QUALEB
QUALITY PROGRAMME

QUALITY Guide

An ABC Guide on
EU NEW and GLOBAL APPROACH

Booklet 5 July 2008

an EU funded project

QUALITYGuide

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An ABC Guide to the EU NEW and GLOBAL APPROACH

This is the fifth in a series of booklets produced by the Quality Programme, as a guide to understanding the role and importance of relevant issues, under the EU New and Global Approach

Produced in the framework of the MEDA Project:
Strengthening Quality Management, Capabilities and Infrastructure in Lebanon - QUALEB, the Quality Programme, hosted at the **Ministry of Economy & Trade** - Europe Aid/17725/D/SV/LB

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Dear Reader,

This guide is part of a series published by the Quality Programme. This programme, funded by the European Union, supports Lebanese Companies to increase their goods and services exports to foreign markets. It also aims at increasing the level of quality and safety of products distributed in the Lebanese market in order to better protect the health of the Lebanese consumers.

The Quality Programme is in the process of supporting the creation and development of institutions that will assist the business sector to comply with international standards and requirements for product manufacturing and distribution. Therefore, building a Quality Infrastructure in Lebanon is imperative.

Such infrastructure consists of testing and calibration laboratories, inspection and certification bodies, standardisation and accreditation institutes, and governmental organisations that are responsible of products verification, certification and other activities.

It is a fact that some issues related to Quality Infrastructure might be confusing. Therefore, these guides are intended to explain these different aspects. They are not reference books, but simply introductory channels to different quality related topics.

Nevertheless, the guides provide solid references to documents and websites that contain more elaborate, detailed and specific information.

The major objective is to provide useful and accessible updates to everyone. Suggestions are highly appreciated and accepted through the contact details of the Quality Programme.

We hope that you will benefit from this ABC Guide which is proposed to assist you in better understanding related quality issues.

Ali Berro, PhD
Director, Quality Programme

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An ABC Guide on the
EU New and Global Approach

1 - LIST OF ABBREVIATIONS

ACAA	Agreement on Conformity Assessment and Acceptance of Industrial Products
CE	Conformité Européenne
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardisation
EA	European Co-operation for Accreditation
EEA	European Economic Area
ETSI	European Telecommunications Standards Institute
EU	European Union
ISO	International Organisation for Standardisation
IEC	International Electrotechnical Commission
MRA	Mutual Recognition Agreement
NANDO	New Approach Notified and Designated Organisations
TBT	Technical Barriers to Trade
WTO	World Trade Organisation

References to terminology

CE marking – a marking affixed to a product by its manufacturer before it is put on the EU market, demonstrating that the product complies with all the requirements of all New Approach directives applicable to the product.

Essential requirements – the requirements laid down in New Approach directives for protecting the public interest, like health, safety, environment. Only products complying with essential requirements may be placed on the market, or put into service.

European Standard Bodies – the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI), recognised by the EU as the European standards bodies.

Global Approach - a consistent approach to a quality controlled conformity assessment system in the EU. The approach formulates modules for the various phases of the conformity assessment procedures and for the designation of bodies performing these procedures. The approach is applicable for both mandatory and voluntary conformity assessment.

Harmonised standard – A standard, developed and adopted by one of the European Standards Bodies, in order to specify (an aspect of) an essential requirement of a New Approach Directive. Although the European Commission has requested, via mandate to the European Standards Bodies, the development of such standards, they are actually developed through the normal, open and transparent standardisation process and built on consensus between all interested parties.

Harmonised standards have an important legal result. Compliance in the design and manufacturing of a product with harmonised standards, the reference numbers of which have been published in the Official Journal and which have been transposed into national standards, provides a presumption of conformity with the corresponding essential requirements of the New Approach directives.

Market Surveillance - activities carried out and measures taken by public authorities to ensure that products are in compliance with legal requirements or do not endanger health and safety or other issues of public interest protection.

Modules – popular term for the standardised conformity assessments procedures of the Global Approach.

Mutual Recognition Agreement - an international agreement by which two or more countries agree to recognise the results of one another's conformity assessments procedures.

New Approach – EU concept for legislative harmonisation of product requirements.

Notified Body – a third party certification body, inspection body, or testing laboratory selected and appointed by a member state to carry out (part of) conformity assessment procedures according to a New Approach directive

Official Journal of the European Union – official gazette of the European Union. The 'L-series' contains EU legislation including regulations, directives, decisions, recommendations and opinions. The 'C-series' contains reports and announcements including the judgments of the European Court of Justice and the Court of First Instance. An electronic version is available (see annex).

Peer-assessment – for the purpose of this guide, assessment of an accreditation body against specified requirements (ISO/IEC 17011) by a team from other accreditation bodies. ISO/IEC has published a standard on peer assessment, ISO/IEC 17040, 'General requirements for peer assessment of conformity assessment bodies and accreditation bodies'.

Presumption of conformity – a legal concept, compelling authorities to take the compliance of a product with essential requirements initially for granted, when the manufacturer has applied harmonised standards in the design and production of a product.

Standards – agreed documents, which provides for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods. Standards should be developed through an open and transparent process. Standards are voluntary documents, but can be made mandatory through references in technical regulations.

Technical Barrier to Trade (TBT) – obstacles to international trade due to differences in mandatory technical requirements for products and/or conformity assessment requirements between countries.

Technical Regulation – mandatory legal rules, which lay down product characteristics and/or their related processes and prodution methods, as well as the requirements how to assess the conformity of a product with the rules and the applicable administrative provisions. It may also include, or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

1 - INTRODUCTION

According to the Association Agreement between Lebanon and EU, which came into force on April 1, 2006, the parties shall co-operate in reducing divergences which include standardisation and conformity assessment issues. Furthermore, the parties shall use their best endeavours to approximate their respective laws. It is also forecasted that the parties shall negotiate mutual recognition agreements, as soon as the conditions for them are met.

To facilitate these objectives, the EU is funding a technical assistance project, QUALEB, the Quality Programme. The project started in October 2004 and will continue until autumn 2009. The overall objective of the programme is to improve and develop the major functions of the Lebanese conformity assessment chain in order to protect consumers health and safety and increase Lebanese exports to EU markets. This entails among others, bringing Lebanese legislation for the safety of products, more in line with EU regulations and support to institutional development e.g. draft legal acts on technical regulations and conformity assessment, on standardisation and on market surveillance, have been prepared within the project. These draft laws support international and EU principles and best practices. These draft laws are still awaiting the approval by Parliament at the time of writing this guide.

This ABC guide has been developed to increase the understanding of international principles for technical regulations, standardisation and conformity assessment. It is especially focused on the EU concepts of the New and Global Approach.

2 - TECHNICAL BARRIERS TO TRADE (TBT)

2.1 Technical Barriers to Trade (TBT)

During the last decade, trade has rapidly become more globalised. Abolishing customs duties and lowering customs tariffs, through the continuous efforts of the World Trade Organisation, have speeded up the expansion. This development has put the focus on other obstacles to international trade. Incompatible national product requirements and/or incompatible conformity assessment procedures between countries make trade more complicated and costly. Obstacles to trade constituted by differences in mandatory technical product requirements, are known as Technical Barriers to Trade, or TBT for short.

Existing differences in technical requirements between countries can be explained by a variety of factors, such as national traditions, the existing domestic technical systems and infrastructure, climatic or environmental needs. Requirements for re-testing and re-certification of products imported into a country, often find their background in a lack of confidence in the technical competence of certification bodies, inspection bodies and testing laboratories in the exporting countries.

There are in principle, two techniques to reduce TBTs: harmonisation and mutual recognition agreements, or a combination of the two.

Harmonisation means that countries align their legislation, so that the same requirements apply in two or more countries. This is often done by reference to international or regional standards.

Through mutual recognition agreements, countries agree to accept products that meet the safety requirements of the other country. This is put into practise, even if the technical requirements are not exactly the same. It is based on the assumption that the products still meet equivalent safety

levels. Mutual recognition agreements are also concluded to establish the mutual recognition of conformity assessment results between countries.

But one cannot totally ignore the fact that sometimes technical barriers are in place in order to protect domestic industry. By applying non-standardised technical requirements, products produced in other countries must be adapted to the special requirements in the importing country and will thus be more costly. Requirements of domestic re-testing could be a way of creating a base and revenue for the domestic conformity assessment bodies. However, the drawback is that in the long run, it will mean a less competitive domestic industry and more expensive products for the consumers.

Given the importance of the problem, the international community is making efforts, both on global and regional levels, to reduce technical barriers to trade.

2.2 Word Trade Organisation TBT Agreement

On the global scene, the Word Trade Organisation (WTO), is the most important organisation dealing with TBT issues. Lebanon is currently negotiating its membership to WTO and should, therefore, prepare itself to comply with the WTO requirements.

The WTO system is composed of a large number of agreements, covering goods, services and intellectual property. As members of WTO, each country undertakes to observe the rules laid down in these agreements.

The WTO-TBT Agreement is an agreement aiming to minimise technical barriers and to facilitate international trade by laying down fundamental principles, obligations and rights for its members. The principles in the WTO TBT Agreement comprise technical legislation, standardisation, conformity assessment, accreditation, metrology, etc.

The TBT agreement makes a clear difference between technical regulations and standards. Technical regulations are defined as documents, which lay down product characteristics, or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Technical Regulations are issued as laws, or governmental or ministerial decrees and decisions and must be applied in order to protect citizens safety and health, the environment, etc. Technical Regulations should be developed in a transparent way and clearly define the obligations and rights of economic operators and individuals. Furthermore, a technical regulation must, according to the agreement, not discriminate against imported products. Also conformity assessment procedures should not create unnecessary obstacles to international trade and should be equally applied to domestic and imported products. The WTO-TBT agreement promotes that technical requirements in national technical regulations are as much as possible based on international standards.

Standards, on the other hand, are defined as documents, which provide for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. However, a standard can be made mandatory, if it is referred to as the applicable technical requirement in a technical regulation.

On the national level, standards shall be developed by a fully independent standardisation body with participation of all interested stakeholders (industry, trade, trade unions, consumers, authorities, universities, etc.) on

an equal basis. The standardisation body should apply the TBT Agreements 'Code of good practices for the preparation, adoption and application of standards', referred to in the agreement. These principles and the Code have been observed and implemented in the new Lebanese draft law on standardisation.

In order to prevent the introduction of new TBTs, members of WTO are obliged to notify all draft technical regulations. This must be done before they are issued, giving other Member States the opportunity to comment on the draft. The notifying country shall take account of received comments when issuing the final regulation.

2.3 Mutual recognition agreements

One of the main difficulties exporters face, is costly multiple testing and/or certification of products. These costs would be drastically reduced, if the conformity of a product could be assessed in the manufacturer's home country and the results would be accepted in the importing country. In mutual recognition agreements, (MRA) countries agree to accept the results of one another's conformity assessment procedures.

The WTO TBT Agreement strongly encourages WTO members to enter into negotiations with other members for the mutual acceptance of conformity assessment results. The presence of a high degree of confidence in testing and certification bodies is, in fact, a prerequisite for the good functioning of a MRA. For this reason, the TBT Agreement recognises that prior consultations may be necessary to arrive at a mutually satisfactory understanding regarding the competence of the conformity assessment bodies. It also points out that compliance by conformity assessment bodies with relevant international standards or guides can be regarded as an indication of adequate technical

competence. The TBT Agreements point out that accreditation can be a tool to verify compliance.

EU has concluded MRAs with several countries; USA, Australia, New Zealand, Japan, to mention just a few. The EU is offering a special variant of MRA to the countries with Association Agreements, the so-called 'Agreement on Conformity Assessment and Acceptance of industrial products', or ACAA.

The conclusion of a bilateral ACAA on specific sectors has the objective of facilitating the access of industrial products from the partner country to the EU Internal Market and vice versa. After the conclusion of an ACAA, the partner country can designate domestic conformity assessment bodies (notified bodies) according to EU legislation. The products covered by the agreement can be certified in the partner country and enter the EU without additional testing and conformity assessment procedures. EU products can freely enter the market of the partner country. The conclusion of an arrangement of this type presupposes the full approximation and implementation of the EU product legislation in the sectors covered by the agreements. It also assumes the establishment of supporting structures like standardisation, accreditation and metrology. Lebanon and EU have opened negotiations on an ACAA covering the sectors of electrical appliances, construction products and pressure equipment.

3 - EU HARMONISATION OF TECHNICAL REQUIREMENTS

Free movement of goods has always been one of the four cornerstones of the European Union. In order to facilitate the free flow of goods between the Member States without any obstacles, the EU has used harmonisation of technical regulations as one of its principle tools. Common

requirements are given in EU directives, which Member States are obliged to implement into their national legislation.

3.1 'Old approach'

When the EU started to harmonise product legislation between the Member States, directives were drafted in a traditional way. Today this method is often referred to as the 'old approach'.

Each directive mainly regulated one specific type of product e.g. mechanical taxi meters, or mercury fever thermometers. The technical product requirements were very detailed and needed frequent updating, due to advancing technical developments. As the updating process was slow, directives often became obsolete.

Conformity assessment requirements were not well developed. The directives did not stipulate any quality or competence requirements for the conformity assessment bodies in the Member States. It was left to each Member State to freely designate their national conformity assessment bodies.

Directives were normally optional. A Member State could still apply national deviating requirements, as long as the country did not deny market access for products compliant with the directive. A manufacturer, who follows the directive, could thereby be granted market access to all countries. The drawback was that different requirements could be applied in the Member States and the market was thus fragmented.

The system worked quite well in some sectors, like the automotive and pharmaceutical industries, but not in others. Today many old approach directives are still in effect, as for instance with all motor vehicle directives.

3.2 'New Approach' to product regulation

In the mid 1980s, the EU decided to speed up the completion of the internal market in Europe. The objective was to achieve a completely free flow of goods from 1992 onwards. To achieve this objective, it was necessary to eliminate all technical barriers to trade between the member countries. Differences between national laws, standards, and conformity assessment procedures made trade between the countries difficult, contentious and expensive. The old approach legislative technique had proven to be very inefficient. In order to speed up the process, a new legislative technique and strategy was introduced .

The New Approach was designed to harmonise only the health, safety, environmental and other public interest requirements of products in all EU Member States, into one European-wide legislative package. This new legislative method has proven to be very successful. By the end of 2007, 21 New Approach directives (listed in annex 1) have been enacted. These directives cover a major part of the industrial products traded in Europe.

Member States of the EU are required to implement the directives, by adopting new harmonised laws. The directives are mostly total harmonising, meaning that the same requirements should apply in all member countries. No country is allowed to introduce more or less stringent requirements then those prescribed in the directives. As a result, a product which is put on the market in one member country must be allowed in all other Member States. On the other hand, Member States are obliged to ensure that, products which do not comply with the harmonised requirements, are banned from their markets.

Another fundamental element of the New Approach is that authorisation

or approval by a public authority is never required or allowed, before a product is put on the market or put into service. The manufacturer is trusted, but also bears total responsibility to put on the market, only products which are compliant with the mandatory requirements.

Today, products meeting the requirements of the directives can be placed on the market in any of the 27 member countries of the EU. This also applies to countries, which have chosen to harmonise their legislation with EU, like members of the European Economic Area, EEA (Iceland, Lichtenstein, Norway) and Switzerland. As more countries outside Europe, like countries in North Africa and the Middle-East, are in the process of harmonising their product legislation with the EU, products in compliance with these directives will in the future, also have access to these markets.

3.3 Essential requirements

Regulating and harmonising laws for every product with specific, highly detailed technical requirements had proved to be an impossible task. The new, more practical approach applied in the New Approach, is to regulate quite broad families of products in each directive – e.g. all machines or all electrical appliances. The technical requirements are given in a rather general format. They are limited to requirements that are essential for the protection of health, safety, environment and other aspects of public interest. Accordingly, the essential requirements do not deal with other aspects of the product, for instance, whether a machine is suitable for its tasks. Such quality related aspects are left for assessments and decisions by the end-users or consumers.

Example of the essential requirement on lightning from the Machinery Directive (1998/37/EC)

Lighting
The manufacturer must supply integral lighting suitable for the operations concerned where its lack is likely to cause a risk despite ambient lighting of normal intensity. The manufacturer must ensure that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects, due to the lighting provided by the manufacturer. Internal parts requiring frequent inspection and adjustment and maintenance areas must be provided with appropriate lighting.

The aim of 'essential requirements' is the elimination of risks, accidents or damage to health, to the greatest possible extent. They can also focus on other aspects, like protection of the environment. Products may be placed on the market and put into service only, if they are in compliance with the applicable essential requirements.

The essential requirements define the results to be attained, but do not specify or indicate the technical solution for doing so. This flexibility allows the manufacturers to choose their own way to reach the requirements. It also allows that, for instance, materials and product design can continuously be adapted to technological progress. Consequently, directives do not require frequent adaptation to changing technology.

On the other hand, it places certain responsibilities on the manufacturers. The essential requirements must be applied as a function of the hazards inherent in a given product. The manufacturer needs to carry out a risk analysis to determine the essential requirements applicable to the product. This analysis should be documented and included in the technical documentation.

The directives do not distinguish between European manufacturers and manufacturers of other countries. All products, regardless of origin, must meet all relevant essential requirements before it can be put on the EU market.

For many products, more then one directive is applicable. A machine with an electrical installation is regulated by both the machinery directive and the directive on electrical appliances. All relevant essential requirements from both directives must accordingly be analysed and complied with.

3.4 Harmonised standards

Even though the mandatory requirements are given in essential requirements, standards do play an important role in the new approach. The standards that support European product safety legislation are called harmonised standards. They are developed by the European Standards Bodies (CEN, CENELEC and ETSI) on a mandate from the European Commission. The harmonised standards address essential requirements of New Approach directives, specifying at least one way to technically meet the essential requirements.

Harmonised standards are developed in exactly the same way as other standards; that is, in a transparent way and as consensus documents with participation of stakeholders like industry, trade, consumers, universities and public authorities on equal terms. When appropriate, the European standards are harmonised with corresponding international standards.

As soon as the standard is completed and the conditions of the European Commission's mandate are met, the Commission publishes a notice of its completion in the Official Journal of the European Union. Once that notice is published, the standard grants presumption of conformity. If a manufacturer applies a harmonised standard in the design and/or production of a product, it is presumed to be in conformity with the

essential requirements of the directive.

Harmonised standards are voluntary to follow, but grants presumption of conformity with essential requirements.

Harmonised standards are developed by the European Standards Bodies on mandates from the European Commission.

Harmonised standards, are voluntary by definition, just like general standards, which are developed according to international principles. A manufacturer can chose to apply the harmonised standard directly, or to follow another standard (e.g. international or Lebanese) to meet the essential requirements. The important difference is that, when using a harmonised standard, the manufacturer is presumed to be in conformity with the essential requirements. Therefore, most manufacturers find it rather convenient to follow the harmonised standards.

Using a standard, which is not a harmonised standard, will impose additional responsibilities on the manufacturer. The application of other standards, places the burden of proof upon the manufacturer that the product meets the essential requirements. This proof may be provided by the manufacturer's technical file, by the employment of a third party (consultant, testing house, etc.), or by a combination of the two.

3.5 Global Approach to conformity assessment

In the early nineties, the New Approach was complemented by a new European policy on conformity assessment, called 'Global Approach to Certification and Testing'.

Technical barriers to trade are to a large extent due to countries different conformity assessment systems and to a lack of confidence in each others systems. The Global Approach sets out to establish a harmonised and quality controlled conformity assessment system, which would create

confidence between Member States. It is applicable both for mandatory and voluntary conformity assessment. This was a necessary initiative, in order to establish a well functioning internal market.

To support the system, conformity assessment standards were developed in the EN 45000-series, which in the meantime, have been replaced by the ISO/IEC 17000-series. The Global Approach also gives strong incentives for manufacturers to implement quality management systems according ISO 9000. Furthermore, it has promoted the establishment of national accreditation bodies, as the guardians, for the control of quality within this system.

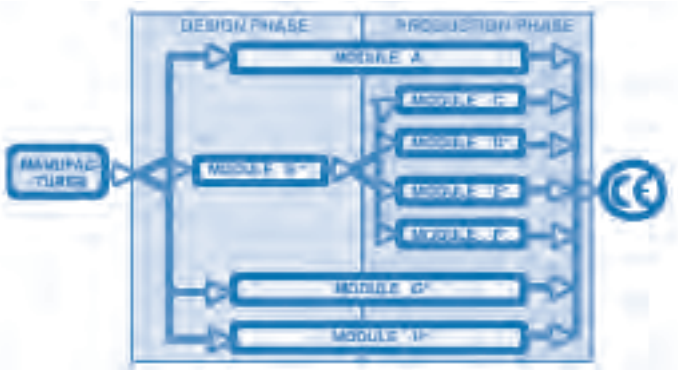
Although the Global Approach was primarily developed for support to the New Approach, it has gained a much wider application. For instance, according to EU legislation on foodstuffs, which is not part of the New Approach, laboratories testing food must be accredited to international laboratory standard for laboratories (ISO/IEC 17025). Similarly, it is prescribed in the motor vehicles directives, that tests can only be carried out by bodies fulfilling the same standard.

Most Member States of the EU are today also applying the Global Approach principles more and more to domestic, non-harmonised conformity assessment systems. For instance, mandatory recurring inspections of lifts, or verification of measuring instruments are in many countries carried out by independent bodies, accredited to the applicable standards.

The Global Approach is embodied in two decisions: the Module decision (93/465/EEC) and the regulation on CE Marking (93/68/EEC).

3.6 Conformity assessment procedures

Conformity assessment in New Approach directives refers to the processes through which compliance with essential requirements is determined. In the Module decision (93/465/EEC) of 1993, eight different and standardised conformity assessment procedures are described, which have to be used in New Approach directives (for more details see annex 2). These procedures are often referred to as the modules.



*Requires intervention of notified body

The design and production phases of a product are covered, either by one of the modules A, G or H), or by a combination of module B together with one of the modules C, D, F, or E.

Under module A 'Internal control of production' (also commonly called manufacturers self-declaration), the manufacturer is allowed to independently carry out the whole conformity assessment procedure. However, all other modules (with the exception of module C), require the involvement of a third party conformity assessment body (either a certification body, an inspection body, or a testing laboratory) - a so called notified body.

All modules have in addition a more stringent variant (so, actually there are 16 modules).

Modules D, E and H are based on the application of quality management systems. They require that the manufacturer has implemented an ISO 9000 quality management system, which is certified by a notified body. This helps the manufacturer to meet simultaneously the obligations based on directives, as well as market and customer needs. This is a distinctive advantage and benefit to manufacturers who have invested in quality management systems.

Not all modules are applicable to every directive. Each directive makes a choice and prescribes a limited range of conformity assessment procedures, which can be applied under that specific directive. These choices are based on the type of products, nature of risks involved, the economic infrastructure of the given sector, etc.

Normally, the directives offer the manufacturers the possibility to use more than one procedure to demonstrate compliance. It is for the manufacturer to decide which one he will use. For instance, a manufacturer, who has a certified ISO 9000 quality managment system could opt for module H, while for a small manufacturer, modules B + C could probably be more appropriate.

Directives can prescribe different modules for different families of products falling under the same directive, based on differences in the typical risks associated with the different types of products. For instance, the machine directive lists in an annex high risk machines, which must always be assessed by a third party, while for lower risk machines, the manufacturers declaration (module A) is sufficient. Furthermore, directives sometimes make a difference on whether or not a harmonised standard has been

followed. Manufacturers declaration (module A) can be applied for toys, which are designed and produced in accordance with a harmonised standard. Otherwise, the toy must be assessed by a notified body.

The New Approach conformity assessment procedures cover both design and production phase of the products.

Respective New Approach directives specify which of the standardised conformity assessment procedures (modules) may be applied for products, regulated by the directive.

The manufacturer chooses which procedure to apply, should the directive offer more than one option.

Manufacturers, who have implemented a quality management system according to ISO 9000, certified by a notified body, have an obvious benefit in using this system.

3.7 Technical documentation and EC declaration of conformity

Before a product is put on the market, the manufacturer is obliged to compile a technical file. The documentation in this file shall be sufficient to demonstrate that the product complies with requirements of the directive(s). The specific contents of the technical documentation are laid down in the respective directives. As a rule, the documentation should cover the design, the manufacturing process and the operation of the product.

Before a product is put on the market, the manufacturer is also obliged to draw up an EC declaration of conformity. With this document the manufacturer declares that the product satisfies the requirements of the applicable directive(s).

Minimum content of EC declaration of conformity

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

The technical file and the EC declaration of conformity shall be kept by the manufacturer normally for 10 years. It shall be provided to relevant authorities on request. Some directives (e.g. machinary, recreational crafts, lifts) require that each product is accompanied by the EC declaration of conformity.

3.8 CE marking

Before any product, which is regulated by a New Approach directive, is put on the market or put into service, the manufacturer must affix the CE marking to the product. This applies equally, whether the manufacturer is located in EU, or in a third country. By affixing the CE marking, the manufacturer declares that the product conforms to all applicable New Approach requirements and that it has successfully undergone the prescribed conformity assessment procedures. If the product is subject to several New Approach directives, the manufacturer indicates by the

marking, that the product conforms to all these directives.

The CE marking, with a minimum height of 5 mm, must be affixed visibly, legibly and indelibly to the product. Under specifically described circumstances, the marking may instead be affixed to the package, or, if provided for in the directive, to accompanying documents.

If a notified body has been involved in the production control phase (modules D to H) according to the applicable directives, its identification number must be on the CE marking.

The CE marking should be in the following form:

3.9 Notified Bodies

Most products within the scope of the New Approach directives can be self-certified by the manufacturer (module A). There are products however, which require the intervention of a third party for conformity assessment. This is the case when the directive prescribe EC type-examination by a third party (module B) and/or where the product, production, or quality management system must be verified by a third party (modules D, E, F, G and H). Conformity assessment bodies carrying out such tasks under the New Approach directives, are called Notified Bodies.

Notified bodies are independent test laboratories, certification bodies, or inspection bodies selected and appointed by an EU Member State to

perform the conformity assessment tasks specified in directives. Also countries outside the EU, which have concluded mutual recognition agreements with EU, for instance ACAAs, may designate such bodies.

Notified Bodies are assessed and selected by the government of a Member State. There is no limitation to the number of bodies that can be notified, as long as they meet the requirements. On the other hand, there is no obligation for Member States to designate notified bodies. They can be either private, or public legal entities, but they must be under the jurisdiction of the notifying state.

The bodies must have the necessary qualifications to meet the testing and/or certification requirements set forth in a specific directive. A notified body must not only be technically competent and capable of carrying out the specified conformity assessment procedures, but it must also have a thorough knowledge of the relevant directives and legislation. In addition, it should be able to demonstrate its independence, impartiality and its integrity. This implies, inter alia, that the notified body must not have given consultancy to the manufacturer, or given advice on the design of products, that they are assessing for conformity.

The directives list minimum criteria that notified bodies must meet. However in actual practice, the ISO/IEC 17000 series of standards has become the normative documents that are used by most Member States to assess notified bodies. Furthermore, most Member States today rely on their national accreditation bodies for the assessment of technical competence, independence and impartiality. If a body has been accredited to the relevant standard, it is presumed to fulfil the notified body's criteria.

ISO 17000 series standards relevant for assessment 0f notified bodies			
	Certification bodies	Testing laboratories	Inspection bodies
Criteria for accreditation bodies	ISO/IEC 17011	ISO/IEC 17011	ISO/IEC 17011
Operational criteria	ISO/IEC Guide 65 ISO/IEC 1702 ISO/IEC 17024	ISO 17025	ISO 17020

Notified bodies must be regularly surveyed by the notifying Member State, to ensure that the bodies continuously fulfil the notification criteria. In practice, surveillance and re-assessment methods developed within the accreditation system are normally followed. If a body fails to meet the requirements, the notification must immediately be withdrawn.

A body can be notified for all or several of the modules provided for in the directive. At least, it must always be capable to perform all the procedures within a whole module; that is to say, a module may not be divided into subparts. The designation shall also specify the types of products falling under the directive, for which the body is notified. The product scope of most directives is so wide, that it is not feasible for one body to have the technical competence to assess conformity for all types of products regulated by the directive.

Notified bodies are nowadays notified electronically to the European Commission. A unique identification number is assigned to each notified body. A comprehensive database, NANDO, lists all notified bodies highlighting which directives, modules and products are covered. The NANDO database is accessible via Internet as follows: (http://ec.europa.eu/enterprise/newapproach/nando/).

In order to harmonise the notified bodies assessment activities,

co-ordination groups for the respective New Approach directive are established. The bodies are obliged to participate in the groups work, as well as in European standardisation work.

Notified bodies, often being private companies, are competing and set their own fees. The bodies are free to offer their conformity assessment services to any economic operator established inside or outside the EU. To satisfy customer needs, well established notified bodies offer services under several directives and also services for voluntary conformity assessment schemes, e.g. environmental certifications. The manufacturer can address one body, which will cover all his conformity assessment needs, which saves time and money. Notified bodies may also have activities and personnel in the territories of other member countries or in third countries. However, certificates shall always be issued by and in the name of the notified body.

Likewise, a manufacturer who needs conformity assessment services for a product under New Approach directives, can turn to any notified body in any member country. The conformity assessment results must be accepted by all Member States. The same applies for manufacturers outside EU.

Schematic of New Approach concept

3.10 Market surveillance

Member States are obliged to enforce New Approach directives. As pre-marketing approvals of products and border controls between Member States are not allowed, the enforcement activities must be directed towards products that have been placed on the market, or put into service. This implies an obligation for Member States to organise and carry our market surveillance. The surveillance must be effective and sufficiently extensive to discover non-compliant products. This is to protect the health and safety of consumers, workers and other users, but also in the interests of economic operators and to eliminate unfair competition.

Governments must nominate authorities that are responsible for market surveillance activities. These authorities must be given the necessary resources and powers for their surveillance activities. The staff shall have the relevant technical competence and professional integrity.

Market surveillance involves two main stages; monitoring the compliance of products placed on the market and subsequently, if necessary, taking corrective actions.

Monitoring should be carried out in different ways:

- visits to commercial, industrial and storage premises
- inspection of work places where products are put into service
- taking samples of products and subjecting them to examination and testing
- control of documentation

Corrective actions should be proportionate to the level of non-compliance. As a starting point, the manufacturer shall be given the option to make the product compliant. If such measures fail, or are considered insufficient, the responsible authorities should have the powers to restrict or prohibit the placing on the market of the product. As a last remedy, the

authority shall have the power to order the product to be withdrawn from the market, or even recalled from consumers or end users.

To make the market surveillance on the internal market more efficient, close administrative co-operation between market surveillance authorities in member countries, is promoted and supported.

3.11 Review of New Approach

Even though, the New Approach is regarded as successful and an advanced manner to harmonise product legislation, there are some problems and details that need be refined. Therefore, in 2003, a review of the New Approach concept was initiated. In February 2007, the European Commission presented proposals for two legal acts, proposing important amendments and in some respect more stringent requirements. These proposals are presently being discussed among the Member States in the European Council and in the European Parliament. A final decision is not expected before late 2008. Nevertheless, the final outcome is rather predictable with regard to the major principles.

Among the problems addressed in the review, is a lack harmonisation in the way notified bodies are assessed by designating Member States. Most states relay on accreditation for the technical assessment of notified bodies, but not all do so. The result is a lack of confidence in conformity assessment results from some notified bodies. The solution proposed is to further strengthen the role of accreditation.

According to present EU legislation, it is not mandatory for Member States to establish accreditation bodies. The new proposal is now that all countries will be obliged to have one nationally recognised accreditation body. Only the very smallest countries may get an exemption and instead rely on neighbouring countries for accreditation. Minimum criteria, based on applicable international standards for accreditation bodies, must be

observed for the national accreditation bodies. Technical assessment and surveillance of notified bodies should be carried out, in all countries by the national accreditation body.

European accreditation bodies have for many years co-operated on a voluntary basis within the organisation 'European Co-operation for Accreditation' (EA). It is now proposed that EA will be formally recognised by the EU in the same manner as the European standards organisations. EA will also be given a role, when it comes to the development of new conformity assessment schemes, called for, by EU legislation. The national accreditation bodies will be obliged to be members of EA and to participate actively in co-operation. The peer-assessment scheme run by EA, is expected to have an important role for harmonisation of the assessment and surveillance of notified bodies.

Today's minimum requirements for notified bodies are very basic and general. More stringent and well-defined requirements, based on international standards for conformity assessment bodies, will be introduced in New Approach directives.

Another important initiative within the framework of the review concerns market surveillance. Experiences have shown that in some product sectors (e.g. toys), a large number of non-compliant products, often imported, circulate within the internal market. Existing New Approach directives are rather vague and not harmonised with regard to the obligations of Member States, to practice active and efficient market surveillance. Extended and better defined obligations in this respect are proposed. Member State authorities will also be obliged to actively co-operate over the borders.
Further proposals concern better defined responsibilities for distributors, retailers and importers, as well as improved traceability of products through the distribution chain.

3.12 Related websites

European Commission guide to the implementation of directives based on the New Approach and the Global Approach published in 1999
http://ec.europa.eu/enterprise/newapproach/legislation/guide/index.htm

European Commission Enterprise web site on New Approach
http://ec.europa.eu/enterprise/newapproach/index_en.htm

NANDO database of Notified Bodies
http://ec.europa.eu/enterprise/newapproach/nando/

European Commission lists of harmonised standards for respective directives
http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist.html

Eur-Lex, Internet accession to all EU legislation in full text
http://eur-lex.europa.eu/

European Commission information on review of New Approach
http://ec.europa.eu/enterprise/newapproach/review_en.htm

New Approach standards with searchable list of harmonised standards for type of product
www.newapproach.org/

Official Journal of the European Union
http://europa.eu.int/eur-lex/lex/JOIndex.do?ihmlang=en

WTO TBT Agreement
www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

Annex 1: New Approach Directives with CE marking

Subject of directive	Directive reference
Appliances burning gaseous fuels	90/396/EEC
Cableway installations designed to carry persons	00/9/EC
Construction products	89/106/EEC
Electromagnetic compatibility	04/108/EC
Equipment and protective systems in potentially explosive atmospheres	94/9/EC
Explosives for civil uses	93/15/EEC
Lifts	95/16/EC
Low voltage equipment	2006/95/EC
Machinery safety	98/37/EC
Measuring instruments	04/22/EEC
Medical devices: Active implantable	90/385/EEC
Medical devices: General	93/42/EEC
Medical devices: In vitro diagnostic	98/79/EC
New hot-water boilers fired with liquid or gaseous fluids (efficiency requirements)	92/42/EEC
Non-automatic weighing instruments	90/384/EEC
Personal protective equipment	89/686/EEC
Pressure equipment	97/23/EC
Radio and telecommunications terminal equipment	99/5/EC
Recreational craft	94/25/EC
Simple pressure vessels	87/404/EEC
Toys safety	88/378/EEC

Directives based on New Approach but without CE marking

Subject of directive	Directive reference
Conventional rail system	2001/16/EC
High-speed rail system	96/48/EC
Marine equipment	96/98/EC
Packaging and packaging waste	94/62/EC

Annex 2: Basic conformity assessment modules

Subject of directive	Directive reference
A Internal control of production	Covers internal design and production control. This module does not require a notified body to take action.
B EC type -examination	Covers the design phase, and must be followed up by a module providing for assessment in the production phase. The EC type-examination certificate is issued by a notified body.
C Conformity to type	Covers the production phase and follows module B. Provides for conformity with the type as described in the EC type-examination certificate issued according to module B. This module does not require a notified body to take action.
D Production quality assurance	Covers the production phase and follows module B. Derives from quality assurance standard EN ISO 9000, with the intervention of a notified body responsible for approving and controlling the quality system for production, final product inspection and testing set up by the manufacturer.
E Product quality assurance	Covers the production phase and follows module B. Derives from quality assurance standard EN ISO 9000, with the intervention of a notified body responsible for approving and controlling the quality system for final product inspection and testing set up by the manufacturer.
F Product verification	Covers the production phase and follows module B. A notified body controls conformity to the type as described in the EC type-examination certificate issued according to module B, and issues a certificate of conformity.
G Unit verification	Covers the design and production phases. Each individual product is examined by a notified body, which issues a certificate of conformity.
H Full quality assurance	Covers the design and production phases. Derives from quality assurance standard EN ISO 9000, 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.