FREE MOVEMENT AND SAFETY OF INDUSTRIAL PRODUCTS

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1. Introduction

In any modem society there are many products that can cause death or injury if they are poorly designed or manufactured. For example, a machine, toy, hot water boiler etc. has to be designed and manufactured in such a way that it will not cause harm or endanger its users. For these reasons governments develop legislation in an endeavour to protect their citizens from the risks of unsafe products. These technical rules can differ between countries often due to their unique history of regulatory and industrial practice. also in some cases it is suggested that such differences are motivated by a desire to protect local industry. Whether by accident or design. the technical differences often provide very effective barriers to trade (known as technical barriers to trade - TBT). TBTs arise mainly due to differences in national :

- technical regulations and standards

- conformity assessment procedures (testing. certification) before a product is placed on the market and inspection of products in use.

TBTs can arise any time during a products life cycle, from design and conception to manufacturing and final disposal or recycling. In order to ensure the free circulation of goods it is necessary to harmonise both the requirements related to the product and to the approval procedure. The effect of TBTs can be said to be:

- increased production costs and time to market in order to meet various national requirements;
- increased conformity assessment costs owing to multiple testing and certification requirements.

The free movement of goods is. at one and the same time. one of the principles and one of the aims of the EU Single Market. Since the EU is a legal entity the free circulation of goods is ensured primarily by legislative measures at Community level. This is done for example by applying the principle of mutual recognition as laid down in the jurisprudence of the Court of Justice, the harmonisation of the laws of the Member States by means of directives and other measures to increase transparency. However, it is also essential to create a technical environment which gives the necessary level of confidence for the free placing on the market and the free circulation of products. This involves reinforcing the quality infrastructure in terms of standardisation, metrology, testing and certification, accreditation and quality management of the EU.

The Internal Market is thus composed of many (legal) components of which CE-marking is one of the most visible. Like people need a passport to cross borders, CE-marking can be said to be a “passport” for products. The New Approach and Global Approach Resolutions, adopted in the context of the Internal Market programme, have made a considerable contribution to the creation of the conditions for a redistribution of responsibilities for health and safety (etc.) protection between the public authorities and the economic operators by basing conformity to Community requirements on quality instruments (quality assurance, product certification, etc.).

It is clear that conformity to Community regulatory requirements through quality instruments is a necessary condition for marketing products in the Union. but is not necessarily sufficient to ensure the proper level of competitiveness of European industry. Overall quality strategies geared to competing with the best in the market place will ensure competitiveness as well as conformity to regulations.

2. The Legislative Framework

2.1. Basic Principles

The Treaty of Rome laid down the basic principles for the free movement of goods (elimination of customs duties and quantitative restrictions. competition rules, state monopolies, state aid etc.). Articles 30 and 36 and the meaning these articles have been given by the Court of Justice. has laid down the ground rule of the free circulation of goods. Exception from this rule is only allowed for reasons related to the protection of essential public interests.

Since the beginning of the 1980s the Community has, in the field of technical barriers to trade, passed through a silent revolution in terms of the mechanisms for ensuring that only safe products can be placed on the market. wherever they come from. i.e. both inside and outside the EU. The ”Cassis de Dijon” case in 1981 and a large number of other cases related to articles 30 and 36 in the European Court of Justice gave the Community the key elements which were later to form the basis for the new Community legislation. fixing the following principles:

- products manufactured in a Member State should benefit from free circulation throughout the Community;
- .it is up to the Member States to demonstrate that a product does not fulfil an essential health and safety requirement and no longer the responsibility of the manufacturer to demonstrate that it does;
- Member States can intervene only when a product does not respect an essential requirement. that means that in all other cases Member States must accept the products on their market.

2.2. Transparency

The adoption by the Council of Directive 83/189/EEC, which laid down a procedure for the provision of information in the field of standards and technical regulations, aimed at assuring the transparency of national activities and on reinforcing the commitment in standardization. This directive obliges a Member State to notify their draft technical regulations to the Commission and the other Member States and prevents its adoption during a so called standstill period as well as allowing the Commission and the Member States to comment on the draft. Thus the directive both provides transparency on national technical regulations and a tool for preventing technical barriers to trade.

Directive 83/189/EEC also gives the Commission, after consultation with the Member States, the possibility of giving mandates to the European standards organisations, to prepare standards in support of Community policy in different areas.

Another measure to increase transparency is a Decision of the Council and the Parliament obliging a Member States to inform the Commission and the other Member States of measure taken against products (withdrawal from market. modification etc.) under national legislation not harmonised at Community level.

2.3. Harmonisation

Until the mid 1980s harmonisation of the laws of the Member States had taken place according to the so called Old Approach directives. These directives were often narrow in scope. contained detailed mandatory standards or technical requirements. type approval by national authorities, optional in application and were often subject to amendments due to technical progress. .This led to the need of adopting a new legislative "technique".

The Council of the European Communities approved in May 1985 a resolution on the New Approach to technical harmonisation and standardisation. which combined both the harmonisation of regulations and national standards and the mutual recognition of the results of tests and certification via the adoption of a new strategy based on the following four principles:

- the harmonisation Directives determine the *essential requirements* relating to health and safety to be met by products that are to be placed on the market and circulate freely within the Community;
- the technical specifications governing the production and marketing of products meeting the essential requirements set out in the Directives will be laid down by the European Standardisation Bodies (CEN.CENELEC, ETSI) in so called Harmonised Standards (EN, ETS;
- application of the Harmonised Standards remains voluntary;
- the manufacture of products in line with the harmonised European Standards leads to a "presumption of conformity" with the said essential requirements, and normally leads to less burdensome conformity assessment processes.

The groundwork for the New Approach formed only one part of the policy devised in order to achieve the Internal Market. The existence of standards specifying essential requirements was seen as a necessary prerequisite although it was not sufficient. It was essential to provide conditions whereby conformity assessment could be carried out in accordance with transparent, reliable procedures which guaranteed the quality of the results obtained.

In its Resolution of 21 December 1989 on the Global Approach to Certification and Testing[2] the Council stated its aim of providing within the Internal Market, a homogeneous, transparent and credible technical environment within which public authorities, economic operators and users would be able to have confidence and which would ultimately lead to the existence on the market of higher quality products.

This confidence had to be based on technical competence on the part of manufacturers, test laboratories. the bodies responsible for quality audits, certification and inspection bodies. and on transparency in the conformity assessment procedures whether subject to regulations or voluntary (thus covering all of the Internal Market).
The resolution on the Global Approach fixes the guiding principles for Community policy as regards conformity assessment:

- use of the "modules" concerning the different stages of the conformity assessment procedures (modular approach) and of the criteria for the designation and notification of bodies under those procedures;
- generalised use of the European standards relating to quality assurance and to the requirements to be fulfilled by conformity assessment bodies (EN 45000), and the setting up of accreditation systems;
- promotion of mutual recognition agreements concerning testing and certification in the non-regulatory sphere, under the aegis of the European Organisation for Testing and Certification (EOTC);
- reinforcement of the development of existing quality infrastructures within the Community to minimise their differences;
- promotion of external Community relations with third countries by means of:
- mutual recognition agreements;
- co-operation and technical assistance programmers.

Aware as it is of the importance of quality standards in order to put into practice the Community policy stated under the **Global Approach**. the Council boosted the role of those quality standards in its Decision of 13 December 1990 (amended and brought up to date by the Council on 22 July 1993[4]), which approved the **"modules"** framework deadline with the **"conformity assessment procedures".**

Those procedures use basic conformity assessment structures. either by a first party (manufacturers) or by a third party (certification bodies, inspection bodies, testing laboratories), which relate to the "design phase" and "production phase" of products.

The "modules" give the legislator, in relation to the type of products and risks involved, the means for setting up the appropriate procedures for manufacturers to demonstrate their product's conformity to the essential requirements.
In parallel this Decision introduced the harmonised criteria for affixing and using the **CE Marking.**

CE-marking is the visible sign of conformity with the applicable Directives that harmonise the essential requirements. It shows that a product that bears the marking conforms to the requirements of the applicable Directives and hence has to be accepted on all Member States markets. At this moment there are 17 New Approach Directives that harmonise products or common features of products, like toys, gas appliances, construction materials or electromagnetic compatibility. and low voltage components

What is fundamental in this new approach is not the new legislative technique in itself. but rather the recognition that professionals in the market place can be called upon to contribute to the completion of the Single Market and that it is not only the national authorities who can ensure that safety requirements are met. The new approach is above all a redistribution of the responsibilities between the public authorities and the private sector.
To date. seventeen "New Approach" Directives (considering the Directive 73/23/EEC as part of them) have already been approved on this basis. and these cover the following areas:

- Simple pressure vessels (87/404/EEC) amended by (93/68/EEC)
- Toys (88/378/EEC) amended by (93/68/EEC)
- Construction products (89/106/EEC);
- Electromagnetic compatibility (89/336/EEC) amended by (92/31/EEC) and by (93/68/EEC);
- Machinery (98/37/EC);
- Personal protective equipment (89/686/EEC) amended by (93/68/EEC),and by (93/95/EEC), and by (96/95/EEC);
- Non-automatic weighing instruments (90/384/EEC) amended by (93/68/EC)
- Active implantable medical devices (90/385/EEC) amended by (93/68/EEC) and by amended by (93/42/EEC);
- Appliances burning gaseous fuels (90/396/EEC) amended by (93/68/EEC);
- Hot water boilers fired with liquid or gaseous fuels (92/42/EEC) amended by (93/68/EEC);
- Electrical equipment designed for use within certain voltage limit (73/23/EEC) amended by (93/68/EEC);
- Explosives for civil uses (93/15/EEC);
- Medical devices (93/42/EEC) amended by (98/79/EC) and by 2000/70/EC
- Equipment and protective systems intended for use in potentially explosive atmospheres (94/9/EC);
- Recreational craft (94/25/EC);
- Lifts (95/16/EC).

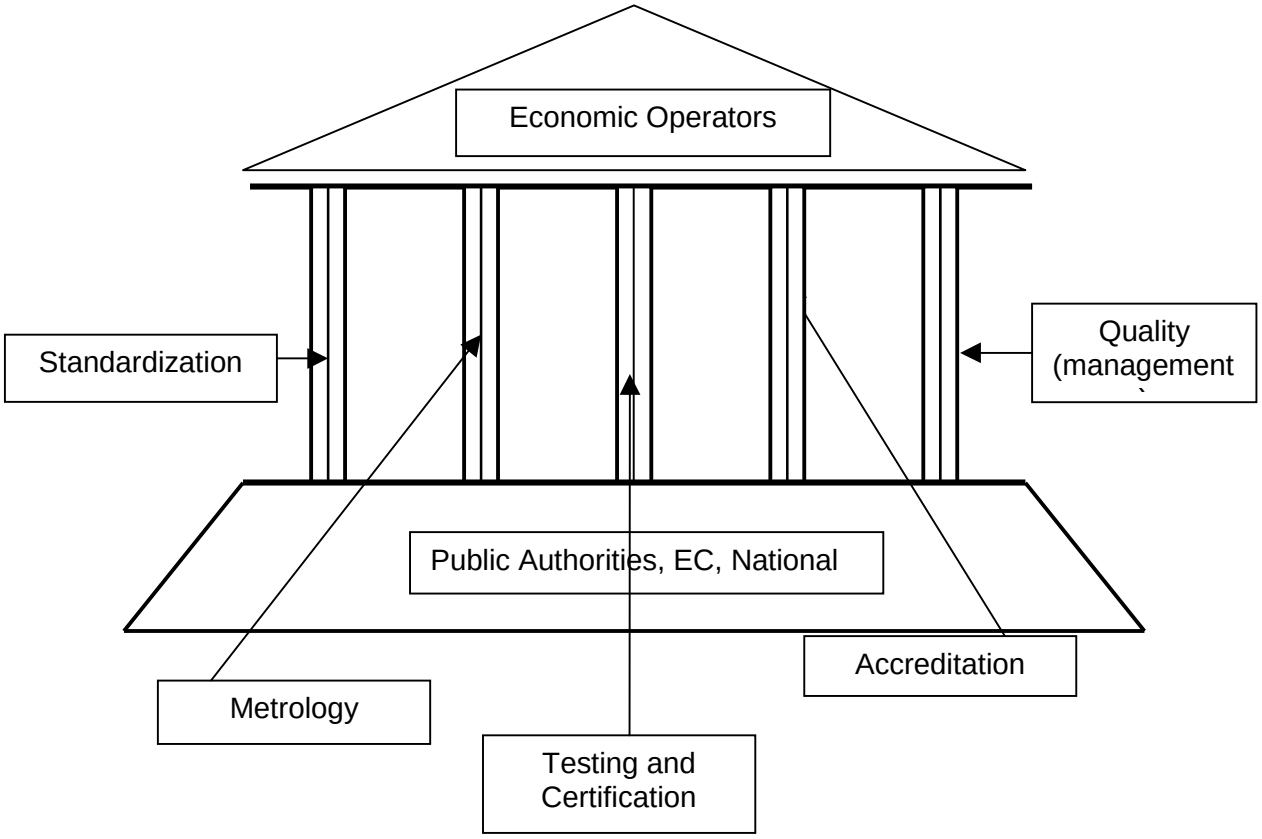
3. The European Quality House

In order to stress its potential, the Single Market needs a homogeneous, transparent and credible technical environment within which public authorities, economic operators and users/consumers will have confidence.

This confidence must be based on technical competence on the part of the components of what we can call the “European Quality House”. The European Quality House is composed of the different public and private, structures both at European and National level which are necessary to demonstrate conformity, both in order to assure free circulation and to increase and strengthen the competitiveness of the European economy.

It is composed of the institutional pillars: Standardization, Testing & Certification. Metrology and Accreditation and the managerial pillar of Quality Management.

In the same way that in the Standardization field we never pretended to develop standardization infrastructures for regulated purposes preferring all the standardization needs to be met by the existing standardization bodies. As tar as the other pillars are concerned. there was never an intention to only develop infrastructures for regulated purposes: we sought to rely as much as possible on the quality infrastructures that the market and the economic operators had already provided.



3.1. The Standardisation Pillar

Standards are technical specifications which ensure compatibility between products and services, appropriate levels for their safety, quality or efficiency and test methods needed to establish conformity to these specifications. Standards are therefore an instrument for economic and industrial integration and as a technical basis for the support of legislation.

Standardisation can operate at international, regional and national level. Recognised standards organisations at world level are IEC (International Electrotechnical Commission), competent in the field of electrotechnology, ITU (International Telecommunications Union) in the field of telecommunications and radiocommunications and ISO (International Organisation for Standardisation) is competent in all other fields.

At European level, three standards organisations have been created, which are CENELEC (European Committee for Electrotechnology Standardisation) in the area of electrotechnology. ETSI (European Telecommunications Standards Institute) competent for telecommunications and CEN (European Committee for Standardisation) in all other areas. The members of CEN and CENELEC, as well as of ISO and IEC. are the corresponding national standardisation bodies in the EU and EFT A countries. Most of-central and eastern European countries are affiliate Members of CEN and CENELEC and recently the Czech national standards body became a full member of CEN. In contrast the CEN and CENELEC, the members of ESTI are not national delegations but may be parties, public or private, which are involved in ~ telecommunications.

The New Approach, introduced essentially as a new way to prepare harmonised legislation to reduce the proliferation of excessively technical directives per individual products, asked for the participation of economic operators in the legislative process.

Such an approach has constituted a major political breakthrough in this field in many ways. Firstly, it has meant putting into the European Union legislation only the fundamental safety and health questions (the essential requirements), leaving the detailed (technical) specifications to the standardisation process, involving all interested parties, . Secondly, it meant setting the framework and conditions under which the European standards bodies CEN, CENELEC and ETSI can develop harmonised standards in support of the New Approach directives, as well as standards in support of Community policy in other fields, for example public procurement.

Directive 83/189/EEC sets much of this framework and the main instrument used is so called mandates. A mandate is a formal invitation by the Commission, after consultation with the Member States. to European standards bodies to elaborate European standards for a given purpose. The mandates sets the objectives. explains the Community's needs for standards and indicates the legal or political framework that standardises have to take into account.

The European standardisation process works along the following principles:

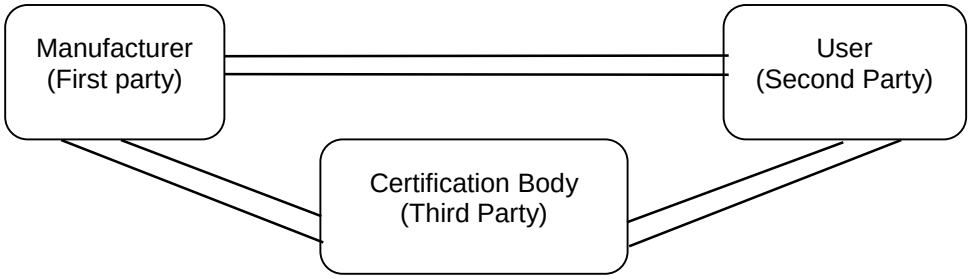
- **Openness and transparency**: all interested concerns take part in the work;
- **Consensus**: standards are developed on the basis of voluntary agreement between the interested parties;
- **National commitment**: formal adoption of European standards are decided by majority vote of all national members and is binding on all of them;
- **Technical coherence at the European and national level**: standards form a collection. which ensures its own continuity for the benefit of users. both at European and national level through compulsory national implementation of European standards and withdrawal of conflicting national standards.

3.2. The Testing, Certification and Inspection Pillar

The existence of standards specifying the essential requirements is necessary but not sufficient. It is necessary to build up a transparent framework to carry out the conformity assessment of products to EC Directives.

In order to create the conditions that are conducive for confidence in this technical environment (composed of product specifications (expressed in the European standards) and structures for the conformity assessment (testing and calibration laboratories, certification, inspection and accreditation bodies,)], the **Global Approach** is aimed at making these structures as homogeneous, transparent and credible as possible throughout the Community. This is in order to consolidate the certification pillar.

Certification is the procedure by which a third party gives written assurance that a product, process or service conforms to specific requirements. Testing involves the determination of one or more characteristics of a given product, process or service to specified procedure. Inspection means conformity evaluation by observation and judgement. In this context it is important to make a distinction between first, second and third party. The figure below attempts to do this.



In 1989 it was possible to put together a “conformity assessment menu” from which the Council could choose the appropriate procedures according e to the dangers or risks linked to the products in different industrial sectors. They did not have to impose only one procedure because, in the presence of a coherent policy, it was possible to identify the elements which permitted equivalence of the different results of the certification procedures even though these procedures remained technically different.

Under the modular approach to certification adopted on 13 December 1990, superseded by the Decision 93/465/EEC, approved on 22 July 1993, the Council set out a number of basic principles on how these procedures should be used in the Community. This introduced the certification of quality systems as set out in the EN-ISO 9000 series of European standards as a means of contributing to the demonstration of conformity of products for which the directives set out the levels of safety.

Among the eight conformity assessment modules, the Council decided to include the three modules related to quality assurance, as contained in the EN-IS09001, 9002 and 9003 standards, four modules related to product testing, certification and/or inspection and one module devoted to the manufacturers declaration of conformity.

Indeed, that Decision points out that the setting up of quality systems by manufacturers in compliance with EN 150 9000 European standards. confers a presumption of conformity with the requirements of the Directives in respect of quality systems and that compliance with the EN 45000 series of European standards confers a presumption of conformity with the requirements of the Directives related to the notified bodies (for conformity assessment purposes).

The Decision referred to above sets out, amongst other basic guidelines to be used in the technical harmonisation (New Approach) Directives, the following principles:

- as a general rule a product should be subject to assessment in both phases (design and production) before being placed on the market;

- the Directives should set a range of possible choices among the different modules which cover the two phases in order to guarantee a high level of safety, for a given product or product sector. In setting the range of possible choices, the Directives will take into consideration the appropriateness of procedures in relation to the to type of products, risks involved, etc.

- whenever Directives provide the manufacturer with the possibility of using modules based on quality assurance techniques. the manufacturer should also be able to have recourse to a combination of modules not using quality assurance, and vice versa.

By accepting the notion of the equivalence of levels of protection at the end of all procedures, the Council leaves a far wider choice to the manufacturers, which means greater flexibility and allows them to take decisions based on economic parameters rather than on arbitrary obligations stemming from the application of the law. W e may say, in general terms, that four main “conformity assessment routes" may be set up by the following combinations of possible procedures :

- manufacturer's declaration (module A);

- product certification inspection (modules B+C. B+F module G).

- product certification in addition to quality assurance certification (modules B+D, B+E);

- Full quality assurance certification, that can include product design audit (module H);

Nevertheless it is important to stress that the conformity assessment mechanisms introduced under this legal framework are based on. a two step, balanced approach. A first before the product is put on the market which includes the criteria for affixing the CE Marking, the second after marketing based on the market surveillance mechanisms. The first phase is the more stringent as there is a lesser need at the second phase.

3.2.1. Notified Bodies

Under the conditions set out in the Global Approach it has become possible to move away from the system in which reports, certificates and approvals can only be granted by public authorities because they are the only institutions to be credible. In the field of testing and certification it has been possible to convince these authorities to increase their trust in the private operators on the condition that their competence can be demonstrated by the corresponding European standards.

The conformity assessment procedures set out in the directives are carried out by Notified Bodies. Notified Bodies can be public or private bodies but must always be third parties. It is Member States that designates Notified Bodies situated on it's territory. Member States can only designate those bodies that are technically competent and must ensure that they continuously maintain their competence. For the assessment of the technical competence, the Council has stated that compliance to the EN 45000 series of standards gives a presumption of conformity to the requirements of the directives on the basis of accreditation or other documentary evidence. Accreditation and the use of the EN 45000 standards is not mandatory but have been given a privileged status by the Council.

Notification is the act by means of which a public authority in a Member State notifies the Commission and other Member States that a body is responsible for assessing conformity under a New Approach directive.

Notification may be divided into two acts:

- the act of assessing the technical competence, thus enabling technical capability. objectivity. independence and transparency.

- the act of identifying the body deriving from the political responsibility of the national authorities:

Notified can subcontract certain specific technical tasks to other bodies that have also a proven competence. However. a notified body cannot under any circumstances subcontract all of its activities, as that would make the notification meaningless. It cannot subcontract assessment and appraisal activities. which are the essential tasks for which it was notified.

3.2.2. European Organisation for Testing and Certification (EOTC)

A key structure of the Certification Pillar is EOTC. EOTC was created to develop the framework for the non-regulatory sphere with regard to conformity assessment issues. whilst operating in such a manner as to give technical support to legislation of the European Union and EFT A Countries regarding conformity assessment in the regulatory sphere.

The creation of EOTC has led to the setting up of national structures to assure representation at European level (currently there are 18 National Members). The constitution of Agreement Groups (to date there are 11) and of four Sectoral Committees was also another important result.

3.3. The Metrology Pillar

Metrology is the science of measurement. Measurements have a great impact on the everyday life of citizens an plays an important role in fields such as research and development, manufacturing, agriculture. medicine and trade. Sound, accurate and reliable measurements, be they physical, chemical or biological in nature. are therefore essential to the functioning of modern society.

Ensuring the reliability in measurements can be done by traceability and calibration. Traceability is the characteristic/quality with a measurement which permits the result to be related to appropriate norms. national or international, by an unbroken chain of comparison. Calibration of a measuring instrument means ascertaining of its mistake in comparison with a reference which is traceable by an unbroken chain of comparison to an international norm.

The EN IS0 9000 standards require that inspection. measuring and test equipment used by the supplier to demonstrate the conformance of a product to specified requirements, to be controlled. calibrated and maintained.

Calibration laboratories play, an important part to industry. trade and society , as a whole in ensuring traceable calibrations. The demonstration of their competence by accreditation according to the EN 45001 standard is therefore encouraged.

The national institutions responsible for metrology in the EU and EFT A countries have organised themselves in an organisation called EUROMET in order to co-operate with the aim reinforcing confidence and mutual recognition of calibration results. At the international level this co-operation takes place within the framework of BIPM (Bureau International de Poids et de Measures).

A specific field of metrology is the one related to legal metrology. The legal application of metrology corresponds to the implementation of regulations for measuring instruments used by and for the public. Even here co-operation take place at European level, through WELMEC (Western European Legal Metrology Co-operation) and international level within OIML (International Organization of Legal Metrology).

The Community supports research in the field of metrology within the Standards, Measurement and Testing Programme (SMT) under the Fourth Framework Programme. The objectives of the SMT are to provide research and technical support for the continued institution of harmonised systems of measurements, reference materials and written standards, essential to ensure the efficient operation of the Single Market and other Community policies and the competitiveness of European industry.

3.4. The Accreditation Pillar

Accreditation is a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Or in other words, accreditation entails laboratories, certification and inspection bodies being assessed and audited at regular intervals by a third party as to their technical competence against published technical criteria.

As a third party assessment technique accreditation is an important instrument for the generation and maintenance of confidence in conformity assessment bodies and is therefore fundamental to the proper operation of a transparent, credible and quality driven conformity assessment market in Europe. It is imperative for industry to have an independent validation service for certification in order to be fully competitive. It is fundamental to the public authorities, whether national or European, in order to assure confidence and credibility in the certificates issued anywhere in Europe and thus to facilitate the free circulation of goods. It is also fundamental for the conformity assessment bodies themselves, in order to demonstrate their technical competence and to assure credibility and transparency in their procedures.

Accreditation is an instrument which can bring confidence in conformity assessment activities. In order to do so, it must be credible and transparent. The national authorities have a responsibility to take appropriate measures to ensure that the national accreditation system is independent, non-commercial, organised efficiently and takes part in European and international co-operation.

At European level, a unified accreditation organisation will facilitate the identification of a common European accreditation system facilitating co-operation and mutual recognition at European level and in relation to third countries. At the European level EAL (European Co-operation for Laboratory Accreditation) and EAC (European Accreditation of Certification) which organise the co-operation between the national accreditation bodies of the EU and EFT A countries are merging into one organisation. EAL and EAC are running mutual recognition agreements based on peer evaluation which can contribute to one stop testing and certification.

Accreditation is not mandatory for bodies seeking notification but, it should be considered by national authorities as the most favoured technical basis for the assessment of bodies seeking notification in order to reduce differences in the criteria applied.

A clear distinction must be made between accreditation and certification. Accreditation bodies should not engage in other conformity assessment activities so as to not compromise their independence and integrity.

A unified, coherent and transparent European accreditation structure can contribute to the objectives of the Community’s external trade policy in the field of standards and conformity assessment. This will of course be facilitated by ensuring coherence between the European and international levels in terms of standards. guidance and terms for mutual recognition.

3.5. The Quality Pillar

The European Quality Promotion Policy is at the same time a pillar and a link of the European Quality , House Pillar. It is aimed at creating a homogenous European Framework to assure the complementarily. cohesion and increased synergies between the different European, national and local policies and initiatives in the Quality area. Involving public and private operators. taking account of the principle of subsidiary, in order to promote and increase competitiveness of European economic operators.

In formulating this innovative quality , promotion policy. integrated into the new dynamic and wide ranging approach of the policy of industrial competitiveness fur the European Union, the Commission aims to **centre** and to **generalise** the debate with regard to quality, amongst societal structures:

- **To centre the debate on quality** as an element of the overall strategy of companies aiming at universal competitiveness and no longer as a technical approach. centred for example on the certification of quality systems. The certification of the quality systems constitutes for the companies, in particular for the SMEs, an important way of proving their capacity in fulfilling the requirements, and thus becomes important within the framework of the Internal Market. Nevertheless. it must not be regarded as an end in itself In parallel, the use of ISO 9000 by companies can be regarded as a first step towards a more global management of companies.

To generalise the debate around a new conception of quality,
which covers not only the traditional technical and economic aspects but also the social, environmental, fiscal and legal aspects, and which takes into account the needs of society as a whole. A new paradigm is being created - "**The society towards excellence**". Not only the economic operators, but also public services (schools and public administrations - at local, regional or national level) reinventing together their relationship and the way to work, to organise and to manage on a joint **project "Quality at the service of Society"**.

The European Quality Promotion Policy is intended to stress the importance of the development of a European quality image and culture, based on the cultural diversity and wealth of Europe, in order to encourage economic growth, increase employment and competitiveness to the companies.

The accent has to be placed on a strategic management of quality based on the satisfaction of the customers. the motivation and satisfaction of the personnel, work well done. the effectiveness of the companies aiming at excellence. rather than on exclusively technical elements such as quality assurance. which primarily seeks to ensure compliance with specifications.

A strategic Vision of Quality for Europe will stress the importance of the development of a European image and culture in order to encourage economic growth. increase employment and give greater overall competitiveness to companies. to give a vision of the role of the various public and private partners within a European framework.

This initiative does not aim to create new infrastructures or special initiatives in this field. unless they can contribute to increasing to a significant degree the synergies between existing infrastructures and policies, and contribute to the effectiveness of their promotion.
The liaison and co-operation structure **- The European Quality Platform** - created in 1994 between the two main European organisations in the quality domain (EFQM and EOQ) is consolidating its role as one of the fundamental pillars to the European approach to quality, and is essential for the development of the main actions under the EQPP initiative:

- The strengthening of the European Quality Award and the expansion of its application to the SMEs and to services will enable all European companies better to understand the advantages of quality and to check their situation in relation to objective criteria, with the aim of evaluating their operational results in the light of the strategy and policy established.

Over and above the award, there exist other means of spreading management best practices so that industry in general, and small and medium-sized companies in particular, can benefit from the experience of others without contravening Community competition rules. There are, for example, a number of private and public benchmarking initiatives. The disparate nature and the diverse techniques and processes employed do not contribute to promoting properly the usefulness and effectiveness of such quality techniques. The industrial co-operation and networking which are inherent to benchmarking are strong instruments for the development of a European way of doing things, for the real development of a European quality culture which can strengthen European industry internally and help it face up to its external competitors.

- A **European quality week** aims to concentrate. over one week. the carrying out of a campaign of public awareness. promotion and demonstration of the advantages and the importance of quality for the competitiveness of the European economy, for the economic operators. public services and customers. These actions take place in the second week of November. in order to include "World Quality Dai". the second Thursday in November

- The existence of a system and a formal programme **of training and qualification of personnel at European level** has become an essential and even a pre-requisite for the successful realisation of the quality approach in the European companies. It is. therefore. very important to encourage the European Quality Platform. in particular via the EOQ. in the strengthening and the transformation of the existing systems for the qualification of quality professionals into an open, transparent and credible genuine European system..

- A **Quality observatory** is intended in order for a network for the collection, processing and distribution of information available on quality to be established. This network will disseminate the information available, develop data bases on the various aspects of quality and promote the performance of studies on the various aspects of quality.
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European Directives and Market Surveillance

Introduction

The free movement of goods within the Single Market of the European Union is legally based on European product legislation. However, such legislation can take only practical effect, if the citizens of Europe have the necessary level of confidence in its fair and effective operation. Offering the same level of protection and safety to consumers, workers and other users wherever they are located in Europe and at the same time ensuring the manufacturers of goods the unrestricted circulation of their products throughout the whole Union, is indeed a major challenge in confidence building.
One of the measures to underpin the confidence of consumers and manufacturers in the effective operation of the Single Market is by effective law enforcement in the member states. The system of law enforcement must be able to demonstrate to its citizens that infringements upon the basic requirements for safety, health and environment can be detected and will be acted upon in a corrective manner. By doing so, it will not only protect the user of the product, but it will also protect the manufacturer from unfair competition.

Law enforcement will also protect the value of the CE-mark. Under the New Approach to European product legislation manufacturers have got a fairly large area of discretion in which the public authorities do not interfere anymore. Product development and production are the responsibilities of the manufacturer. However, in return to this freedom it is expected that manufacturers act in a responsible manner by placing on the market only those products that can fulfil the basic requirements for safety, health and environment. The CE-mark should be the visual proof of their responsibility That can only be a true attestation of basic requirements and a sign of confidence to the consumer, if false products can be taken of the market.

The control over the products in the market, or market surveillance, is an inextricable part of the system of law enforcement in the field of product legislation. It is a public task for which the public authorities in the member states have to designate or create the necessary organizations. To be effective they have to endow them with essential powers of authority and sufficient means, which have to be intelligently applied to monitor the market and to detect defective products.

Market surveillance is an essential activity in ensuring the effective operation of the Single Market. Therefore, market surveillance takes a prominent place in the process of enlargement of the European Union, as far as the aspect of the free movement of goods is concerned. If the concept of the Single market is to be applied in the new member states from Central and Eastern Europe, then it has to offer there the same level of protection to consumers and manufactures as in the rest of the Union.

Therefore, the new member states do not only have to transpose the European product legislation into their own legal systems, but also to adopt the kind of-market surveillance system along Community lines. The implementation of an effective market surveillance system has become a part of the “acquis communautaire” and is a necessary condition for future membership.

The prospective member states are engaged in an effort to qualify for entry at the earliest possible date. In that effort they are also working to achieve the conditions for an effective market surveillance system.

3.6.1. The conditions for market surveillance

There are five areas of attention that play a role in market surveillance.
The basic idea is that, the better the developments are in any of these areas, the better the conditions for an effective market surveillance system.

The first area is the **legislation**. Market surveillance needs to have a legal basis, expressed in national laws, government regulations and ministerial orders, or whatever the system is that is used in a specific country. That legal basis will define both the scope of action and the basis of the authority of the market surveillance organisation In order implement the European product legislation - and in the specific scope of this study that means New Approach Directives and Harmonised Directives in the fields of foodstuffs, pharmaceuticals and chemical - it needs to be transposed. Within this process of transposition several stages can be discerned. The ultimate stage is, of course, the situation in which the directives have become fully effective as an integral part of the national legislation. Still, even in that case a distinction can be made according to the time elapsed since the moment of official publication. The longer that period, the more experience there is with the related market surveillance. Other stages can be related to the legislation being approved by Parliament, but not yet officially published and effective, being in the Parliamentary process, being discussed in the cabinet of ministers before being sent to Parliament, being part of inter-ministerial discussion, being in the drafting stage, or the lowest stage only being an intention to something about it at some future date. However, it is not only the development stage of the individual directives that matters. It is also about the interconnections of the directives. What is the use of implementing the Machinery directive, if the EMC directive and the Low Voltage directive are not implemented at the same time, or at short notice. Are the horizontal directives implemented first, or at a later stage? Why is there often a preference to start the process with the harmonised, Old Approach directives?

The second area is the **market surveillance organisation**. It is obvious that without market surveillance organizations being present, there is no effective way to protect consumers and manufacturers. The basic question is, whether some organisation has been designated to survey a specific directive. The next question is, whether that organisation does have the full legal authority, the capacity the know-how and the means to effectively implement its market surveillance activities. That question is as relevant for the monitoring activities, as it is for corrective action against offenders.
Other aspects too may be of relevance in this area. One is the question of the delineation of the authorities of the different market surveillance organizations, because competing organizations are not conducive to the efficiency of the system.

The third area of attention is formed by industry. What is at stake here, is the level of understanding among the business community of the new rules they will have to abide to. The European product legislation is primarily effectuated by industry, because it states requirements for some of the intrinsic qualities of their manufactured goods. Besides, it refers to certain control systems, like HACPP, the Conformity Assessment modules, GMP, GLP, that industries will have to apply. The introduction of such new measures depends to a large extent upon the understanding, the willingness and the ability of the entrepreneurs to integrate them in their business practices. It also depends on their perception of and their confidence in the effectiveness and impartiality of the market surveillance system. One way to increase the knowledge about the new legislation is the use of awareness campaigns by the authorities to explain the upcoming changes in the rules, the use of national or regional information centers, the free use of expert help, or any other measures of public information. The dissemination of information is, however not only a task of the public authorities, but also one for the industry organizations themselves. They can provide information that is much more focused on the specific needs of their membership.

The fourth area is the **supporting structure of testing laboratories, standardization and accreditation**. Both the market surveillance organizations and the industry will have to make use of the services of accredited laboratories and certification institutes and of national and international standards that the legislation refers to. The market surveillance bodies may use their own in-house laboratories or do the testing of product samples in third party laboratories. In either case, it is an advantage if the laboratories are accredited for their testing methods by an internationally recognized and fully independent accreditation body. For industries the use of third parties can be mandatory under the rules for conformity assessment depending on the risk factor of the product. In that case it is useful if accredited laboratories are available, especially if they are also recognized abroad with a view to confidence of foreign importers in the product. The incorporation of international standards, and especially European standards, into the body of national standards will make it much more convenient for industries to serve the international market and the national market. This will be further enhanced if calibration and tractability are well-organized activities.

The fifth and last area, in which positive signs of development are needed, is the area of **consumer awareness and protection**. One of the central objectives of the European product legislation is to offer a single level of protection to consumers and employees in all member states. However, to realize this level of protection the consumer on his part has to be aware of his rights and the ways and means to effectuate these rights The reaction of the consumer to products of poor quality and to defective products forms an important input for the market surveillance bodies. A population well educated in consumers rights will greatly help to direct the work of the market surveillance officers to defective products and unfair trading practices. On the other hand, consumer complaints, if handled intelligibly, can also help industries in their continuous striving to improve quality. However if producers do not react and continue o deliver poor quality the power of the consumers in the market will eventually correct them.

Conformity Assessment Procedure and Market Surveillance

The main objective of the New Approach Directives is to ensure that products, which freely circulate through Community market have a proper level of safety. Necessary element to correctly implement this principle is Market Surveillance.
There is clear distinction between Conformity Assessment Procedure and Market Surveillance System. Conformity Assessment Procedure takes place **before** the product has been placed on the market while Market Surveillance System takes place **after** the product has been placed on the market. Market Surveillance Actors within the European Union are:

- Manufacturers – before the product has been placed on the market,
- Customs officials - for products originating outside EU,
- Market surveillance authorities - after the product has been brought on the market,
- Court – when incidents occur.