to make them available to the public.

Decision on a common framework for the marketing of products (768/2008)

- This Decision is addressed to the EU-institutions. It serves as a template for future product legislation. Thus, its provisions will apply only when taken up in specific sector regulation.
- It introduces common definitions; implements the main principles of the New Approach, including the conformity assessment procedures; and clarifies the obligations of the economic operators (manufacturers, authorised representatives, importers and distributors). Furthermore, it specifies the procedures and competences required for the notification of Notified Bodies. It is recommended that notification is based on accreditation in order to ensure a uniform level of technical competence. Of special interest to manufacturers it is stated that notified bodies are to apply the modules without creating unnecessary burdens for economic operators.

Definitions (Extract from Decision No 768)

“Manufacturer” shall mean any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark.

“Importer” shall mean any natural or legal person established within the community who places a product from a third country on the Community market.

“Distributor” shall mean any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market.

Obligations of economic operators (Extract of Decision No 768, articles R2.1,2,6; R4.1,2; R5.1,2)

When placing their products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in...

Manufacturers shall draw up the required technical documentation and carry out the conformity assessment procedure applicable or have it carried out.

Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted.

Importers shall place only compliant products on the community market

Before placing a product on the market importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer...

Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product.

When making a product available on the market distributors shall act with due care in relation to the requirements applicable.

Before making a product available on the market distributors shall verify that the product bears the required conformity marking or markings, that it is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the product is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in ...

Regulation laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State... (764/2008) - to be applied as of 13 May 2009

- As mentioned in section II on notification of national technical standards and regulations, Member States are obliged to communicate to the Commission and the other Member States any draft technical regulation concerning products. The aim of the regulation is to ensure that, following the adoption of such a technical regulation, the principle of mutual recognition is correctly applied to specific products.
- Thus, the Regulation lays down a procedure for the application of the principle of mutual recognition in individual cases. This includes that Member States are obliged to justify the possible application of the technical rule to a product lawfully marketed in another Member State and to demonstrate in each case to the economic operator, based on technical or scientific elements available, that there are overriding reasons of public interest for imposing such a national rule to the product in question.
- In order that enterprises can gain access to information in a transparent and correct manner, the Regulation also stipulates that Member States shall establish Product Contact Points. These Contact Points shall - free of charge - provide information concerning their respective national technical rules and the application of the principle of mutual recognition.

Useful websites:

General information, Guidelines etc.

ec.europa.eu/enterprise/newapproach

europa.eu.int/comm/enterprise/pressure_equipment/ped

europa.eu.int/comm/enterprise/mechan_equipment

europa.eu.int/comm/enterprise/atex

Search for specific directives (by indicating year and number)

europa.eu.int/eur-lex

List of directives and shortcut to standards

www.newapproach.org

National technical regulation, i.e. 98/34 information site:

europa.eu.int/comm/enterprise/tris

STANDARDS AND CERTIFICATION

Emilija Bratož, MSc.

Slovenian Chamber of Craft and Small Business

GENERAL PRINCIPLES OF CERTIFICATION AND USE OF STANDARDS

1. Legislation and technical regulations for technical products - in general

- Directive 2001/95/EC on general safety of product
- Directive 85/374/EEC concerning liability for defective products

Legislation for different products	HARMONIZED		NON-HARMONIZED	
	EU DIRECTIVES		NATIONAL	unpublished
	TECHNICAL		OTHER	
Approach	OLD	NEW		
Horizontal legislation	GENERAL SAFETY OF PRODUCTS			
	NATIONAL			

Hierarchy of using legislation and other tools for conformity assessment:

- Directives 2001/95/EC and 85/374/EEC cover necessary requirements that manufacturer or his authorized representative shall fulfil for each group of products before they are placed on the internal market
- Appropriate New Approach Directives
- List of standards that assume presumption of conformity:
 - compliance with harmonized standards implies “presumption of conformity” to the regulations
 - since compliance with the standard is voluntary, it is a “praiseworthy” act on the part of the manufacturer
 - the manufacturer remains free not to follow the standard
 - non-compliance with a standard never necessarily means that the product does not conform to regulations.

2. Use of standards

The conformity of a product to the general safety requirement shall be assessed by taking into account the following elements in particular, where they exist:

Where neither a specific Regulation nor national safety law applies, safety will be assessed taking each of the following into account in turn:

- voluntary European standards (i.e. SR EN, BDS EN, HRN EN, TS EN)
- community technical specifications (TS)
- national standards (which are not versions of European standards)
- industry codes of good practice
- “state of the art” and technology, and the safety which consumers may reasonable expect.

3. Types of standards.

3.1 Harmonized standards - harmonization documents are European standards or harmonization documents drawn up by the European standards bodies on the basis of a general specification agreed between these organizations and the European Commission.

Harmonized standards are drafted on the basis of a mandate setting out the purpose of the standard.

- The Member States are consulted for their opinion on the mandate via a committee set up by Directive 83/189/EEC.
 - The European standards bodies present the harmonized standard to the Commission which publishes the references in the Official Journal.
 - The harmonized standard is taken over unchanged in the Member States' national collections.
- Member States shall publish the references of national standards transposing harmonized standards.

Harmonization documents (HDs for short):

- CEN and CENELEC draft harmonization documents if transposition into identical national standards is unnecessary.
- This happens when there are certain national divergences.
- In practice CEN has not been drafting harmonization documents for several years. CENELEC has published many and tends to transform them into European standards when they come up for revision.

3.2. European standards are standards established by the European standards bodies to meet industrial or commercial requirements but with no particular link with a "new approach" Directive or legal constraint.

- Any national standard dealing with the same subject must be withdrawn and replaced by the transcription of the European standard.
- European standards, whether or not harmonized, are available only through the Member States' national collections. They are characterized by the letters "EN" in the name of the standard.

3.3 National standards can be of strictly national, European or international origin. Some European standards also take over the contents of international standards.

- Notification under the procedures of Directive 83/189/EEC is needed for such standards.

4. Mandatory use of standards.

CEN has defined three types of harmonized standards

This terminology is specific to the standards drafted under the Machinery Directive (98/37/EC & 2006/42/EC). Classes A, B and C do not have the same meaning under other Directives, such as "construction products" (89/106/EEC).

- A standards deal with basic concepts concerning all machinery; standard EN 292 is an example of this category.
- B standards:
 - B1 standards deal with safety aspects concerning a range of machinery such as safety distances, calculation methods for lifting equipment, etc.; examples are EN 294 on safety distances and EN 563 on temperatures of touchable surfaces.
 - B2 standards deal with components or devices, such as safety devices, which are used on a wide variety of machinery; EN 281, on the design of pedals, is an example.
- C standards are "vertical" standards covering a single type of machinery.

Standards are mandatory in only three cases:

- If standard is imposed by regulation. Within this framework, the provisions of the standard become full regulatory provisions. With a few exceptions (like CPD), this is not the case of the “new approach” Directives.
- If standard is incorporated into a private or public contract. Compliance with the standard then becomes a contractual obligation which, like any undertaking of that nature, is freely negotiable.
- If standard codifies “good engineering practice”. Contrary to popular opinion this happens very rarely. It is not the standard which is mandatory but rather the rules of good practice. A standard cannot claim always to reflect good engineering practice. It must really be an incontestable expression of actual professional practice widespread in the trade concerned.

MACHINERY DIRECTIVE

I. Machinery Directive - 98/37/EC & 2006/42/EC

Coverage

- essentially all machines which have at least one moving part
- an assembly of linked parts or components, at least one of which moves, with the appropriate actuators, control and power circuits, etc., joined together for a specific application
- interchangeable equipment which can modify the function of a machine (this equipment is not a spare part or a tool)
- safety components
- mechanic equipment either for workplace or domestic use where the major risk to safety is deemed to be mechanical (in particular for the processing, treatment, moving or packaging of a material,...)

Any component of machinery, whatever it is, must be safe and reliable owing to the general safety obligation and obligation to observe good engineering practice. The Directive (Annex I) lays down essential requirements for human health and safety mostly concerning operators and persons near to machinery. The essential safety requirements do not directly concern environmental protection or the technological performance of machinery.

Exclusions from the scope:

- machinery whose only power source is directly applied manual effort
- machinery for medical use used in direct contact with patients
- steam boilers, tanks and pressure vessels
- machinery specially designed or put into service for nuclear purposes
- firearms
- storage tanks and pipelines for petrol, diesel fuel, inflammable liquids and dangerous substances,
- transport products, i.e. vehicles,...
- cableways, including funicular railways, for the public or private transportation of persons,
- agricultural and forestry tractors
- machines, specially designed and constructed for military or police purposes
- lifts which permanently serve specific levels of buildings and constructions.

II. Certification procedure - Article 8

- Article 8 (1)... is the most important for manufacturer
 1. The manufacturer or his authorized representative established in the Community must draw up an EC declaration of conformity based on the model given in Annex II, A or C as appropriate - for all

machinery or safety components manufactured. In addition, for machinery by itself, the manufacturer or his authorized representative established in the Community must affix to the machine the CE marking referred to in Article 10.

Additional annexes

- Annex II.A is the general declaration of conformity for machinery
- Annex II.B is the declaration of incorporation of a subassembly into machinery
- Annex II.C is the declaration of conformity for safety components.

The Global Approach lays down the general guidelines and procedures (modules) for conformity assessment that are to be used in New Approach directives. Modules are determined in accordance with the level of possible RISK.

Conformity assessment according to the modules is either based on the intervention of a first party (manufacturer) or a third party (notified body) and relates to the design phase of products, to their production phase or both (see the list of modules). Should a manufacturer subcontract design or production, he still remains responsible for the execution of conformity assessment for both phases.

Module A: Internal control of production

Covers internal design and production control. This module does not require a notified body to take action.

Module 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.

Module 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.

Module 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.

Module 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.

Module F: Product verification

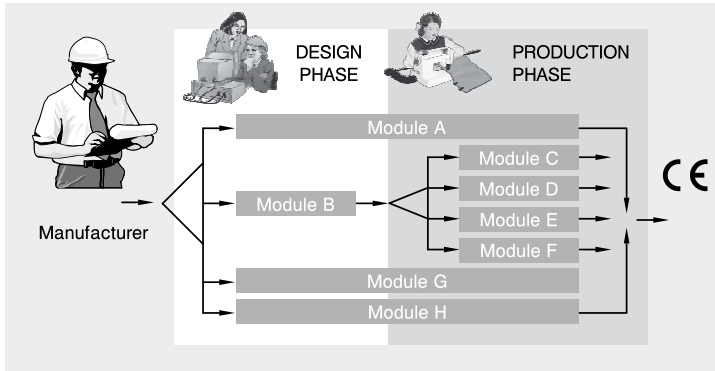
Covers the production phase and follows module B. A notified body controls conformity to the type as described in the EC type-examination certificate issued according to module B, and issues a certificate of conformity.

Module G: Unit verification

Covers a design and production phases. Each individual product is examined by a notified body, which issues a certificate of conformity.

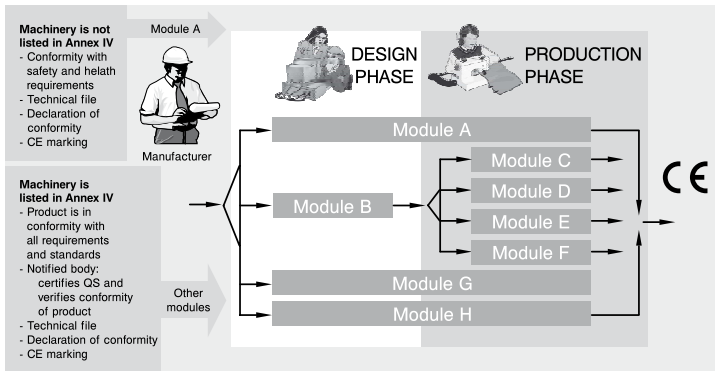
Module H: Full quality assurance

Covers a 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.



Conformity assessment procedures of the New approach: the modules

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



Obligation for marking depends of Directive that covers different products or components (see the table).

EACH MACHINE UNDER DIRECTIVE [listed in Annex IV]	CE - MARKING under MD	EC-declaration under MD
SAFETY COMPONENTS *	Not marked MARKED ACCORDING TO OTHER DIRECTIVES	EC - declaration according to other directives **

* Safety components are a special case because the safety function depends on the performance of the product.

** The content of this declaration is specified in detail in Annexes II.A and II.C

Basic standards for machinery

EN 292-1: 1991 Safety of machinery. Basic concepts, general principles for design. Basic terminology, methodology includes a list and description of the hazards that can be generated by machinery:

- mechanical hazards
- electrical hazards
- thermal hazards
- hazards generated by noise and vibration
- hazards generated by radiation including RF, light and radiation sources
- hazards generated by materials and substances
- hazards generated by reflecting ergonomic principles in machine design
- combination of hazards.

A strategy for selecting safety measures is described in a detail. It defines the duties on the designer and the relationship between the duties of the designer and that of the user.

EN 292-2:1991 is giving an advice on how this philosophy can be applied using available techniques and methods of avoiding different hazards.

III. Technical documentation (Annex VII)

A construction file for each type of machinery is needed to prepare before putting on internal market and shall include:

- a general description of the machinery
- the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery
 - full detailed drawings, accompanied by any calculation notes, test results, certificates, etc.
 - the documentation on risk assessment (a list of the essential health and safety requirements which apply to the machinery and the description of the protective measures implemented to reduce risks)
- the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards
- any technical report giving the results of the tests carried out either by the manufacturer or a notified body
- a copy of the instructions for the machinery, (for use, for maintenance, other instructions)
- where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery, or copies of the EC declaration of conformity for such machinery
- a copy of the EC declaration of conformity.

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. It has to be made available to the competent authorities of the Member States for at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced. It does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. However, it must be capable of being assembled and made available within a period of time commensurate with its complexity by the person designated in the EC declaration of conformity.

IV. Declaration of conformity

The EC declaration of conformity is a document that ensure either

- 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.

Particulars

- Name and address of the manufacturer or the authorized representative, established in the Community.
- Description of the machinery or machinery parts.
- Where appropriate, the name and address of the notified body and the number of EC type-examination certificate (or technical file has been forwarded in accordance with the first indent of Article 8(2)(c), or which has carried out the verification referred to the second indent of Article 8(2)(c)).
- Where appropriate, a reference to the harmonized standards.
- Where appropriate, a reference to the technical standards and specifications used.
- Different statements; e.g.: A statement that machinery must not be put into service until the machinery into which it is to be incorporated has been declared in conformity with the provisions of the Directive.
- Identification of the person, empowered to sign the declaration.

V. CE marking

CE marking is the practical way to physically show on a given product that it is presumed to comply with the provisions of the relevant directives and, in most cases that an EC declaration of conformity to the relevant essential requirements has been issued for the product under the responsibility of a manufacturer.

- The CE conformity marking shall consist of the initials “CE” taking the following form:



- If the CE marking is reduced or enlarged the proportions shown in the above drawing must be respected.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. The minimum dimension may be waived for small-scale machinery.
- The CE marking must be affixed in the immediate vicinity of the name of the manufacturer or his authorised representative, using the same technique.
- Where the full quality assurance procedure has been applied, the CE marking must be followed by the identification number of the notified body.

Affixing the CE mark

- **MUST**
 - When the product belongs to one or more New Approach directives.
 - When the product complies with the provisions of the applicable New Approach directives.
- **MUST NOT**
 - When the product is not covered by a New Approach directive.

- When the product does not comply with the provisions of the applicable New Approach directives.

Therefore, if the EEA State's authorities find out that the CE marking has been wrongly affixed (i.e. wrong conformity assessment procedure, labelling problem...) the manufacturer or his authorised representative will be obliged to put an end to the infringement under conditions imposed by the member state.

VI. Instructions (Annex I - 1.7.4)

Must include the following information (see 1.7.4.2)

- Business name, address of manufacturer, designation of machinery, EC declaration of conformity, general description of the machinery, drawings, diagrams.
- Essential health and safety requirements (material, control devices, conditions for use, assembly, installation and connection instructions, ...).
- Adjustment and Maintenance.
- Operating method, using of tools and spare parts.
- Errors and their meaning.
- Information on airborne noise emissions.
- Protective measures to be taken.
- Transport, handling and storage operations.

Language, translation

- Instructions shall be written in the official language of the Member State.
- Translation of the original instructions must be accompanied by the original.

VII. Overlap with other directives, for example:

- Relationship with the LVD Directive.

Certain electrical equipment are also machinery within the meaning of MD. Both directives cover a wide range of risks, what is better explained in standard.

EN 1050: Safety of Machinery - Principles for risk assessment

When the results of risk assessment made by manufacturer show that they are mainly of electrical origin the machinery equipment will be covered exclusively by the LVD.

- Relationship with the EMC Directive.

Compliance with some chapters of a relevant harmonized standard provides presumption of conformity with the specific essential requirements of Directive.

Necessary steps before placing machinery on a market for the manufacturer are:

- a) ensure that it satisfies the relevant essential health and safety requirements set out in Annex I
- b) ensure that the technical file referred to in Annex VII, part A is available
- c) provide, in particular, the necessary information, such as instructions
- d) carry out the appropriate procedures for assessing conformity in accordance with Article 12
- e) draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery
- f) affix the CE marking in accordance with Article 16.

VIII. Inspection - non-conformity and dangerous products (Art 7)

Where a Member State ascertains that

- machinery bearing CE marking but safety components accompanied by the EC declaration of conformity, used in accordance with their intended purpose, are liable to endanger the safety of persons, and, where appropriate, domestic animals or property,
- not bearing CE marking or not used in accordance with its intended purpose.

It shall take all appropriate measures to withdraw such machinery or safety components from the market, to prohibit the placing on the market, putting into service or use thereof, or to restrict free movement thereof. Only Member State may initiate an administrative procedure prohibiting marketing against a manufacturer (safeguard clause). In practical terms, as soon as the hazard to the health and/or safety of persons has been recognized, the Member State takes appropriate measures - proportionate to the danger. The measures taken cannot be permanent: they are precautionary measures intended to protect users, without prejudice to the responsibilities or errors of the manufacturer. They can be lifted at any time.

Non-conformity or incorrect application; examples

The Member State shall immediately inform the Commission of any such measure, indicating the reasons for its decision and, in particular, whether non-conformity is due to:

- a) failure to satisfy the essential requirements referred to in Article 3, examples:
 - the manufacturer wishes to avoid an EC type-examination of machinery listed in Annex IV,
 - where the technical file merely declares that the machinery conforms to a harmonized standard without giving further details
- b) incorrect application of the standards referred to in Article 5(2)
- c) shortcomings in the standards referred to in Article 5(2) themselves.

Examples:

- The standard may have proposed a technical solution which proves dangerous in practice.
- The standard may have proposed a safety solution which proves inadequate in practice.
- The standard may have dealt correctly with a hazard but not solved other related technical problems. Certain safety solutions can create more problems than they solve. One example is reconciling the need for cleaning in food hygiene and prohibiting access to moving parts.
- The standard may be obsolete in relation to good engineering practice.

IX. Answers on some frequent questions

What are manufacturers' obligations at trade fairs, exhibitions, demonstrations, etc:

- Showing of machinery or safety components which do not conform to the provisions of this Directive, shall be provided with a visible sign clearly indicates that such machinery or safety components do not conform and that they are not for sale until they have been brought into conformity. This is an obligation of the manufacturer or his authorized representative established in the Community.
- During demonstrations, adequate safety measures shall be taken to ensure the protection of persons.

Concept of second-hand machinery

- Second-hand applies to work equipment which have already been used in a country of the EEA and are once again being placed on the EEA market. This fact assumes that the second-hand machinery has passed the stage of first being placed on the market and first being put into service in the EEA.

Concept of “reconditioned” machinery

- Reconditioned machinery is existing machinery which has undergone technical work designed to modify its condition, its performance, its safety, etc. This work may consist of modifying the machinery to a greater or lesser extent.
- Concept of “reconstructed” or “rebuilt” machinery.
“Reconstructed” or “rebuilt” machinery is new machinery consisting, entirely or in part, of parts taken from old machinery.

Can European directives be applied to second-hand or reconditioned machinery?

- “NA” Directives were designed exclusively for new products or for products regarded as new.
- Application might result in a loss of credibility for the “CE” marking. It might also affect fair trading and cause unacceptable distortion of competition.

Second-hand machinery from third countries

- Machinery in service in a third country has never been placed on the market in the EEA. When such machinery leaves the third country and crosses the frontier of the EEA it counts as being placed on the market in the EEA for the first time. As such, all European Directives are applicable, and the machinery must meet all the obligations of new machinery.
“Reconstructed” or “rebuilt” machinery is regarded as “new” machinery!
- Where existing machinery is completely “stripped down” and only a few original parts remain, the question arises as to whether this is reconditioned machinery or new machinery consisting partly of “recovered” components.
- The “reconstructor” can decide to consider this machinery as “new”. This machinery has undergone effective “reconstruction”. It is “rebuilt”. It is ecological “new” machinery in a way in that it consists, entirely or in part, of recovered parts.
- The original machinery has not been used by the renovator as initial machinery, but as a source of spare parts in order to make something new.

PACKAGING

I. Why to talk about packaging?

- Packaging is the science, art and technology of enclosing or protecting products for distribution, storage, sale, and use. Packaging also refers to the process of design, evaluation, and production of packages. Package labelling is any written, electronic or graphic communications on the packaging or on a separate but associated label.
- Packaging can be described as a coordinated system of preparing goods for transport, warehousing, logistics, sale, and end use. Packaging contains, protects, preserves, transports, informs and sells. It is fully integrated into government, business, institutional, industry and personal use.
- Packaging and package labelling have several objectives: physical protection, barrier protection, containment or agglomeration, information transmission, convenience, etc.
- Environmental aspects: Development of sustainable packaging is an area of considerable interest by standards organizations, government, consumers, packagers and retailers.

II. Package development considerations.

- Package design and development are often thought of as an integral part of the new product development process.

- Can be a separate process, but must be linked closely with the product to be packaged.
 - Within a company or with various degrees of external packaging engineering: contract engineers, consultants, vendor evaluations, independent laboratories, contract packagers, total outsourcing, etc.
 - Package design starts with the identification of all the requirements: legal, regulatory, environmental, structural design, marketing, shelf life, quality assurance, logistics, graphic design, end-use, etc.
 - The design criteria, time targets, resources, and cost constraints need to be established and agreed upon.
 - An effective quality management system and verification and validation protocols are mandatory for some types of packaging and recommended for all.
 - Package development involves consideration for:
 - sustainability
 - applicable environmental and recycling regulations
 - life cycle assessment (considers the material and energy inputs and outputs to the package, the packaged product (contents), the packaging process, the logistics system, waste management, etc.
- It is necessary to know the relevant regulatory requirements for point of manufacture, sale, and use.

III. Packaging types

- Packaging may be looked at as several different types:
 - transport package or distribution package is the package form used to ship, store, and handle the product or inner packages
 - consumer package is one which is directed toward a consumer or household
- Packaging may be discussed in relation to the type of product being packaged.
- Packaging by layer or function: "primary", "secondary", etc.:
 - Primary (sales) packaging is the material that first envelops the product and holds it. This usually is the smallest unit of distribution or use and is the package which is in direct contact with the contents.
 - Secondary (grouped) packaging is outside the primary packaging - perhaps used to group primary packages together.
 - Tertiary (transport) packaging is used for bulk handling, warehouse storage and transport shipping. The most common form is a palletized unit load that packs tightly into containers.

IV. Aims and goals

- Minimize the impact to the environment.
- Reducing quantity of packaging waste.
- The management of packaging and packaging waste requires the Member States to set up return, collection, reuse and recovery systems concerning the nature of the packaging material(s) used.
- Target:
 - 50 - 65% as a maximum by weight of the packaging waste will be recovered
 - 25 - 45% by weight will be recycled with a minimum of 15 % by weight for each packaging material.
- Sorting at source.
- Limiting the presence of noxious metals and other substances in packaging.

V. Directive 94/62/EC of 20 December 1994 on packaging and packaging waste

(Directive 91/689/EEC on hazardous waste)

- Lays down measures aimed at reusing packaging, at recycling and other forms of recovering packaging waste and, hence, at reducing the final disposal of such waste.
- Covers all packaging placed on the market in the Community and all packaging waste, whether it is

used or released at industrial, commercial, office, shop, service, household or any other level, regardless of the material used.

- Identification system (Annex I).
- Essential requirements on the composition and the reusable and recoverable nature of packaging (Annex II).
- Data to be included by member states in their databases (Annex III).

Identification system (Annex I)

The numbering used shall be:

- from 1 to 19 for plastic
- from 20 to 39 for paper and cardboard
- from 40 to 49 for metal
- from 50 to 59 for wood
- from 60 to 69 for textiles and
- from 70 to 79 for glass.

The identification system may also use the abbreviation for the relevant material(s) (e. g. HDPE: high density polyethylene). Materials may be identified by a numbering system and/or abbreviation. The identification marks shall appear in the centre of or below the graphical marking indicating the reusable or recoverable nature of the packaging.

Return, collection and recovery systems - Annex II

A. Requirements specific to the manufacturing and composition of packaging

- Packaging shall be so manufactured that the packaging volume and weight be limited to the minimum adequate amount to maintain the necessary level of safety, hygiene and acceptance for the packed product and for the consumer.
- Packaging shall be designed, produced and commercialized in such a way as to permit its reuse or recovery, including recycling, and to minimize its impact on the environment when packaging waste or residues from packaging waste management operations are disposed of.
- Packaging shall be so manufactured that the presence of noxious and other hazardous substances and materials as constituents of the packaging material or of any of the packaging components is minimized with regard to their presence in emissions or ash when packaging or residues from management operations or packaging waste are incinerated or landfilled.

B. Requirements specific to the reusable nature of packaging

- The physical properties and characteristics of the packaging shall enable a number of trips or rotations in normally predictable conditions of use.
- Possibility of processing the used packaging in order to meet health and safety requirements for the workforce.
- Fulfil the requirements specific to recoverable packaging when the packaging is no longer reused and thus becomes waste.

C. Requirements specific to the recoverable nature of packaging

- Packaging recoverable in the form of material recycling must be manufactured in such a way as to

enable the recycling of a certain percentage by weight of the materials used into the manufacture of marketable products, in compliance with current standards.

- Packaging recoverable in the form of energy recovery shall have a minimum inferior calorific value to allow optimization of energy recovery.
- Packaging recoverable in the form of composting shall be of such a biodegradable nature that it should not hinder the separate collection and the composting process or activity into which it is introduced.
- Biodegradable packaging waste shall be of such a nature that it is capable of undergoing physical, chemical, thermal or biological decomposition such that most of the finished compost ultimately decomposes into carbon dioxide, biomass and water.

The waste hierarchy

- Prevention - primary goal. Packaging should be used only where needed. Proper packaging can also help prevent waste. Packaging plays an important part in preventing loss or damage to the packaged-product (contents). Usually, the energy content and material usage of the product being packaged are much greater than that of the package. A vital function of the package is to protect the product for its intended use: if the product is damaged or degraded, its entire energy and material content may be lost.
- Minimization - (also "source reduction") The mass and volume of packaging (per unit of contents) can be measured and used as one of the criteria to minimize during the package design process. Usually "reduced" packaging also helps minimize costs. Packaging engineers continue to work toward reduced packaging.
- Reuse - Returnable packaging has long been useful (and economically viable) for closed loop logistics systems. Inspection, cleaning, repair and recoupage are often needed.
- Recycling is the reprocessing of materials (pre- and post-consumer) into new products. Emphasis is focused on recycling the largest primary components of a package: steel, aluminum, papers, plastics, etc. Small components can be chosen which are not difficult to separate and do not contaminate recycling operations.
- Energy recovery - Waste-to-energy and Refuse-derived fuel in approved facilities are able to make use of the heat available from the packaging components.
- Disposal - Incineration and placement in a sanitary landfill are needed for some materials. Material content should be checked for potential hazards to emissions and ash from incineration and leachate from landfill. Packages should not be littered.

Standardization

The Commission shall promote using European standards relating to:

- criteria and methodologies for life-cycle analysis of packaging
- the methods for measuring and verifying the presence of heavy metals and other dangerous substances in the packaging and their release into the environment from packaging [CR 13695-1, CR 13695-2]
- criteria for a minimum content of recycled material in packaging for appropriate types of packaging [EN 13428]
- criteria for recycling methods [EN 13429]
- criteria for composting methods and produced compost [EN 13432]
- criteria for energy recovery [EN 13431]
- criteria for the marking of packaging.

Basic standard on the requirements for the use of European Standards in the field of packaging and packaging waste is EN 13427.

Table includes the best possibility of recovery of different types of material and relating standards.

Material	Possible type of recovery	Standard
Glass	Material recycling; packaging - requirements for packaging recoverable by material recycling Taljenje	EN 13430
Metal / Al	Material recycling	EN 13430
Paper and board	Material reuse and recycling; razbarvanje, mletje, stiskanje, sušenje, razrez Organic degradation Packaging. Requirements for packaging recoverable through composting and biodegradation	EN 13430 EN 13432
Plastic (PE, PP, PET, PS)	Recycling; Energy recovery; requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value [combustion]	EN 13430 EN 13431
Plastic (PVC)	Energy recovery; combustion	EN 13431
Wood	Material recycling Energy recovery Organic degradation	EN 13430 EN 13431 EN 13432

VI. Declaration of conformity.

Issuing of declaration of conformity is final obligation of manufacturer and users for different purposes.

Obligation for	Purpose	Who / from who	What / how
Glass	Before placing on market or using by his own reduction	By his own; when the packaging meets requirements of Directive	Issue the declaration about conformity with the standard EN 13427
Packer	For packaging goods/ products (for himself or for market)	Get from a producer or trader / distributor	Declaration of conformity
Transferee, trader / retailer, distributor	For packaging of goods	From supplier of packaged goods/ products	Announcement that declaration exists and was issued
Trader / retailer, distributor	To the inspector	From supplier of packaged goods/ products	Copy of declaration

VII. Symbols used on packages and labels

- Packaging shall bear the appropriate marking either on the packaging itself or on the label. It shall be clearly visible and easily legible. The marking shall be appropriately durable and lasting, including when the packaging is opened.
- Many types of symbols for package labelling are nationally and internationally standardized. For consumer packaging, symbols exist for product certifications, trademarks, proof of purchase, etc. Some requirements and symbols exist to communicate aspects of consumer use and safety. Recycling directions and package environmental claims have special codes and symbols.
- The numbering and abbreviations on which the identification system is based and shall specify which materials shall be subject to the identification system.
- Shipments of hazardous materials or dangerous goods have special information and symbols (labels, posters, etc) as required by law or regulations:



Plastics

- There are a wide range of plastics used in packaging. To make sorting and thus recycling easier, the American Society of Plastics Industry developed a standard marking code to help consumers identify and sort the main types of plastic. These types and their most common uses are shown below:
- PET 01 - Polyethylene terephthalate - Fizzy drink bottles and oven-ready meal trays.
- HDPE 02 - High-density polyethylene - Bottles for milk and washing-up liquids.



- PVC Polyvinyl chloride - Food trays, cling film, bottles for squash, mineral water and shampoo.
- LDPE Low density polyethylene - Carrier bags and bin liners.
- PP Polypropylene - Margarine tubs, microwaveable meal trays.
- PS Polystyrene - Yoghurt pots, foam meat or fish trays, hamburger boxes and egg cartons, vending cups, plastic cutlery, protective packaging for electronic goods and toys.
- OTHER: Any other plastics that do not fall into any of the above categories. - An example is melamine, which is often used in plastic plates and cups.

Graphical symbols specified in some standards:

ISO 7000: Graphical symbols for use on equipment - Index and synopsis



EN ISO 14021: Environmental labels and declarations- Self-declared environmental claims

- Another symbol often appearing on packaging is the German “Green Dot”. This does not have any environmental significance, it means only that the manufacturer has paid a fee towards the packaging recovery system in Germany.



- The European Eco-label has been developed by the European Union to encourage the development of products which keep the impact on the environment to a minimum.
- This symbol has a meaning you can put the packaging into compost collection box or bag (if they provide one!). This is a relatively new symbol found on biodegradable plastic packaging. The symbol signifies that the packaging has been tested and is suitable for putting into local authority compost collections.



- With transport packages standardised symbols are also used to aid in handling in a physical distribution chain. Some common ones are shown below while others are listed in ISO 780 “Pictorial marking for handling of goods”.



fragile



keep away from heat



keep dry indicator (on a carton)



this side up

Standard does not include instructions specific to the handling of dangerous goods.

MATERIALS AND ARTICLES IN CONTACT WITH FOODSTUFFS (ACF)

I. Packaging in a contact with foodstuffs - Legislation:

- requirements for materials and articles and duties for registration (Directive 1935/2004/EC)
- requirements for plastic materials and articles (Regulation 2002/72/EC + Commission Directive 2005/79/EC)
- good manufacturing practice (Regulation 2023/2006/EC)

Any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to cause an unacceptable change in the composition of the food or a deterioration in its organoleptical properties! In addition, adequate labelling or information should support users in the safe and correct use of active materials and articles in compliance with the food legislation, including the provisions on food labelling.

II. Directive 1935/2004/EC

Specific measures for some groups of materials and their combinations may include:

- a) a list of substances authorised for use in the manufacturing of materials and articles
- b) list(s) of active or intelligent materials and articles
- c) purity standards for substances referred to in (a)
- d) special conditions of use for substances referred to in (a) and/or the materials and articles in which they are used
- e) specific limits on the migration of certain constituents or groups of constituents into or on to food,
- f) an overall limit on the migration of constituents into or on to food
- g) provisions aimed at protecting human health against hazards arising from oral contact with materials and articles
- h) basic rules for checking compliance with points (a) to (g)

When a Member State, as a result of new information or a reassessment of existing information has detailed grounds for concluding that the use of a material or article endangers human health, it shall immediately inform the other Member States and the Commission and give reasons for the suspension or restriction.

Declaration of compliance - Traceability:

- The specific measures shall require that materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them.
- Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.

Traceability

- The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.
- With due regard to technological feasibility, business operators shall have systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products used in their manufacture are supplied. That information shall be made available to the competent authorities on demand.
- The materials and articles which are placed on the market in the Community shall be identifiable by an appropriate system which allows their traceability by means of labeling or relevant documentation or information.

Package labeling

- materials and articles, which are not yet in contact with food when placed on the market, shall be accompanied by:
 - (a) the words "for food contact", or a specific indication as to their use, such as coffee machine, wine bottle, soup spoon, or the symbol reproduced in Annex II

- b) if necessary, special instructions to be observed for safe and appropriate use
- c) the name or trade name and, in either case, the address or registered office of the manufacturer, processor, or seller responsible for placing on the market established within the Community
- d) adequate labeling or identification to ensure traceability of the material or article, as described in Article 17
- e) in the case of active materials and articles, information on the permitted use or uses and other relevant information such as the name and quantity of the substances released by the active component.

Registration duties

THE REGISTRATION at authority IS OBLIGED to enterprises that:

- Manufacturing of ACF.
- Import of materials and articles from third countries.
- Distribution and direct supply from EU countries.

Special examples:

- Producers or manufacturers of foodstuffs that directly import articles from third countries or from Europe for their own use or distribution.
- Retailers or marketplaces in the case of direct import from third countries.
- Restaurants, guesthouses, removable canteens, catering, ... (pizza boxes, table cutlery, plates, glasses... etc. for serving, packing for food from serving machines).
- Internet shops, catalogue or TV-selling.
- In the case that they directly import articles from third countries or from Europe for their own use or distribution.

III. Commission Directive 2002/72/EC, amended by Directive 2005/79/EC

- Only monomers, listed in Annex II, may be used for the manufacture of plastic articles (organic macromolecular compounds obtained by polymerisation, polycondensation, polyaddition and similar processes).
- Current list of additives that are currently accepted to use - Annex III.
- Quantity of substance in a finished material.
- Overall migration limit (articles shall not transfer constituents in quantities exceeding 10 mg/dm² of surface area) - Annex III; Section A, Section B.

The aim of amendment is to:

- Include a new list of monomers in the Community list of permitted substances in Directive 2002/72/EC.
- Include other additives, which may be used in the manufacture of plastic materials and articles.
- Decrease the specific migration limit.

IV. COMMISSION REGULATION (EC) No 2023/2006 - on good manufacturing practice for materials and articles intended to come into contact with food shall apply from 1 August 2008. This Regulation shall be binding in its entirety and directly applicable in all Member States.

Articles should be manufactured in compliance with general and detailed rules on good manufacturing practice (GMP). The business operator shall ensure that manufacturing operations are carried out in accordance with the:

a) general rules on GMP (as provided for in Article 5, 6 and 7)

Article 5: Quality assurance system

Article 6: Quality control system

Article 7: Documentation

b) rules in a detailed information on GMP as set out in the Annex.

Quality assurance system

The business operator shall establish, implement and ensure adherence to an effective and documented quality assurance system. That system shall take into account the adequacy of personnel, their knowledge and skills and the organization of the premises and equipment such as is necessary to ensure that finished materials and articles comply with the rules applicable to them and have to be applied taking into account the size of the business run by the operator, so as not to be an excessive burden on the business.

- Starting materials shall be selected and comply with pre-established specifications that shall ensure compliance of the material or article with the rules applicable to it.
- The different operations shall be carried out in accordance with pre-established instructions and procedures.

Quality control system

The business operator shall establish and maintain an effective quality control system.

- The quality control system shall include monitoring of the implementation and achievement of GMP and identify measures to correct any failure to achieve GMP.
- Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.

Documentation

The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to:

- specifications and processing which are relevant to compliance and safety of the finished material or article;
- records covering the various manufacturing operations performed which are relevant to compliance and safety of the finished material or article;
- results of the quality control system.

The documentation shall be made available by the business operator to the competent authorities at their request.

STANDARDS AND CERTIFICATION - REPORT OF CROATIA

Snjezana Zima, M. Sc., Assistant Director General, HZN (Report for Croatia)

DEVELOPMENTS OF EU – CROATIA RELATIONS

- | | |
|------|--|
| 2001 | Stabilization and Association Agreement (SAA) |
| 2002 | First National Program for the Integration of the Republic of Croatia into the European Union for 2003 |
| 2003 | National Strategy for Technical Harmonization |
| 2005 | Stabilization and Association Agreement ratified and entered into force |
| 2003 | Republic of Croatia applied for membership in EU |
| 2004 | Republic of Croatia candidate country for EU |
| 2005 | Start of negotiations; start of screenings; opening of negotiations in first chapters of aquis communautaire |
| 2006 | Screening in 1. chapter, Free movement of goods |
| 2007 | Benchmarks for opening negotiations in 1. chapter |
| 2007 | Strategy for the implementation of the aquis communautaire in the field of free movement of goods |
| 2006 | April - Letter of Intent - Agreements on Conformity Assessment and Acceptance of Industrial Products |
| 2008 | July 2008 - opening of negotiations in 1. chapter |

STABILIZATION AND ASSOCIATION AGREEMENT

Article 73

Standardization, Metrology, Accreditation and Conformity Assessment

1. Croatia shall take the necessary measures in order to gradually achieve conformity with Community technical regulations and European standardization, metrology, accreditation and conformity assessment procedures.
2. To this end, the parties shall start at an early stage to:
 - promote the use of Community technical regulations and European standards, tests and conformity assessment procedures
 - conclude, where appropriate, European Conformity Assessment Protocols
 - foster the development of the quality infrastructure: standardization, metrology, accreditation and conformity assessment
 - promote the participation of Croatia in the work of specialized European organizations, in particular CEN, CENELEC, ETSI, EA, WELMEC, EUROMET.

NEW HORIZONTAL LEGISLATION - EU REQUIREMENTS

Institutionally, separation of the regulatory, standardization, accreditation and conformity assessment functions is absolutely necessary for a proper implementation of the relevant directives!

Public authorities should retain only the legislative and enforcement (market surveillance) functions.

New quality infrastructure - legal basis

LAW ON STANDARDIZATION - establishment of a national standards body

LAW ON ACCREDITATION - establishment of a national accreditation body

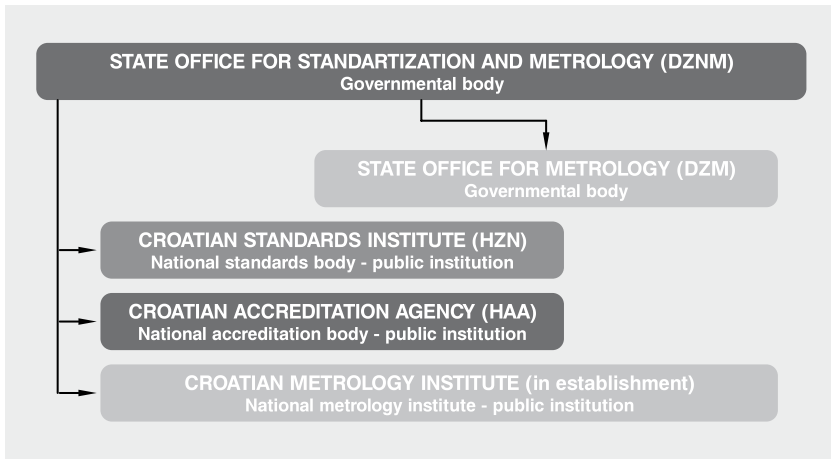
LAW ON METROLOGY - establishment of a national metrology institute

Decree on the establishment of the Croatian Standards Institute (HZN) (November 2004)

Decree on the establishment of the Croatian Accreditation Agency (HAA) (November 2004)

HZN and HAA started operations on 2005-07-01

Decree on the establishment of the Croatian Metrology Institute (July 2008)



Law on technical requirements for products and on conformity assessment

- horizontal law
- legal basis for the transportation of New Approach directives

Ministry of Economy, Labour and Entrepreneurship

- responsible for the free movement of goods
- responsible for the coordination of technical harmonization process
- responsible for the implementation of some directives
- responsibility for notifications
- responsibility for information exchange

Additional responsibilities:

Croatian Standards Body (HZN)

- adoption of harmonized European Standards

Croatian Accreditation Agency (HAA)

- accreditation of conformity assessment bodies
- assessment of competence of CABs

State Inspectorate (SI)

- market surveillance

Implementation of new approach directives

- provisions of directives transposed into national legislation
- harmonized European standards adopted as national standards (national standards bodies)
- conformity assessment bodies competent to apply standards
- national accreditation body established and operational
- market surveillance staffed and educated

Croatian Standards Institute (HZN) - facts and figures:

500 members (full members and observers)

45 governmental bodies, technical committees, subcommittees

More information about Croatian Standards Institute (HZN): www.hzn.hr

Croatian Accreditation Agency (HAA) - facts and figures:

Member of European Accreditation (EA) from 2005, in the process of peer assessment; preparation for MLA; all accreditation schemes established.

HOK Workshop, 2008-09-08

PUBLICATION OF NEW TECHNICAL REGULATIONS

Directive		Regulation published (OG)
89/106/EEC	Construction products	76/2007, 86/2008
93/15/EEC	Explosives for civil use	178/2004 etc.
90/384/EEC	NAWI	1/2005 etc.
1999/5/EC	RTTE	5/2005
89/336/EEC	Electromagnetic compatibility	16/2005
94/25/EC	Recreational craft	27/2005 etc.
90/385/EEC	Active implantable MD	67/2008
93/42/EEC	Medical devices	67/2008
98/79/EC	In vitro diagnostic	67/2008
94/62/EC	Packaging	97/2005

HOK Workshop, 2008-09-08

PUBLICATION OF NEW TECHNICAL REGULATIONS (2)

Directive		Regulation published (OG)
94/9/EC	ATEX	123/2005
95/16/EC	Lifts	135/2005
90/396/EEC	Appliances burning	135/2005
		gaseous fuels
87/404/EEC	Simple pressure vessels	135/2005, 42/2006
73/23/EEC	LVD	135/2005
98/37/EC	Machinery	135/2005
97/23/EC	New hot water boilers	135/2005
2004/22/EC	Pressure equipment	135/2005, 42/2006
89/686/EEC	PPE	106/2007, 121/2007

STANDARDS AND CERTIFICATION - REPORT OF ANTALYA UNION OF TRADESMEN AND CRAFTSMEN

Selvet Mergen, Antalya Center Director, Antalya Union of Tradesman and Craftsman

GENERAL PRINCIPLES OF CERTIFICATION AND USE OF STANDARDS

The nature and the importance of standardisation

Mankind has always attempted to get rid of chaos and to set up a definite order since he was Created. The fact of standard and standardization, which came out as the natural result of this process, is as old as the history of mankind. Standardization, which is a result of the efforts to use the world's inadequate economic sources in an optimum way, is not a luxury, but a "must".

According to definitions made by international standards organization:

Standard is the uniformity in manufacturing, understanding, measuring and testing.

Standardisation is the process of setting specific rules and applying them with the help and collaboration of related parties for the purpose of gaining economic benefit related to a definite activity. Not only does the standardization process aim at the safety of life and goods process, but it also doesn't allow goods and services below the determined level to be produced. Therefore, it has to be considered for anyone as a national and humanly task to produce and consume conveniently to standards. Only so, will it be possible to use the sources in an optimum way and will a rise in the wealth of community be likely to be gained. Today, in which a rapid globalization is being experienced due to the development in technologies of information and production, the standards have become the common language of international trade. To be able to challenge in the international markets, it is necessary to produce the production of quality goods and service convenient to the standards.

The advantages the standardization provides

1. Its advantages for the **producer**

- It helps the production to be done according to definite plans and programs
- It enables suitable quality and mass production
- It reduces the loss and leftovers to minimum level
- It increases productivity and outcome
- It makes storage and to transportation easier and decreases the amount of stocks
- It reduces the cost.

2. Its advantages for the **economy**

- it encourages the quality, eliminates the waste of labor, time and raw material, which will occur as a result of the low quality production
- it steers the industry into definite targets. It helps the development of quality in production
- it helps supply and demand to be balanced
- it eliminates misunderstandings and disagreements
- it provides superiority in export and import
- it helps to settle the sub industry and to develop them
- it improves the competition
- it eliminates the low quality goods.

3. Its advantages for **consumers**

- it provides life and property safety
- it makes comparison and selection easier
- it protects people from being deceived in price and quality matters
- it causes cheapness
- it protects the mental health. It eliminates stress
- it plays an effective role in consumer's getting consciousness.

Standardisation is a voluntary process based on consensus amongst different economic actors (industry, SMEs, consumers, workers, environmental NGOs, public authorities). It is carried out by independent standards bodies, acting at national, european and international level. The european union has, since the mid-1980s, made an increasing use of standards in support of its policies and legislation. The european standards organisations are cen, cenelec and etsi. Standardisation has contributed significantly to the support of the completion of the internal market in the context of the new approach legislation, which refers to european standards developed by CEN, CENELEC and ETSI. Furthermore, european standardisation supports european policies in the areas of competitiveness, ICT, public procurement, interoperability, environment, transport, energy, consumer protection.

The role of european standardisation in the framework of european policies and legislation

Standardisation is an integral part of the EU's to achieve the Lisbon goals by carrying out better regulation and by simplifying legislation, by increasing competitiveness of enterprises and by removing barriers of trade at international level. On 18 October 2004, the Commission adopted a Communication on "the Role of European Standardisation in the Framework of European Policies and Legislation" accompanied by a staff working paper dealing with "the challenges for European Standardisation". Both documents analyse the current situation of European standardisation and identify the key areas where the European standardisation system and the instruments available to European standardisation policy can and should be further improved. Both documents are a response to the Council Conclusions of March 2002 and the Council Resolution of October 1999 on "the Role of Standardisation in Europe" in which the Council had acknowledged the important role of standards and invited the Commission to analyse the current situation of European standardisation and to respond to the challenges the European standards system is faced with. In its Conclusions of December 2004 on "European Standardisation", the Council has acknowledged the Commission's findings and invited the Commission to pursue the activities proposed in the Communication and in the staff working paper.

Towards an Increased Contribution from Standardisation to Innovation in Europe

The Competitiveness Council of 4 December 2006, addressing in its conclusions the subject of innovation, stressed the need to enhance the European standards-setting system, and invited the Commission to put forward proposals for action to be taken by the relevant stakeholders.

On 11 March 2008, the Commission adopted a Communication on "Towards an increased contribution from standardisation to innovation in Europe", responding to the invitation of the Council. The Communication places in focus a greater contribution from standardisation to innovation and competitiveness.

European policy principles for international standardisation

1. Europe has an interest in international standardisation because of its potential to eliminate technical barriers to trade and to increase market access for all. International standardisation also offers the possibility to promote and disseminate technologies.
2. The standards making process should respect some basic requirements: openness, transparency,

consensus and participation of all interested parties.

3. International, European and National Standardisation complement each other. It is important that the national standardisation systems allow for effective participation by all interested parties, and that national positions are coherent with European policies and legislation, if existing.
4. To have one applied standard and one accepted test for each product, process or service is a trade-facilitating objective.
5. The voluntary use of standards in regulation requires a clear definition of each party's roles and competencies. Voluntary standards can nevertheless reduce the need for regulation, respectively government intervention.
6. Measures to improve efficiency of international standards bodies should further be deployed. Striving for more efficiency should not conflict with accountability.
7. It may be beneficial to channel standards, specifications and other deliverables into the international standardisation process that have reached a certain consensus outside international standards bodies. Co-operative arrangements with international standards bodies offer a systematic framework to take over international standards and/or to contribute to the international standards making process.
8. The Community generally supports, in line with its political objectives, the development of a (preferably regional) infrastructure for standardisation. The EC also promotes the creation of legal and economic conditions which facilitate trade and which are receptive to the use of voluntary consensus standards.
9. European actors should communicate with each other to ensure mutual understanding and positions in respect of legal requirements or in support of policies of the EC.

Old approach

One of the primary objectives of the Treaty of Rome in 1957 was to facilitate the free movement of goods within what has since become the European Union. The Single European Act of 1987 introduced amendments to the Treaty with the aim of completing a real single European market by 1992. To achieve this goal, a radical change to the methods used to harmonize regulations within the individual member states was necessary. Before the adoption of the New Approach in 1985, CENELEC would write the standards, the standards would be implemented into directives, and the directives would be transposed into the laws of the member states. In essence, standards-making bodies were writing the laws in Europe.

By contrast, the New Approach harmonizes safety objectives through a set of generally worded essential health and safety requirements (EHSRs), which lay down in broad terms the requirements equipment must meet. These EHSRs are supported by Harmonized Standards, although you will not find a list of them written in the directives.

The new approach and the role of harmonised standards

The establishment of an internal market based upon the free movement of goods critically depends upon an adequate level of technical harmonization. The New Approach and European standardisation have contributed significantly to the development of the Single Market. The success of the European standardisation system, in removing technical barriers to trade, has played a vital role in ensuring the free

movement of goods between Member States.

The “New Approach”, defined in a Council Resolution of May 1985, represents an innovative way of technical harmonisation. It introduces, among other things, a clear separation of responsibilities between the EC legislator and the European standards bodies CEN, CENELEC and ETSI in the legal framework allowing for the free movement of goods.

Such a new approach is based on a few key principles :

- There is a clear separation between the EEC legislation and European standardisation.
- EEC legislative harmonisation (e.g. EEC Directives) is limited to the essential requirements (safety requirements of general interest) needed to ensure the free movement of products throughout Community.
- The task of drawing up the corresponding technical specifications is entrusted to the standardisation bodies.
- Products manufactured in conformity with harmonised standards are presumed to be conformant to the essential requirements.
- Standards are not mandatory, they remain voluntary 2 . Alternate paths are possible but the producer has an obligation to prove his products are conformant to the essential requirements.
- Standards must offer a guarantee of quality with regard to the essential requirements of the directives.
- Public authorities are still responsible for the protection requirements on their territory (e.g. market surveillance).
- Safety clauses require the Member States to take all appropriate measures to withdraw unsafe products from the market.

In comparison with the former directives, some improvements have to be noted since the new approach:

- deals with large families of products (e.g. machinery, toys, etc.)
- covers horizontal risks (e.g. EMC) and not specific products
- establishes a close co-operation between public authorities and market operators
- is based on total harmonisation (replacing diverging national legislation) as compared to optional harmonisation (dual regime).

A summary of the key features of the “New Approach” would not be complete without mentioning the degree of flexibility which is allowed in most of the directives. The flexibility of the “New Approach” is linked to the following features:

- it indicates what has to be achieved but not the details of the technical solutions
- it presents different options for conformity assessment (see the “global approach”)
- it does not necessitate regular adaptation to technical progress.

The “New Approach” directives are supported by “harmonised standards” which play a significant role in ensuring their application. “Harmonised standards” are European standards, adopted by CEN, CENELEC or ETSI, following a mandate issued by the European Commission after consultation of Member States. They are developed through an open and transparent process, built on consensus between all interested parties. Such standards have first the characteristics inherent to European Standards:

- The standards (typically EN, ETSs) are drafted by one of three European Standard Organisations (CEN, CENELEC, ETSI).
- The work is based on consensus.
- Standards are adopted after a public inquiry with the national votes based on corresponding weighting features.

- Standards remain voluntary but their transposition into national standards and the withdrawal of diverging national standards is mandatory according to the internal rules of the European Standards Organisations.

Within the context of the “New Approach” additional conditions are superposed to the European Standards to cover the specific role of harmonised standards:

- The Commission issues a standardisation mandate according to the procedure of Directive 98/34/EC (consolidating Directive 83/189/EEC).
- The standards are developed in taking due account of the essential requirements.
- The reference of the standard is published in the Official Journal with the indication of the Directive for which the presumption of conformity should apply.

Conformity assessment

Conformity assessment is a demonstration that specified requirements relating to a product, process, system, person or body are fulfilled (EN ISO/IEC 17000). From its creation in 1973, CENELEC has included within its terms of reference the promotion of mutual recognition agreements for testing and/or certification of electrical products, as a natural complement to its activities for the harmonization of European standards in the electrotechnical area.

The purpose of conformity assessment is; to provide confidence for users that requirements applicable to products, services and systems have been met. Such confidence, in turn, directly contributes to the market acceptance of those products, services and systems. Such user confidence can be achieved through cooperation among conformity assessment bodies and/or accreditation bodies, resulting in mutual recognition and promotion of each participant’s work across borders.

CEN, in co-operation with CENELEC, provides a comprehensive range of European Standards and other publications for the implementation and recognition of good conformity assessment practices, suitable for all forms of first, second and third party involvement and evaluation, widely used by all interested parties. CEN has developed four systems for conformity assessment to European Standards and other CEN publications:

- the CEN/CENELEC European Mark of Conformity to European Standards, the Keymark
- the CEN Workshop Agreement (CWA) Certification Rules
- the CENCER Mark
- European Standard Agreement Group (Mutual Recognition).

The Certification Board of CEN is responsible for the CEN policies on certification and other conformity assessment issues. The Board consists of delegates from the CEN National Members, Associates and representatives from industry, laboratories and inspection bodies and acts in an advisory role to the Administrative Board of CEN.

Creation and Basic Concept of CCAF

The CENELEC members created at their 39th General Assembly, held in Edinburgh on 8th and 9th June 1999, a new body called CENELEC Conformity Assessment Forum, CCAF. This body has replaced the sectoral committee ELSECOM and is meant to become a focal point for conformity assessment in the electrotechnical field at European level, based on the following policies:

- to establish a formal link between the standards work of CENELEC and conformity assessment schemes operating in the electrotechnical field, with due regard to other interested parties
- the testing and certification bodies should have freedom to manage and operate their individual schemes in line with their market demands
- the principal aim of the CCAF is the promotion of European standards as the basis for conformity assessment.

CCAF will provide a forum for discussion of policies and strategies related to conformity assessment in the electrotechnical area, between representatives of the different conformity assessment schemes, representatives of their advisory structure, national interests represented by the concerned CENELEC National Committees and advisors from European regulatory, economic and social partners. The CCAF will also provide a contact point for coordination and cooperation at the level of CEN and ETSI, the European Commission, the EFTA Secretariat, and the IEC.

European standardisation organisations

CEN (The European Committee For Standardization)

The majority of the current National Members of CEN founded the association in 1961. It was first based in Paris under the aegis of AFNOR (the National Member for France). In 1975, CEN moved to Brussels, acquired formal Statutes and was registered as a non profit-making, international, and scientific and technical institution. It is therefore an independent organization. CEN's mission is to promote voluntary technical harmonization in Europe in conjunction with worldwide bodies and its partners in Europe. Harmonization diminishes trade barriers, promotes safety, allows interoperability of products, systems and services, and promotes common technical understanding. CEN affiliates are the national standards bodies of Central and Eastern European countries which can in principle become members of the Union or EFTA, and which therefore can become full National Members of CEN on fulfilment of certain criteria, most importantly the adoption of European Standards as national standards. They may participate in the General Assembly and in technical bodies. They receive all technical and general documentation from CEN. Current Affiliates are: Albania; Bulgaria; Croatia; Cyprus; Estonia; Latvia; Lithuania; Poland; Romania; Slovenia; The former Yugoslav Republic of Macedonia; Turkey.

CENELEC (The European Committee for Electrotechnical Standardization)

was created in 1973 as a result of the merger of two previous European organizations: CENELCOM and CENEL. Nowadays, CENELEC is a non-profit technical organization set up under Belgian law and composed of the National Electrotechnical Committees of 23 European countries. In addition, 12 National Committees from Central and Eastern Europe are participating in CENELEC work with an Affiliate status. Their ultimate goal as affiliates is gaining full membership to CENELEC Standardization activities. CENELEC members have been working together in the interests of European harmonization since the 1950s, creating both standards requested by the market and harmonized standards in support of European legislation and which have helped to shape the European Internal Market. CENELEC works with 35,000 technical experts from 22 European countries. Its work directly increases market potential, encourages technological development and guarantees the safety and health of consumers and workers.

CENELEC's mission is to prepare voluntary electro technical standards that help develop the Single European Market/European Economic Area for electrical and electronic goods and services removing barriers to trade, creating new markets and cutting compliance costs. Recently CENELEC has set up an ICT unit (Information and Communication Technologies) in order to enhance its profile in this field. This unit works in close cooperation with CEN and ETSI. In addition to the traditional European standard deliverables, the dynamic Workshop (CWA: CENELEC Workshop Agreement) has been included in its portfolio, offering an open platform to foster the development of pre-standards for short lifetime products where time-to-market is critical. The 23 current CENELEC members are national organizations entrusted with electrotechnical standardization, recognized both at National and European level as being able to represent all standardization interests in their country. Only one organization per country may be member of CENELEC.

CENELEC members are: Austria, Belgium, Czech Republic, Denmark, Germany, Finland, France, Greece, Hungary, Netherlands, Iceland, Ireland, Italy, Lithuania, Luxembourg, Malta, Norway, Portugal, Spain,

Slovakia, Sweden, Switzerland, United Kingdom. CENELEC presently counts 12 Affiliates. The ultimate goal of an affiliate is to become a full member once they fulfill the required membership conditions.

CENELEC Affiliates are: Albania, Bulgaria, Bosnia and Herzegovina, Croatia, Cyprus, Estonia, Latvia, Poland, Romania, Slovenia, Turkey, Ukraine. CENELEC maintains a very close and relevant relationship with both the European Commission and the EFTA Secretariat. This partnership has been reinforced in March 2003 with the signature of the General Guidelines for the Cooperation between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association.

CEN/CENELEC Deliverables:

EN - European Standard

It is a normative document available, in principle, in the three official languages of CENELEC (English, French and German) that cannot be in conflict with any other CENELEC standard. EN's are the most important deliverable published by CENELEC. Its development is governed by the principles of consensus, openness and transparency, a national commitment to implement it in each and every one of the countries member of CENELEC, its technical coherence regarding both national and European levels. Before its implementation, the EN must follow the following steps: Drafting by a CENELEC Technical Committee or Working Group, Inquiry at national level, a formal vote followed by a standstill at national level and the final approval by the Technical Board before its implementation in all member countries.

HD - Harmonization Document

Same characteristics as the EN except for the fact that there is no obligation to publish an identical national standard at national level (may be done in different documents/parts), taking into account that the technical content of the HD must be transposed in an equal manner everywhere.

TS - Technical Specification

A TS is a normative document produced and approved by a Technical Committee (not by CENELEC as such). Several of the compulsory requirements needed to have a standard do not apply to Technical Specifications: there is no standstill, no public enquiry, the vote does not follow the same rules as in the CENELEC Technical Board (where it is weighted). A TS must only be produced in one of the official languages and its maximum lifetime is reduced to two or three years. Technical Specifications are explained in terms of supporting the European Market and act as a guidance method towards evolving technologies and experimental circumstances that would not gather enough consensus as to publishing an EN. A TS may not be in conflict with any other CENELEC standard. If a conflicting standard (EN) is published in the meantime, then the TS must be withdrawn.

TR - Technical Report

A Technical Report is an informative document on the technical content of standardization work. Only required in one of the 3 official languages, a TR is approved by the Technical Board or by a Technical Committee by simple majority. No lifetime limit applies.

G - Guides

CENELEC Guides are informative documents related to the "internal system". They may specify information about standardization principles and guidance to standards writers. Guides must be approved at General Assembly or Technical Board level. No lifetime limit applies.

CWA - CENELEC Workshop Agreement

As indicated by their name, CWA's are an agreement developed and approved by a Workshop through consensus reached among identified individuals and organizations. They must be published at least in one of the official languages. Revision is possible.

TURKISH STANDARDS INSTITUTE (TSE)

The Establishment and the Tasks

TSE has been established by the law numbered 132 dated 18.11.1960 for the purpose of preparing standards for every kind of item and products together with procedure and service. The Institute is responsible to the Prime Ministry. The Institute is a public founding which is conducted according to the special rules of law and has a juristic personality. Its abbreviation and trademark is TSE. This mark is represented in different ways. This mark can not be used without the permission of TSE in no way and under no condition. Only the standards that have been accepted by TSE get the name of Turkish Standards. These standards are voluntary and can be made compulsory by the approval of the ministry that the standard is relevant to. It is essential that a standard be a Turkish one so that it could be made compulsory. The standards made compulsory are published in Official Gazzette.

The Tasks of TSE are as below:

- To prepare and to get every kind of standard prepared
- To inspect the standards which have been prepared within or out of the Institution and to accept them as Turkish Standards if approved
- To publish the standards which have been approved and to encourage their application as voluntary to submit the ones thought may be useful when made compulsory to come into force to the relevant ministry
- To prepare the standards or the projects of them and to declare its opinion upon request of public sector and private sector
- To perform the technical inspections and researches about standards, to follow up the resembling studies done in foreign countries, to establish relations with international and foreign companies of standard and to collaborate with them.
- To collaborate with universities and other scientific and technical associations and institutions, to make publications on standardization, to constitute archives from national and international standards and to submit them to the ones whom they may concern who are concerned with.
- To conduct research on standards and to establish laboratories in order to check the application of voluntary standards, to perform technical studies requested by public or private sector and report about them.
- To train personnel in order to maintain and develop the standard works in the country and to open courses and arrange seminars for this purpose
- To perform studies which will encourage the quality production convenient to the standards and to prepare the documents about them.
- To perform studies on research and development about metrology and calibration and to establish necessary laboratories
- The organization of these tasks of Turkish Standards Institution is determined according to the order of the distribution by General Assembly and announced to people who are interested in.

The Services Conducted by TSE

- Quality and System Certification
- Product and Service Site Certification

- Personnel Certification
- Laboratories
- Calibration
- Standard Preparation
- Legal Adviser
- Research Planning and Coordination
- Consumer Services
- International Relations
- Data Processing and Information
- Public Relations
- International Representatives and Our Cooperations
- Library and Documentation

TSE's Relationship with CEN and CENELEC

TSE is an affiliate member of CEN and CENELEC since 1991. Having started an initiative to become a full member of both organizations in the recent years, TSE is currently carrying out the task of harmonization of Turkish Standards with EU standards as part of Turkey's obligations within the context of the Turkey-EU relationship. In order to do this, TSE is actively following the standardization activities of CEN and CENELEC and about 85 percent of existing CEN and CENELEC standards have already been adopted as Turkish Standards and the unadopted standards, including the new ones, are being included in the standardization work programme of TSE. It is very important that the representatives of the Turkish industry sector are contributing voluntarily to the Technical Committee work by giving their opinions about the related documentation in order that TSE is able to carry out its standardization activities parallel to those of CEN and CENELEC. TSE is also a part of the common certification system within the European Union such as CCA, HAR, KEYMARK. Thus, TSE is able to offer some convenience in this context for the Turkish industry sector by the mutual recognition of certificates.

Inspection, supervision

The inspection and the supervision of the market is the total of the activities of the public bodies which are authorised by law to prepare and execute the technical legislation about the product. The activities include the inspection and supervision if the product is safe or not, if it is produced in accordance with the technical arrangements during the supply or delivery to the market or while the product is in the market. EU sets the member states free while determining the infrastructure of the market inspection and supervision. Therefore, the legal and administrative infrastructure about the market inspection and supervision differs from one member state to another. In Turkey, market supervision is under the responsibility of public bodies. In order to realise an effective market supervision, the possibilities should be concentrated on the products which the risk potential is high or on the places where nonconformity may emerge more often. For this purpose, the authorised agencies may use accident statistics, consumer complains and risk analysis. In order to follow the products in the market, the authorised agencies:

- May have regular visits to the commercial, industrial sites and warehouses.
- If necessary, may have regular visits to the work places where the products submitted to the market or to the other places.
- May have spot-checks or random checks.
- When necessary, may take samples from the products and may put them to test.
- May request any kind of necessary information about the product.

Although the market inspection and supervision basically can not be realised during the design and production stages, the authorised agency may also check the production sites in order to prove a

permanant fault after a nonconformity has been set. During the market inspection and supervision, the authorised organisations control the conformity signs which a product should carry according to the technical arrangements, the documents and the information which should be attached to the product. "The Law about the Preparation and Application of the Technical Legislation of the Products" which as entered into force on 11 January 2002, numbered 4703, regulates the issues such as; the supply conditions of the products, the burdens of the producers and distributors, market supervision and inspection, the forbidding of the supply of the unsafe products, withdrawal and disposition of them, the competences of inspection organisations, punitive sanctions, the informative actions to the EU Comission and to the member states. One of the regulations of this law, "The Regulation About the Market Supervision and Inspection of the Products" sets the details on how to organise the inspection and supervision in the internal market. However, the basic principles which the producer should obey or the details about the supply of the product to the market is regulated with the Regulation on the Market Inspection and Supervision published by the authorised bodies.

The delivery of the responsibilities among these authorised public institutions is based on "The decree about the designation of the institutions which are esponsible to prepare the technical legislation to increase the export of Turkish products". The coordination among different authorised organisations is achievd by the "Coordination Committe of Market Supervision and Inspection" which meets every 4 months under the Undersecretariat of Foreign Trade and takes recommendatory decisions. The authorised institutions responsible from the market inspection & supervision in Turkey are:

- Ministry of Industry and Trade
- Ministry of Health
- Ministry of Employment and Social Security
- Ministry of Public Works and Settlement
- Ministry of Environment and Forestry
- Ministry of Culture and Tourism
- Ministry of Energy and Natural Resources
- Ministry of Agriculture and Rural Affairs
- Ministry of Transport
- Undersecretariat of Maritime
- Telecommunication Institution
- Tobacco and Alcohol Institution
- Energy Market Regulatory Auhority.

Turkish accreditation agency

Turkish Accreditation Agency (TÜRKAK) is established, tied up to the Prime Ministry, subject to private law provisions, with its headquarters in Ankara, as a legal entity having administrative and financial autonomy, to accredit the local and international bodies rendering laboratory, certification and inspection services, ensure them to operate in accordance with established national and international standards, and thereby ensuring international recognition of product / service, system, personnel and laboratory certificates. The core business of TÜRKAK is to accredit conformity assessment bodies and make them trusted service organizations. The principal condition for the successful performance of this function is TÜRKAK's operation as a competent and a dependable agency sought for its services. To fulfill this condition, establishing cooperation with international and regional accreditation bodies, pursuit of current developments on conformity assessment, and offering of accreditation service that satisfies the expectations and needs of the market are essential.

Duties and authorities of the Agency

Duties and authorities of the Agency are as follows:

- a) Make arrangements regarding the activities of the Agency, establish the criteria and measures related with accreditation, implement and, when required, modify, revise and annul the same.
- b) Evaluate the private and/or public agencies and organisations, which carry out activities on laboratory, product/service, system, personnel and similar certification issues, applying for accreditation according to relevant standards and criteria and decide whether to accredit such organisation as a result of this evaluation, monitor accredited organisations, suspend the decision of accreditation temporarily or permanently, when required, and provide coordination among all agencies and organisations that will carry out activities in these fields.
- c) Make arrangements encouraging the use of markings and certificates issued by accredited organisations.
- d) Establish relationships and cooperate with international and regional accreditation bodies and those of other countries.
- e) Ensure the confidentiality of information obtained in relation with the application, evaluation and accreditation of the organisations applying for accreditation.
- f) Carry out activities promoting the importance of accreditation and the consciousness of quality.
- g) Carry out training, research and publication activities on issues within its terms of reference.
- h) Purchase services on the issues within its scope of activities.
- i) Purchase, build, sell, lease and put lien and mortgage on movables and immovables required for carrying out the services.
- j) Perform other duties related with its field of activity.

Number of Accredited Bodies in Turkey

Testing Laboratories (152)

Calibration Laboratories (44)

Quality Management System (37)

Inspection Bodies (30)

Product Certification (6)

Personel Certification (8)

1 - Protocols between the ministries and TURKAK on assessment of conformity assessment bodies working in the regulated area

2 - Certification of measuring equipment of testing labs by accredited calibration labs

CE MARKING AND DECLARATION OF CONFORMITY

Significance of CE

By affixing the CE marking, the manufacturer, its authorized representative, or person placing the product on the market or putting it into service asserts that the item meets all the essential requirements of the relevant European Directive(s). Examples of European Directives requiring CE marking include toy safety, machinery, low-voltage equipment, terminal equipment and EM compatibility. There are about 25 directives requiring CE marking. [1]. Officially, CE has no meaning as an abbreviation, but may have originally stood for Communauté Européenne (European Community) or Conformité Européenne (European Conformity).

Declaration of conformity

The CE marking is a mandatory European marking for certain product groups to indicate conformity with the essential health and safety requirements set out in European Directives. To permit the use of a CE mark on a product, proof that the item meets the relevant requirements must be documented. Sometimes this is achieved using an external test house which evaluates the product and its documentation. Often it is achieved by a company-internal self-certification process. In any case the responsible organization

(manufacturer, representative, importer) has to issue a EC-Declaration of Conformity (EC-DoC) indicating his identity (location, etc.), the list of European Directives he declares compliance with, a list of standards the product complies with, and a legally binding signature on behalf of the organization. The EC-DoC underlines the sole responsibility of the manufacturer. Parts of the certification process for the CE marking could be performed by 3rd party test houses or certification bodies; in case that this is mandatory the CE symbol also includes a number that identifies the so called Notified Body. To be strictly accurate, there are two forms of Declaration, either a "Declaration of Conformity" or a "Declaration of Incorporation". Generally speaking this is only the case under the Machinery Directive. For example, a stand-alone machine that requires only a power source to operate would be issued with a Declaration of Conformity; whereas a machine that requires additional systems, attachments, feed conveyors etc, before it can provide its intended function must be issued with a Declaration of Incorporation. In this latter case it is illegal to CE Mark such a machine. This can only be achieved once the machine has been finally installed and all other elements incorporated into the system. A final risk assessment is performed to verify compliance of the system and a final Declaration of Conformity is then issued.

Furthermore, these directives are based upon what the European Commission calls a New Approach, whereby if any of the Article 100A Directives apply to a product, then they must be followed. Directives providing the requirements for the CE marking are created by the European Union (EU), but the markings are required throughout the European Economic Area (EEA). According to information provided by the Swiss Government for Swiss Exporters the CE Mark is not compulsory in Switzerland except for products for export to the European Union.)

Acquise Communautaire Corresponding Turkish Legislation Aim of the Law Notes

Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery. Directive namely "Regulation on Machinery Safety" under the responsibility of Ministry of Industry and Trade, published on the Official Gazette d.d. 30.12.2006, no.26392 Explaining the criterias about the proper usage of the machines, periodical maintenance requirements in order not to give any harm to human health and safety and also to the pets and other animals and to the goods. Parallel to this directive, there are 633 standards in force actually. Another 20 standards were repealed. 274 firms have received Standards Certificate. Construction Products 89/10/EC Harmonised Standards Council Directive 89/106/EEC of 21 Dec. 1988 on the approximation of laws, regulations and administrative provisions of the member states relating to constructions products. Directive published on the Official Gazette num.24870 dated 8/9/2002 under the responsibility of Ministry of Public Works and Settlement. To determine the procedures and principles; basic necessities which the construction materials should carry to be produced and used while all the construction works including building and other civil engineering works. Explaining all the conformity evaluation procedures, market supervision and inspection rules they are subjected. There are 53 standards in number related with the subject actually. The old 8 ones were repealed. 6 firms have received the Certificate. 73/23/EEC on low voltage equipment LVD, Directive published on the Official Gazette num.24637 dated 11/1/2002 under the responsibility of Ministry of Industry and Trade Directive 2006/95/EC of the European Parliament and of the Council of dd 12 Dec.2006 on the harmonisation of the laws of member states relating to Directive published on the Official Gazette num.265392 dated 30/12/2006 under the responsibility of Ministry of Industry and Trade namely "Regulation on Electrical Equipment designed for use within. To determine the procedures and principles; the necessary safety rules and conformity evaluation procedures for the electrical equipments subject to this directive before their supply to the. This directive was prepared parallel to the directive 73/23/EEC which was amended by the directive 93/68/EEC of Electrical Equipment designed for use within certain voltage limits certain voltage limits market EU 89/336/EEC on Electromagnetic Compatibility EMC Standards 91/263/EEC, 92/31/EEC, 93/68/EEC ve 93/97/EEC explaining the subjects and the procedures on the directive of 89/336/EEC about electromagnetic compatibility

Council Directive 89/686/EC of 21 Dec.1989 on the approximation of the laws of the member states relating to Personal Protection Equipment Standard entered into force after the publication of the Directive under the responsibility of Ministry of employment and Social Security. There are 311 standards about the subject actually. 24 standards were repealed. There are 33 firms which has Certificate. 87/404/EC Simple Pressure Vessels Harmonised Standards Council Directive 87/404/EEC of 25 June 1987 on the harmonisation of the laws of the member states relating to simple pressure vessels Directive published on the Official Gazette num.24712 dated 31/3/2002 under the responsibility of Ministry of Industry and Trade To determine the procedures and principles; basic necessities which should be obeyed during the design, production, montage, distribution, supply to the market, supply to te service, usage, examination and certification of the simple pressure vessels for the safety of people, pets and goods.

90/396/EEC Appliances burning gaseous fuels Council Directive of 29 June 1990 on the approximation on the laws of the member states relating to appliances burning gaseous fuels Directive published on the Official Gazette num.24713 dated 01/4/2002 under the responsibility of Ministry of Industry and Trade To determine the procedures and principles; the supply of the appliances burning gaseous fuels to the market without giving any harm to the security of people, pets and the goods.

92/42/EEC Council Directive
92/42/EEC of 21

May 1992 on efficiency requirements for new hot water boilers fired with liquid or gaseous fuels Directive published on the Official Gazette num.24712 dated 31/3/2002 under the responsibility of Ministry of Industry and Trade Efficiency requirements for new hot water boilers fired with liquid or gaseous fuels Council Directives 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the member states relating to lifts Directive published on the Official Gazette num.26420 dated 31/1/2007 under the responsibility of Ministry of Industry and Trade To determine the basic health and security requirements they should have before the supply to the market of the lifts and their security accessories used for the transport of the people, people and freights or only freights.

PACKAGING

Development of Packaging Directives, Summary of 1994 Packaging Directive

The European Community first introduced measures on the management of packaging waste in the early 1980's. Background on the topic provided in this fact sheet begins with the 1994 Directive on Packaging and Packaging Waste (94/62/EC). This directive harmonized actions taken by EU nations to promote reuse and recycling and to manage packaging and packaging wastes. The 1994 Packaging Directive focuses on prevention, reuse, recycling, and other forms of recovery, and also establishes the rudiments of extended producer responsibility principles. These principles require manufacturers to play a role in mitigating the post-consumer environmental impacts of products from which they profit.

Key Topics in Amending the 1994 EU Packaging Directive

Recycling and recovery targets. For all materials other than plastics, most EU member States achieved or surpassed the 1994 Directive's minimum recycling and recovery targets well ahead of the June 2001 deadline. Critics have sought unsuccessfully to increase recycling goals and to eliminate the recovery target in order to discourage incineration. Furthermore, they unsuccessfully advocated for both minimum packaging reuse targets and for mandatory requirements that producers and traders of packaging cover the costs of their return, collection, reuse, and recycling.

Package marking systems and indicators

Article 4 of the 1994 Packaging Directive stipulates that the Commission shall help to promote the prevention of packaging waste formation by encouraging the development of suitable European standards. In 2005, the European Committee for Standardisation (CEN) approved revised versions of all five packaging standards. Article 8 of the 1994 Packaging Directive requires a marking and identification system of packaging materials in order to facilitate collection, reuse, and recovery. In January 1997, the European Commission established the identification system (Commission Decision 97/129/EC). A contentious issue in the 2004 revision of the Directive was introduction of a packaging environment indicator (PEI) based on greenhouse gas emissions and waste going to final disposal. Such a PEI could be used as a 'pass/fail' test for entry of new packaging into the EU market. While many in the European Parliament were enthusiastic about developing this proposal, the European Commission recommended further analysis of the PEI idea and further debate among stakeholders before taking action.

Incineration/energy recovery

The EU agreed in 2004 when revising the Packaging Directive that incineration in a facility equipped with energy recovery systems may be counted toward achieving recovery targets. The EU hierarchy for waste management, established by the Community Strategy for Waste Management in 1996, is, in order of priority: prevention, recovery (including energy recovery), and disposal (including incineration). The U.S. EPA's solid waste management hierarchy places source reduction and reuse first, recycling (including composting) second, and land disposal or combustion last.

Acquise Communautaire Corresponding Turkish Legislation Aim of the Law Notes

Directive 94/63/EC on packaging and packaging waste. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste. TS EN 13427 - Packaging - Requirements for the use of European Standards in the field of packaging and packaging waste. This Standard specifies requirements and a procedure by which a person or organization responsible for placing packaging or packed products on the market (the supplier) may combine the application of five (mandated) packaging standards and one (mandated) CEN report (in two parts) TS EN 13428 / 23.01.2007 packaging requirements specific to manufacturing and composition prevention by source reduction. This standard specifies a procedure for assessment of packaging to ensure that the weight and/or volume of its material content is at the minimum commensurate with the maintenance of; Functionality throughout the supply and user chain, safety and hygiene for both product and user/ consumer, acceptability of the packed product to the user consumer TS EN 13429 / 23.01.2007 Packaging - Reuse This standard specifies the requirements for a packaging to be classified as reusable and sets out procedures for assessment of conformity with those requirements including the associated systems. TS EN 13430 / 23.01.2007 Packaging - Requirements for packaging recoverable by material recycling. This standard specifies the requirements for packaging to be classified as recoverable in the form of material recycling whilst accommodating the continuing development of both packing and recovery technologies and sets out procedures for assessment for conformity with those requirements.

TS EN 13431 / 23.01.2007 Packaging

- Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value. This standard specifies the requirements for a packaging to be classified as recoverable in the form of energy and set out procedures for assessment of conformity with those requirements.

TS EN 13432 / 05.03.2003 Packaging

- Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging. This standard specifies requirements and procedure to determine the compostability and anaerobic treatability of packaging and packaging materials.

MATERIALS AND ARTICLES IN CONTACT WITH FOODSTUFFS

The following subjects are being designated by the communiques published by the concerne department of the Ministry of Agriculture and Rural Affairs; to prepare the legislation about the food and the materials in contact with foodstuffs, to plan the supervision and inspection on the full stages of the food chain, import and export, to prepare and implement projects about food and nutrition, to help to the preparation of development and implementation plans about food and to follow them up.

Acquise Communautaire Corresponding Turkish

Legislation Aim of the Law Notes

82/711/ECC

Regulation number 2005/34 namely "Regulation on the basic rules for the migraton test about the components of plastic materials which are in contact with foodstuffs", published on the Official Gazette d.d. 4.07.2005 , no.25865 This regulation includes the materials or substances in contact with foodstuffs which are made of plastics or has one or more layers and at least one layer is plastics , joined via sticking or with any other method.

2002/16/EC

Regulation number 2008/23 namely "Regulation making amandments on the regulation about the epoxy derivative materials which are in contact with foodstuffs", published on the Official Gazette d.d. 22.05.2008, no.26883 With this regulation, the regulation which was entered into force with the publication on the Official Gazette dated 4,7,2005 - number 25865 has been harmonised according to EU legislation framework.

2002/72/EC

The present regulation about the subject was amanded according to the EU directive with the regulation number 2008/7 published on the Official Gazette dated 5,3,2008 numbered 26807

This directive is determining the characteristics of the plastic materials and articles which are in contact with foodstuffs in order to have them produced, processed, stored, transported and marketed accordingly to the technique and hygiene rules.

89/109 EEC

With the Commission Directive entered into force with the publishment on the Official Gazette dated 22,04,2002 numbered 24734, namely "The Commission Directive on the harmonisation of the legislation of the member states about the materials and articles in contact with foodtuffs", the materials and articles in contact with the foodstuffs were taken into consideration.

OTHER TOPICS

HACCP And Food Safety

HACCP is the Hazard Analysis Critical Control Points system that was developed to ensure the safety of food for United States astronauts nearly 30 years ago. This system is now being used in our restaurants because these guidelines make good sense. When customers go into a restaurant, most of them are looking for a clean, safe place to eat. By applying the basic principles of HACCP to your restaurant business, you will be making sure you serve safe food to your customers.

Analyze hazards

Potential hazards associated with a food and measures to control those hazards are identified. The hazard could be biological, such as a microbe or chemical, such as a toxin; or physical, such as ground glass or metal fragments.

Identify critical control points

These are points in a food production from its raw state through processing and shipping, to consumption by the consumer, at which the potential hazard can be controlled or eliminated. Examples are cooking, cooling, packaging, and metal detection.

Establish preventive measures with critical limits for each control point

For a cooked food, for example, this might include setting the minimum cooking temperature and time required to ensure the elimination of any harmful microbes.

Establish procedures to monitor the critical control points.

Such procedures might include determining how and by whom cooking time and temperature should be monitored.

Establish corrective actions to be taken when monitoring shows that a critical limit has not been met.

For example, reprocessing or disposing of food if the minimum cooking temperature is not met.

Establish procedures to verify that the system is working properly.

For example, testing time and temperature recording devices to verify that a cooking unit is working properly.

Establish effective record keeping to document the HACCP system.

This would include records of hazards and their control methods, the monitoring of safety requirements and action taken to correct potential problems. Each of these principles must be backed by sound scientific knowledge. For example, published microbiological studies on time and temperature factors.

Transport Industry

Conditions of access to market and profession (operator licensing, Regulations 881/92, 3118/93, 12/98; Directives 96/26, 98/76)

By-Law on Road Transport (Official Gazette: 25 February 2004, no 25384) and By-Law on Training for Professional Competence in Road Transport Operations (Official Gazette: 03 September 2004, no 25572) lay down the rules on access to the profession and access to the market for operators engaged in national and/or international transport of passengers and goods. Through these new regulations 3 qualitative criteria, namely,

a) financial standing;
b) professional competence;
c) good repute are required for access to the profession and access to the market. The main requirements for financial standing and good repute are clearly defined in the By-Law on Road Transport while the professional competence is regulated in the By-Law on Training for Professional Competence in Road Transport Operations.

a) Financial standing; one condition for obtaining a license is a minimum number of trucks or tonnage, respectively number of busses and seats. The operators must have the necessary capacity or tonnage conditions and financial standing-values indicated in the relevant article of the By-Law. Depending on the type of license, a certain amount of capital is also required.

b) Professional competence; By-Law on Training for Professional Competence in Road Transport Operations lays down in detail the rules and procedures for:

- training and examination of professional competence
- qualifications of the institutions in charge of the training
- authorizations to be issued to the training institutions
- the issuing of Certificates for Professional Competence.

The applicants prove such competence by passing a written examination that contains variety of questions about the subjects indicated in the abovementioned Legislation. 10 institutions have been

authorized by the MoT to provide professional competence education. The examinations are carried out by the MoT or by the Ministry of Education Examination Centre, authorized by the MoT.

c) Good repute; the applicants should not be convicted of any freedom-limiting penalty for crimes such as smuggling, fraud, false bankruptcy, falsification, narcotics and gun smuggling, human trafficking or trade, theft, corruption. Not to often violate the rules on weights and dimensions, driving and resting times, working and wage conditions during their operation. All the official documents justifying the abovementioned conditions are required when applying for an operating license. MoT and Ministry of Interior (Road Traffic Police, Gendarmerie) are main authorities for the enforcement and implementation of these rules laid down in the By-Law on Road Transport and in the By-Law on Training for Professional Competence in Road Transport Operations. The Ministry of Transport performs the inspection, control and monitoring of the road transport market through its own personnel as well as safety forces and other authorised public institutions and organisations.

****Turkey has made necessary technical and legal arrangements in terms of harmonization of these three criteria (good repute/ financial standing/ professional competence) with the EU legislations. Therefore, there would not be any difficulty in ensuring the mutual recognition of proof of good repute/ financial standing/ professional competence documents before or as Turkey becomes an EU member.*

The rules governing market access for national and international road passenger transport for resident operators

Like in goods transport, the 3 qualitative criteria, namely, financial standing, Professional competence and good repute are main requirements for obtaining a license in national and international passenger transport. Regular and occasional services are subject to authorization. National and international passenger transport operations are licensed under different label of authorizations ('B' type for international, 'D' type for national). There is no authorization requirement for special regular services in the By-Law on Road Transport. Issuing licenses for special regular services and passenger transport up to a distance of 100 kilometres have been delegated to local and provincial authorities for the time being. The applicants for domestic regular passenger transport must have a total of 150 seats capacity consisting of buses with minimum 25 seats capacity recorded and registered in their names and a capital of 30.000 €. The INTERBUS Agreement for occasional bus services is in force on the territory of Turkey from 1st of July 2006. For regular international bus transport, the operators are also required to provide the regular bus line agreement/contract concluded with a foreign partner company.

Prices and fiscal conditions

- For the time being, we do not have an annual tax according to Directive 1999/62/EC. However; according to the Law on Motor Vehicle Tax, no 197 lorry, pickup-truck and other similar vehicles, used for freight transport are taxed based on their ages and their maximum total weights.
- Tolling is the primary ITS (Intelligent Transport Systems) application of General Directorate of Highways on motorways in Turkey. Urban roads in some major cities and some parts of inter-city roads have been installed with ITS focus on traffic management systems and traveller information systems. ITS installations are continuing on motorway-network now. There is no centralized authority for implementation of ITS. Implementation and control are carried out by related establishments that installed the ITS.
- Non-stop tolling system is one of the three toll collection systems. DSRC operates at 5.8 Ghz microwave frequency as mentioned in Directive 2004/52.
- A protocol signed between the General Directorate of Highways and the Turkish Radio Television Institution (TRT) with regard to contribution of radio broadcasting to increase road safety. Variable

Message Signs (VMS) are used on very limited road sections. ITS installation activities have been carried out on motorways. Additional VMS devices and internet services will be put into service for dissemination of traffic information to users. Road users can receive information concerning road conditions (such as road winter conditions, road works, lane closures) by dialling toll-free “159 Highways”.

Social conditions

Social legislation (Regulations 561/2006 and 3821/85 and Directives 2002/15 and 2006/22)

Turkey has ratified the AETR Agreement (European Agreement on the Work of Crews of Vehicles Engaged in International Road Transport-Official Gazette: 25 July 1999, no 23766) and the ILO Convention no:153 on Hours of Work and Rest Periods in Road Transport (Official Gazette: 22 July 2003, no 25176). Turkish legislation on driving times, breaks and rest periods for drivers has fully been harmonised with provisions of the AETR Agreement and the ILO Convention in question. As for the relevant EU Regulations and Directives, alignment has been secured to some extent thus further adjustments might be needed on some respects. Several definitions contained in the working time Directive (2002/15/EC) does not exist in the Turkish Legislation. Article 4(b) of the Directive 200/15/EC (working time for different employers are the sum of the working hours) has not yet been transposed. Legal texts regulating social aspects of Road Transport are indicated below:

- Labour Law No. 4857 (Official Gazette: 10 June 2003, no 25134).
- By-Law on Working Time that Cannot Be Divided into Weekly Working Days (Official Gazette: 06 April 2004, no 25425).

The purpose of this By-Law is to lay down methods and principles to be applied to working time and period of the works that cannot be carried out, due to their nature, by dividing into weekly working hours, such as the transport work which is done on board the vehicles moving on highways, railways, sea, lake and rivers and do not fall into the scope of the Maritime Labour Law no 854. This Turkish legislation does not apply to self-employed drivers.

- By-Law on Road Traffic (Official Gazette: 02 September 2004, no 25571) This By-Law applies to the drivers of the vehicles with weight limits exceeding 3,5 tonnes and carrying commercial goods and the commercial passenger vehicles with transport capacity of 9 persons including the driver. By-Law on Recording Equipment (Tachographs) used in Road Transport (3821/85/EC) has been prepared by the Ministry of Industry and Trade, considering the amendments by Council Regulations (EEC) 3314/90, (EEC) 3572/90, (EEC) 3688/92, (EC) 2479/95, (EC) 1056/97, (EC) 2135/98, (EC) 1360/2002, (EC) 1882/2003 and (EC) 432/2004. Draft version of the By-Law will be sent to the European Commission for comments within the framework of the notification procedure of the technical legislation, when translation into English has been completed.

According to the By-Law on Road Traffic

1. The operators of vehicles transporting goods and passengers.

- are obliged to make tachograph available in buses, trucks and towing vehicles and ensure that these tachographs are in function;
- are obliged to keep the tachograph records of their vehicles for 1 month in the vehicles and for 5 years in their offices. If the operators do not have an office, then they shall keep these records or have them kept for 5 years in the vehicles;
- are obliged to keep the records regarding types and license plates of their vehicles in the traffic, the identities of the drivers, the start date and place of work and destination;
- the authorized persons of the establishments performing transport of goods and passengers are obliged to monitor the working hours of the drivers and check whether the drivers obey these rules, and to train the drivers who are accustomed to violate the rules and to take the necessary measures for this matter;

- for the vehicles which conduct intercity transport of goods and passengers, the driving and resting hours foreseen under this By-Law are taken into account, the destination and route of the drivers are taken into consideration and accordingly these vehicles have second drivers available in the provinces, districts and roadside stations where the vehicle would stop.

2. The drivers of the vehicles.

- are obliged to obtain Professional Competence Certificate to drive the vehicles;
- can not drive the vehicles which do not have a tachograph or in function;
- are obliged to keep the records of the tachograph in the vehicles for 1 month as from the date of record. Also checked during the controls carried out by the authorized persons in the premises of undertakings are 1 weekly resting hours and the driving hours between these resting hours:
 - 2 weeks driving period limitation;
 - whether the reduced daily or weekly resting hours are compensated or not;
 - whether the certificates of entry are used or not;
 - whether the working hours of the driver are organized or not.

The controls which are done according to the submission of the necessary documents requested by the authorized bodies are regarded as the controls carried out in the premises.

National legislation concerning the installation of tachographs in trucks and busses

The national legislation concerning installation of tachographs in trucks and busses:

- Law on Road Traffic (Official Gazette: 18 October 1983, no 2918);
- By-Law on Road Traffic (Official Gazette: 18 July 1997, no 23053);
- By-Law on Manufacturing, Modification and Assembly of Motor Vehicles (AITM). (Official Gazette: 21 October 2004, no 25620 According to Law on Road Traffic, Article 31/1-b and By-Law on Road Traffic, Article 64/1-b; it is compulsory to have and keep in function tachographs in trucks, wreckers and busses. Tachographs may be mechanical, electronic or electro mechanical. Furthermore, according to By-Law on Road Traffic Article 99/a;
 - The affirmative opinion of the Ministry of Interior is a prerequisite for the qualifications, functions and technical features of the tachographs, and in accordance with the technical specifications to be prepared by the Ministry of Industry and Trade, the mechanical, electronic or electro mechanical tachographs are produced or imported.
 - The buses, trucks and wreckers which conduct intercity transport of goods and passengers are obliged to have a tachograph in function and to use it.
 - The operator and the driver of every vehicle supplied with tachograph shall have these devices in function as from the first day.
 - The buses, trucks and wreckers which conduct transport of goods and passengers within city and within contiguous zone of the municipality, are not obliged to have a tachograph.
 - Vehicles manufactured in 1984 or in previous years are not obliged to have or use tachograph.
 - Obligation of using tachographs does not apply to official vehicles.

Technical studies on digital tachograph are carried out by the Ministry of Industry and Trade

Roadside Controls

Drivers' working and rest times are controlled in two ways. Roadside controls of working and rest times of drivers are carried out by Ministry of Interior personnel (traffic police and gendarmerie) and controls of working and rest times of drivers at the premises of the companies are carried out by Ministry of Labour and Social Safety inspectors.

Official Gazette Entry into force

Council Directive 1999/36/EC of April 1999 on Transportable Pressure Equipment By-Law on Transportable Pressure Equipment (99/36/AT) 24766, 05.06.20003 01.01.2004 Mandatory use 01.07.2005

The accreditation and certification of the inspection bodies and certification of the equipment

According to Communiqué on the Basic Criteria for the Designation of Notified and Approved Bodies in accordance with the By-Law on Transportable Pressure Equipment, accreditation of the notified and approved bodies are not obligatory, but if the bodies were accredited, the evaluation should be made on the file bases by TURKAK (Turkish Accreditation Agency).

Conformity Assessment

In order to ensure transparency and independency of notified and approved bodies to be designated by the Ministry of Industry and Trade (MIT), the application, assessment and designation procedures and the criteria for the NBs and CABs were determined through the following legislation (Official Gazette No. 25030 dated, 24 February 2003):

- Communiqué on the Basic Criteria for the Designation of Conformity Assessment Bodies in Accordance with the By-Law on Pressure Equipment.
- Communiqué on the Basic Criteria for the Designation of Notified and Approved bodies in accordance with the By-Law on Transportable Pressure Equipment According to the above-mentioned criteria, CABs to be appointed by the Ministry as a notified body should meet the following requirements:
- The requirements laid down in the By-Law on Conformity Assessment and Notified Bodies (No. 2001/3531), which is an implementing regulation of the Law No. 4703 and published in the Official Gazette 17 January 2002, no: 24643,
- Minimum criteria set out in the Annex of the relevant By-Law for notified bodies, Communiqué covers:
 - Technical and administrative criteria to be met by CABs (no additional criteria other than those mentioned in the Directive, reference to EN 45000 series standards)
 - Application procedure (where to apply, accompanying documents for application)
 - Evaluation procedure
 - Designation
 - Duties and responsibilities of CABs.

Ministry signed a Protocol with TURKAK on 18.4.2003.

- According to this Protocol, TURKAK makes all necessary assessment for designation.
- Upon the positive assessment report of TURKAK, the MIT makes the final decision to notify the candidate body to the Commission.

The monitoring of the inspection bodies

Monitoring is made by MIT or TURKAK on behalf of the MIT according to the Communiqué on the Basic Criteria for the Designation of Conformity Assessment Bodies in Accordance with the By- Law on Pressure Equipment and Communiqué on the Basic Criteria for the Designation of Notified and Approved Bodies in Accordance with the By-Law on Transportable Pressure Equipment. But Turkey has not designated any notified or approved bodies yet. Positive evaluation reports for TSE and Turk Loydu have been received from EA.

STANDARDS AND CERTIFICATION - THE ACTUAL SITUATION IN BULGARIA

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The requirements of the EU market are strictly differentiated and aim at the fulfillment of main requirements regarding the manufacturing conditions and ecological consequences as well as regarding the product quality including its safety and innocuousness of consumption.

The activity of the European Commission (EC) on harmonizing the national technical legislation of Member States is initiated in the beginning of the 60's of last century and the purpose is to remove the technical barriers of free trade. Practice until 1985 is based on harmonization of standards and technical requirements by creating detailed community legislation.

EC develops a separate Directive for each product containing a detailed technical specification which must be approved by the Council of Ministers with complete unanimity and after that the Directive is transposed in the national legislation of each country. The method is known as Old Approach. Practice shows that this method of harmonizing the European standards is clumsy, connected with slow procedures and bulky legislation. Only a few hundred common standards have been prepared and approved until the mid-80's compared to the tens of thousands of standards existing on national level. The harmonized standards are useful especially in spheres where a strict unification of products is needed - automobiles, some chemical products, some foods. Its implementation leads to non-acceptance of a series of statutory documents.

The new strategy is formulated in Resolution of the Council of Europe from 1985 as a New Approach for technical harmonization and standardization.

The difference between the New and Old Approach is redirection of the requirements from being technically worked out in details for each separate product towards precise and essential safety requirements to types of products. The New Approach is a strategy for market regulation without governing it. It creates conditions and drives for technical progress without applying specific instructions for the companies of how to achieve that. Every product in compliance with the essential safety requirements which are of public interest (safety and innocuousness for people, animals and environment when used as intended) can move freely among EU Member States, irrespective of what technology and in conformity with what technical standards it has been produced. The New Approach is based on four main principles:

- The harmonization of legislation is brought to approval of essential requirements that products must conform with in order to be placed on the Community market and move freely.
- The technical specifications of products are formulated in the harmonized standards. They ensure conformity with the essential requirements of the New Approach Directives.
- The application of harmonized or other standards is voluntary and the manufacturer has the right to apply other technical specifications as well in order to fulfill the requirements.
- Products manufactured in conformity with the harmonized standards are presumably considered as conformable to the essential requirements.

The key elements in this regard refer to building mutual trust on the basis of competence and transparency as well as establishing a common policy and framework for conformity assessment. This policy is defined as "Global Approach". It is used to introduce procedures for conformity assessment on module principle, regulations for the use of these procedures and notified bodies certifying the conformity and the "CE" marking of products. The placing of CE marking means that the product has an assessed conformity with the essential requirements of the New Approach Directives concerning it and the product can move freely within the European market.

The modules for conformity assessment of the New Approach are also approved in Bulgarian legislation with some terminological differences but with no change in the meaning of contents.

The introduction of the modules /8 major modules and 6 sub-modules/ can be used as instructions for assessment of the conformity of products with the requirements of Bulgarian legislative regulations /we can insert a diagram here/.

The Resolution of the Council from 1989 for Global Approach when assessing conformity formulated the following guiding principles of conformity assessment:

- The European standards for quality assurance (standards of series EN ISO 9000) and the standards for requirements to the assessment bodies that must take part in quality assurance (standards of series EN ISO/IEC 17000) are widely used.
- The establishment of systems for accreditation and the application of methods for mutual comparisons is encouraged at the territory of Member States and Community itself.
- The conclusion of agreements for mutual recognition of results from examinations and of certificates in the unregulated area is encouraged.

While the New Approach Directives regulate only the essential safety requirements, technical and economically expedient ways for fulfilling these requirements are recommended in the harmonized standards. Harmonized standards are not mandatory but their observance leads to presumption of conformity with the essential requirement of directives.

When a given product, subject to a New Approach Directive, is produced under a nonharmonized standard in order to be placed on the market the manufacturer must prove that it complies with the essential requirements of the relevant directive. This is performed by certification from a third independent party - bodies for conformity assessment.

Harmonized standards are those European standards which are approved by the European standards bodies and developed according to the common guiding principles agreed between the Commission and the European standards bodies, Bulgarian standards introducing harmonized European standards and other international standards, can be purchased only by Bulgarian Institute for Standardization www.bds-bg.org.

The Bulgarian Institute for Standardization (BDS) is the National Standards Body in the Republic of Bulgaria. BDS has been created according to the Law on National Standardization, published in 2005 (State Gazette, issue 88 of 4 November 2005). The Bulgarian Institute for Standardization is an independent non-governmental organization whose members are all interested in standardization activities companies, organizations and institutions. As a non-profit organization BDS operates for the public benefit of society.

The Bulgarian Institute for Standardization (BDS) as the national standardization body is entitled to represent the interests of the Republic of Bulgaria in the international and European standards

organizations. Since 1955 BDS is a member of ISO. Since 1958 BDS is a member of IEC. In 2007 Bulgaria was accepted as a National Member of CEN and CENELEC. At the present moment there are 16 Technical Councils and 91 Technical Committees working in BDS.

There are harmonized standards under 21 from the New Approach Directives, under 4 Directives based on the principles of New Approach or Global Approach but without CE marking and under 4 Directives based on some principles of New Approach or Global Approach till the present moment.

Application of the standards for quality systems

The use of quality systems for the purposes of the procedures for conformity assessment within the directives is presented in modules D, E, H and their versions. A quality system applied on the grounds of EN ISO 9001 gives presumption for conformity with the relevant modules regarding the regulations which are within the scope of this standard as far as the quality system allows the manufacturer to prove that the product conforms to the essential requirements of the concrete directive.

The manufacturer is responsible for the introduction and permanent application of the quality system by thus observing the requirements of technical legislation. The Certification body must follow within the scope of his obligations if the manufacturer observes the requirement mentioned above.

There are more than 20 Certification organizations in the Republic of Bulgaria, some being foreign with offices in the country and others - accredited by Executive Agency Bulgarian Accreditation Service or Bulgarian Council for Voluntary Accreditation and Authorization. Data indicate a permanent tendency of increase in the number of certified companies being 3200 as of December 2007.

The New Approach Directives oblige the manufacturer to prepare a technical file (technical documentation) which contains information proving conformity of the product with the requirements of the Directive applied.

The Declaration of conformity is prepared by the person who places the product on the market and/or into operation as a part of the procedure for conformity assessment mentioned in the relevant directive.

The Declaration of conformity must contain: the directive according to which it is issued; the manufacturer, his authorized representative if necessary, the person who places the product on the market and/or into operation; the notified body that has assessed conformity if he has participated in the conformity assessment; the product and where required, indication of the harmonized standards and other normative documents.

The meaning of this declaration is to certify that the product complies with the requirements of applicable regulations and that the product complies with the type for which a certificate of type examination has been issued and it conforms to the essential requirements of applicable regulations.

Notified Bodies

Most of the modules provided in the New Approach Directives require the intervention of a third independent party in the person of a notified body for conformity assessment. This is required in the case of high risk products. The notified bodies undertake obligations in areas of public interest and are therefore dependent on the competent national authorities. Member States bear the obligation to guarantee that the bodies notified by them have the necessary technical competence.

Upon execution of the activities regarding conformity assessment the notified bodies must take adequate measures in order to keep the confidential character of the obtained information. Manufacturers have

the right to choose a notified body among those that have been nominated to apply the procedure for conformity assessment according to the applicable directive.

In Bulgarian legislation the notified bodies are defined as “persons who have received a permit for conformity assessment” and this permit is issued by Directorate “Permits for Conformity Assessment” under the State Agency for Metrology and Technical Supervision /SAMTS/. SAMTS - <http://www.damtn.government.bg> is responsible for the nomination of the bodies for conformity assessment, on one hand, and market supervision in the sectors of “new approach”, on the other, except for the medical equipment and construction products. The Register of persons who have received a permit for conformity assessment is kept by SAMTS and published at www.sasm.government.bg.

The Bulgarian notified bodies are 33 for the moment, a big part of them being in the area of construction.

In most cases the notified bodies use accredited laboratories in their activity. In Bulgaria the number of accredited laboratories as of July 2008 is 222.

The New Approach Directives contain a safeguard clause which obliges Member States to restrict or prohibit the placing on the market or the putting into operation of dangerous products (or of the so-called non-conforming products) or to withdraw these products from the trade network. The procedure for the safeguard clause concerns only those products which are within the scope of the New Approach Directive and which have a CE marking.

What is and what is not a CE marking

CE marking represents an indication that the requirements under each of the applied Directives have been fulfilled. It is directed to the authorities of Member States and is safeguarded by them.

CE marking is placed only on products within the scope of New Approach Directives for which a certification of conformity is by all means necessary.

The CE marking is not a mark of product origin. It is not a trademark for quality but has to be considered as a declaration of manufacturer or his authorized representative that the product complies with all applicable harmonized regulations.

In a country where a New Approach Directive has come into force the placing of a product on the market without a CE marking is considered as violation. The manufacturer is legally responsible for the assurance of product conformity with the essential safety requirements and for the placement of CE marking.

The European Commission considers the CE marking as a “Passport” which will allow products to move freely in the Common market of the European Union.

STANDARDIZATION AND CERTIFICATION IN ROMANIA

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The standardization, together with conformity assesment, represents an important tool, used to achieve the objectives that refer to the free movement of merchandise and services, the protection of employees and consumers, the prevention, protection and improvement of environment, industry competitiveness.

For the business environment, the standards contribute to the realization of a common commercial language. They assure the compatibility of components, regardless of the place where they are produced, and also the networks interoperability, having an important contribution to the reduction of production and storage costs.

For the consumers, the existance of standards leads to a reduction of costs, through minimizing time and effort dedicated to option selection, and facilitating comparisons between functions.

For governments, the standardization offers an opportunity for regularisation and better political management, through the reduction of regulation details necessary to achieve the health, security and environment protection objectives. The standards also contribute to the promotion of know-how and technical evolution.

The free movement of merchandise, one of the four pillars of the EU Market, through its mechanisms, has a contribution to the prevention of commercial barriers occurrence, to the mutual recognition and technical harmonization. Having the purpose to eliminate the technical barriers to trade, in 198

5 there was elaborated and implemented a new strategy, named "The New Approach", that reffers to technical and standards harmonisation. This approach was supported by a coherent policy in the certification and attestation domains, drawing clear, consistent and transparent principles, that will be applied for the certification procedures used at European level for the products that enter the EU Market.

The new concept regarding the technical harmonisation and standardization intended to simplify and accelerate the European legislative process. This desideratum was fulfilled mainly through replacing the detailed technical hamonisation (The Old Approach) with a system based on essential requirements, stated in an unitary manner, and through the introduction of the concept of harmonised standard, as a tool that offers the products presumption of conformity with the essential requirements.

Until 1985 the harmonisation was done through old type directives (Old Approach Directives) that, often, referred to a very narrow domain, contained detailed mandatory technical requirements and there were frequently modified in accordance with the industrial progress.

Since 1985, all New Approach Directives represent - unlike the Old Approach Directives - total harmonisation directives, which means that it is forbidden (or, if exists, it is unapplicable) the existance at the same time of more than one form of national regulation regarding the same public interests. In 1989, the New Approach was consolidated by the Global Approach regarding testing and certification; this is the basis of the ample European Policy regarding conformity evaluation.

Presently, it is considered that the New Approach and the Global Approach promote a credible, transparent and homogeneous technical environment, that leads to mutual trust between public authorities, economic operators and consumers.

The New Approach Directives are based on the following principles:

- harmonisation is limited to the essential requirements;
- only the products that respect these essential requirements can be put on the market and used;
- the harmonised standards that were adopted as national standards offer the presumption of conformity with the adequate essential requirements;
- the application of the harmonised standards or other technical specifications is voluntary;
- producers can choose among different evaluation of conformity procedures provided by the applicable directive.

For the domains regulated according to the New Approach and Global Approach principles, the European Standardization Bodies (CEN, CENELEC and ETSI) elaborate European harmonised standards, that the national standardization bodies of the Member States have the obligation to adopt as national standards. Testing laboratories and certification bodies were created, being capable to test and evaluate the conformity (to the essential applicable requirements) of products; the national certification bodies, according to the EN 45000 voluntary standards requirements, are involved in competence and capability evaluation process of laboratories and certification/inspection bodies, regarding their ability to fulfill the specific tasks present in the technical regulations.

With the EU ascension, Romania committed itself to a sustainable development and there was imposed, at national level, a new way of thinking and acting; two of the global objectives are:

- cumulation of the economic development requisitions with the ones of social and cultural development;
- creation and consolidation of a functional and competitive market economy.

Regarding the creation of a new legislative framework in the free movement of merchandise domain, for the coherence and consistency of the legal harmonisation process with the EU directives for the technical regulations regarding products, Law no. 608/2001 regarding products conformity evaluation was elaborated and adopted with the subsequent modifications and addenda.

For an unitary and transparent implementation of the requirements specified in the harmonised technical regulations, the horizontal legislative framework was consolidated by a series of regulations subsequent the above mentioned law, that vise mainly the procedures used in the conformity evaluation process and the rules for applying the conformity marking, the procedure for designation of the bodies involved in evaluation of the products conformity, some measures regarding the market surveillance and also some measures regarding the exchange of informations between Romania and EU in the standards and unharmonised technical regulations fields.

The producers have to perform risk analysis, to know which are the essential requirements applicable for a product. These analysis have to be well documented and included in the technical documentation, that must contain all the phases, from the designing, to production and usage of the product.

Nevertheless, the application of the harmonised standards remains voluntary. The producer decides if he will apply or not a harmonised standard. If he chooses not to use it, then he has the obligation to demonstrate the conformity of the product or the conformity with the essential requirements through other methods (using other technical specifications e.g.).

The domains vised by the technical regulations are included in No. 1 Annex to the 608/2001 Law regarding products conformity evaluation, with all the subsequent modifications and addenda and they are as follows: low voltage equipment, pressure vessels, toys, construction products, electro-magnetic

compatibility, industrial machines, individual protection equipment, mechanical weighing machines, active medical implants, gas burners, boilers for hot water, explosives for civil purposes, medical devices, potential explosive environments, recreational boats, elevators, cooling devices, equipment under pressure, radio and communication equipment, medical devices for in vitro diagnose, marine equipment, packages and package wastes, cable transport equipment for people, movable equipment under pressure, noise emissions generated by equipment destined for outdoor use, interoperability of transeuropean railway transport.

At the European level, the domains specified in the no. 1 Annex to the 608/2001 Law are the subject of harmonised technical regulations - European directives based on New Approach principles. These directives are transposed in national legislation through technical regulations approved by Government Decisions.

In Romania the European standards, including the harmonised ones, are adopted as national standards by the national standardization body, Romanian Standards Association - ASRO, private law and public interest juridical person, association without patrimonial purpose, that functions according to the 355/2002 Law that approved the 39/1998 Government Ordinance regarding national standardization activity in Romania, and is recognised as the national standardization organism according to 985/2004 Government Decision.

The Romanian Standards Association - ASRO, is a full member of: CEN - European Committee for Standardization (01.01.2006), CENELEC - European Committee for Electro-technical Standardization (01.02.2006), ISO - International Organization for Standardization (1950), IEC - International Electro-technical Commission (1920) and observing member of ETSI - European Telecommunications Standards Institute (2005).

The main attributions The Romanian Standards Association - ASRO are:

- Drawing the national standardization principles and methodology.
- Evaluation of the necessity to elaborate new standards.
- Elaboration and approval of the national standards and also participation in the European and international standardization activity.
- Management of the documentary fund of standards and publications in national and international standardization domain.
- Public information in national standardization domain.
- Publishing and distribution of the standards and standardization publications.
- Standardization promotion, qualification training.
- Represents Romanian interests at international and non-governmental standardization forums;
- Represents ISO and IEC in Romania and protects the copyrights on adopted international standards.
- Offers products and services to standards users.
- ASRO gives upon request national conformity marks SR (conformity with Romanian product standards) and SR-S (conformity with Romanian security standards).

ASRO co-ordinates and guides the activity of the national standardization committees, that, on their competency sectors, have the duty to stimulate the standardization activity, to formulate points of view at national level to be presented in European and international bodies and to prepare and elaborate standard projects. ASRO has an important place among the institutions that help the companies to comply the EU Market requirements, to be able to become part of it and to make Romanian products competitive and able to move freely on European territory. The structure of ASRO contains the Center for information exchange regarding the standards, which has the responsibility of information exchange in standardization domain. Thus, ASRO is one of the standardization bodies from EU member states that

send to the above mentioned institutions (and implicitly to the European Commission) informations regarding the new themes of national standards or their revises.

Elaboration of the Romanian standards and adoption of European standards

Elaboration of the Romanian standards is made by the technical standardization committees, setted up by ASRO.

During the elaboration process they take into account:

- the existance of a published European standard, that is still not adopted as Romanian standard; in this case, the European standard will be adopted. European standards are published only as identical national standards (as technical content and presentation).

The European standards can be adopted using the following methods:

- publication of the Romanian version;
- publication by reproduction of an official version (in English, French or German);
- confirmation of adoption, namely publishing in the specialised literature of a confirmation of adoption file or announcement;
 - the existance of a published international standard that is still not adopted as Romanian standard; in this case, the international standard will be adopted (identical or modified);
 - the existance of a project for elaboration of an European standard, having the same subject and application domain as the ongoing national standardization project; in this case, according to the 98/34/EC Directive specifications, modified by 98/48/EC Directive, the national initiatives are stopped.

The Romanian national standards can be classified as follows:

- Original Romanian standards, with SR or STAS indicative.
- Romanian standard that adopted an European standard, with SR EN indicative.
- Romanian standard that adopted an international standard, with SR ISO indicative.
- Romanian standard that adopted an amendment, with SR EN ISO indicative.
- Romanian standard that adopted an erratum, with SR EN indicative.

The examination of the standards is carried out periodically, according to the SR 10000-3:2004 standardization methodology, as follows:

- National standards that are in conflict with the standards that adopted the European standards must be canceled.
- Romanian original standards or Romanian standards that adopted an international standard must be verified after 5 years from their publication, then they must be reconfirmed, revised, modified or canceled.

In Romania, the entire set of international standards was adopted (ISO 9001/2001 regarding the implementation and certification of the quality management system, ISO 14001/2005 regarding the implementation and certification of the environment management system, OHSAS 18001/2004 and OHSAS 18002/2004 regarding the implementation and certification of the health and occupational safety management system, SA 8000/2001 regarding the implementation and certification of the social responsibility management system).

Advantages of standards usage

- removal of the technical barriers on free trade;
- lower prices, through removal of certain costs;
- modernization of industry and products;

- encouragement of real competitiveness and reduction of disloyal competition;
- increased security of usage of goods and services;
- unification of testing methods used in laboratories;
- decreasing of pollution through promotion of the best practices;
- increasing of the users trust degree;
- increasing of the industrial competitiveness;
- free trade, at national and international level;
- competitive Romanian products on the EU Market;
- economic efficiency.

Another important aspect is product conformity. The evaluation of conformity is a method used to verify if a product satisfies a certain level of quality and security, and gives the user clear informations about its characteristics. Thus, the products on the market have to not endanger the security and health of the people, environment or other public interests (mentioned in the European directives) when they are properly installed, maintained and used according to purpose indicated by the producer. The conformity evaluation process is finished, if the product is in accordance with all applicable directives, by applying of conformity marking CE.

CE marking symbolises the conformity of a product with all the EU requirements that must be respected by a producer, according to the EU directives that impose its existence. CE marking is mandatory and must be applied before putting the product on the market or in use; this marking doesn't have a commercial purpose.

To apply the CE European conformity marking, depending on the evaluation procedure chosen by the producer, the conformity evaluation can be performed by the producer itself or by the notified (recognised) bodies: testing laboratories, certification or inspection bodies, juridical persons with the headquarters in Romania or in another EU Member State that were designated and notified by an empowered authority, a member state respectively, included on the notified bodies list, to perform conformity evaluation in a regulated field.

To remove from the market the products that don't comply with the specifications of the current standards, there are Romanian authorities empowered to make a permanent market surveillance, through the control bodies mentioned in the technical regulations.

The control bodies actions vise the specifications of the technical regulations from their competency field, and also the principles and requirements established by the 891/2004 Government Decision regarding market surveillance measures on the vised domains, mentioned in Law no. 608/2001 regarding products conformity evaluation, with the subsequent modifications and addenda. The same above mentioned regulation, respective Law no. 608/2001 modified and addended, establishes a unitary legal framework for technical regulations elaboration, conformity evaluation and market surveillance for the products put on the market and/or used in Romania.

Certification is a procedure through which a third part gives a written assurance that a product, process or service is in accordance with the specified requirements; this procedure is different from other conformity attestation systems, such as supplier statement, testing laboratories or inspection bodies reports. Certification is based on tests, inspections and audits results and assures the client regarding the systematic intervening of a capable third party.

Certification represents an advantage, for the producer and also for the buyer, consumer or distributor, adding an incontestable value to the product or service. For the producer or for the services provider, certification increases the value of the products and services, opens the markets and simplifies the business relations. From the user point of view, certification facilitates apparently identical products or services differentiation and gives the assurance that the product purchased fulfills the defined characteristics or that the organization processes fulfill the specified requirements.

The producer or its authorised representative have the obligation to assure, before putting the products on the market and/or usage the products, the following:

- a) the application of the procedures for the products conformity evaluation, according with the essential requirements, specified in the technical regulations;
- b) preparing the documentation of the product: usage manual (that has to contain the product assembling, usage and maintainance instructions, a presentation of its characteristics), guarantee certificate, conformity declaration, test reports, other documents that certify conformity;
- c) conformity marking application, when necessary. The conformity of the products with the essential requirements is attested by the conformity declaration made by the producer or its authorised representative, through test reports or through conformity certificates elaborated by laboratories or certification or inspection bodies, chosen by the producer, according to the evaluation procedures, and through conformity marking, according to the applicable technical regulations.

CE Marking indicates the fact that the product is authorised to be put freely on the EU Market. The Marking is put on the product or on the package by the producer or by its authorised agent and certifies that the product is in accordance with the specifications of the Directive(s) in the analysed field

- doesn't specify the applied modules
- is accompanied by a code that identifies the approved body involved in production control phase
- doesn't exclude the marking that indicates conformity with national or European standards

CE Marking implications

If CE marking is put on a product, it is authorised to be freely distributed on the EU Market. CE marking is put directly on the product or on its package by the producer or by its authorised agent. It doesn't have a certain colour. CE marking doesn't interdict other markings (e.g. The ones that indicate conformity with national standards).

Among the European Directives transposed in Romanian legislation we can mention the ones that vise the following domains:

Nº	European Directive	Romanian technical regulation
1.	73/23/EEC Directive Low voltage electrical equipment	457/2003 GD regarding security assurance for low voltage electrical equipment users. 1514/2003 GD that modifies and supplements 457/2003 GD regarding security assurance for low voltage electrical equipment users. 384/2004 ECMO for approval of the List that comprises the Romanian standards regarding security assurance for low voltage electrical equipment users that adopt the harmonised European standards.
2.	87/404/EEC Directive Simple vessels under pressure	454/2003 GD regarding the conditions for introduction on the market of the simple vessels under pressure. 185/2003 IRMO regarding approval of the List that comprises the Romanian standards regarding simple vessels under pressure that adopt the harmonised European standards. 865/2007 EFMO for replacing the annex of the 185/2003 IRMO regarding approval of the List that comprises the Romanian standards that adopt the harmonised European standards regarding simple vessels under pressure.

Nº	European Directive	Romanian technical regulation
3.	88/378/EEC Directive Toys users security	396/2003 GD regarding toys users security 393/2003 ECMO regarding approval of the List that comprises the Romanian standards regarding toys users security that adopt the harmonised European standards 121/2005 ECMO for replacing the annex of the 393/2003 ECMO regarding approval of the List that comprises the Romanian standards regarding toys users security that adopt the harmonised European standards
4.	89/106/EEC Directive Construction products	622/2004 GD regarding the conditions for introduction on the market of construction products 796/2005 GD that modifies and supplements 622/2004 GD regarding the conditions for introduction on the market of construction products 1708/2005 GD that supplements the 39 article of 622/2004 GD regarding the conditions for introduction on the market of construction products 1822/2004 TCTMO and 394/2004 IAMO for approval of the Regulation regarding the clasification of construction products, based on fire behaviour 133/2006 TCTMO and 1234/2006 IAMO that modify and supplement the Regulation regarding the clasification of construction products, based on fire behaviour, approved by 1822/2004 TCTMO and 394/2004 IAMO 808/2005 GD for approval of the Regulation regarding the authorization of the analysis and testing laboratories in construction activity 448/2007 PWDMO regarding the approval of the List that comprises the main guidelines of Romanian standards that transpose the harmonised European standards and of recognised technical specifications for construction products 1558/2004 TCTMO that approves the Regulation regarding construction products conformity certification 896/2005 TCTMO that modifies and supplements the Regulation regarding construction products conformity certification, approved by 1558/2004 TCTMO

Nº	European Directive	Romanian technical regulation
		<p>2134/2004 TCTMO and 460/2004 IAMO regarding the approval of the Procedure for designation of the bodies that certify the construction products conformity</p> <p>620/2005 TCTMO regarding the implementation and usage of eurocodes in constructions</p> <p>607/2005 IAMO for approval of the control Methodology regarding surveillance of the construction products market, that vises fire security</p> <p>270/2005 TCTMO regarding the approval of the Procedure for evaluation and designation of the bodies authorised to give European technical specific documentation for construction products</p> <p>1746/2005 TCTMO regarding the approval of the List that comprises the recognised bodies in construction products domain</p>
5.	2004/108/EC Directive Electromagnetic compatibility	<p>497/2003 GD regarding the conditions for introduction on the market and for functioning of electric and electronic devices, from the electromagnetic compatibility point of view</p> <p>1554/2003 GD that modifies and supplements the 497/2003 GD regarding the conditions for introduction on the market and for functioning of electric and electronic devices, from the electromagnetic compatibility point of view</p> <p>381/2004 ECMO and 1620/2004 CTIMO for approval of the List that comprises the Romanian standards, that adopt the harmonised European standards regarding electromagnetic compatibility</p>
6.	89/686/EEC Directive Individual protection equipment	<p>115/2004 GD regarding individual protection equipment essential security conditions and their introduction on the market</p> <p>94/2006 ESHFMO for approval of the List that comprises the Romanian standards, that adopt the harmonised European standards regarding individual protection equipment</p>
7.	90/384/EEC Directive Mechanical weighing machines	<p>617/2003 GD regarding the conditions of introduction on the market and usage of mechanical weighing machines</p> <p>365/2003 IRMO for approval of the List that comprises the Romanian standards, that adopt the harmonised European standards regarding mechanical weighing machines</p>

Nº	European Directive	Romanian technical regulation
8.	90/385/EEC Directive Active medical implants	344/2004 GD regarding the conditions of introduction on the market and/or usage of active medical implants 1298/2004 GD that modify the 7 Annex of 344/2004 GD regarding the conditions of introduction on the market and/or usage of active medical implants
		535/2004 HMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to active medical implants
		962/2005 HMO that replaces the annex of 535/2004 HMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to active medical implants
9.	90/396/EEC Directive Gas burners	453/2003 GD regarding the conditions of introduction on the market of gas burners 1480/2003 GD that modifies and supplement 453/2003 GD regarding the conditions of introduction on the market of gas burners
		47/2006 ECMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to gas burners (updated)
10.	92/42/EEC Directive Boilers for hot water with liquid/gas fue	574/2005 GD regarding the conditions for new boilers for hot water with liquid / gas fuel efficiency
11.	93/15/EEC Directive Explosives for civil purposes	207/2005 GD regarding the essential requirements of explosives for civil purposes and the conditions for their introduction on the market
		561/2005 ESHFMO for approval of the Methodologic Norms regarding the recognition and designation of testing laboratories and of certification and inspection bodies that evaluate conformity of explosives for civil purposes
		628/2005 ESHFMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to explosives for civil purposes

Nº	European Directive	Romanian technical regulation
12.	93/42/EEC Directive Medical devices modified by the 98/78/CE, 2000/70/CE, 2001/104/CE, 2003/12/ CE Directives and the 1882/2003 Regulation	911/2005 GD regarding the conditions of introduction on the market and usage of medical devices
		466/2007 GD that modifies and supplements 911/2005 GD regarding the conditions of introduction on the market and usage of medical devices
		789/2006 HMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to medical devices
13.	94/9/EC Directive Protection equipment and systems in potential explosive environments	752/2004 GD regarding the conditions of introduction on the market of protection equipment and systems in potential explosive environments
		461/2006 GD that modifies 752/2004 GD regarding the conditions of introduction on the market of protection equipment and systems in potential explosive environments
		642/2005 ESHFMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to protection equipment and systems in potential explosive environments
14.	94/25/EC Directive Modified by the 2003/44/EC Directive Recreational boats	2195/2005 GD regarding the conditions of introduction on the market and / or usage of recreational boats
		1681/2005 TCTMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to recreational boats
		45/2007 TCTMO regarding the replacement of the annex of 1681/2005 TCTMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to recreational boats
15.	95/16/EC Directive Elevators	439/2003 GD regarding the conditions of introduction on the market of elevators
		184/2003 IRMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to elevators

№	European Directive	Romanian technical regulation
		101/2005 ECMO for the replacement of the annex of 184/2003 IRMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to elevators, like it was modified through the Ordinance of the Minister of State, the Minister of Economy and Commerce no. 395/2004
16.	96/57/EC Directive Domestic cooling devices	<p>1039/2003 GD regarding the conditions for the labeling and energy efficiency of domestic cooling devices, for their introduction on the market</p> <p>972/2004 GD that modifies and supplements 1039/2003 GD regarding the conditions for the labeling and energy efficiency of domestic cooling devices, for their introduction on the market</p> <p>1144/2006 GD that modifies no. 1 Annex at 1039/2003 GD regarding the conditions for the labeling and energy efficiency of domestic cooling devices, for their introduction on the market</p>
17.	97/23/EEC Directive Equipment under pressure	<p>584/2004 GD regarding the conditions for introduction on the market of equipment under pressure</p> <p>393/2005 ECMO regarding some measures for designation of inspectorates for conformity evaluation of equipment under pressure, according the specifications of art. no. 17 from the 584/2004 GD regarding the conditions for introduction on the market of equipment under pressure</p> <p>440/2004 ECMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to equipment under pressure</p> <p>867/2007 EFMO that replaces the annex of the 440/2004 ECMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to equipment under pressure</p>
18.	1999/36/EC Directive Movable equipment under pressure	<p>941/2003 GD regarding the conditions for introduction on the market and repeated usage of movable equipment under pressure</p> <p>1941/2004 GD that modifies the 941/2003 GD regarding the conditions for introduction on the market and repeated usage of movable equipment under pressure</p>

Nº	European Directive	Romanian technical regulation
19.	98/37/EC Directive Industrial equipment	119/2004 GD regarding the conditions for introduction on the market of industrial equipment 242/2004 ESHFMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to industrial equipment
20.	98/79/EC Directive Medical devices for in vitro diagnose	798/2003 GD regarding the conditions for introduction on the market and usage of medical devices for in vitro diagnose 355/2004 HMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to medical devices for in vitro diagnose 1219/2005 HMO that modifies the 355/2004 HMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to medical devices for in vitro diagnose
21.	99/5/EC Directive Radio and communication equipment	88/2003 GD regarding radio and communication equipment and the mutual recognition of their conformity 236/2004 GD that modifies and supplements the 88/2003 GD regarding radio and communication equipment and the mutual recognition of their conformity 42/2005 CITMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to radio and communication equipment
22.	2000/9/EC Directive Cable transport equipment for people	1009/2004 GD regarding the conditions for usage of cable transport equipment for people 1589/2006 GD that modifies the 1009/2004 GD regarding the conditions for usage of cable transport equipment for people 198/2006 ECMO that updates the List that comprises the Romanian standards that adopts harmonised European standards that refer to cable transport equipment for people
23.	94/62/EC Directive Modified by the 2004/12/EC Directive and 2005/20/EC Directive	621/2005 GD regarding packages and packaging wastes administration

№	European Directive	Romanian technical regulation
	Packages and packaging wastes	<p>1872/2006 GD that modifies and supplements 621/2005 GD regarding packages and packaging wastes administration</p> <p>128/2004 ECMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to packages and packaging wastes</p>
24.	96/48/EEC Directive Modified by the 2004/50/EC Directive Interoperability of the fast transeuropean railway transport	<p>1533/2003 GD regarding interoperability of the fast transeuropean railway transport</p> <p>1563/2006 GD that modifies and supplements 1533/2003 GD regarding interoperability of the fast transeuropean railway transport and 850/2003 GD regarding the interoperability of the conventional Romanian railway system with the transeuropean railway transport</p>
25.	96/98/EC Directive Modified by the 98/85/CE, 2001/53/CE, 2002/75/CE, 2002/84/CE Directives Marine equipment	582/2003 PWITHMO for approval of the technical Norms regarding approval of equipment and products for marine ships, stipulated by international conventions that Romania is part of, code MLPTL. ANR-EM-2003
26.	2000/14/EC Directive Noise emissions generated by equipment destined for outdoor use	539/2004 GD regarding the limitation of noise emissions generated by equipment destined for outdoor use
27.	2001/16/EC Directive Modified by the 2004/50/EC Directive Interoperability of the conventional transeuropean railway transport	<p>850/2003 GD regarding the interoperability of the conventional Romanian railway system with the transeuropean railway transport</p> <p>1563/2006 GD that modifies and supplements 1533/2003 GD regarding interoperability of the fast transeuropean railway transport and 850/2003 GD regarding the interoperability of the conventional Romanian railway system with the transeuropean railway transport</p>
28.	2004/22/EC Directive Measuring instruments	<p>264/2006 GD regarding the conditions of introduction on the market and usage of measuring instruments</p> <p>1690/2007 EFMO for approval of the List that comprises the Romanian standards that adopts harmonised European standards that refer to measuring instruments</p>