THE CE MARKING AND THE IMPLEMENTATION IN TURKEY: THE CHALLENGES AND THE COMPLEXITIES

A THESIS SUBMITTED TO
THE GRADUATE SCHOOL OF SOCIAL SCIENCES
OF
MIDDLE EAST TECHNICAL UNIVERSITY

BY

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IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR
THE DEGREE OF MASTER SCIENCE
IN
THE DEPARTMENT OF SCIENCE AND TECHNOLOGY POLICY STUDIES

FEBRUARY 2012

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ABSTRACT

THE CE MARKING AND THE IMPLEMENTATION IN TURKEY:

THE CHALLENGES AND THE COMPLEXITES

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M.S., Science and Technology Policy Studies

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February 2012, 111 Pages

The CE mark confirms that all applicable provisions are fulfilled with regard to conformity assessment within the scope of "New Approach" directives. The CE mark is a mandatory conformity mark for products placed on the market in the European Union. As a candidate country Turkey is obliged to achieve constitutional modifications in the quality infrastructure institutions to succeed European Union harmonization. The aim of this thesis is to research the harmonization problems in Turkish quality infrastructure system and analyze the challenges and complexities in legal approximation and implementation. Turkey has harmonization problems in standardization, conformity assessment and accreditation; proceed from inability of implementing operating methods and lack of specialized knowledge. These problems disorganize the quality infrastructure system and create disadvantage against Turkish manufacturer and consumer.

Keywords: The CE marking, quality infrastructure, harmonization.

ÖZ

CE İŞARETİ VE TÜRKİYE'DEKİ UYGULAMALARI:
KARŞILAŞILAN GÜÇLÜKLER VE SORUNLAR

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Tez Yöneticisi: Sevilay Kahraman

Şubat 2012, 111 Sayfa

CE İşareti "Yeni Yaklaşım" direktifleri kapsamında uygunluk değerlendirmesi faaliyetleri açısından tüm yasal yükümlülüklerin yerine getirildiğini göstermektedir. CE işareti Avrupa Birliği'nde pazara sunulan ürünler için zorunlu bir işarettir. Aday ülke olarak Türkiye Avrupa Birliği'ne uyum çerçevesinde kalite altyapısı alanında faaliyet gösteren kurumların yapısal değişikliklerini sağlamakla yükümlüdür. Bu tez, Türkiye kalite altyapısı sisteminde Avrupa Birliği ile bir uyum problem olup olmadığını araştırmayı, yasal uyumlaştırma ve uygulamada karşılaşılan sorunları tartışmayı hedeflemektedir. Türkiye'nin standardizasyon, uygunluk değerlendirmesi ve akreditasyon alanlarında teknik bilgi ve uygulama yetersizliklerinden kaynaklı uyum problemleri bulunmaktadır. Bu problemler kalite altyapısı sisteminin işleyişini bozmakta, üretici ve tüketici için dezavantaj yaratmaktadır.

Anahtar sözcükler: CE işareti, kalite altyapısı, Avrupa Birliği'ne uyum.

To my father

ACKNOWLEDGEMENTS

I would like to thank to my supervisor Ms. Sevilay Kahraman, as she was so generous in sharing her valuable time, deep knowledge and gracious kindness.

I would like to express special thanks Mr. Erkan Erdil, as he was so encouraging and supportive to me from the beginning of my graduate education.

I am so grateful to Mr. Ilhan Uzgel for his unique guidance and extremely valuable contributions.

,.. it is a miracle to have such a perfect family and excellent friends.

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LIST OF ABBREVIATIONS

CAB	Conformity Assessment Body
CE	Conformity Européenne
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
EA	European Cooperation for Accreditation
EC	European Commission
EEC	European Economic Community
EN	European Standard
ETSI	European Telecommunications Standards Institute
EU	European Union
EUROMED	Euro-Mediterranean Partnership
EURAMET	European Association of National Metrology Institutes
GATT	General Agreement on Tariffs and Trade
IAF	International Accreditation Forum
ICTA	Information and Communication Technologies Authority
IEC	International Electrotechnical Committee
ILAC	International Laboratory Accreditation Cooperation
IPA	Instrument for Pre-Accession Assistance
ISO	International Organisation for Standardisation
KOSGEB	Small and Medium Enterprises Development Organization
MLA	Multilateral Agreement
MoE	Ministry of Economy
MoEUA	Ministry for EU Affairs
MoEUP	Ministry of Environment and Urban Planning

MoFAL	Ministry of Food, Agriculture and Livestock
MoH	Ministry of Health
MoLSS	Ministry of Labor and Social Security
MoPWS	Ministry of Public Works and Settlement
MoSIT	Ministry of Science, Industry and Technology
MRA	Multilateral Recognition Arrangement
NANDO	New Approach Notified and Designated Organizations
NB	Notified Body
SME	Small and Medium Sized Enterprise
TAPDK	Tobacco and Alcohol Market Regulatory Authority
TBMM	Turkish Grand National Assembly
TBT	Technical Barriers to Trade
TC	Technical Committee
TSE	Turkish Standards Institution
TÜBİTAK	Scientific and Technical Research Council of Turkey
TÜİK	Turkish Statistical Institute
TÜRKAK	Turkish Accreditation Agency
TÜSİAD	Turkish Industry and Business Association
UDDER	Association of Conformity Assessment Bodies
UMA	Undersecretariat of Maritime Affairs
UME	National Metrology Institute
WELMEC	Western European Legal Metrology Cooperation
WTO	World Trade Organisatio

CHAPTER 1

INTRODUCTION

The international trade is supported by the manufacturers who want to extend the market and increase their sales, and also by the consumers who want to benefit from competitive prices, and reach new goods that are not available in their country. In addition, the countries maximize production by specialization in international trade. However; the different quality infrastructure implementations, standards and technical regulations act like technical barriers and violate the integration of the national markets.

The European Union (EU) focused on the removal of technical barriers in 1969 with its General Program, which would later we called the "old approach". The idea was based on a unified economic area, functioning like a single market. Nonetheless there were several complexities in the implementation, and new provisions were required as the "Old Approach" was based on very detailed and product specific directives and technical regulations. Within the scope of harmonization the EU adopted "The New Approach" policy in 1985 to eliminate the technical barriers to trade between the Member States. The New Approach aims to achieve harmonization through establishing general rules on quality infrastructure (European Council, 1985). The quality infrastructure is composed of four components:

- Standardization
- Conformity Assessment
- Accreditation

- Metrology

Standardization is the procedure of developing best technical application by establishing a technical standard including specifications, test methods, definitions or practices. Each country has a national standardization body which prepares national standards and cooperates with other national standardization bodies on international standards. Conformity Assessment, on the other hand, is the process of activities in order to determine whether the product fulfills the requirements as described in the technical standards. Testing, inspection and certification are key activities of the conformity assessment process. Conformity assessment procedures are performed by CABs (Conformity Assessment Bodies) according to the procedures and elements as lay down in the individual directives. There are agreements on mutual recognition in relation to conformity assessment. As accredited CABs conform to the same standards and procedures, they are recognized by all the parties of mutual recognition agreements. Accreditation is the activity of certifying the credibility of CABs. The accreditation ensures that the conformity assessment practices are compliant with the relevant technical standards and procedures. Each country has a single accreditation body which operates according to same standard (ISO/IEC 17011). Accordingly all the national accreditation bodies apply the same rules and accreditation procedures to CABs in order to establish global acceptance of the services. Lastly, metrology is the science of measurement. The key term in metrology is "metrological traceability" which is defined as the property of the result of a measurement whereby it can be related to stated references, through a chain of comparisons (BIPM, 2010). All four components generate the "quality infrastructure". The EU Member States have developed a unique mark which demonstrates the conformity of a product in the

scope of the European quality infrastructure, which is known as the "CE (Conformity Européenne) mark." The CE marking is a declaration by the manufacturer that the product fulfills all the appropriate provisions of the relevant New Approach Directives implemented in the Members or associated countries as Turkey. At present there are 24 New Approach Directives:

Table 1: New Approach Directives

Active implantable medical devices	Appliances burning gaseous fuels	Cableway installations designed to carry persons
Construction products	Electromagnetic compatibility	Equipment and protective systems intended for use potentially explosive atmospheres
Explosives for civil uses	Hot-water boilers	In vitro diagnostic medical devices
Lifts	Low voltage	Machinery Safety
Measuring Instruments	Medical devices	Noise emission in the environment
Non-automatic weighing instruments	Personal protective equipment	Pressure equipment
Packaging and packaging waste	Radio and telecommunications terminal equipment	Recreational craft
Safety of toys	Simple pressure vessels	

Source:http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.main

The CE mark is the final process of the harmonization. In the other words, it is a passport for the free movement of the products in European market in terms of health and safety. By the Council Directive 93/68/EEC[1], the CE mark became compulsory for the marketing of a product in Europe (European Council, 1993).

[1] O J L 220 , 30/08/1993 P. 0001 - 0022

Turkey has been participating in the EU single market for products and processed agricultural goods since 1996 and was recognized as a candidate for full membership in 1999, at the Helsinki summit of the European Council. Thus, Turkey is obligated to eliminate the technical barriers to trade and adopt the Community instruments in legal orders on the purpose of harmonization. Cooperation in the fields of standardization, conformity assessment, accreditation and metrology fields come into prominence.

Having made an introduction about the issue in focus, the purpose of this thesis is to examine the status of Turkish quality infrastructure system in relation to the EU harmonization. The main research question is "What are the harmonization problems in Turkish quality infrastructure system?" The challenges and complexities in the legal approximation and implementation are discussed in line with the existing and foreseen problems.

For this aim, the European quality infrastructure system is explained in the first chapter, starting from a literature review focused on the importance of standardization. Head organizations (CEN/CENELEC, ETSI, EA, EURAMET, WELMEC) in the European quality infrastructure are introduced and their contributions are presented by referring to Commission directives, regulations and official guides. After the European quality infrastructure is defined and its institutions are elaborated, in the second chapter, Turkish quality infrastructure is explained in four sections which are standardization, conformity assessment, accreditation, and metrology. The discussion in this chapter is reinforced with interviews that were conducted with key persons involved in Turkish quality

infrastructure system, such as civil servants, association managers, notified body directors, officers in the decision making process and transposition of the EU legal documents. In the third chapter, complexity and challenges in the Turkish system is analyzed through dealing with Turkish quality infrastructure actors, such as TSE and TÜRKAK. The level of harmonization is presented in this chapter by comparing the establishment laws of the Turkish institutions and European regulations in the subject. Harmonization problems were detected by examining the management structure of Turkish quality infrastructure institutions, identifying the implementation success, and benchmarking with other European Member States. Eventually the findings were justified by analyzing the progress reports of European Commission and country reports of EUROMED and IPA projects.

CHAPTER 2

THE EUROPEAN QUALITY INFRASTRUCTURE SYSTEM

The purpose of establishing a single market has started with the Treaty of Rome. The Treaty of Rome was obligating the sides to regulate their fiscal policies, such as the elimination of custom duties, the establishment of a common customs tariff toward third countries, and the abolition of barriers to free movement of goods (The Treaty of Rome, 1957). The single market purpose set targets for customs union and the harmonization of legislation. The policy-makers were concerned about tariffs and non-tariff barriers to trade, as a result the General Agreement on Tariffs and Trade (GATT) concentrated on regulating the barriers. Even the tariffs came down other barriers came up. With the raise in the technology development new standards started to act as a tool for protection (Wallace & Young, 1996). Therefore, the standards were needed to be harmonized as well. In 1973 the European Commission has started to cooperate with the private standard bodies for producing reference to standards. The European standard bodies; The European Committee for Standards (CEN) and the European Committee for Electrical Standards (CENELEC) provided only technical assistance. Only 270 directives were adopted between 1969 and 1985 due to the technical problems. In 1985, the European Commission began to focus on the "new approach" to standards harmonization which encouraged "mutual recognition" of existing national rules, and underlined the essential requirements (Wallace & Young, 1996). The standards were used as the policy instruments for harmonization.

Surely the importance of standards has increased in the process of time. The actors who have the impact on standards had chance to control the rules of trade.

2.1. An Introduction to the Standards

The development of technological change has highlighted the strong link between standards, economic welfare, and market performance. The literature distinguishes three types of standard (David, 1987):

- Reference standards
- Compatibility standards
- Quality standards

Reference standards are used in product descriptions. Briefly, reference standards are market measurements. For instance 95 RON[2] is used as a standard for regular unleaded petrol. The producer can confirm that the product to be sold is indeed what he expects it to be. The customer can buy with confidence that the product is what it is supposed to be (Swann, 2000).

Compatibility standards are the physical design of interfaces and other specifications as a result of coordinated production. The development in information and technology sciences has increased the importance of standards for compatibility. For example, audio playback technology has changed during the last 50 years: long plays, audio cassettes, compact discs and recently mpeg3 audio files. The music recorded on one standard cannot be played back using the equipment of another

[2] Research octane number is a standard measure of the anti-knock properties of a fuel.

standard (Stango, 2004). However, each standard allows the customer to play back the recorded music in various brands of music players.

The standards generate two economic aspect that influence producer and customer decisions. First, producers and customers face “switching costs” if they invested in a particular system and would find it expensive to switch to another (Farrell & Shapiro, 1988). For instance, the customers made their preferences in 1980s by choosing one of the video cassette recording formats: VHS or Betamax. Switching from one standard to the other meant to buy a new video player. Second, producer and customer choices are influenced by “network effects” (Farrell & Saloner, 1985). Producers and customers are desirable to choose a system that is widely used by others. Instant messaging software, Skype, is an example for network effect. Because the members of Skype are more than any other competitor, people prefer to sign up a new account in Skype. When network effects are important to the customer, manufacturers start producing a product that conforms to the “industry standard” (Swann, 2000). One of the widely known industrial standard is USB (Universal Serial Bus) developed in 1990s. USB defines the connectors and protocols used for communication between computers and electronic devices. It is designed by several companies such as Compaq, IBM, Microsoft, Intel, etc. (Lenova, 2011). In some of the “standards races” the winner is not necessarily the best technology performance; usually the winner is the one that has been the most effective building a network of customers (Swann, 2000).

Quality standards are technical documents intended to be used as a rule, guideline or definition. For example one of the best-known standards, ISO 9000 describes fundamentals of quality management systems. Quality standards describe:

- The level of accomplishment or knowledge for certification,
- The quality of a service, system or a product,
- Specific business process (BSI, 2005).

Standards[3] can be purchased from International Standardization Organization (ISO) or national standardization organizations. The potential customers of standards are:

- The organizations who seek advantage through the implementation of a standard;
- Users of the products;
- Supplier, customers, and regulators who concerned with a mutual understanding of the terminology used in the related area;
- Auditors, certification bodies, and regulator who assess or audit the organizations for conformity with the requirements of the related standard;
- The organizations who give advice or training on the related standard;
- Developers of related standards (ISO, 2011a).

Standards contribute to economy in several aspects and, thus, supported by governments at various levels. Standardization defines some of the characteristics of product or processes which should be followed to make them suitable for use

[3] The term "standard" will be used instead of "quality standard"

(Kretchmer, 2000). Companies use standards to perform better, to succeed in the market, to be known by the customer and to be consistent with other producers. Standardization reduces transactions costs between different producers and between producers and customers (David, 1987). Standards reduce business costs by representing the accumulation of knowledge and experience gathered by industry. "By reducing transaction costs, standards can make it cost-effective for companies to use the market to source specialized components. This increases the use of the market, and may indeed increase the geographical extent of the market." (Swann et al., 1996). There is a positive link between standards and the extent of trade. Standards reduce barriers to trade and increases competition in open markets (Swann, 2000).

Furthermore, the companies which are involved in standard works benefit with regard to cost and competitive status than those which do not participate (DIN, 2000). A survey of over 4000 companies in Germany, Austria and Switzerland was carried out, and the final report was published by DIN German Institute for Standardization. According to that survey, companies are generally unaware of the importance of standards. European and International Standards open new markets for the companies which conform to the related standards. Lower trading costs and lower trade barriers are the advantages of harmonized standards[4]. Standards improve the company know-how by providing the framework which product development is carried out.

[4] See 2.3.1 for further discussion.

Standards have a positive effect on the new customers. By following the common standards companies attract new customers. Standards promote competitive advantage by increasing customer confidence and improving internal organization (CEN, 2000). Customers can identify suppliers who they can trust. Standards are prepared by bringing together all interested parties such as consumers, manufacturers and public authorities. Consumer's confidence is increased by enabling the participation to the process of standardization (David, 1987). Standards protect the safety and health by ensuring essential requirements[5].

The results of the DIN's survey show that standards are a positive stimulus for innovation (DIN, 2000). Moreover, standardization is a form of technology transfer. Swann (2000) explains that standardization does constrain innovation activities, on the contrary creates an infrastructure to help trade and subsequent innovation. "Standardization is not just about limiting variety by defining norms for given technologies in given markets. Standardization helps to achieve credibility, focus and critical mass in markets for new technologies. Moreover, well-designed standards should be able to reduce undesirable outcomes" (Swann, 2000). Corporate culture can develop of innovation trough norms and standards. Standards can facilitate innovation trough developing technology that meets users' needs (Galetic, et al., 2009).

In addition to promoting economic efficiency, standards can have negative sides in certain circumstances. Especially in the computer industry, standards tend to act as a barrier to entry. This has been discussed in the context of Microsoft in several

[5] See 2.3.2 for futher discussion.

studies. As an example, Microsoft developed a version of Java that was optimized for Windows and encouraged programmers to write applications for this version (Gilbert & Katz, 2001). Hence, standardization of programming language was a barrier to entry. It was stated that a combination of an application and a compatible operating system is necessary to perform any useful task. An application will not run without a compatible operating system, an operating system alone servers no useful purpose (Hanna, 1994).

Furthermore, safety and environmental standards can impose costs on firms that have to meet these standards. In an empirical study, Aldrich (1988) represented that health standards have been criticized for being cost ineffective and because the Occupational Safety and Health Administration seems willing to impose enormous costs on the private sector to achieve relative modest health benefit.

It was discussed that one of the benefits of standardization is the cost reduction. For example there are a number of paper sizes in the industry. By limiting the number of sizes produced, it is possible to have larger production runs, which lead to a reduction of the costs per unit. On the other hand, standards restrict freedom of choice which the user of standardized product has (Bongers, 1988). In a case study Bongers (1988) showed that it is best if the density of the product range follows the distribution of demand.

Lastly, the standards can become a technical barrier to trade by obstructing the entry for international producers. Standards balance the interest of different producers and consumers, but if a standard is prepared with the interest of domestic producers, it gives a competitive advantage to domestic producers, and imposes additional costs

on importers of a product (Swann, 2000). For that reason, national standardization organizations participate in drafting standards.

There are two types of technical barriers to trade: technical regulations and non-regulatory barriers. Technical regulations are imposed by national governments mainly for health and safety for consumers; however, non-regulatory barriers are imposed by users groups, trade institutions in order to advice customers (Atkins, 1996). The decision to create the internal market in Europe raises questions regarding the integration effects on trade and specialization. This process implies the elimination of a number of nontariff barriers, and technical barriers to trade (Lundberg, 1992). It is difficult to distinguish whether a standard serves the public interest or protectionist. Good governance requires regulation to protect the health and safety (UME, 2012). On the other hand the technical barriers to trade need to be eliminated (Baldwin, et al., 2000).

2.2. Eliminating the Technical Barriers to Trade and the "Old Approach" Directives

In order to eliminate the technical barriers to trade, the European Commission, decided to elaborate directives on certain product areas for the free movement of goods. This approach was materialized through at number of directives of which the Member States were obliged to implement in their national legislation and withdraw any conflicting legal acts or administrative provisions on their territory.

It is important to understand the legal acts of the Union in order to comprehend the mechanism. Article 288 of the Treaty on the Functioning of the European Union[6] (European Council, 2008) explains that:

> To exercise the Union's competences, the institutions shall adopt regulations, directives, decisions, recommendations and opinions.
>
> A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States.
>
> A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.
>
> A decision shall be binding in its entirety. A decision which specifies those to whom it is addressed shall be binding only on them.
>
> Recommendations and opinions shall have no binding force.

Regulations have to be published in the Official Journal and they are binding upon all the Member States but there is no formal hierarchy between these provisions. Regulations are not superior to directives (Craig & De Burca, 2003). Regulations are norms made by an international body but should enter a national legal system by the transforming the measure into national law. Member states need to modify their national law in order to comply with a regulation. Compared with the regulations, directives do not have to be addressed to all Member States. Secondly there is no duty to publish directives in the Official Journal, whereas many were published (Craig & De Burca, 2003). Directives are useful to harmonize the laws within a certain area, such as quality infrastructure. Finally, decisions are chosen method for introducing a new policy area or for establishing general procedures. The European

[6] O J C 115, 09/05/2008 P. 047-199

Council may delegate power to the Commission to take decisions (Craig & De Burca, 2003).

The EU launched the General Program in 1969 to remove the technical barriers to trade. The General Program (the old approach) was based on the idea that the EU would function like a single national economy. (Baldwin, et al., 2000). "Old Approach" Directives, only dealt with design requirements. The directives that were elaborated were very detailed in relation to technical details and specific requirements for a certain product group. Therefore the development of a directive on a specific product group was a very time consuming procedure. The final approved document could be outdated before they came into force, because of the technical development and innovation during the preparation process. An example is the directive on mechanical taxi meters, the devices were no longer used when the directive was published, but in the meantime substituted by electronic taxi meters, which the directive could not address technically (Skjernov, 2011).

In order to overcome the difficulties encountered from the "Old Approach" directives, the Council in 1985 adopted the "New Approach" by a Council Resolution of 7 May 1985 on a New Approach to Technical Harmonization and Standards[7] (European Council, 1985). Table 2 shows a comparison between "Old Approach" and "New Approach" (CEN, 2004).

[7] OJ C 136, 4.6.1985, p. 1–9

Table 2: The Differences of the “New Approach” and “Old Approach” Directives

New Approach	Old Approach
Families of products.	The product-based approach.
Co-operation between public authorities and market operators.	Functions of "notified bodies" are carried out by national authorities.
Essential requirements.	Technical specifications.
Do not need regular adaptation to technical progress.	Need regular adaptation to technical progress.
New Approach Directive gives various options and allow manufacturers a significant degree of flexibility.	
Based on total harmonization.	Based on optional harmonization.

Source: The table is prepared by the author according to information from the CEN - Guidance - The "New Approach" 2004.

The new approach deals with large families of products, such as construction products, machinery, toys, etc. or horizontal risks such as electromagnetic compatibility. On the other hand, the old approach was product-based. The new approach established cooperation between public authorities and private bodies. The functions of notified bodies can be carried by the private entities. On the contrary, the old approach the technical specifications are adopted by authorities and the conformity assessment activities of notified bodies are carried out by public authorities. The new approach directives defines the essential requirements that products must meet, and do not mention about the technical specifications. Conversely the old approach directives consist of the technical specifications of the products as well. As a result old approach directives need regular adaptation to technical progress. However the new approach directives do not need regular adaptation since the directives do not contain technical specifications. The new

approach directives allow manufacturers flexibility that they can choose technology to meet the essential requirements. Finally, the new approach based on total harmonization although the old approach based on optional harmonization by leaving a choice to manufacturers to follow the harmonized Community rules.

2.3. The "New Approach" and Standardization

The new approach meant that directives were designed to address only essential requirements. The purpose of the new approach was to establish general rules and avoid extensive decision-making procedures. This approach was significantly different from the Old Approach. The "New Approach", represents an innovative way of technical harmonization by introducing a clear separation of responsibilities between the EC legislator and the European standards bodies[8] in the legal framework allowing for the free movement of goods (European Council, 1985). European Economic Community legislative harmonization is limited to the "essential requirements"[9] and the EU legislator produces directives, on the other hand the standardization bodies draw up the corresponding technical specifications. The producer has an obligation to prove his product meet the "essential requirements" of the directives, he may use or not use the relevant the EU standard; that is the reason of defining the standards as voluntary. Directives are always binding and subject to the EU legislator while the EU standards are not mandatory.

[8] CEN, CENELEC and ETSI

[9] See 2.3.2 for futher discussion.

Instead of establishing technical harmonization through detailed and product specific directives, the New Approach aimed at demonstrating the fulfillment of the "essential requirements" by making reference to product characteristics. These product characteristics should be documented to meet a certain level of safety in the individual European Member States and should reflect the technical specifications of a certain product (European Council, 1985).

The conformity assessment procedures for the affixing the CE mark is laid down in the directives according to the "New Approach" and the "Global Approach". The European Council adopted a Resolution on a New Approach to technical harmonization and standards, providing new perspective for the harmonization of national regulations for products, services and procedures (European Council, 1985) It was complemented in 1989 by the Council Resolution on a "Global Approach" to conformity assessment[10] (European Council, 1989) followed by 93/465/EEC Council Decision of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives[11] (European Council, 1993). The directives following the "New Approach" are framework directives addressing the essential requirements for a certain product. The fulfillment of the essential requirements can be demonstrated by referring to "European harmonized standards".

[10] OJ C 010, 16/01/1990 P. 0001 - 0002

[11] OJ L 220, 30/08/1993 P. 0023 - 0039

2.3.1. Harmonized European Standards

The formal definition of a standard is:

> A document for common and repeated application that provides rules, guidelines or characteristic features of activities or result of these activities. The documents has been drawn up by consensus and adopted by a recognized body. The objective is to achieve optimal order in a given context (ISO, 1996).

Standards are drawn up by the committees of manufacturers, consumers, research institutes, and public authorities. Standards are designed for voluntary use and do not impose any regulations. Nonetheless, regulations may refer to certain standard to make compliance with them compulsory (CEN, 2010b).

In the Directive 98/34/EC[12] (European Council, 1998), European Commission defines:

- International standard: a standard adopted by an international standardization organization (ISO)
- European standard: a standard adopted by the European standardization organizations (CEN/CENELEC/ETSI)
- National standard: a standard adopted by a national standardization body and made available to the public"

The national standardization bodies take into account legal aspects, research, interests of manufacturers and consumers when developing a standard. On the other hand, national standards may pose an obstruction to the free movement of goods and services. Therefore, it was decided to develop common European standards. The

[12] OJ L 24, 21/7/1998, P. 37

European standards are developed by a mandate issued by the Commission in order to support the directive. The mandates were given to European Standardization Organizations to develop the necessary technical specifications addressing only the essential requirements[13]. The resulting European standards may include other voluntary requirements, but these requirements shall be clearly differentiated from the essential requirements on safety and health. The other requirements must not be related to the CE marking and any confusion shall be avoided. Voluntary marks may be affixed if they are clearly separated and do not address any essential requirement.

There are three European Standards Organizations which enable the requirements to be accomplished by referring harmonized European Standards (B. Pasa, G. A. Benacchio, 2005):

- European Committee for Standardization (CEN)
- European Committee for Electro-technical Standardization (CENELEC)
- ETSI European Telecommunications Standards Institute (ETSI)

2.3.1.1. European Committee for Standardization (CEN)

The European Committee for Standardization (Comité Européen de Normalisation) was founded in 1961 as a major provider of European standards. It is the only recognized body for the planning, drafting and adoption of European Standards (ENs) in all areas with the exception of electro technology and telecommunication according to Directive 98/34/EC (European Council, 1998). CEN has 31 National Members. (i.e. Turkish Standardization Institute) These members work together to

[13] The mandates include the decision on the level of conformity assessment related to the module for the conformity assessment procedure.

develop voluntary European standards and these standards have a unique statue since they also are national standards in each of its Member States (CEN, 2010b). European standards help building a European Internal Market for goods and services. More than 60.000 technical experts from industry, associations, and academia are involved in the CEN network. Business federations, consumer and societal organizations are involved in this network as well (CEN, 2001).

> In 2010, CEN produced 1090 documents (ENs - Standards, ENVs - Pre-Standards, TSs - Technical Specifications, TRs - Technical Reports, CRs - CEN Reports, CGs - CEN Guides and CWAs - CEN Workshop Agreements). The total number of living documents to date is 14.134 (end December 2010).
>
> CEN currently has 1918 Technical Bodies, whereof:
>
> 299 active CEN Technical Committees
> 26 active CEN Workshops
> 57 CEN Technical Committees/Sub-committees
> 1411 CEN Working Groups
> 13 CEN-CENELEC Technical Committees
> 2 CEN-CENELEC Working Groups (CEN, 2010a)

2.3.1.2. European Committee for Electrotechnical Standardization (CENELEC)

European Committee for Electrotechnical Standardization (Comité Européen de Normalisation Électrotechnique) was founded in 1973 and is responsible for standardization in the Electrotechnical engineering field (CENELEC, 2001). CENELEC prepares the standards for safety in the design and construction of electrical equipment. National Committees of CENELEC may circulate or publish the text in a way which serves best the relevant work on the national level. CENELEC facilitates the market access at European level but also at international

level by adopting international standards, through its cooperation with the International Electrotechnical Commission.

2.3.1.3. The European Telecommunications Standards Institute (ETSI)

The European Telecommunications Standards Institute produces standards for information and communication technologies (i.e. mobile, radio, broadcast, internet technologies). ETSI was created by European Conference of Postal and Telecommunications Administrations in 1988 and has more than 700 member organization from 62 countries (ETSI, 2011). Similar to CEN and CENELEC, ETSI produce standards and specifications through Technical Committees.

Standardization is both the development of standards and the promotion of standards to the widest community, as a best practice. CEN/CENELEC Members engage with stakeholders to promote participation in standardization – whether by encouraging SMEs to participate in the standards committee, building awareness with government ministries on the value of the standards consensus process to support new legislation or increasing the involvement of consumers in standards and representation at international consumers' for, such as ISO Committee on Consumer Policy, Committee on Conformity Assessment, Committee on Developing Countries Matters, Committee on Reference Materials (CEN/CENELEC, 2010c).

The harmonized European standards are accepted by the European standardization organizations and prepared in accordance with the General Guidelines[14] agreed between the Commission and the European standards organization represented in

[14] OJ C 91, 28/03/2003, P 7-11

CEN / CENELEC / ETSI (European Commission, 2003a). National regulations shall be withdrawn and adopted the EU legislation transposed into the national legislation. The General Guidelines for the cooperation between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association is summarized in Appendix A.

By addressing the harmonized and transposed European standards, manufacture presume that the essential requirements are fulfilled. Those products can be marketed in the Community area, or in countries having an agreement on mutual recognition and custom agreement on technical barriers to trade (European Commission, 2000). The harmonized standards need to address legal aspect with specific directives by addressing the essential requirements for health and safety.

2.3.2. Essential Requirements

"New Approach Directives" defines essential requirements with safety, health and protection of environment. No Member State can deviate from these essential requirements. Essential requirements lay down the necessary elements for the protection of public interest and they are mandatory. Only products which are complying with the essential requirements may be placed on the market and put into service. The essential requirements are either addressed directly in a directive or annexed to it with an explanation to highlight the scope of the requirements.

The aim of the Essential Requirements is protecting consumers' health and safety and workers must be taken into account as consumers when they are using the

equipment (Tricker, 2000). Essential Requirements are developed to comprise all necessary issues for the protection of public interest.

The Essential Requirements in a Directive are composed to procure protection from possible hazards and risks related to the product. For example:

- Resistance to fire,
- Mechanical stability
- Hygiene and health
- Biological, chemical reactions or hazards
- Electrical properties.

Recycling and environmental requirements are being considered and expected to be included as a requirement for products in the future. These risks associate with materials, manufacturing and assembling process, installation, design and construction of the products as well as the used when incorporated in a product or works (Tricker, 2000). Releases of formaldehyde, asbestos content, water soluble chromate content in cement are examples of certain hazards.

It is the responsibility of the manufacturer to ensure the fulfillment of the essential requirements for a given product. Additionally manufacturer is in charge of finalizing the risk analysis for determining the essential requirements that are appropriate for the product. The analysis must be documented in manufacturers' technical files (Tricker, 2000). Depending on the level of conformity assessment, a third party (Notified Body) may be involved in the evaluation and testing before a certificate can be issued to prove to conformity to a certain standard or the essential

requirements. Further to this, the conformity assessment system was described in the "Global Approach", for which the CE marking was introduced to demonstrate that.

2.4. Conformity Assessment and CE Marking

2.4.1. General Information on Conformity

The "New Approach" was designed to harmonize essential safety and health requirements in European legislation (Delaney, 2008). As it was discussed in the previous section, essential requirements are mandatory and legally binding obligations. The aim of essential requirements is to eliminate the risks and hazards and there must be an agreement on these requirements to free the trade among European countries.

Conformity assessment is the process of evaluation of the essential requirements. Affixing the CE marking is the positive result of this process. As European harmonized standards are voluntary, a manufacturer may apply other technical specifications or standards if he can demonstrate the conformity to the essential requirements. However the harmonized standards represent the easiest way for a manufacturer to prove the conformity. The basic activities of the conformity assessment procedure are (Baldwin, et al., 2000):

- Testing
- Inspection
- Certification

Testing laboratories carry out the testing activities according to essential requirements in the relevant directive applying the European harmonized standards

and they issue test reports to the manufacturer. Inspection is performed when surveillance is requested. The certification bodies demonstrate the competence in their field of notification, collect the data from test reports, and certify the conformity with the requirements.

The harmonization was introduced through “the Global Approach” for the conformity assessment which has two decisions (European Council, 1998):

- The Modular Approach Decision
- The Regulation on the CE Marking.

Conformity assessment is subdivided into modules and manufacturers must follow the modules as identified in the individual directives. To indicate the complexity and the various modules, Table 3 shows the application of the modules (European Commission, 2000):

Table 3: Conformity Assessment Modules

A	Factory Production Control	Covers internal design and control	This module does not require the intervention of a notified body
B	EC Type examination	Covers the design phase and must be followed 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 according to B.	This module does not require the intervention of a notified body
D	Production quality assurance	Covers the production phase and follows module B. Derives from QA standard EN ISO 9002.	Intervention of a notified body responsible for approving and controlling the final product inspection and testing set up by the manufacturer
E	Product quality assurance	Covers the production phase and follows module B. Derives from QA standard EN ISO 9003.	Intervention of a notified body responsible for approving and controlling the QA 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 QA standard EN ISO 9001.	Intervention of a notified body responsible for controlling the QA system for design, manufacture, final product inspection and testing set up by the manufacturer.

Source: European Commission Blue Guide 2000.

The modules in the table are ordered from simple to difficult. Module A, which covers the internal design and control, does not require the intervention of a notified body. The module B covers only design phase and must be followed by one of the production phase modules. The EC type examination certificate is issued by a notified body, after that the intervention of the notified body changes according to the provision of the relevant directive. If the relevant directive points out the module H, than the notified body is responsible for controlling the quality assurance system for design, manufacture, final product inspection and testing set up by the manufacturer. This module is suitable for high risk products.

In some cases, the manufacturer can perform the procedure by himself, depending on the significance and the impact of the product. The more significant is the product, more involvement will be needed from a Notified Body[15] specialized in the area. In the Figure 1, the blue color indicated the elements that can be performed by the manufacturer whilst the yellow color represents the involvement of a Notified Body (European Commission, 2000)**.**

[15] See 2.4.2 for further discussion.

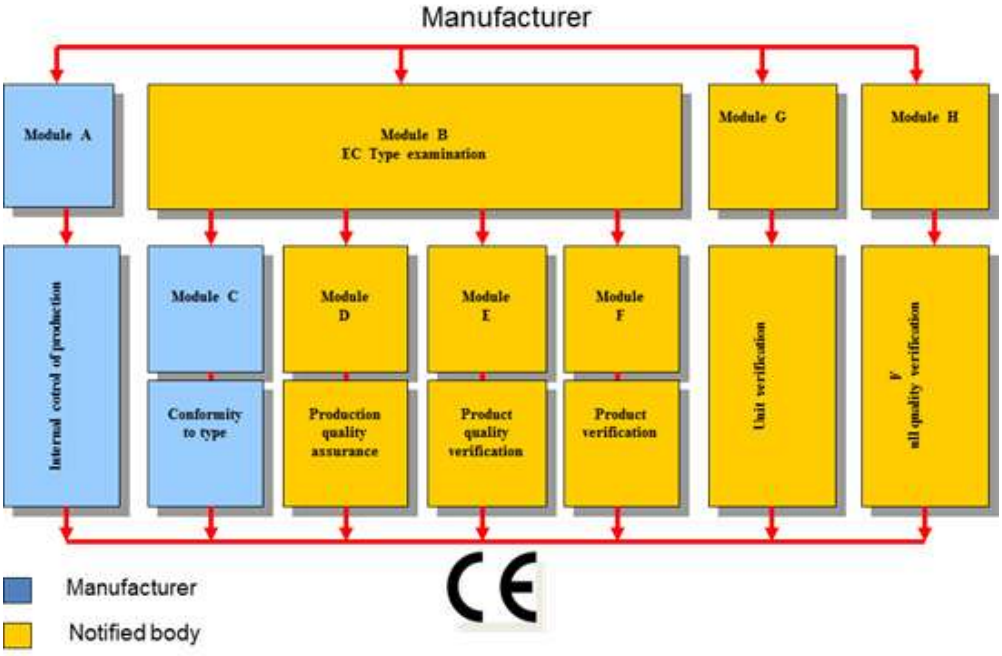

Figure 1: The Involvement Of A Notified Body To Conformity Assessment

Source: European Commission Blue Guide 2000.

In the simple cases, the manufacturer issues a declaration of conformity based on his documentation. If a Notified Body is involved, this body issues the documentation as a certificate or similar as attachment to the manufacturers declaration. Likewise this process underlines the responsibility of the manufacturer in the conformity assessment procedure. In any case the manufacturer shall keep a technical dossier available for control in order to prove the conformity to a given technical specification.

2.4.2. Notified Bodies

Notified bodies are the accredited and/or designated bodies who are judged by Member States in their territory to be competent to make the necessary assessment of the products whenever the conformity assessment procedure calls for the third-

party's involvement for the CE marking (CEOC, 2002). It shall be emphasized that the directives do not require a notified body to be accredited, but leaves it to the relevant authorities in the Member States to designate the notified bodies.

New Approach Notified and Designated Organizations are listed in Commission's web page "NANDO". Presently there are 1674 active Notified Bodies covering 24 Directive, 1 Regulation and 1 Decision[16] (European Commission, 2011). The principles of notification are explained in "Guide to the Implementation of Directives Based on the New Approach and the Global Approach" which is a European Commission's document published in 11 EU official languages. According to the Guide, notified bodies carry out the conformity assessment activities referred to in the applicable new approach directive when a third party is required. Member stated are responsible for their notification according to the principles of Decision 93/465/EEC (European Commission, 2000).

The requirements for the Notified Bodies may show alteration in each "New Approach" Directive but in general the Notified Bodies must examine the safety component to check its adequacy in terms of the technical dossier and perform the other tests to check whether the safety component meet the requirement of the relevant Directive. For instance in the Directive 95/16/EC, if the safety components comply with the provisions of the Directive, the notified body issues an EC type-examination certificate to the applicant. Lastly each Notified Body must inform the

[16]335 of them are from Germany, 304 of them are from Italy, 228 of them are from United Kingdom and 21of them are from Turkey.

Member States on the EC type-examination certificates issued and EC type-examination certificates withdrawn[17] (European Council, 1995).

The independence, impartiality and integrity of the Notified Body are the basic principles that are explained by European Co-Operation for Accreditation's Guidance and According to *impartiality* principle the Notified Body cannot be a part of a relationship which based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing and payment of a sales commission or other inducements for the referral of new clients with the external organizations that subject to assessment. A Notified Body shall be *independent* from the organization or the product it assesses (European Cooperation for Accreditation, 2009). Notified bodies shall carry out the conformity assessment activities with the *integrity* and must be free from all pressures and inducements. Their judgment or the results of their conformity assessment activities should not influence from persons with an interest in the results of those activities. (European Cooperation for Accreditation, 2009)

2.4.3. Affixing the CE mark

The CE mark is the positive result of the conformity assessment procedures and symbolizes the conformity of the product to a given technical specification. When it is affixed to a product it confirms that all applicable provisions are fulfilled. The CE mark is mandatory and must be affixed before the product is placed on the market or put into service. Besides, the second hand products which are imported from third countries or modified products are subject to CE marking. If a product is not covered

[17] OJ L 213 , 07/09/1995 P. 0001 - 0031

by a specific directive, it may not be CE marked. National voluntary marks and certificates may apply in such cases, but they must not be confused with the CE marking. Apart from the CE mark, the EU Member States shall prohibit affixing any other conformity mark (CEOC, 2000).

The responsibilities for the conformity declaration and affixing the CE mark in control off:

- The manufacturer and / or his employees,
- His authorized representative (if any)
- The importer,
- The distributor,
- The assembler,
- The installer (European Commission, 2000)

2.5. Accreditation

The national accreditation bodies are the superior institutions which are in charge of evaluation of conformity assessment bodies. This means that all policies, procedures and instructions are subject to evaluation and control as well as the competence of the employees and their integrity and impartiality. The national accreditation bodies evaluate conformity assessment bodies if they are competent to carry out a specific conformity assessment activity, and issue accreditation certificates to prove it related to relevant standards. The conformity assessment bodies shall be accredited within their scope of activities in order to provide assessment services (Delaney, 2008). Accreditation ensures that testing laboratories, inspection bodies and certification bodies follow and implement the relevant accreditation standards. The conformity

assessment bodies have to apply the globally accepted requirements. Accordingly, all the national accreditation bodies have to apply the same rules and procedures to conformity assessment bodies in order to establish a global acceptance of the service.

The European Cooperation for Accreditation (EA) is the European network of nationally recognized accreditation bodies located in the European geographical area. EA is a nonprofit association which was founded in November 1997 (EA, 2010). EA builds consistency by defining and harmonizing the accreditation standards. By maintaining the multilateral agreements (MLA) on mutual recognition between accreditation agencies, EA harmonizes the accredited conformity assessment bodies. Multi Lateral Agreements (MLA) are signed between the members of EA. Presently there are 33 EA Members. The complete list of the EA members is shown in Appendix B. The MLA signatories accept that the accredited certification activities are valid across Europe, thus all the accreditation is regarded as reliable by definition. MLA agreements ensure that a certificate which is issued in one Member States is valid in other Member States (European Council, 2008). Therefore the notified bodies and conformity assessment bodies do not need to be accredited in each country where they provide their services. The National Accreditation Body's mark on test reports guarantee the testing service is provided by an accredited laboratory. Additionally, the EA-MLA is recognized at international level by The International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF). As a consequence, the EA-MLA signatories are also recognized by the signatories of the ILAC, thus, it facilitates not only European free trade both also international trade.

EA confirms the transparency of the operations performed by national accreditation bodies by managing a peer evaluation system. National accreditation agencies are monitored on their accreditation practices. EA can give consultancy for technical matters related to the implementation of the EU accreditation policy. According to Regulation 765/2008[18] the national accreditation bodies must work as a public authority and operate on a nonprofit basis and shall not provide consultancy services to an individual conformity assessment body. National accreditation bodies shall establish appropriate structures to ensure the equal involvement of all parties and has no financial and managerial interest in any conformity assessment body (European Council, 2008). The national accreditation bodies are allowed to operate across national borders but they should not compete with other national accreditation bodies (European Council, 2008).

2.6. Metrology

King Henry's foot had been used for many years as a unit of measurement but on May 20th, 1875 the International Bureau of Weights and Measures was established in the Convention of the Metre (BIPM, 2010). The Convention has been signed between 17 countries as a result these countries have received a sample of "meter" and "kilogram". These units have started to be used as standards measuring units.

Furthermore, accuracy of measurement, and standards of measuring units are important components of testing standards. Metrology is the science measurement and separated into three categories (Bewoor, 2009):

[18] OJ L 218, 13/08/2008, P.30-47

- Scientific Metrology
- Industrial Metrology
- Legal Metrology

Scientific Metrology studies the measurement standards and supports the development of standards. Industrial Metrology assures that the measuring instruments used in the industry works adequate and are calibrated to international standards. Legal Metrology is concerned with the accuracy of measurements in economic, health and safety perspective (Bewoor, 2009).

2.6.1. Scientific Metrology

European countries use the same units of measurements: the International System of Units (abbreviated SI from French). The European Association of National Metrology Institutes (EURAMET) carries out the scientific metrology by providing support to scientific research. EURAMET coordinates the cooperation of National Metrology Institutes. EURAMET supports economic competitiveness, quality of manufacturing, and free trade. Through the EuropeAid Projects and Twinning Programmes, European Commission provides technical assistance to EURAMET members. EURAMET strengthens the cooperation of its members with EA in areas of common interest associated with accreditation (EURAMET, 2011a). Traceability and reliability are the most important criteria for international acceptance of measurements (Badadhe, 2006).

EURAMET has 12 Technical Committees which are the forum for scientific and technical cooperation in the respective fields, such as: acoustics, ultrasound,

electricity and magnetism, length, mass, radiometry, thermometry, time, frequency and etc. (EURAMET, 2011b).

2.6.2. Legal Metrology

Western European Legal Metrology Cooperation (WELMEC) was established in June 8th, 1990 with a Memorandum of Understanding (WELMEC, 1990). It coordinates the European national authorities of legal metrology. The aim of WELMEC is to facilitate the exchange of information and experience to harmonize the regulations and promote mutual recognitions (Placko, 2006). Currently there are 30 Members and 7 Associated Members in the WELMEC Committee. The list of the members of WELMEC was shown in the Appendix C.

Currently WELMEC has 7 Working Groups which provide guidance documents about legal metrology:

- WG2: Directive Implementation (2009/23/EC)
- WG5: Metrological Supervision
- WG6: Prepackages
- WG7: Software
- WG8: Measuring Instruments Directive
- WG10: Measuring Equipment for Liquids Other Than Water
- WG11: Utility Meters

The guidance documents which these groups have produced are listed in Appendix D. Besides Working Groups, WELMEC support the exchange of information between WELMEC members. WELMEC provides cooperation and, promotes the

harmonization of Directives. Legal metrology institutions do not study scientific measurement; their aim is to develop technical and administrative procedures by establishing laws. Therefore the legal metrology institutions are public authorities and assure the quality of measurements in relation to health and safety.

2.7. Concluding Remarks

With reference to general definitions and exploring the links between the components (standardization, conformity assessment, accreditation and metrology) the quality infrastructure in Europe was explained in this chapter. Figure 3 shows the relationship between the institutions.

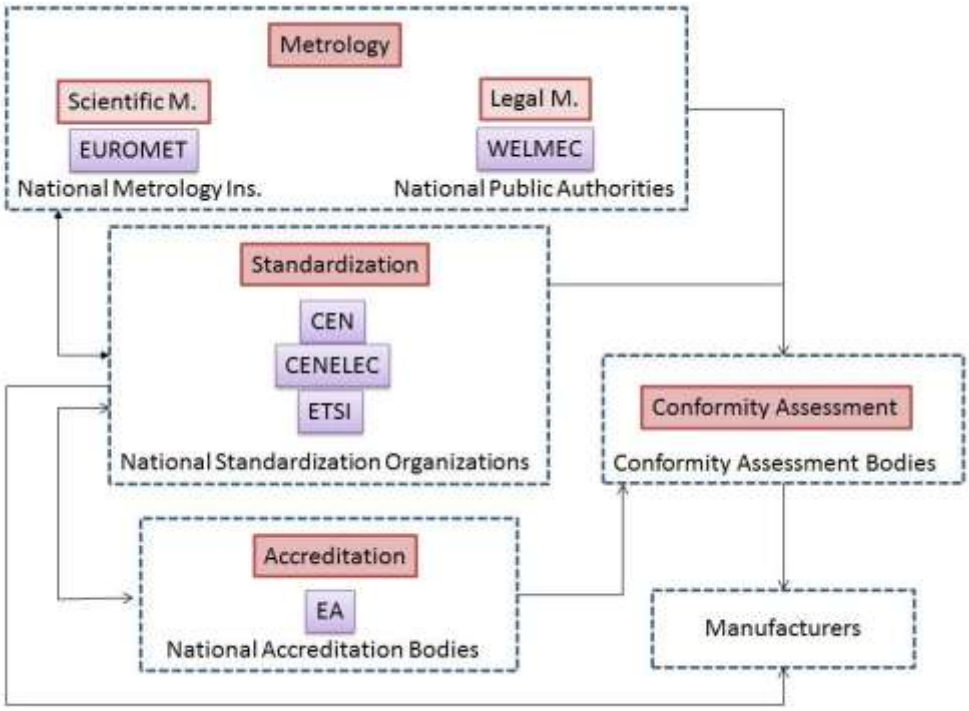

Figure 2: Relations Between European Infrastructure Actors

Source: The figure is made by the author.

The quality infrastructure system is an interactive system, including standardization bodies, CABs, accreditation bodies and metrology institutions. The manufacturer who stands on the center of the structure receives support from standards in order to produce his product. Standards are prepared by the standardization bodies through the instruments of metrology. CABs use the standards performing conformity assessment activities. Finally, accreditation bodies need standards to run their function.

There is an upper structure in order to coordinate the national quality infrastructure actors in European level. The European quality infrastructure system was established to manage the technical barriers and enable the free movement of goods within European Member States.

The European organizations such as CEN, CENELEC and EA were introduced in detail. The Commission regulations for these committees and associations are vital for the success of the implementation of Turkish quality infrastructure. In the next chapter the importance of the EU harmonization will be discussed and the national actors of Turkish quality infrastructure system will be explained.

CHAPTER 3

TURKISH INDUSTRY AND QUALITY INFRASTRUCTURE

3.1. Turkey and the European Union Relations

Turkey and the EU have strong trade relations based on long term commitments to improve relations and industrial development. Turkey made the first application to join the European Economic Community in July 1959 (MoEUA, 2011). The Ankara Agreement which entered into force on 1 December 1964 introduced the provision of legal harmonization. The Additional Protocol of 13 November 1970 was also supported the harmonization of Turkish legislation (MoE, 2011a). Turkey applied for full membership in 1987 and continued to carry out the provisions.

On 6 March 1995 the Turkey-EU Association Council adopted the Decision 1/95 on the completion of the Customs Union between Turkey and the EU in industrial and processed agricultural goods (The EC-Turkey Association Council, 1995). Turkey is started to process of harmonizing its laws with the EU legislation to eliminate the technical barrier to trade. The cooperation between Turkey and the EU in the fields of quality infrastructure has also started with Decision 1/95. Ministry of Economy announces that 80% of the EU legislation has been adopted by the relevant Turkish public authorities in scope of Decision 2/97 of Turkey-EU Association Council (MoE, 2011b). The Decision 2/97 lays down the rules of product safety as well as the abolishment of the technical barrier to trade. On 10-11 December 1999 in the Helsinki European Council, Turkey was declared as a “candidate” country to the EU.

The harmonization process has gained speed after this progress. Another Association Council decision has been taken in order to guarantee the elimination of technical barriers to trade. Decision 1/2006 of the EC-Turkey Association Council of 15 May 2006 has introduced the assessment of technical legislation and notification of Turkish conformity assessment bodies (The EC-Turkey Association Council, 2006). In consequence Turkey has strengthened the relations with the EU significantly.

Turkey has a large population, over 73 million (TÜİK, 2011) and GDP over $735 billion (TÜİK, 2011) and is also located in a strategic geographical position on the South-East border of Europe. According to Turkish Statistical Institute's foreign trade statistics, Turkey and the EU have a deep trade relationship. The EU ranks number one in both Turkey's imports and exports. Figure 3 shows the volume of trade between the EU and Turkey. When the years 2000-2011 is examined, it can be seen that there is an increasing trade trend between Turkey and the EU Member States. In 2000, the export to the EU was valued at $15.6 billion, in a three year period the amount was almost doubled. In 2008, the highest export volume has been realized as $63,4 billion. A similar picture can be seen for the import figures. The import volume has been increased tremendously till 2003. In 2003 the import from the EU was valued at $35 billion. It continued increasing till 2009. After a sharp fall in 2009 from $74.4 billion to $56.6 billion, the import volume has started to increase in 2010. As a result the trade between Turkey and EU Member States continues to rise consistently.

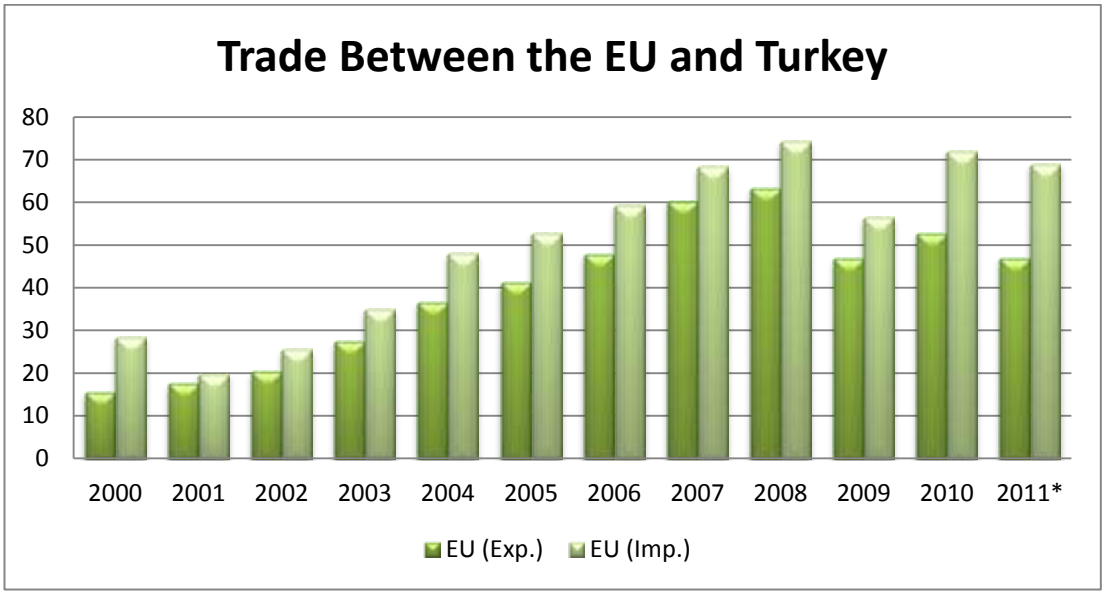

Figure 3: Trade Between The EU And Turkey

Source: http://www.turkstat.gov.tr/VeriBilgi.do?tb_id=12&ust_id=4

The Helsinki European Council recognized Turkey as a candidate for membership to the EU (European Council, 1999). The Customs Union Decision 1/95[19] between the EU and Turkey governs the area of Free Movement of Goods between Turkey and the EU and supplemented by an Accession Partnership (The EC-Turkey Association Council, 1996). The development of quality institutions - including standardization, metrology, accreditation, conformity assessment, and market surveillance - is crucial to help Turkish enterprises improve their capacity to reach export markets and support economic growth. Turkey has the duty to approximate the whole body of the EU legislation known as the "*Acquis Communautaire*". Therefore Turkey is supposed to finalize the harmonization of its technical legislation.

[19] OJ L 35, 13/02/1996 P. 0001 - 0047

3.2. Technical Legislative Alignment on Quality Infrastructure

Custom Union came into effect on 1 January 1996 with the Decision 1/95 between Turkey and the EU by the removal of custom duties, quantity restrictions and other related taxes for industrial products and processed agricultural products in the trade with the EU Member States (The EC-Turkey Association Council, 1996). However, abolition of custom duties, taxes and quantity restrictions (in short, fiscal barriers) were not sufficient enough for the free movement of goods; therefore Turkey needs to make legislative alignment to remove the technical barriers to trade. The implementation process was determined in the Decision 2/97 of Association Council[20] the public authorities who were responsible for the alignment of technical tools were elected with the law under the coordination of Undersecretariat of Foreign Trade[21] (The EC-Turkey Association Council, 1997).

On 11 July 2001, Turkey prepared the Law No. 4703 on the Preparation and Implementation of the Technical Legislation on the Products which lays down the rules relevant to general product safety and horizontal aspects of all technical regulations including: sectoral "New Approach" Directives, sectoral "Old Approach" Directives and those in the non-harmonized areas[22] (TBMM, 2001). The EU product legislation is the combination of the "New Approach" Directives, (machinery, toys, medical devices, etc.), the "Old Approach" Directives (food, automotive, cosmetics, etc.) and the non-harmonized area (furniture, bicycles, etc.).

[20] OJ L 191, 21/07/1997,P. 001-067

[21] The UFT became the Ministry of Economy in 2011.

[22] Official Gazette No 24459, 11/07/2011

In the non-harmonized area, the products are not covered by the common EU legislation; therefore Member States can make their own regulations. The objective of Law No.4703 is to clarify the lay down the rules and procedures for:

- conformity assessment,
- notified bodies,
- affixing and use of the CE mark,
- market surveillance.

It also regulates the notification of the technical legislation and standards between Turkey and the EU (Bayram & Şirinoğlu, 2008). Undersecretariat of Foreign Trade which was founded in 1983 was in charge of the preparation of the by-laws by taking the advice of the relevant public authorities (MoE, 2011c). Ministry of Industry and Trade[23] is responsible of the implementation of the Law No. 4703. The public bodies which are authorized by other laws are shown Appendix E.

With respect to the regulations supporting the quality infrastructure the main horizontal legislation is in place and many product-specific regulations have been drafted. A number of regulations supporting the New Approach still need to be transposed and the necessary conformity assessment bodies (Notified Bodies) assessed and appointed.

3.2.1. Mutual Recognition Agreements

As it was discussed in the first chapter, there are some products that are not covered by the EU legislation or even in case they are covered by the EU

[23] The Ministry of Industry and Trade became the Ministry of Science, Industry and Technology in 2011.

legislation, they are inapplicable to the common regulation. Member States are free to make their national regulations for these products. Decision 2/97 of Association Council lays down the rule of obligation of "mutual recognition" in non-harmonized area for the EU and Turkey. "Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition"[24] states that Turkish products must be subject to the same procedures with member state oriented products in non-harmonized area (European Commission, 2003b). It protects the goods which are produced in Turkey by not allowing any inspection at custom services of the Community. The Member States should lay down conditions of recognition of Turkish products in non-harmonized area (TAPDK, 2008). The Mutual Recognition Regulation will apply when all the following conditions are met (European Commision, 2010):

> The (intended) administrative decision must concern a product lawfully marketed in another Member State
>
> The (intended) administrative decision must concern a product which is not subject to harmonized EU law
>
> The (intended) administrative decision must be addressed to an economic operator
>
> The (intended) administrative decision must be based on a technical rule

The Articles 28, 29 and 30 of Treaty Establishing European Community[25] regulates the supplying of goods without any barriers, and Turkish manufacturers and importers are simply protected from the violation of these articles (European

[24] OJ C 265, 04/11/2003, P 002-016

[25] OJ C 325, 22/12/2002, P 33

Commission, 2002). It was mentioned that both Turkish goods and the EU goods should come across with the same procedures in non-harmonized area and should not be inspected in any condition.

Since the "mutual recognition" principle has been agreed between the EU and Turkey in non-harmonized area, the "notification system" by sector is established. The public authorities publish the "legislation regulation notification list" consists of draft regulations in non-harmonized area sent by European Commission to the Ministry of Economy.

3.3. Quality Infrastructure Institutions in Turkish Industry

3.3.1. Turkish Standards Institution (TSE)

The Turkish Standards Institution was established in 1960 by the law numbered 132[26] for drawing up standards for every kind of product, service and procedure (TBMM, 1960). TSE is a public founding institute however conducted according to the special rules of law and has a juristic personality. TSE represents the Turkish standardization system on national and international level as a full member of ISO/IEC and CEN/CENELEC. TSE applied to CEN/CENELEC for full membership and inspection was completed in January 2011. The European Committee for Standardization and the European Committee for Electrotechnical Standardization have both decided to grant full membership status to the Turkish Standards Institution (CEN/CENELEC, 2011). CEN and CENELEC will have 32 members, covering more than 590 million consumers in total.

[26] Official Gazzette 10661, 18/11/1960

Two different functions are implemented under TSE trade mark: Standardization and Certification. The organization schema of TSE is shown in Appendix F. In this section standardization tasks will be illuminated. TSE is also performing in the certification area, and does inspection activities as well. TSE's certification activities will be represented in the "Conformity Assessment Bodies" section.

TSE has a standardization body named "TSE Standards Preparatory Department" responsible for establishing a committee which drafts the proposed standards. TSE publishes the standards when they are accepted and approved. TSE standards (National Standards) are voluntary and can be made compulsory by the approval of the relevant ministry. It is TSE's duty to prepare the standards upon the request of private and public sector. TSE collaborates with the technical institutions, universities and other research centers to prepare standards.

3.3.1.1. The Preparation of Standards

The process of developing standards can be explained in 5 stages:

1. Preparation of the programme: At the beginning of every year, TSE sends a questionnaire to all parties to collect the information regarding their standardization needs. At this stage parties send their requests for registering a new work item. A new work could easily be accepted, the only requirement is supplying a preliminary draft in 2 months.
2. Approval of the programme: The General Assembly approves the registered programmes and organizes each programme as a project to "Standards Preparatory Department".

3. Preparation of the draft: Each Standards Preparatory Group works on the selected programme and prepares a draft standard.
4. Circulation of the draft standard: The draft standard is sent by TSE to the interested parties. At least in 2 months period the feedbacks are collected by TSE and announced on the web site.
5. Preparation of the final draft: Standards Preparatory Department prepares the final draft of the standards based on the comments.
6. Approval: The final draft is approved by National Technical Board and it is announced as a Turkish Standard (Usta, 2010).

3.3.1.2. National Technical Committees

National Technical Committees consist of part time experts who are experienced in their fields; they must be representatives from universities, private and public sector. There are 22 National Technical Committees in TSE and 87 national experts working on Turkish Standards (Usta, 2010). "Specialized Boards" of TSE are in charge of the preparation of national Turkish Standards, coordinate the Technical Committees. The draft standards which are prepared by Specialized Boards should be discussed among all parties (i.e. manufacturers, customers, and university staff). The sectors that have been covered by TSE are shown in Table 4:

Table 4: The Sectors Which Are Covered By National Standards

Mining	Electronics	Manufactured food
Environment	Service standards	Agriculture
Electric	Construction	Metallurgy group
Health	Chemistry	Authorized services standards
National defence industry	Petro chemistry	Textile
Engineering services	Petroleum	Machinery
Information Technology and Communication	Installation and pressurized vessels committee	Electro technical safety committee
Forest and forest products		

Source: http://www.tse.org.tr/turkish/standard/ihtisasgruplari.htm

3.3.1.3. Mirror Technical Committees

TSE is the member of international standardization organizations (ISO/IEC); and European standardization organizations (CEN/CENELEC). Therefore, it is TSE's responsibility to work with the standardization committees of these organizations for the preparation of standards. As it was indicated, the most important fact is the national consensus on the standards. With this approach TSE is legally responsible for the coordination of the stakeholders' contributions (private sector, NGOs, customers, etc.) about the standards. For this purpose, Mirror Technical Committees work parallel with international and European technical committees. Mirror Committees were founded in 2004 and TSE is in charge of establishing new committees in line with the demands (Bektaş, 2010). Information about the

development in certain sectors have passed through the TSE to Mirror Committees, in the meanwhile, TSE performs as the secretariat of these Mirror Committees. In the Appendix G the active Mirror Committees are shown. In principle, both Mirror Committees and National Technical Committees are working on the same standards. It is waste of time and source to have two separate committees. Subsequently, operating the coordination between two different working groups is not easy and coherent. The Technical Committee and Mirror Committees should work in parallel. 183 International and European Technical Committees and 71 Mirror Committees covering 20 sector are working by October 2011 (Usta, 2010).

TSE is performing as the secretariat of ISO Committees for "Leaf tobacco" and "Food products" (ISO/TC 126/SC 2 and ISO/TC 34/SC 14) and a member of Executive Committee of IEC System for Conformity Testing to Standard for Safety of Electrical Equipment since 1990 (ISO, 2011b). TSE is a full member of Certification Bodies Scheme in recognition of the need to facilitate international trade in electrical equipment, primarily intended for use in homes and offices and is responsible to give Certificate for Testing for this equipment (TSE, 2011).

For the purpose of promoting harmonization and removing the technical barriers to free trade, the TSE is responsible to withdraw national standards if there is an EU standard dealing with the same subject. TSE informs the relevant ministry about the revision of mandatory standard and replacement with the EU standard. TSE is also in charge of announcing the "withdrawn standard" on its website. The ministries are in charge of the regulations of the old and new approach directives and limit the number of mandatory standards because the major principle of standards is its

voluntary basis. Figure 4 shows the process of withdrawing national standards, replacement with the European standard, and the reflection of this change to the mandatory standards.

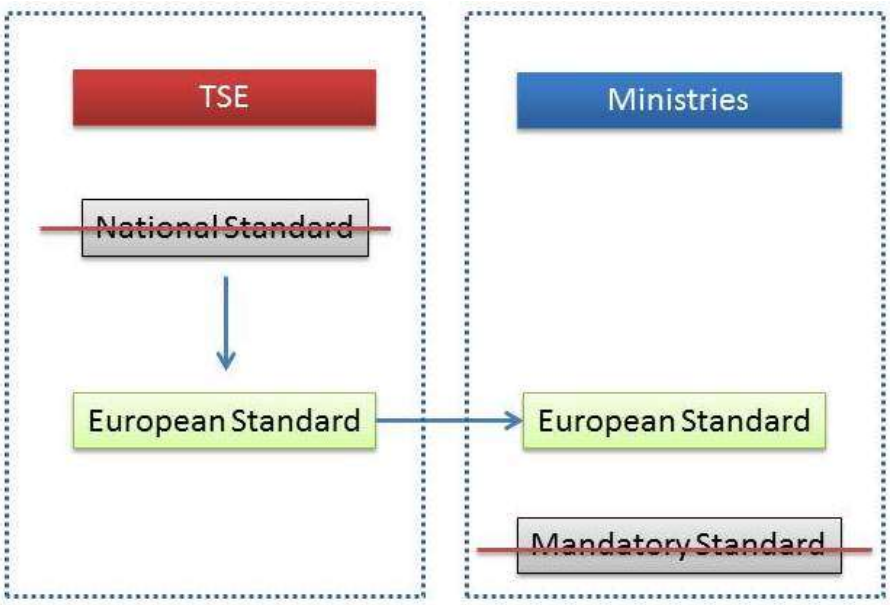

Figure 4: Process of Replacement the National Standards with European Standards

Source: The figure is prepared by the author.

Ministries are also responsible of adaptation the European Standards. "The Regulation on the Notification of the Technical Legislation between Turkey and EU" is the substantial document for implementation of notification. The related ministries and the other public authorities are shown in the Table 4 with the areas of their responsibility.

Table 4: Public Authorities And The Fields Of Their Responsibility

Public Authorities	**Areas of Responsibility**
MoSIT	Motor Vehicles, Agricultural and Forestry Tractors, Legal Metrology and Pre-packaging, Electrical Risk and Electrical Equipment and other product groups such as machinery, lifts or pressure vessels, transportable pressure equipment, explosives for civil uses, Energy, Environment/Air Quality, Environment/Noise Emission, Environment/Climate Change.
ICTA[27]	ETSI Standards and IT safety
MoH	Toys, medical devices, implantable medical devices, in vitro diagnostic medical devices, cosmetics, detergents, ionizing radiation
MoFAL	Codex Alimentarius [28]
UMA	Recreational crafts
MoEUP	Construction products
MoLSS	Personal protective equipment

Source: The table is prepared by the author according to information from the Decision 1/96

[27] The Information and Communication Technologies Authority, is member of ETSI (European Telecommunication Standards Institute) and member of ITU. (International Telecommunication Union)

[28] The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations. For detailed information please see: http://www.codexalimentarius.net/web/index_en.jsp

3.3.2. Conformity Assessment Bodies

Conformity assessment is the process of demonstrating requirements relating to a product, service, system, and person have been fulfilled according to the EU legislation. Conformity Assessment Bodies are the actors who perform testing, inspections, calibration and certification. The substantial clients of conformity bodies are manufacturers. A conformity assessment body must be accredited in order to perform conformity activities. When the conformity assessment bodies are approved by the Authorized Bodies (relevant public authority) they designate as a Notified Body. The first three Conformity Assessment Bodies designated in Turkey by the end of 2006 with the EC-Turkey Association Council Decision 2006/54/EC[29] (The EC-Turkey Association Council, 2006). The number of conformity assessment bodies is on the rise in Turkey and the designation of Notified Bodies, will continue until the national capacity has been realized.

Authorized Bodies, (in Turkey, they are generally ministries) are effectively work with the EU Member State Government Departments which are responsible for overseeing legislation for a particular sector. Besides approving conformity assessment bodies as Notified Bodies, Authorized Bodies are also in charge of drafting and transposing regulations, and consulting with stakeholders on the new regulation. Authorized Bodies propose new Notified Bodies to the European Commission. Furthermore, Authorized Bodies present opinion on difficulties, improvements and amendments to EU legislation and directives. Above all

[29] OJ L 271, 30/09/2006, P 058-060

Authorized Bodies issue national guidance and ensure the standardization adequately supports the legislation (Greenaway, 2011).

Turkey has 21 Notified Bodies work in 13 different New Approach Directives (European Commission, 2012). The list of Notified Bodies and the Directives which are covered by them is shown in Table 4. In the next chapter there will be a detailed discussion about the competence of Notified Bodies in Turkey.

Table 4: Notified Bodies From Turkey And The New Approach Directives

NB No.	Body	Total Notification	Toys	Construction Products	Personal Protection Equipment	Hot Water Boilers	Medical Devices	Recreational Crafts	Lifts	Pressure Equipment	Machinery	Simple Pressure Vessels	App. burning gaseous fuels	In vitro diagnostic med. dev.	Non-automatic weighing ins.	Equipment and protective s. intended for use in P.E.A.
1783	TSE	9		•	•	•	•		•	•			•	•	•	
1784	TCMA-CQE	1		•												
1785	Türk Loydu	5				•		•		•		•	•			
1984	MEYER	6		•			•		•	•	•		•			
2022	TMMOB Asansör Kontrol Merkezi	1							•							
2055	THBB	1		•												
2138	Alberk QA	5		•			•		•	•	•					
2159	S & Q MART	4				•				•		•	•			
2163	Universal C.S.S.T. Ltd. Co.	2		•	•											
2164	TEBAR A.S.	1		•												
2179	Kalitest Bel.Egit.Hiz. Ltd. Sti.	3		•			•		•							
2184	ERA A.Ş.	1		•												
2195	Szutest Ltd.	7		•		•	•		•	•	•		•			
2218	SGS A.Ş.	1									•					
2271	Standart B.D.M.T..K..Ltd. Şti.	1		•												
2284	IEP Ltd.Şti.	1														•
2287	Bureau Veritas Ltd.Şti	2								•		•				
2292	UDEM A.Ş.	3					•		•		•					
2336	SCA A.Ş.	1														•
2344	BVA	1		•												
2354	TUV	1										•				
	Total number of bodies operating for the directive	57	0	12	2	4	6	1	7	7	5	4	5	1	1	2

Source:http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=country.notifiedbody&cou_id=792

All of the Notified Bodies are conformity assessment body but not all the conformity bodies are Notified Body. In Turkey there plenty of conformity assessment bodies

perform testing and certification and they are potential Notified Bodies. Table 5 shows the numbers of conformity assessment bodies in Turkey[30]:

Table 5: Conformity Assessment Bodies Accredited To TÜRKAK

Type of Body	**Number of Bodies**
Testing Laboratories	354
Calibration Laboratories	67
Inspection Bodies	74
Quality System Certification Bodies	52
Environmental Management System Certification Bodies	39
Food Safety Management System Certification Bodies	16
Medical Devices Management System Certification Bodies	5
Information Security Management System Certification Bodies	5
Product Certification Bodies	27
Person Certification Bodies	14
Medical Laboratories	3

Source: http://www.turkak.org.tr

In fact the number of accredited laboratories is far beyond European counterparts. For instance, the number of accredited testing laboratories in the United Kingdom is 1483, and the number of accredited calibration laboratories is 478. (UKAS, 2012). The total number of the accredited laboratories in Europe is approximately 15.000

[30] http://www.turkak.org.tr/online/search/akredite.asp

(EA, 2012), and only 2,8% of them are Turkish accredited laboratories. The number of accredited laboratories must increase in order to satisfy the market needs.

With regard to build credibility for the conformity assessment bodies Association of Conformity Assessment Bodies (UDDer) was established in 2006 as a consequence of "Support to the Quality Infrastructure in Turkey Project"[31]. As a non-governmental organization, UDDer's purpose is to gather the public and private sector in the field of conformity assessment and increase the credibility and efficiency of conformity assessment bodies in Turkey. UDDer's aim is to develop cooperation among its members for the legislation issues and provide flow of information about the progression in the International area (UDDER, 2007). There are 60 Conformity Assessment Bodies registered to UDDer.

National Marks

Conformity assessment bodies demonstrate that specified requirement relating to a product (or process, system and person) are fulfilled. In Turkey conformity assessment bodies deal with two other marks besides the CE mark: the TSE mark and the G mark. In fact only the CE mark guarantees *conformity* with the essential requirements in the EU (European Commission, 2000). Unfortunately there is confusion about the TSE mark and the CE mark; Turkish manufacturers do not know the importance of the CE mark and its procedures (Erkal & Konukseven, 2008).

CE marking is a result of being compliance with the EU directive in terms of standards and conformity assessment. TSE mark is a national quality mark.

[31] An EU funded MEDA Project.

Moreover the G mark was introduced my MoPWS[32] on 1 January 2008 as a national, compulsory safety mark[33], for the products which are not in the harmonized area or where CE mark could not be affix (MoPWS, 2006). There are several problems regarding TSE and G mark which will be held in Chapter 4 as well.

3.3.3. Turkish Accreditation Agency (TÜRKAK)

The Turkish Accreditation Agency is an institution in quality infrastructure, may not draw the attention of the average customers; since there is only an indirect link between the accreditation and the customer. It would be better to give an example through customer:

Lifts represent a good example for the accreditation process. The CE mark is mandatory for the lifts, and can be affix if the product covers the essential requirements of "European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts"[34]. This Directive is no longer than 10 pages which describes the responsibility of the designer, manufacturer, the one who places the product on market, affixes the CE marking and draws up the EC declaration of conformity (European Council, 1995). In addition to that the conformity procedure is explained in the same Directive's 8. Article by giving references to the Annexes, which includes EN standards. In conclusion, all lifts should bear the CE mark and a four digit number on a visible area. The CE mark proves that the lift's conformity assessment has been done by a

[32] Ministry of Public Works and Settlement became Minisrty of Environment and Urban Planning in 2011.

[33] Communiqué No: YİG-15/ 2006-07

[34] OJ L 213, 07/09/1995

notified body. The four digit number is the identification number of the related notified body. The notified bodies get the identification number when they accredited by an accreditation body. In Turkey, TÜRKAK provides an authoritative statement of the technical competence of bodies whose duty is to ensure conformity.

Turkish Accreditation Agency (TÜRKAK) was established in 1999 with the related Law No: 4457 for accreditation of the local and international bodies rendering laboratory, certification and inspection services. TÜRKAK ensure them to operate in accordance with established national and international standards, and thereby ensuring international recognition of product, service, system, personnel and laboratory certificates (TBMM, 1999). There were separate requirements for testing/calibration laboratories and certification bodies in terms of assessing and accrediting, but in 2004 the requirements have been merged in one standard EN ISO/IEC 17011 (TÜRKAK, 2011a).

The TÜRKAK law is very authoritative structure without defining the practical needs, just covers the internal market implementations (Yılmaz, 2011). The organization scheme of TÜRKAK is shown in Figure 5.

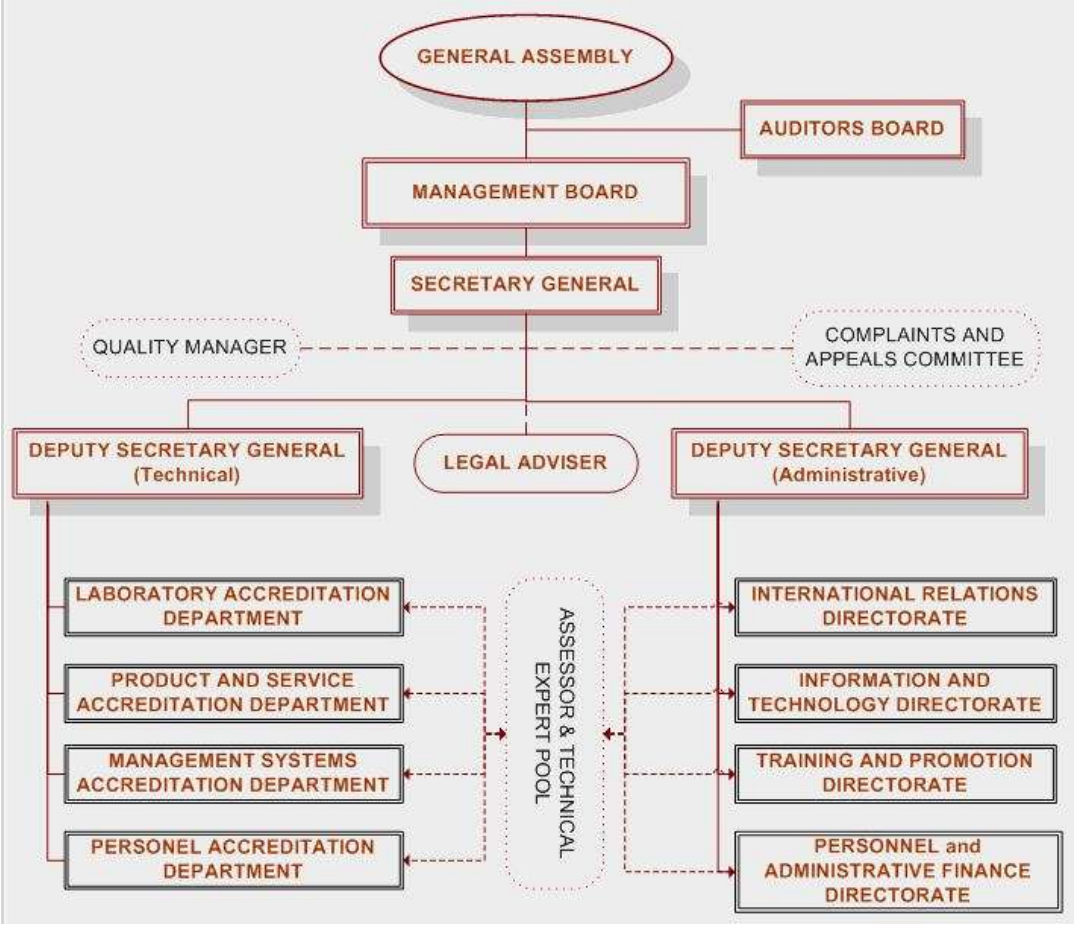

Figure 5: Organization Schema Of TÜRKAK

Source: http://www.turkak.org.tr/index.php/kurumsal,4,organizasyon_semasi

TÜRKAK is an affiliate of Ministry of Science, Industry and Technology. TÜRKAK's highest decision-making body is the General Assembly and there are 8 active departments in TÜRKAK. There is a majority of public sector representatives in TÜRKAK; board chairman is from Ministry of Science, Industry and Technology, deputy board chairman is from Ministry of Economy, one of the board members is from Ministry of Environment and Urban Planning, the other are from, TSE, KOSGEB, Istanbul Chamber of Industry and Aegean Chamber of Industry (TÜRKAK, 2012). As a conclusion this managerial structure does not promote private sector in TÜRKAK.

TÜRKAK has formally been appointed to assess the Turkish candidate notified bodies. The purpose of TÜRKAK is to provide evaluation to the conformity assessment bodies on their performance with objectivity and independently (TBMM, 1999). The Law describes TÜRKAK as a body who gains the resources but can only be paid from the services. However there are some conflicts about this item which will be discussed in the next chapter. If the body is not found to be competent, an accreditation certificate is not issued; there is no fine or legal sanction at all. Conformity assessment bodies are the clients of TÜRKAK, for this reason TÜRKAK should operate accurate and should be transparent for the fair competition among conformity assessment bodies.

Since 2008 TÜRKAK is a signatory of all the MLA agreements of EA (TÜRKAK, 2011b). These MLAs cover the areas of:

- test laboratories,
- calibration laboratories,
- quality system management,
- certification and inspection bodies,
- product certification,
- personnel certification,
- and environmental management systems certification (Greenaway, 2011)

There are several advantages of being a full member of EA and having international recognition, such as easier access to the European markets, having impact on the decisions of the international cooperation activities. Besides, Turkey can provide

accreditation service to the other countries which do not have accreditation body or have not become signatories of international MLA agreements yet. The scope of MLA is shown in Table 6. TÜRKAK will have to confirm the accreditation activities and to prove competence in assessment and accreditation for each of them.

Table 6: The Scope of MLA

Accreditation of laboratories	Testing, Calibration	ISO/IEC 17025
	Medical analyses	ISO 15189
Accreditation of certification bodies	Certification of products	EN 45011 (ISO/IEC Guide 65)
	Certification of persons	ISO/IEC 17024
	Certification of management systems	ISO/IEC 17021
Accreditation of inspection bodies	Inspection	ISO/IEC 17020

Source: http://www.european-accreditation.org/content/mla/what.htm

MLA provides confidence in the accuracy of the reports. The results of the accredited laboratories, certification bodies and inspections bodies are accepted by internationally without any review. The accreditation standard for laboratories are divided into two; ISO 17025 for testing and calibration laboratories and ISO 15189 for medical analyses laboratories. This division is a result of different procedures and requirements of the laboratories. This differentiation is also seen among certification bodies. Certification of products, persons and management systems rely on different accreditation standards.

In the framework of Regulation 765/2008, Turkey notified the Commission that TÜRKAK is the national accreditation body and listed in the Commission's national accreditation bodies, this means: Turkey operates accreditation through TÜRKAK and rely on the national accreditation body operates the accreditation as a public authority and concur it official recognition (European Council, 2008). Existing legislation covers the criteria on monitoring the CABs and non-conformity activities but there are several problems raised from the legislation which will be discussed in the Chapter 3.

The Law 4457 does not require TÜRKAK to undergo peer evaluations for all existing multilateral agreements; however The Parliament and Council of the EU adopted the EU Regulation 765/2008: "Requirements for Accreditation and Market Surveillance relating to the marketing of products" (European Council, 2008). This regulation establishes a legal framework for the provision of accreditation services in the EU. It lays down the rules of the organization and the operation of accreditation of Conformity Assessment Bodies in both voluntary and regulated sectors. The objective of this regulation is to create confidence in accredited certificates and to harmonize accreditation across the EU to ensure that one accreditation certificate is valid for the whole EU. This regulation took effect on 1 January 2010.

3.3.4. National Metrology Institution (UME) and MoSIT

3.3.4.1. National Metrology Institution (UME)

The Ottoman Empire was one of the 17 states who were the founders of the Meter Convention on 25 May 1875 (Taylor & Thompson, 2008). There was no significant development in metrology until the law of Weights and Measures has been put in act on 26 March 1931 (Uluatam, 2001). The volume of the market for calibrations was not large enough to justify a major investment in metrology until 1980. Scientific and Technical Research Council of Turkey (TÜBİTAK) established the National Metrology Institute (UME) in 1992 (UME, 2011). UME is in charge of establishing and maintaining national measurements standards in accordance with the SI Units and ensuring the traceability of national measurement standards to international standards. UME provides services to the laboratories in terms of consultancy on calibration and accreditation activities. UME contributes to research of measurement techniques which directly influences the metrology and calibration.

UME is a member of EURAMET, thus the countries who are the signatories of International Mutual Recognition Agreement recognize UME at international level. UME is accredited to TÜRKAK in both calibration and test services. UME is working on four groups of laboratories: mechanics, physics, electricity and chemistry (UME, 2012). Fluid mechanics, acoustics, mass, electromagnetic, optics, high voltage and organic analytic metrology laboratories are some of the sections which are included UME's working groups (UME, 2012).

3.3.4.2. Ministry of Science, Industry and Technology

Directorate General of Metrology and Standardization of Ministry of Science, Industry and Technology is in charge of "legal metrology". Former Ministry of Industry and Trade has become Ministry of Science, Industry and Technology on 06.04.2011 with the Law No: 6223 (MoSIT, 2011). After this change the responsibilities of MoSIT was described in detailed. MoSIT develops metrology policy, designs national strategies, and monitors its implementation. Preparing the technical regulations in the field of legal metrology and organizing the standards and market surveillance activities are in scope of MoSIT's tasks.

MoSIT defines the measurement instruments which are included in content of legal metrology. MoSIT constitutes the technical and administrative infrastructure for the traceability of these measurements. Adding to these, MoSIT makes regulations for the standards which are prepared by TSE. If there is no standard in the scope of legal metrology MoSIT is in charge of determining the requirements for assessment. It has been expected from MoSIT to establish strategies in metrology, standardization, accreditation and conformity assessment and to coordinate the relevant institutions on the implementation process. Legal metrology is also important for public health and safety. MoSIT organizes regular market surveillance activities to inspect the measurement devices regarding public interest, such as petrol pumps.

3.4. Concluding Remarks

In this chapter, the Turkish quality infrastructure actors in four main components (standardization, conformity assessment, accreditation, metrology) were described.

There is no missing link in Turkish system regarding the institutions that must exist in the European quality infrastructure.

- Standardization: TSE – Member of CEN/CENELEC
- Conformity Assessment: 21 Notified Bodies – Internationally recognized
- Accreditation: TÜRKAK – Member of EA
- Metrology: UME – Member of EUROMET, MoSIT – Member of WELMEC

However, these institutions do not correspond with the other European institutions completely, there are full of complexities and challenges. The findings of this chapter will be discussed in the following chapter. The low participation to standardization activities and the ineffectiveness of TSE in European standards preparation process will be pointed out in "standardization" section. The insufficient number of notified bodies, the dependence of TSE as a conformity assessment body, and poor awareness of the CE mark will be noted in the "conformity assessment" section. The incompatibility of the TÜRKAK law with the Regulation 765/2008 and the potential consequences of the conflicts will be indicated in the "accreditation" section. Finally, the problems in the scientific and legal metrology field will be explained individually in the "metrology" section in the third Chapter.

CHAPTER 4

HARMONIZATION PROBLEMS OF THE TURKISH QUALITY INFRASTRUCTURE

4.1. Problems in Standardization

In the previous chapter it was described that standardization is a task undertaken by the stakeholders and all the parties benefit in various ways. Therefore, it is an interactive process by the involvement of public and private sector, universities, associations, government and consumers. The desired expectation of this involvement is transparency for all the stakeholders and strengthening of consumers' confidence in products and services.

Unfortunately, not all of the public authorities have substantial relation with TSE in the area of standardization. ICTA cooperates with TSE as a member of some Technical Committees. However, the Ministry of Health could not adopt the directives on the safety of toys, medical devices, and cosmetics, even though MoH participates Technical Committees and Mirror Committees, Ministry of Food, Agriculture and Livestock was consulted by TSE for being a member of Mirror Committees but did not participate for the time being (Alan, 2012).

One of the weak sides of the Turkish standardization system is the low participation of stakeholders in standardization activities (SQIT, 2011). The negation of interest can be seen in other public authorities, such as UMA and Ministry of Labor and Social Security, the only involvement of UMA is commenting on draft standards for

enquiry, and Ministry of Labor and Social Security does not participate in TSE Mirror Committees and left the institutions alone in the international area (Alan, 2012). One of the good examples of participation of the public authorities to the standardization process is Ministry of Environment and Urban Planning. MoEUP is a member of TSE Standardization Board, and encourages manufacturers to join standardization tasks.

The participation problem is not only for the public authorities; private sector is also reluctant to join the standardization activities both in Technical Committee and Mirror Committee level. The individual firms do not participate the working committees and expect the chambers of commerce and the other professional associations act as an intermediary in the standardization process. It was followed up that after the financial support (covering travel and accommodation expenses) was stopped; private sector abandoned their participation in TSE Technical Committees significantly (SQIT, 2011). It must be underlined that most of the SMEs do not have the knowledge about the process, and they wait for an invitation from TSE. It is obvious that there is a lack of awareness about the standardization in Turkey (Alan, 2012). In addition, the consumer associations are not involved in the standardization process, although they are aware of the importance of their participation especially on hazardous and risky products for heath. The financial problems were pointed again for the consumers associations (Güzel, 2011).

As it was discussed in the previous chapter, TSE is responsible of withdrawing national standards and replacement with the EU standard by informing the relevant ministry about the revision. However the verification process of mandatory standards

and the withdrawal of them are not sufficient enough in compared with the EU Member States (Alan, 2012). This situation causes another harmonization problem in terms of manufacturing and international trade.

The European Commission's Turkey 2011 Progress Report underlines the harmonization problems in standardization (European Commission, 2011):

> "As regards horizontal measures, further progress can be reported in the area of standardization. The adoption of European standards by the Turkish Standards Institute (TSE) continued during the reporting period. TSE has so far adopted a total of 16,506 standards of the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). Turkey has so far harmonized a total of 377 standards of the European Telecommunication Standards Institute (ETSI). The overall rate of harmonization with European standards is around 98%. TSE is running 73 operational mirror committees. Stakeholder participation is a crucial aspect of voluntary standardization. TSE is encouraged to ensure more active participation by SMEs and consumers organizations in its standardization work. TSE underwent an assessment by CEN and CENELEC in 2010 for its full membership of this organization. The assessment is still ongoing with further exchange of documentation between the TSE and CEN. The revised law reflecting the new structure of TSE has not yet been adopted."

However, the application of TSE to become a full member of CEN and CENELEC has been formally accepted by the General Assemblies (CEN/CENELEC, 2011). Financially, technically and administratively TSE is not completely independent, especially TSE Standardization Preparatory Department is seen as a governmental body (TBMM AB Uyum Komisyonu, 2008). The process of revising the "Establishment Law of TSE" is still pending.

TSE was controlled in terms of reorganization, transparency and revision of working procedures. The amendments to the current legislation were submitted to the Turkish Grand National Assembly for enactment however it is still pending. Draft Law

Amending the Act No 132 for the Establishment of the Turkish Standards Institution intends to reflect a new structure for TSE. Turkey could not adapt the legislative framework of European Practices. TSE's current organizational structure is not flexible and there is no significant separation between standardization activities and conformity assessment (SQIT, 2011). It is extremely important because conformity assessment is a profit generating activity and TSE must be an equal actor with the other Conformity Assessment Bodies in conditions of free competition.

Full openness can only be achieved the participation of stakeholders in standardization work. Still, many modifications are needed to carry TSE to an equal level with the similar organizations in Europe. TSE must be financially, technically and administratively independent. Nonetheless being an affiliated organization of the Ministry of Science, Industry and Technology is damaging the independency of TSE. TSE must encourage the voluntary nature of standards by awareness rising among the relevant parties and establish new technical committees with the equal distribution of members among public, private sectors, universities and sector representatives (Alan, 2012).

TSE should generate commercial activities to inform the consumers, companies and other institutes about the services on European standards and advantages of participation the TSE standardization process. A network of standardization experts should be established for gathering the sufficient number of technical experts who are technically competent.

4.2. Problems in Conformity Assessment

4.2.1. Legislation

The transposition of Council Decisions 764/2008, 765/2008 and 768/2008 regarding CE marking, notification, accreditation, market surveillance, general product safety is being coordinated by Ministry of Economy. The legislation is implemented in Turkey but the consultation with stakeholders is limited. Ministry of Economy has already completed the legislation but industry, universities and consumers stayed out of these regulations. Unfortunately, during the adaptation period the new regulation brings new burdens on industry. One of the biggest problems of industry is not having an impact assessment, thus, the private sector feels desolated. In general, the Ministries tend to add more requirements rather than the standard itself and the process of designation could be more costly and time consuming (Adak, 2011). There is no clear difference between the accreditation and designation, the ministries tend to add more requirements for the process of designation, that brings extra cost and delay in the process for the potential notified bodies. The conclusion that can be drawn is that “designation” should be an “administrative verification procedure” after the accreditation has been carried out adequately, not a two phase process. Herein it is a questioning point of the transparency in terms of the roles of the Ministries and TÜRKAK. Instead of repetition in the process, Ministries must ensure the manufacturers and customers that there are distinctions between CE mark and other conformity marks.

4.2.2. Notified Bodies

For comparing the competence of Notified Bodies in Turkey, it would be better to have a benchmarking Notified Bodies against other Member States. Table 7 shows five different Member State's Notified Bodies. The selection criteria are different for each state. The United Kingdom is selected to present an example of an advanced state in the EU quality infrastructure system. The GDP of the Netherlands[35] is the closest value to GDP of Turkey[36] (IMF, 2011). Finally, Romania is one the most recent member state of the EU. The different selection criteria provide different comparison means.

Table 7: Benchmarking Notified Bodies

Country	Total NB	Toys	Construction Products	Personal Protect Equip	New Hot Water Boilers	Medical Devices	Recreational Craft	Lifts	Pressure Equipment	Machinery	Simple Pressure Vessels	Gas Appliances	Low Voltage	Electro-Magnetic Compatibility
U. Kingdom	228	4	52	15	6	6	4	7	25	19	9	6	20	26
Netherlands	68	1	41	1	1	1	3	4	10	7	1	1	4	6
Romania	33	0	20	2	1	1	0	2	4	5	5	1	2	0
Turkey	21	0	12	2	4	6	1	7	7	5	4	5	0	0

Source: http://ec.europa.eu/enterprise/newapproach/nando/

Turkey has 21 notified bodies, less than other Member States. In the field of construction products, Turkey has 12 notified bodies. One of the most important sectors in Turkey is construction, but even in this sector the number of notified bodies is less than other countries. For the toys directive, TSE was the only notified

[35] $783 billion.

[36] $741 billion.

body until August 2010. However, with the withdrawing of the TSE from that directive; there is eventually no notified body on this directive. This is not an indicator that there is no production in this field, but products without CE marking will come to the market and in a nutshell would likely to discredit Turkey (Skjernov, 2011). For machinery, having five notified bodies is insufficient for Turkish industry as Turkey attempts to become a major producer in heavy industry. Compared with Romania, Turkey has almost 5 times more GDP (IMF, 2011), but has the same number of notified bodies in this sector. For pressure equipment and simple pressure vessels, Turkey needs to expand the number of notified bodies and bring them at least to a reasonable level. For personal protective equipment, while Turkey has two notified bodies, the United Kingdom has 15. Among five different Member States, Turkey is the only one which has no notified bodies on low voltage directive. ICTA has some testing capacity for electro-magnetic compatibility but no notified bodies. It should be stated that almost all of the notified bodies are located in Istanbul and a few of them are in the Western part of Turkey; this is apparently not encouraging industrialization in other sides of Turkey. The dominance of TSE as a conformity assessment body is the main factor of the insufficient number of the notified bodies in Turkey. TSE has been working in the field alone for more than 50 years. Conformity assessment is a new concept for Turkish industry therefore entrance to the sector is beyond European level. Another factor is the high costs of being notified body and low profit rates compared with testing and certification activities (Skjernov, 2011).

As mentioned earlier; the basic principles for Notified Bodies are: independence, impartiality and integrity. As a Notified Body TSE has facing with problems on independence, because of being an affiliate of Ministry of Science, Industry and Technology. As TSE is an affiliate organization of MoSIT, TSE's conformity assessment department and Standards Preparatory Group has a relationship based on governance and management. The two departments are sharing resources and personnel. There is a unity in their finance and marketing. The management of TSE in such conditions is against impartiality principle.

4.2.3. The CE Marking

CE marking is still not very well known by the manufacturers and consumers. (Çelebi, 2011) There is no clarity about the differences between the CE mark and other quality marks (Dellaloğlu, 2006). The scope of the TSE mark differs from CE mark; CE mark covers the essential requirements in relevant directive, it is in the mandatory area and directly related with product safety. The impression in Turkey is that the CE mark is not sufficient, even though it addresses the health and safety (Hürriyet, 2011). This misimpression arises from the popularity of TSE mark which has been well known by Turkish consumers for many years. In the meantime, TSE mark is still a requirement in public procurement agreements, which strengthens the credibility of TSE mark. On the other hand TSE mark is a "quality mark" given by TSE certification; this is also leads to confusion in TSE's standardization activities.

TSE generates profit by selling the TSE mark. On 4 July 2011; TSE published a standard on "Halal Food" for considerations of maintaining a common sensibility among Muslim countries. After a research period, Standards and Metrology Institute

for the Islamic Countries has accepted Halal Standards (Halal World, 2011). It has been announced in TSE's web site and applications have started for these standards. This is an example of a standard, adopted by a national standards body and recognized within countries but does not necessarily have a direct link with safety and health. Halal Food might be very import for groups in a community and would like to be sure about the product, or method of production but the conformity mark on the product proves only conformity of the standard that has been agreed between the manufacturer and the certification body. Cooperation with Islamic Countries on standards is an alternative development for Turkish infrastructure system while struggling with the EU harmonization problems.

Like the TSE mark, the G Mark is also a different mark on construction products to substitute the CE mark in the non-harmonized area or in cases CE mark could not be applied. But a change is expected in a short time because the Construction Products Directive is implemented and the G mark should be abandoned where the directive become valid.

4.3. Problems in Accreditation

The biggest problem in accreditation field is that TÜRKAK is facing a risk of failing the EA peer evaluation (Alp, 2011). This risk is based on the legal gap between TÜRKAK Law and Regulation 765/2008 which regulates the accreditation activities in the EU (Malmqvist, 2011). Some of the conflicts between the TÜRKAK's structure and the ideal position which describes in Regulation 765/2008 are quite illuminating in this respect. First of all, as mentioned in Chapter 2, there is no clear

distinction in legislation for the activities that are run by Ministries and TÜRKAK. The item 4.6 in the Regulation 765/2008 explains that:

> "The responsibilities and tasks of the national accreditation body shall be clearly distinguished from those of other national authorities"

Ministries tend to add extra rules for the designation as Notified Body and enhance the assessment and accreditation process. In some of the ministries they have their own conformity assessment bodies which have to be accredited by TÜRKAK as other CABs, but being embedded in the Governmental organizations creates conflict of interest for TÜRKAK. TÜRKAK's independence is not clear, since Governmental bodies are active in its decision making process. Likewise Ministries can request from TÜRKAK to use a different set of competence requirements for conformity assessment bodies in mandatory sector (Skjernov, 2011). However the Article 3 is clear that the same accreditation process must be used for both compulsory and voluntary basis (European Council, 2008). Another item that is mentioned in the previous chapter was the financial status of TÜRKAK. In the establishment law[37] that TÜRKAK's income sources are listed as (TBMM, 1999):

- % 1 of the turn-over of the clients produced under accredited activities
- Fees covering the services
- Donations from the General Budget
- Aids and other donations
- Incomes of real estates

This is against the rule that "the national accreditation body shall operate on a not-for-profit basis" mentioned in the Article 4.7 (European Council, 2008). A close scrutiny reveals another problem concerning the Article 4.8, which prohibits the

[37] Official Gazette No 23866, 04/11/1999

national accreditation bodies to provide consultancy services. TÜRKAK has close relations with Ministry of Science, Industry and Technology, and the Ministry has its own conformity assessment bodies, (TSE is the biggest conformity assessment body in Turkey) and provides service to the Turkish industry. It seems that TÜRKAK provides consultancy service to a conformity assessment body individually. Of course, TÜRKAK can deliver general training courses on the requirements for accreditation or information seminars on ILAC, IAF and EA, but it must stay out for all the activities which can cause unfair competition (Skjernov, 2011).

As it was mentioned in the previous chapter, TÜRKAK's managerial structure is dominated by government bodies and ministry representatives in its General Assembly and Board of Director. It is in clear violation of Article 11 of Regulation 765/2008 which rules that national accreditation bodies shall establish their structures to ensure the balanced involvement of all interested parties within their organizations.

TÜRKAK must be an independent and autonomous agency, and the accreditation decisions must be taken without the involvement of the ministerial channels. The possibility of being under the influence of the public conformity assessment bodies is a great risk for TÜRKAK. Thus, there must be a balanced representation in the management of this agency. But unfortunately, TÜRKAK is an affiliate of the Ministry of Science, Industry and Technology that terminates all the discussions about its independent status. This position endangers the membership of TÜRKAK in EA, because independency is an extremely important criteria for EA/MLA. In the "Report of Supervising TÜRKAK's 2002, 2003 and 2004 Actions" by The State

Supervisory Council, it was mentioned that TÜRKAK has 220.147 TL net sales in 2002, 1.029.705 TL net sales in 2003 and 2.183.058 TL net sales in 2004 (The State Supervisory Council, 2005). Having an affiliate with high income is a surplus for MoSIT. Because of the different policies of public body which is responsible for the legal harmonization and the executive authority, the obstruction of TÜRKAK's independency has not overcome yet.

If TÜRKAK does not pass the EA peer evaluation, TÜRKAK will not be internationally recognized, and therefore Turkish conformity assessment bodies will have to apply for accreditation by another foreign accreditation body. Any failure of TÜRKAK would have dire consequences for the manufacturers since they will lose their certificates and will have to apply for certification by foreign conformity assessment bodies. The national conformity assessment bodies will lose their clients while waiting to be accredited again and manufacturers will have to pay more for the same service. Probably there will be delays on the marketing which will increase costs drastically. This may have an adverse snow ball effect for Turkish quality infrastructure.

4.4. Problems in Metrology

The most compatible actor in quality infrastructure in Turkey is "metrology" but still there are some problems. UME and MoSIT have separate roles in metrology. UMA is cooperating well with the European scientific metrology organization, EURAMET. There has been a very satisfactory buildup of metrology knowledge. The only missing part is the National Strategy Document of Metrology. This might

cause several problems in the future, because metrology needs scientific research and it must be planned in detailed. Unlike Turkey many EU countries display their strategy documents. For instance, National Measurement Office of United Kingdom has published “The National Measurement System Strategy Document 2011-2015” in July 2011. This document contains the general information on the national measurement system infrastructure and national challenges of the system. Measurement priorities were put on paper and it was described how to support the national challenges such as, the energy, sustainability, health etc. The Strategy document has also defined its working partners and resources, which is extremely important for a five year planning.

In terms of legal metrology, MoSIT needs to work on legislation with compatible personnel and must have an understanding of its international aspects. The transition period for Measurement Instruments Directive expires in 2016, and there in no up to date law on metrology and only one notified body. This means that foreign competitors will overrun the Turkish market due to the lack of legal metrology knowledge here. Eventually, the public interest for Turkish consumer protection may be at stake.

The National Metrology Workshop was organized between 9-11 December 2011 in Gebze (MoSIT, 2012). Current situation analysis was done and strategic aims were identified. The participants from legal, scientific, and industrial metrology fields attended the workshop and explained their concerns about national metrology. The main discussions were similar to the problems which were pointed out in the Country Report 2006 of EUROMED Project (Carneiro, 2006):

- The insufficiency of the number of documents in Turkish in the field of metrology
- Absence of an effective collaboration between university, industry and related institutions
- A very low degree of public awareness about metrology
- Shortage in number of experienced staff in legal metrology
- Insufficiency and non-realization of market surveillance
- Insufficiency of notified body working in the field of metrology in Turkey
- Delays in the required accreditations
- Absence of adequate calibration and testing laboratories due to this reason dependency to abroad.
- The lack of an effective metrology education at university level

CHAPTER 5

CONCLUSION

The CE mark guarantees the free movement within the European market of products that conform to the requirements of the EU legislation, such as safety, health and environmental protection. The CE marking has two faces; one for the manufacturers and one for the consumers. Manufacturers can only introduce their product into European Economic Area by affixing the CE mark according the specific procedures and elements described in the individual directives; therefore harmonization and transparency are crucial for the permanency of production sector. Secondly, consumers provide information about the properties of the product by virtue of the CE mark which supports public health and safety. In both ways, it is very important for Turkey to implement the CE marking procedures properly and strictly at any level, as the implementation would result both in the improvement of the market through more efficiently integrating itself to the European Economic Area and in the enhancement of the consumer safety.

Turkish quality infrastructure components (standardization, conformity assessment, accreditation and metrology) have developed since Turkey accepted the Customs Union agreement in 1996. But the Turkish quality infrastructure actors have not yet achieved the required and expected status. The National Innovation System report of TÜSIAD (Turkish Industry and Business Association) has examined the TSE, TÜRKAK, UME, and the assessment institutions within the 3rd phase keystone institutions of National Innovation System (Akyos, et al., 2003). They were pointed out in the report as the institutions that need structural changes. According to the

same report harmonization of Turkish quality infrastructure system with the EU legislation should carry out organizational innovation which needs social interference-intervention. As reported in "The National Innovation System" the key actors of national innovations are the governments. The report demonstrated that before 3 November 2002 TSE, TÜRKAK and UME were under the Prime Ministry but after the election it was decided to change the dependence of these institutions and refer all of them to the Ministry of Science, Industry and Technology's control (Akyos, et al., 2003). As explained earlier contradictions arise from this situation regarding to the EU harmonization. The EU requires all these kind of institutions and organizations to be independent and have professional integrity, transparency and ensure that there are no conflict of interest, personally as well as financially.

The National Innovation System report claimed that national accreditation system and national metrology system were not functioning efficiently although TÜRKAK was established. The report also underlined that TÜRKAK should be independent in order to provide its international recognition (Akyos, et al., 2003). The authors focused on the importance of TSE and TÜRKAK in the National Innovation System and suggested to detach them from governmental organizations.

Another report which refers to TSE, TÜRKAK and UME is the "National Science, Technology and Innovation Strategy 2011-2016" document. The strategy document shows the institutions in the "Structuring the Turkish National R&D and Innovation in Accordance with Basic Dynamics" table; however does not explain the policy about them (TÜBİTAK, 2010). In fact, the report presents the automotive, machinery, and information technology sectors as the sectors which have capacity of

innovation and R&D, whereas Turkey has only 5 notified bodies on machinery directive, most importantly, no notified body on low voltage directive, electromagnetic compatibility and radio and telecommunications terminal equipment directive. This is a conflict between the existing conditions and developed strategies and it forces producers to search the conformity assessment procedures to be performed from an European notified body, which may lead to increasing costs and thus contributing to more expensive products and unbalanced competition with European producers of the same type of product. .

The overall picture shows that the functions of the quality infrastructure are working in general and supporting the economic development of Turkey. However when it is compared with European organizations, a general harmonization problem arises in all four components. In the consideration of the discussion made in this study so far, the problems in Turkish quality infrastructure can be assessed under two topics which includes particular suggestions that aims at improving the quality infrastructure in Turkey are presented:

- Technical Problems
- Non-Technical Problems

The problems which occurred as a result of inability of implementing the operating methods or lack of specialized knowledge in quality infrastructure were classified in “technical problems”. Other problems which are based on the interaction of persons and institutions with other persons and institutions categorized in “non-technical problems”.

5.1. Technical Problems

Even when TSE became the full member of CEN/CENELEC the verification process of mandatory standards and the withdrawals of them are not sufficient enough when compared with the EU Member States. There is a lack of standardization experts. As it was discussed in the thesis, TSE is not completely independent as a standardization body. Conformity assessment body functions under the same brand may create conflicts of interest and should be administrative and financially separated and independent from each other. This is a general European requirement for all organization covering more or all areas of conformity assessment.

In addition to technical problems in standardization, low number of Notified Bodies and suboptimal scope of the Directives which are covered by Notified Bodies is an important challenge in conformity assessment. Conformity assessment demonstrates that safe products are put on the market. By the Council Decision 1/2006, Turkey was permitted the designation of Notified Bodies which can perform conformity assessment. However Turkey is still far behind other Member States; there are only 21 Notified Bodies. Besides this, the scope of the directives which are covered by the Notified Bodies need to be increased. For instance there are no Notified Bodies for Electromagnetic Compatibility and Low Voltage Directive.

There are also a number of technical problems in accreditation. Firstly there is no clear difference between accreditation and designation; ministries tend to add more requirements for the process of designation, that brings extra cost and delay in the process for the potential Notified Bodies. Moreover there is a legal gap between TÜRKAK law and Regulation 765/2008 which risks the EA peer evaluation.

TÜRKAK is facing a risk of failing a coming EA peer evaluation and if it happens Turkish conformity assessment bodies will have to apply for accreditation by another foreign accreditation body. Adding to that the certificates that they issued for Turkish manufacturers will no longer be acceptable and there will no longer be a mutual recognition which would be a major setback for Turkey and Turkish industry. Organizational changes are needed in TÜRKAK to comply with the requirements at European level. TÜRKAK's legal framework has to be revised according to Regulation 765/2008. The accreditation in both voluntary and mandatory fields has to be updated in reference to peer evaluation criteria.

The development in metrology has been positive. The situation in scientific metrology is sufficient compared with European countries. However; the legal metrology has not developed with the same pace as scientific metrology. There are some technical problems in the metrology, such as the insufficient number of experienced staff in legal metrology, insufficiency of market surveillance, lack of an effective metrology education at university level and the absence of adequate calibration and testing laboratories. Besides TÜRKAK is unable to accomplish the required accreditations in time and thus there is only one Notified Body in Turkey working in the field of metrology

5.2. Non-Technical Problems

The voluntary nature of standards is well known by the stakeholders but there is a low participation of consumers and SMEs in standardization process. The participation of consumers guarantees that standards correspond to consumer needs and requirements for safe products.. The European consumer organizations act

independently and can dominate the standardization work in equal conditions with the other stakeholders. SMEs play important role in standardization to confirm that fair competition rules exist in the market, and no advantage is accord to the large producers. Unfortunately there is lack of awareness about the standardization in Turkey. Even when TSE was granted as a full member of CEN/CENELEC, the amendments to the current legislation, adopting the framework to European practices has not been completed and adopted yet. TSE has to proceed its internal reorganization and review its working procedures in order to be more open and transparent. The National Mirror Committees should follow the European process and working procedures, and comment on the enquiries for draft standards in the same way as the European standardization bodies following the CEN rules. Unlike its European counterparts, TSE Standards Preparatory Department is seen as a governmental body. TSE has to be completely independent but it is unlikely in the present situation as being an affiliated organization of MoSIT.

In addition, the differences between TSE mark and CE mark are not recognized totally. The CE mark is still not very well known by the SMEs and consumers, and there appears a public confusion about differences of the CE mark and quality marks are confused. The CE mark is mandatory and must be affixed before the product is placed on the European internal market. On the contrary TSE mark is a quality mark given by TSE certification, it causes confusion in TSE's standardization activities and conformity assessment activities. It helps TSE to dominate the conformity assessment sector. MoE has completed the transposition of Council Decisions however the conformity assessment actors stayed out of these regulations.

The non-technical problems in accreditation are mostly triggered by TÜRKAK's managerial structure which is predominantly composed of public representatives that obscure the independency of TÜRKAK. Further TÜRKAK has close relations with MoSIT and TSE -which is the conformity assessment body of MoSIT; obviously there is a conflict of interest between the parties.

Lastly, the absence of an effective collaboration between university, industry and related institutions is the major non-technical problem in the metrology, and contributing to non-effective integration. Also there is a very low degree of public awareness about metrology.

5.3. Recommendations

As a conclusion there are a number of problems that avoid total harmonization of Turkey. There is a strong need to change the existing approach to harmonization and quality infrastructure. Organizational innovations are critical and necessary to reach the same level of implementation as the EU Member States. It is impossible to reach the desired trade volume with Europe unless Turkey meets the requirements of the EU harmonization, unless there is a political and social will to overcome the implementation problems in the quality infrastructure in Turkey.

The amendment of the Law 132 should need to be approved in order to support TSEs full and continued membership at CEN/CENELEC. The amendment will give TSE the legislative framework for transparency and openness in the standardization procedures. The withdrawal of mandatory standards should be completed and new approach directives should be promoted. TSE should increase the awareness rising

on the standardization process and should point out the advantages for SMEs and consumers to participate the standardization activities and allow them influence on the process as in the EU Member States. The number of standardization experts and the level of their technical knowledge should be increased in order to play active role in European standardization process, but their impartiality shall be guaranteed, so they represent the needs of society in general. TSE's conformity assessment body and standardization preparatory group should detach from each other to fulfill the impartiality and independency principles. The awareness of the CE mark among Turkish consumers should be raised to encourage the manufacturers to affix the CE mark as it is a mandatory mark, also for domestic marketing.

TÜRKAK law should be revised as the legal gap between TÜRKAK law and Regulation 765/2008 risks the EA peer evaluation. TÜRKAK should be detached from MoSIT to secure the independency. The organization of TÜRKAK should be composed of more private sector representatives. Adding to that, the scope of TÜRKAKs services needs to be widened to cover the needs of Turkish industry and reflect the potential and requirements for accreditation and certification in Turkey. Above all, Ministries should end asking more requirements for the process of designation, and must be a clear difference between accreditation and designation.

The number of notified bodies should be increased by simplifying the designation process. The designation should be an "administrative verification procedure" after the accreditation has been carried out adequately. The scope of the new approach directives which are covered by the notified bodies should be expanded by encouraging the conformity assessment bodies to get experienced on the new

approach directives. The conformity assessment bodies which perform tests and inspections on electromagnetic compatibility, toys and low voltage directive should be promoted to be notified regarding the strategies in the "National Science, Technology and Innovation Strategy 2011-2016" document.

There is consequently a strong need for a national strategy on metrology. MoSIT needs to work on legislation and must adapt international aspects of legal metrology. Inexperienced staff in legal metrology should be trained and metrology education should be supported in the universities. Cooperation between universities, industry and other organization should be established in order to contribute effective integration.

Nevertheless, the problems could be overcome by technical assistance provided by the EU. As a candidate country Turkey make use of the EU funds (Instrument for Pre-Accession Assistance) by utilizing Technical Assistance Projects. The policy makers should be concentrated on transferring the knowledge and experience from the EU Member States to enable better implementation regarding the quality infrastructure by increasing the awareness among CABs concerning accreditation, increasing the interest of private sector conformity assessment activities, improving the organization of the standardization activities, providing support to the metrology sector. The successful implementation of the harmonization will require extensive cooperation and commitment of resources by the national authorities.

REFERENCES

The Treaty of Rome. (1957, March 23). Not Published.

Adak, Ö. (2011, September 23). Interview on Conformity Assessment. (Z. Sarbay, Interviewer)

Akyos, M., Durgut, M., & Göker, A. (2003). *Ulusal İnovasyon Sistemi.* Retrieved January 18, 2012, from TÜSİAD: http://www.tusiad.org/__rsc/shared/file/ulusal.pdf

Alan, M. (2012, January 9). Standardization Problems in Turkey. (Z. Sarbay, Interviewer)

Aldrich, M. (1988). OSHA Fines and the Value of Saving a Life. *Journal of Policy Analysis and Management Vol.7 No.2*, 356-362.

Alp, A. (2011, November 25). *AB'ye İhracat Zora Girecek.* Hürriyet. Retrieved December 1, 2011, from AB TÜRKAK'a müdahalelerden şikayetçi, TSE ve ihracat 2012'de tehlikede: http://www.euractiv.com.tr/ticaret-ve-sanayi/article/ab-turkaka-mudahalelerden-sikayetci-tse-ve-ihracat-tehlikede-022665

Atkins, W. (1996). *Technical Barriers to Trade, Single Market Review.* Office for Official Publication of the EC.

B. Pasa, G. A. Benacchio. (2005). *A Common Law for Europe.* Central European University Press.

Badadhe, A. (2006). *Metrology and Quality Control.* Technical Publications.

Baldwin, R., McLaren, J., & Panagariya, A. (2000). Regulatory Protectionism, Developing Nations, and a Two-Tier World Trade System. *Brookings Trade Forum*, (pp. 273-293).

Bayram, E. G., & Şirinoğlu, E. (2008, April 14). General Product Safety in Turkey: The Legal and Administrative Situation. Ankara: PHARE Business Support Programme III of the European Union for Bulgaria, Croatia, Romania, Turkey.

Bektaş, H. (2010, May 20). Enerji Yönetiminde Standardizasyon. TSE.

Bewoor, A. (2009). *Metrology & Measurement.* Tata McGraw-Hill Education.

BIPM. (2010). *The 'siège de Paris' (1870) and the Convention of the Metre.* Retrieved October 28, 2010, from http://www.bipm.org/en/bipm/history/hist9.html

Bongers, C. (1988). Optimal Size Selection in Standardization: A Case Study. *The Journal of the Operational Research Society, Vol. 33, No. 9*, 793-799.

BSI. (2005). *Standarziation as a Business Investment.* Retrieved October 16, 2011, from British Standardization Institute: http://www.bsigroup.com/upload/Standards%20&%20Publications/Government/BSI_WhitePaper.pdf

Carneiro, K. (2006). *Country Report 2005-2006 of Support to the Quality Infrastructure in Turkey Project.* EUROMED.

CEN. (2000). *Report of the Expert Panel for the Review of the European Standardization System.* Retrieved October 18, 2011, from Standardization for a Competitive Innovative Europe: a vision for 2020: http://ec.europa.eu/enterprise/policies/european-standards/files/express/exp_384_express_report_final_distrib_en.pdf

CEN. (2001). *Status of European Standards.* Retrieved October 21, 2011, from ftp://ftp.cen.eu/BOSS/Reference_Documents/Guides/CEN_CLC/CEN_CLC_1.pdf

CEN. (2004). *Guidance - The "New Approach"*. Retrieved October 12, 2011, from http://www.cen.eu/boss/supporting/Guidance%20documents/GD009%20-%20Guidance%20on%20the%20New%20Approach/Pages/default.aspx

CEN. (2010a). *CEN in Figures.* Retrieved October 10, 2011, from European Committee for Standardization: http://www.cen.eu/cen/AboutUs/Statistics/Pages/default.aspx

CEN. (2010b). *Compass: The World of European Standards.* Retrieved October 26, 2010, from European Committee for Standardization: ftp://ftp.cen.eu/cen/AboutUs/Publications/Compass.pdf

CEN/CENELEC. (2010c, June). *Guidance for writing standards taking into account micro, small and medium-sized enterprises (SMEs) needs*. Brussels.

CEN/CENELEC. (2011, December 12). Press Release. *European Standards Organisations enlarge membership to include Turkey*. Brussels.

CENELEC. (2001). Preparation of Standards for Safety in the Design and Construction of Electrical Equipment. Brussels: CENELEC.

CEOC. (2000, November 29). *Marks and Marking on Products.* Retrieved November 11, 2011, from http://www.ceoc.com/publications/positionpapers/supplement%20bulletin200696135048.pdf

CEOC. (2002). *The Need for Independent 3rd Party Conformity Assessment Bodies.* Retrieved November 5, 2011, from http://www.ceoc.com/publications/positionpapers/the%20need%20for%20independ%203rd%20party%20CA%20bodies%20FINAL200696114914.DOC

Craig, P., & De Burca, G. (2003). *EU Law: Text, Cases, and Materials.* New York: Oxford University Press.

Çelebi, E. (2011, September 19). 4 Tüketiciden 3'ü Alışverişte "Kalite Tedirginliği" Yaşıyor. Hürriyet Newspaper.

David, P. (1987). Some New Standards for the Economics of Standardisation in the Information Age. In P. D. (eds.), *Economic Policy and Technological Performance* (pp. 206-234). Cambridge: Cambridge University Press.

Delaney, H. (2008). *Guide to EU Standards and Conformity Assessment.* DIANE Publishing.

Dellaloğlu, A. (2006, April 8). *Tüketici de İşletmeler de CE İşaretinden Habersiz*. Referans Newspaper.

DIN. (2000). *Economic Benefits of Standardization: Summary of Result.* Berlin: German Institute for Standardization.

EA. (2010, November). *Role of the European co-operation for Accreditation*. Retrieved November 12, 2011, from http://www.european-accreditation.org/content/ea/europNetwork.htm

EA. (2012). *European Co-operation for Accreditation.* Retrieved January 07, 2012, from http://www.european-accreditation.org/content/mla/what.htm

Erkal, G., & Konukseven, E. I. (2008). Türkiye'deki Makina Sektöründe CE İşaretlemesi ve AB Uyumu Konusunda Durum Değerlendirme Çalışması. *Mühendis ve Makina Vol.48 No.574*.

ETSI. (2011, March). *Presentations.* Retrieved from http://www.etsi.org/WebSite/document/aboutETSI/ETSI_Presentation_updated%20March2011.pdf

EURAMET. (2011a, September 15). *EURAMET 2020 Strategy.* Retrieved November 16, 2011, from European Association of National Metrology Institutes: http://www.euramet.org/fileadmin/docs/Publications/strategy/G-GNP-STR-002_EURAMET_2020_Strategy_printout.pdf

EURAMET. (2011b). *EURAMET Technical Committees.* Retrieved November 14, 2011, from European Association of National Metrology Institutes: http://www.euramet.org/index.php?id=tc

European Commision. (2010, February 1). *Guidance document: The relationship between Directive 98/34/EC and the Mutual Recognition Regulation*. Brussels.

European Commission. (2000). Blue Guide. *Guide to the Implementation of Directives Based on the New Approach and the Global Approach*.

European Commission. (2002, December 24). Consolidated Version of the Treaty Establishing the European Community.

European Commission. (2003a, March 28). General Guidelines for the Cooperation Between CEN, CENELEC AND ETSI and European Commision and the European Free Trade Association. Brussels.

European Commission. (2003b, April 11). Commission interpretative communication on facilitating the access of products to the markets of other Member States the practical application of mutual recognition.

European Commission. (2011). *Enterprise and Industry*. Retrieved November 7, 2011, from http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=country.main

European Commission. (2011). *Turkey 2011 Progress Report.* Brussels: European Commission.

European Commission. (2012). *New Legislative Framework: Notified Bodies*. Retrieved January 11, 2012, from http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=country.notifiedbody&cou_id=792

European Cooperation for Accreditation. (2009, June 8). EA Guidance on the horizantal requirements for the accreditation of conformity assessment bodies for norification purposes. EA Gerenal Assembly.

European Council. (1985, June 04). *Council Resolution of 7 May 1985 on a New Approach to Technical Harmonization and Standards*.

European Council. (1989, December 21). *Council Resolution of 21 December 1989 on a Global Approach to Conformity Assessment*.

European Council. (1993, July 22). *93/465/EEC: Council Decision Concerning the Modules for the Various Phases of the Conformity Assessment Procedures and the Rules for the Affixing and Use of the CE Conformity Marking, Which Are Intended to be Used in the Technical Harmonization*.

European Council. (1995, September 7). *Council Directive 95/16/EC of 29 June 1995 on the approximation of the Laws of the Member States Relating to Lifts*.

European Council. (1998, June 22). *Directive 98/34/EC of The European Parliament and Of the Council Laying Down a Procedure for the Provision of Information in the Field of Technical Standards and Regulations and of Rules on Information Society Service.* Retrieved October 26, 2011, from http://ec.europa.eu/enterprise/tris/consolidated/index_en.pdf

European Council. (1999). *Helsinki European Council Presidency Conclusions.* Retrieved December 3, 2011, from http://www.europarl.europa.eu/summits/hel1_en.htm

European Council. (2008, May 9). *The Treaty on the Funtioning of the European Union.*

European Council. (2008, August 13). *Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 Setting out the Requirements for Accreditation and Market Surveillance Relating to the Marketing of Products and Repealing Regulation (EEC) No 339/93*.

Farrell, J., & Saloner, G. (1985). Standardisation, Compatibility and Innovation. *RAND Journal of Economics 16,* 70-83.

Farrell, J., & Shapiro, C. (1988). Dynamic Competition with Switching Costs. *RAND Journal of Economic, 19,,* 127-137.

Galetic, L., Nacinovic, I., & Cavlek, N. (2009). Corporate Culture and Innovation: Implications for Reward Systems. *World Academy of Science, Engineering and Technology,* 397-402.

Gilbert, R., & Katz, M. (2001). An Economist's Guide to US vs Microsoft. *The Journal of Economic Perspectives Vol.15 No.2,* 25-44.

Greenaway, D. (2011). *The World Economy: Global Trade Policy 2010.* John Wiley & Sons.

Güzel, Z. (2011, September 9). View of Consumer Associations on Standardization. (Z. Sarbay, Interviewer)

Halal World. (2011). *Halal World*. Retrieved November 22, 2011, from http://www.halalworld.org/html/index.php?module=%D8%A7%D8%AE%D8%A8%D8%A7%D8%B1&func=display&sid=605

Hanna, R. (1994). The Search for Functional Copyright Misuse Standards. *Stanford Law Review Vol.46 No.2,* 401-448.

Hürriyet. (2011, May 14). *Gıda ve Tekstil Dışında Zorunlu Olmasına Rağmen CE'yi Bilmiyoruz*. Hürriyet.

IMF. (2011). *International Monetary Fund*. Retrieved November 17, 2011, from http://www.imf.org/external/pubs/ft/weo/2011/01/weodata/

ISO. (1996). *ISO/IEC Guide 2.* International Standardization Organization.

ISO. (2011a). *International Organization for Standardization*. Retrieved October 10, 2011, from http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=42180

ISO. (2011b). *List of ISO technical committees*. Retrieved December 22, 2011, from http://www.iso.org/iso/standards_development/technical_committees/list_of_iso_technical_committees.htm

Kretchmer, K. (2000). The Fundamental Nature of Standards: Economics Perspective. *International J A Schumpeter Conference.* Manchester: Paper is available on: http://www.csrstds.com/fundeco.html.

Lenova. (2011). *Lenova*. Retrieved October 10, 2011, from http://support.lenovo.com/en_US/detail.page?LegacyDocID=MIGR-60158

Lundberg, L. (1992). Economic Integration, Inter- and Intra-Industry Trade. *The Scandinavian Journal of Economics, Vol. 94, No. 3*, 393-408.

Malmqvist, M. (2011). Technical Advise Report on Accreditation for the Strenghening the Qualityinfrastrucutre in Turkey Projoect. IPA.

MoE. (2011a). *Ministry of Economy: Ankara Anlaşması*. Retrieved January 3, 2012, from http://www.ekonomi.gov.tr/avrupabirligi/index.cfm?sayfa=DADD3D09-D8D3-8566-4520836010825065

MoE. (2011b). *Ministry of Economy: Gümrük Birliği Kapsamında Gerçeleştirilen Uyum Çalışmaları*. Retrieved from http://www.ekonomi.gov.tr/avrupabirligi/index.cfm?sayfa=DABA3CE2-D8D3-8566-452053C50B72713A

MoE. (2011c). *Ministry of Economy: History*. Retrieved January 3, 2012, from http://www.ekonomi.gov.tr/index.cfm?sayfa=tarihce

MoEUA. (2011). *Ministry for EU Affairs: History of Turkey-EU Relations*. Retrieved January 3, 2012, from http://www.abgs.gov.tr/index.php?p=111&l=2

MoPWS. (2006, December 06). *Communiqué on the National Provisions concerning the Construction Products within the Scope of the Construction Products By-law (89/106/EEC) which do not have to be CE Marked*.

MoSIT. (2011). *T.C. Bilim, Sanayi ve Teknoloji Bakanlığı Metroloji ve Standardizayion Genel Müdürlüğü*. Retrieved October 31, 2011, from http://osgm.sanayi.gov.tr/About.aspx?lng=tr

MoSIT. (2012). *Ministry of Science, Industry and Technology*. Retrieved December 19, 2011, from http://osgm.sanayi.gov.tr/Archive.aspx?selected=Announcements&lng=tr

Placko, D. (2006). *Metrology In Industry: The Key for Quality.* John Wiley & Sons.

Skjernov, C. (2011, October 15). Interview on General Problems of Quality Infrastructure in Turkey. (Z. Sarbay, Interviewer)

SQIT. (2011). *Country Report.* Ankara: Strengthening Quality Infratructure in Turkey Project.

Stango, V. (2004). The Economics of Standards Wars. *Review of Network Economic*, Vol 3, Issue 1.

Swann, P. (2000). *The Economics of Standardization, Report for Department of Trade and Industry.* Report available at:http://www.berr.gov.uk/files/file11312.pdf.

Swann, P., Temple, P., & Shurmer, M. (1996). Standards and Trade Performance: the UK Experience. *Economic Journal 106*, 1297-1313.

TAPDK. (2008). *Non Harmonised Area European Union Notification System*. Retrieved December 16, 2011, from http://www.tapdk.gov.tr/abi.asp

Taylor, B. N., & Thompson, A. (2008). The International System of Units (SI). Washington: NIST Special Publication 330.

TBMM. (1960, November 18). *Law No.132 Establishment of TSE*.

TBMM. (1999, October 27). *Law on Establishment and Tasks of Turkish Accreditation Agency*.

TBMM. (2001, July 11). *4703 Sayılı Ürünlere İlişkin Teknik Mevzuatın Hazırlanması ve Uygulanmasına Dair Kanun*.

TBMM AB Uyum Komisyonu. (2008, December 22). *1/624 Türk Standartları Enstitüsü Kuruluş Kanununda Değişiklik Yapılmasına Dair Kanun Tasarısı*. Ankara.

The EC-Turkey Association Council. (1995, March 6). 1/95 Sayılı Ortaklık Konseyi Kararı. Retrieved January 2, 2012, from Türkiye-AB İlişkilerini Düzenleyen Hukuki Metinler: http://www.ekonomi.gov.tr/upload/DAFEB160-D8D3-8566-4520673B73042A61/1_95%20OKKtr.pdf

The EC-Turkey Association Council. (1996, February 13). *Decision No 1/95 of the EC-Turkey Association Council of 22 December 1995 on Implementing the Final Phase of Customs Union*.

The EC-Turkey Association Council. (1997, July 21). *Decision No 2/97 of the EC-Turkey Association Council of 4 June 1997 establishing the list of Community instruments relating to the removal of technical barriers to trade and the conditions and arrangements governing their implementation by Turkey*. The EC-Turkey Association Council.

The EC-Turkey Association Council. (2006, May 15). Decision 1/2006. *on the implementation of Article 9 of Decision No 1/95 of the EC-Turkey Association council on implementaing the final phase of the Customs Union*.

The State Supervisory Council. (2005). *TÜRKAK 2002, 2003, 2004 Yılları Eylem ve İşlemlerinin Araştırılıp Denetlenmesine İlişkin Rapor.* Retrieved January 16, 2012, from Presidency of the Republic of Turkey: http://www.tccb.gov.tr/ddk/ddk16.pdf

Tricker, R. (2000). *CE Conformity Marking and New Approach Directives.* Butterworth-Heinemann.

TSE. (2011). *Uluslararası Standardizasyon Kuruluşları*. Retrieved December 28, 2011, from http://www3.tse.org.tr/Turkish/tse/iso.asp

TÜBİTAK. (2010). *Ulusal Bilim, Teknoloji ve Yenilik Stratejisi 2011-2016.* Ankara: TÜBİTAK Bilim, Teknoloji ve Yenilik Politikaları Daire Başkanlığı .

TÜİK. (2011). *TÜİK Haber Bülteni 186. Sayı.* TÜİK.

TÜİK. (2011). *TÜİK Haber Bülteni 19.Sayı.* TÜİK.

TÜRKAK. (2011a). *Türk Akreditasyon Kurumu*. Retrieved December 29, 2011, from http://www.turkak.org.tr/index.php/sayfa,29,bilgi_islem

TÜRKAK. (2011b). *What is accreditation?* Retrieved January 3, 2012, from Turkish Accreditation Agency: http://www.turkak.org.tr/index.php/EN/accreditation,11,what_is_accreditation_

TÜRKAK. (2012). *TÜRKAK Yönetim Kurulu*. Retrieved January 6, 2012, from http://www.turkak.org.tr/index.php/kurumsal,7,yonetim_kurulu

UDDER. (2007). *Uygunluk Değerlendirmesi Derneği Strateji Raporu.* Ankara: Uygunluk Değerlendirmesi Derneği.

UKAS. (2012). *Testing Laboratories Schedules*. Retrieved January 07, 2012, from http://www.ukas.com/about-accreditation/accredited-bodies/Testing-laboratories-schedules.asp

Uluatam, Ö. (2001). *Geçmişe Bakmak: Cumhuriyet Dönemi İktisadi, Mali, Siyasi Olaylar Kronolojisi 1920-2000.* Ankara: İmaj Yayınevi.

UME. (2011). *Ulusal Metroloji Enstitüsü*. Retrieved October 31, 2011, from http://www.ume.tubitak.gov.tr/menu_general.php?f=101

UME. (2012). *National Metrology Institution Laboratories*. Retrieved January 07, 2012, from http://www.ume.tubitak.gov.tr/menu_labs.php?f=200

Usta, R. (2010, September 30). Presentation on Turkish Standard Institution in Standards Week Seminar. İstanbul.

Wallace, H., & Young, A. R. (1996). The Single Market. In H. Wallace, & W. Wallace, *Policy-Making in the Europen Union* (pp. 126-155). Oxford: Oxford University Press.

WELMEC. (1990, June 8). Memorandum of Understanding.

Yılmaz, Z. (2011, October 22). Interview on Turkish Accreditation System. (S. Sarbay, Interviewer)

Appendix A: Summary of the General Guidelines for the Cooperation Between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association

1. Maintain the standardization infrastructure and procedures to meet legitimate needs (including safety, health, consumer and environmental protection) in Europe, and actively cooperate to ensure that stakeholders gain the maximum benefit of the European standardization infrastructure and its links with other standards organizations.
2. Ensure that structures and procedures allow for the highest possible degree of openness, transparency and representativeness. Procedures should be transparent and ensure independence from vested interests. Further efforts should be made to increase the participation of interested circles, especially public authorities, manufacturers, small and medium-sized enterprises, consumers, workers and environmental interest groups, at the national and European level in the drafting of standards and other deliverables and in ensuring their views are adequately taken into account.
3. Ensure that all interested parties participating in the development process have access to documents in order to effectively participate.
4. Take the public interest into account, in particular, safety and health, the protection of workers, consumers and environment.
5. Ensure that the environment is fully considered and where relevant taken into account in the development of standards in order to contribute to a high level of environmental protection.
6. Pro-actively support participation of relevant stakeholders in standardization work on national, European, and inter-national level.

Source:http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2003:091:0007:0011:en:PDF

Appendix B: Members of EA

Country	Accreditation Body
Austria	BMWFJ - Bundesministerium für Wirtschaft, Familie und Jugend
Belgium	BELAC - Belgian Accreditation Body
Bulgaria	BAS - Executive Agency "Bulgarian Accreditation Service"
Cyprus	CYS-CYSAB - Cyprus Organization for the Promotion of Quality
Czech Republic	CAI - Czech Accreditation Institute
Denmark	DANAK - Danish Accreditation
Estonia	EAK - Estonian Accreditation Centre
Finland	FINAS - Finnish Accreditation Service
France	COFRAC - Comité Français d'Accréditation
Germany	DAkkS - Deutsche Akkreditierungsstelle GmbH
Greece	ESYD - Hellenic Accreditation System
Hungary	NAT - Hungarian Accreditation Board
Iceland	ISAC - Icelandic Board for Technical Accreditation
Ireland	INAB - National Accreditation Board
Italy	ACCREDIA - Italian Accreditation Body
Latvia	LATAK - Latvian National Accreditation Bureau
Lithuania	LA - Lithuanian National Accreditation Bureau
Luxembourg	OLAS - Office Luxembourgeois d'Accréditation et de Surveillance
Malta	National Accreditation Board - Malta (NAB-Malta)
Netherlands	RvA - Raad voor Accreditatie
Norway	NA - Norsk Akkreditering
Poland	PCA – POLSKIE CENTRUM AKREDYTACJI
Portugal	IPAC – Instituto Portugues de Acreditacao, I.P.
Republic of Croatia	HAA - Hrvatska akreditacijska agencija
Republic of Montegro	ATCG
Romania	RENAR – Romanian Association for Accreditation
Slovakia	SNAS – Slovak National Accreditation Service
Slovenia	Slovenian Accreditation (SA)
Spain	ENAC – Entidad Nacional de Acreditación
Sweden	SWEDAC – Swedish Board for Accreditation and Conformity Assessment
Switzerland	SAS – Swiss Accreditation Service (MRA)

The Former Yugoslav R. of Macedonia	IARM
Turkey	TÜRKAK - Turkish Accreditation Agency
United Kingdom	UKAS

Source: http://www.european-accreditation.org/content/ea/members.htm

Appendix C: Members of WELMEC

Albania	Germany	Poland
Austria	Greece	Portugal
Belgium	Hungary	Romania
Bosnia and Herzegovina	Iceland	Serbia
Bulgaria	Ireland	Slovakia
Croatia	Italy	Slovenia
Cyprus	Latvia	Spain
Czech Republic	Lithuania	Sweden
Denmark	Luxembourg	Switzerland
Estonia	Malta	The Netherlands
Finland	Montenegro	Turkey
France	Norway	United Kingdom
FYROM		

Source: http://www.welmec.org/chairperson/contacts.html#c5

Appendix D: List of the Guidance Documents

	Title	Produced by
1	An Introduction to WELMEC	Secretariat
2	Directive 90/384/EEC: Common Application	WG2 (Weighing instruments)
2.1	Guide for Testing Indicators	WG2 (Weighing instruments)
2.2	Guide for Testing Point of Sale Devices	WG2 (Weighing instruments)
2.3	Guide for Examining Software	WG2 (Weighing instruments)
2.4	Guide for Load Cells	WG2 (Weighing instruments)
2.5	Guide for Modular Approach and Testing of PCc and other Digital Peripheral Devices	WG2 (Weighing instruments)
2.6	Guide for the testing of automatic catchweighing instruments	WG2 (Weighing instruments)
2.7	Directive 90/384/EEC - Explanation and Interpretation	WG2 (Weighing instruments)
2.8	Guide for Conversion of NAWI (Indicators) Test Results for AWI Purposes	WG2 (Weighing instruments)
4.1	Guide for Notified Bodies performing Conformity Assessment of Measuring Instruments	WG4 (EN4500 standards)
4.2	Elements for deciding the appropriate level of confidence in regulated measurements	WG4 (EN4500 standards)
5.1	European Directory of Legal Metrology	WG5 (Market supervision)
5.2	Market Surveillance Guide (NAWI and MID)	WG5 (Market supervision)
5.3	Risk Assessment Guide for Market Surveillance: Weigh and Measuring Instruments	WG5 (Market supervision)
6	Introduction to WELMEC documents on prepackages	WG6 (Prepackages)
6.1	Application of Directives 75/106/EEC and 76/211/EEC concerning the marking and quantity control of e-marked prepackages: Definition of terms	WG6 (Prepackages)
6.2	An Application of Directives 75/106/EEC and 76/211/EEC concerning the marking and quantity control of e-marked prepackages: Translation of terms	WG6 (Prepackages)
6.3	Guidance for the Harmonised Implementation of Council Directive 76/211/EEC	WG6 (Prepackages)

6.4	Guide for packers and importers of e-marked prepacked products	WG6 (Prepackages)
6.5	Guidance on Controls by Competent Department's on "e" marked Prepackages	WG6 (Prepackages)
6.6	Guide for recognition of procedures	WG6 (Prepackages)
6.7	Guidance for Market Control on Prepackages For Competent Departments	Secretariat
6.8	Guidance for the Verification of Drained Weight, Drained Washed Weight and Deglazed Weight and Extent of Filling of Rigid Food Containers	WG6 (Prepackages)
6.9	Prepackages - Uncertainty of Measurement	WG6 (Prepackages)
6.10	Information on Controls on Prepacked Product	WG6 (Prepackages)
6.11	Guidance for Prepackages whose Quantity Changes after Packing	WG6 (Prepackages)
7.1	Software Requirements on the Basis of the Measuring Instruments Directive (MID)	WG7 (Software)
7.2	Software Guide (Measuring Instruments Directive 2004/22/EC)	WG 7 (Software)
8	Measuring Instruments Directive 2004/22/EC, Generalities on the Assessment and Operationof Notified Bodies performing Conformity Assessment	WG8
8.1	Terms and definitions in MID and their relation to terms defined in other international metrologically relevant documents	WG8
8.2	Guide for Measuring Instruments Directive 2004/22/EC Application of Module H1	WG8
8.3	Measuring Instruments Directive 2004/22/EC, Application of Module B	WG8
8.4	Measuring Instruments Directive 2004/22/EC, Application of Module D	WG8
8.5	Measuring Instruments Directive 2004/22/EC, Assessment of Notified Bodies in Charge of Type Examination Presumption of Conformity based on EN 45011	WG8
8.6	Measuring Instruments Directive 2004/22/EC, Presumption of Conformity of the Quality System of Manufacturers with Module D or H 1 when EN ISO 9001:2000 is applied	WG8
8.7	Measuring Instruments Directive 2004/22/EC - Assessment of Notified Bodies Designated for Module F based on EN ISO/IEC 17020	WG8

8.8	General and Administrative Aspects of the Voluntary System of Modular Evaluation of Measuring Instruments	WG8
8.9	Measuring Instruments Directive (2004/22/EC): Common Application – Capacity Serving Measures (CSM)	WG8
8.10	Measuring Instruments Directive (2004/22/EC): Guide for generating sampling plans for statistical verification according to Annex F and F1 of MID 2004/22/EC	WG8
8.11	Guide For Measuring Instruments Directive 2004/22/EC Water Meters Corresponding Tables OIML R 49 2006 and R 49-2 2004 – MID-001	WG11
8.12	Guide for Measuring Instruments Directive 2004/22/EC Gas Meters Corresponding Tables OIML R 137-1 2006– MID-002 I	WG8
8.13	Volume conversion devices Cross Reference Table 2004/22/EC vs. OIML R 140 - 2007	WG11
8.14	Guide For Measuring Instruments Directive 2004/22/EC Heat Meters Corresponding Tables OIML R 75-1 and R 75-2 2002 – MID-04	WG11
8.15	Measuring system for the continuous and dynamic measurement fo quantities of liguids other then water - Cross Refrence Table 2004/22/EC vs. OIML R 117-1 - 2007	WG10
8.16-1	Guide for Automatic Catchweighing Instruments Cross Reference Table 2004/22/EC vs. OIML R 51-1 Edition 2006 (E)	WG2 (Weighing instruments)
8.16-2	Guide for Measuring Instruments Directive 2004/22/EC Automatic Gravimetric Filling Instruments Corresponding Tables OIML R 61-1 2004 – MID-006 III	WG2 (Weighing instruments)
8.16-3	Guide for Measuring Instruments Directive 2004/22/EC Discontinuous Totalisers Corresponding Tables OIML R 107-1 1997– MID-006 IV	WG2 (Weighing instruments)
8.16-4	Guide for Measuring Instruments Directive 2004/22/EC Continuous Totalisers Corresponding Tables OIML R 50-1 1997– MID-006 V	WG2 (Weighing instruments)
8.16-5	Guide for Measuring Instruments Directive 2004/22/EC Automatic Rail Weighbridges Corresponding Tables OIML R 106-1 1997– MID-006 VI	WG2 (Weighing instruments)
8.17	Guide for Measuring Instruments Directive 2004/22/EC Taximeters Corresponding Tables OIML R 21 2007 – MID-007 II	WG8
8.18-3	Guide for Measuring Instruments Directive 2004/22/EC Capacity Serving Measures Corresponding Tables OIML R 138 2007 – MID-008 II	WG8

8.19-1	Guide for Measuring Instruments Directive 2004/22/EC Length Measuring Instruments Corresponding Tables OIML R 66 1985– MID-009 II	WG8
8.19-2	Guide for Measuring Instruments Directive 2004/22/EC Area Measuring Instruments Corresponding Tables OIML R 136-1 2004– MID-009 III	WG8
8.19-3	Guide for Measuring Instruments Directive 2004/22/EC Multidimensional Measuring Instruments Corresponding Tables OIML R 129 2000 - MID-009 IV	WG8
8.20	Guide for Exhaust Gas Analyser Cross Reference Table	WG8
10.1	Guide for Pattern Examination	WG10
10.2	Guide to Metrological Devices for Transferring Measured Quantities (DTMQ) associated to bottom loading measuring systems	WG10
10.3	Guide for the use of an alibi recording device (printer or memory) in Measuring Systems for Liquids other than Water	WG10
10.4	Guide for Testing of Electronic Calculators with Conversion Function and Conversion Devices	WG10
10.5	Guide for Common Application of Marking of Fuel Dispensers	WG10
10.6	Guide for Sealing of Fuel Dispensers (Measuring Systems for Liquids other than Water)	WG10
10.7	Guide on evaluating purely digital self-service devices for direct sales to the public	WG10
11.1	Guide for Measuring Instruments Directive 2004/22/EC,	WG11
11.2	Guideline on time depending consumption measurements for billing purposes (interval metering)	WG11

Source: http://www.welmec.org/latest/guides.html

Appendix E: Public Authorities Which Are Authorized for the Selective Products

Public Authority	Products
The Ministry of Health	Toys, medical devices, medicinal products, detergents and cosmetics
The Ministry of Science, Industry and Technology	Machinery, motor vehicles, lifts, gas appliances, pressure equipment, explosives for civil use, household appliances, measuring instruments, electrical materials, textiles, footwear and etc.
The Ministry of Food, Agriculture and Livestock[38]	Foodstuffs, feed products, fertilizers
The Telecommunications Authority	Radio and telecommunications terminal equipment
The Ministry of Labor and Social Security	Personal protective equipment
The Tobacco and Alcohol Authority	Tobacco and tobacco products, alcoholic beverages and ethyl alcohol.

Source: The table is prepared by the author according to information from the of Law 4703

[38] The Ministry of Agriculture and Rural Affairs became the Ministry of Food, Agriculture and Livestock in 2011

Appendix F: Organization Schema of TSE

Source: http://ikbs.tse.org.tr/Personel/PersonelRehber.aspx

Appendix G: Mirror Committees of TSE

1	MTC-1:Petroleum and related products - Determination of spray ignition characteristics of fire-resistant fluids (CEN/TC 19, ISO/TC 28)
2	MTC-2:Paints and varnishes (CEN/TC 139, ISO/TC 35, ISO/TC 35/SC 9)
3	MTC-3:Bituminous binders (CEN/TC 336)
4	MTC-7:Child use and care articles, safety of toys (CEN/TC 252, CEN/TC 52, ISO/TC 181)
5	MTC-9:Cement and building limes (CEN/TC 51)
6	MTC-10:Ceramic tiles (CEN/TC 67, ISO/TC 189)
7	MTC-11:Thermal insulating materials and products (CEN/TC 88, ISO/TC 163)
8	MTC-12:Concrete and related products (CEN/TC 104, ISO/TC 71, ISO/TC 71/SC 4, ISO/TC 71/SC 5)
9	MTC-13:Timber structures (CEN/TC 124, ISO/TC 165)
10	MTC-16:Roof covering products for discontinuous laying and poducts for wall cladding (CEN/TC 128)
11	MTC-17:Acoustinc properties of building elements and of buildings (CEN/TC 129, ISO/TC 160)
12	MTC-18:Aggregates (CEN/TC 154)
13	MTC-19:Sanitary appliances (CEN/TC 163)
14	MTC-20:Prefabricated reinforced components of autoclaved aerated concrete or light-weight aggregate concrete with open structure (CEN/TC 177)
15	MTC-21:Geosynthetics (CEN/TC 189, ISO/TC 221)
16	MTC-23:Road Materials (CEN/TC 227)
17	MTC-25:Flexible sheets for waterproofing (CEN/TC 254)
18	MTC-28:Switchgear and Controlgear (CLC/SR 17, CLC/TC A, B, C, D, IEC/TC 17A, 17B, 17C, 17D)
19	MTC-29:Electric cables (CLC/TC 20, IEC/TC 20)
20	MTC-33:Light and lighting (CLC/TC 34Z, IEC/TC 34, CEN/TC 169)
21	MTC-36:Electromagnetic compatibility, safety of electronic equipment within the field of audio/video, information technology nd communication technology (CLC/TC 210, IEC/TC 77, 77A, 77B, CISPR A, B, D, F, H, I, IEC/TC 108)
22	MTC-38:Audio, video and multimedia systems and equipment (CLC/TC 206, CLC/TC 209, IEC/TC 100)
23	MTC-39:Water supply, water analysis (CEN/TC 164, CEN/TC 230, ISO/TC 147, SC 2, SC 4, SC 5)
24	MTC-40:Air quality (CEN/TC 264, ISO/TC 146, SC1, SC 2)
25	MTC-41:Characterization of soils (CEN/TC 345, ISO/TC 190, SC3, SC4)
26	MTC-42:Food products (ISO/TC 34 SC8, SC9)
27	MTC-43:Financial services (ISO/TC 68, ISO/TC 68/SC4)
28	MTC-44:Quality management and quality assurance (ISO/TC 176, SC1, SC2, SC3)
29	MTC-45: Environmental management (ISO/TC 207, SC1)

30	MTC-46:Quality management and corresponding general aspects for medical devices (ISO/TC 210)
31	MTC-48:In vitro diagnostic medical devices (CEN/TC 140, ISO/TC 212)
32	MTC-51:Health informations (CEN/TC 251, ISO/TC 215)
33	MTC-61:Transportable gas cylinders (CEN/TC 23, ISO/TC 58, SC2)
34	MTC-66:Liquefied petroleum gas equipment and accessories (CEN/TC 286)
35	MTC-67:Information Technologies (ISO/IEC JTC 1)
36	MTC-69:Software and System Engineering (ISO/IEC JTC 1/SC 7)
37	MTC-70:IT Security Techniques (ISO/IEC JTC 1/SC 27)
38	MTC-73:Wilding (CEN/TC 121, ISO/TC 44)
39	MTC-76:Textiles and textile products (CEN/TC 248, ISO/TC 38, SC 1, SC 2, SC 20)
40	MTC-80:Non-destructive testing (CEN/TC 138, ISO/TC 135)
41	MTC-81:Plastics, plastics piping systems and ducting systems (ISO/TC 61, CEN/TC 249, CEN/TC 155, ISO/TC 138, SC 6,)
42	MTC-82:Metal hoses, hose aseemblies, bellows and expansions (CEN/TC 342, ISO/TC 5 SC 11)
43	MTC-83:Tourism services (CEN/TC 329, ISO/TC 228)
44	MTC-84:Inland navigation vessels (CEN/TC 15, ISO/TC 8, SC2, SC 3, SC 7, SC 8,SC 9, SC 11, SC 12)
45	MTC-85:Packaging (CEN/TC 261, ISO/TC 122, SC 3)
46	MTC-88:Lifts, escalators and moving walks (CEN/TC 10) (ISO/TC 178)
47	MTC-89:Leather (ISO/TC 120, ISO/TC 120/SC 1, ISO/TC 120/SC 2, CEN TC 289)
48	MTC-91:Characterization of waste (CEN/TC 292)
49	MTC-92:Leaf tobacco (ISO/TC 126, SC 2)
50	MTC-94:Geographic information/Geomatics (ISO/TC 211)
51	MTC-95:Non-active medical devices (CEN/TC 205, CEN/TC 285, ISO/TC 150)
52	MTC-96:Manual means of fire fighting equipment (CEN/TC 70, 72, 127, 191, 192, ISO/TC 92, ISO/TC 21 SC 8)
53	MTC-97:Central heating boliers using gaseous fuels (CEN/TC 109, CEN/TC 62)
54	MTC-98:Safety and control devices for burners and appliances burning gaseous or liquid fules (CEN/TC 58, CEN/TC 236)
55	MTC-99:Ceramic ware, glassware and glass ceramic ware in contact with food (ISO/TC 166, CEN/TC 194, ISO/TC 186)
56	MTC-100:Sterilizers for medical purposes (CEN/TC 102, CEN/TC 204)
57	MTC-101:Conformity assesment (ISO/CASCO)
58	MTC-105:Natural gas (ISO/TC 193, ISO/TC 67, ISO/TC 153/SC1, CEN TC 12, ISO/TC 22 / SC 25)
59	MTC-106:Cycles (CEN/TC333, ISO/TC 149)
60	MTC-107:Recreation equipments
61	MTC-108:Energy management
62	MTC-109:Natural stones (CEN/TC 246, ISO/TC 196)

63	MTC-110:Execution of steel structures and aluminium structures (CEN/TC 135, CEN/TC 250, CEN/TC 297, ISO/TC 59 SC 3, SC 8, SC 13, SC 14, ISO/TC 98, ISO/TC 167)
64	MTC-111:Sustainability of construction works (CEN/TC 350, ISO/TC 59 SC 16, SC 17, ISO/TC 205)
65	MTC-113:Equipment for explosive atmospheres (IEC/TC 31, CLC/TC 31)
66	MTC-114:Masonry (CEN/TC 125)
67	MTC-115:Airport and aviation security services (CEN/PC 384)
68	MTC-116:Solar photovoltaic energy systems (CLC/TC 82, IEC/TC 82)
69	MTC-117:Ergonomics of human-system interaction (ISO/TC 159 SC 4)
70	MTC-118:Application of statcitical and related methodology for new technology and product development (ISO/TC 69 SC 8)
71	MTC-119:Aesthetic surgery services (CEN/TC 403)
72	MTC-120:Fuel cell technologies (ISO/TC 197, IEC/TC 105)
73	MTC-121:Rolling bearings (ISO/TC 4, SC 8, SC 9)

Source:http://www.tse.org.tr/hizmetlerimiz/uluslararas%C4%B1-standardizasyon/ayna-komiteler/mevcut-ayna-komiteler

Appendix H: Tez Fotokopisi İzin Formu

TEZ FOTOKOPİSİ İZİN FORMU

ENSTİTÜ

Fen Bilimleri Enstitüsü [ ]

Sosyal Bilimler Enstitüsü [X]

Uygulamalı Matematik Enstitüsü [ ]

Enformatik Enstitüsü [ ]

Deniz Bilimleri Enstitüsü [ ]

YAZARIN

Soyadı : SARBAY
Adı : ZEYNEP SAYGIN
Bölümü : BİLİM VE TEKNOLOJİ POLİTİKASI ÇALIŞMALARI

TEZİN ADI (İngilizce) : THE CE MARKING AND THE IMPLEMENTATION IN TURKEY: THE CHALLENGES AND THE COMPLEXITIES

TEZİN TÜRÜ : Yüksek Lisans [X] Doktora [ ]

1. Tezimin tamamından kaynak gösterilmek şartıyla fotokopi alınabilir. [ ]
2. Tezimin içindekiler sayfası, özet, indeks sayfalarından ve/veya bir bölümünden kaynak gösterilmek şartıyla fotokopi alınabilir. [ ]
3. Tezimden bir (1) yıl süreyle fotokopi alınamaz. [X]

TEZİN KÜTÜPHANEYE TESLİM TARİHİ: