AN ANALYSIS OF TECHNICAL BARRIERS TO TRADE WITHIN THE EUROPEAN UNION PERSPECTIVE

A Master's Thesis

by

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I certify that I have read this thesis and have found that it is fully adequate, in scope and in quality, as a thesis for the degree of Master of Arts in Economics.

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ABSTRACT

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After setting up the necessary framework for the subject on technical barriers to trade (TBT), this study tries to enlighten the removal efforts of the TBT within the European Union (EU) and Turkey. In this respect, this study covers the removal approaches of TBT in the EU together with Turkey's alignment with the EU on the subject, as required by the Customs Union Agreement. This study also tries to evaluate the importance of different approaches on the removal of TBT on the Turkish trade with the EU. This evaluation is prepared by allocating external trade values for product groups into the regulatory approaches of the EU and analyzing the coverage of these approaches in the total external trade of the EU-15 countries. Accordingly, it is found that most of the Turkish trade with the EU-15 countries may be subject to technical regulations. Moreover, it is observed that the shares of the Turkish trade regarding the different EU approaches on TBT evolve over time. This study discovers that the importance of harmonizing the EU legislation on the

removal of TBT on Turkish exports to the EU-15 has been increasing over the timeline. Additionally, it is observed that the number of product groups, which Turkey reveals as comparative advantage in harmonized area, is increasing over time. Thus, Turkey is becoming more competitive in the EU-15 market.

Keywords: Turkish-EU trade, Technical Barriers to Trade, Revealed Comparative Advantage

ÖZET

TİCARETTE TEKNİK ENGELLERİN AVRUPA BİRLİĞİ YAKLAŞIMI PERSPEKTİFİNDE BİR ANALİZİ

Tok, Ertan
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Bu tez çalışması Ticarette Teknik Engeller (TTE) konusu için gerekli altyapıyı kurduktan sonra Avrupa Birliği'nde (AB) Türkiye'de Ticarette Teknik Engellerin kaldırılması çabalarına ışık tutmaya çalışmaktadır. Bu bağlamda, bu çalışma AB'de TTE'lerin kaldırılma yaklaşımlarını, Türkiye'nin AB ile bu konudaki Gümrük Birliği Anlaşması çerçevesindeki uyum durumunu ele almaktadır. Bu tez çalışması ayrıca TTE'lerin kaldırılmasındaki değişik yaklaşımların Türkiye'nin ve AB ile ticareti üzerindeki önemini değerlendirmeye çalışmaktadır. Bu değerlendirme ürün gruplarının dış ticaret değerlerinin AB düzenleyici yaklaşımlarına dağıtılması ve bu yaklaşımların AB-15 ülkelerinin toplam dış ticaretindeki paylarının analizi ile hazırlanmıştır. Buna göre Türkiye'nin AB-15 ülkelerine olan dış ticaretinin çok önemli bir kısmı teknik regülasyonlara tabi olduğu gözlemlenmiştir. Ayrıca, Türkiye'nin AB - 15 ile dış ticaretinin değişik AB yaklaşımlarına göre payı da zaman içinde değişiklik gösterdiği bulunmuştur. Bu çerçevede ticarette teknik engellerin kaldırılmasına

yönelik uyumlaştırılmış AB mevzuatının Türkiye'nin AB-15 ülkelerine yaptığı ihracatta zaman içinde öneminin arttığı ve görülmektedir. Ayrıca Türkiye'nin uyumlaştırılmış alana tabi olan ürün gruplarında zamanla açıklanmış karşılıklı üstünlüğe sahip olduğu ürün grubu sayısını arttırıp, AB-15 pazarında daha rekabetçi bir konuma geldiği gözlenmiştir.

Anahtar Kelimeler: Türkiye-AB ticareti, Ticarette Teknik Engeller, Açıklanmış Karşılıklı Üstünlükler

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CHAPTER 1

INTRODUCTION

This study aims to shed light on the removal efforts of the Technical Barriers to Trade (TBT) subject in the perspective of the European Union (EU) and Turkey. In this manner, we first set up the necessary framework on the standards and related concepts, namely technical regulations, conformity assessment procedures, and market surveillance. Following that, we try to explain the TBT phenomenon and their elimination methods. We then address the TBT subject in the EU by emphasizing on the approaches of their removal. In the EU perspective, we evaluate the position that Turkey possesses in the subject regarding the Customs Union (CU) requirements. After that, in order to detail an EU approach on the subject, we address the new chemicals policy of the EU, REACH, together with Turkey's alignment with it. Finally, referencing the EU members, we recover the importance of different approaches on the removal of TBT for the external trade of Turkey with the EU, as we evaluate the competitiveness of Turkey in those approaches.

In contemporary international economic conjecture, standards are necessary elements for the efficient operation of individual markets as well as smooth functioning of trade among different partners. When complemented with proper

conformity assessment mechanisms and enforced with efficient market surveillance, activities standards can promote information diffusion, competition, productive and innovative efficiency, quality and safety as well as the protection of public welfare and exploitation of network effects in an economy. The discussion on the standards, conformity assessment mechanisms, and market surveillance are addressed in Chapter 2.

On the other hand, standards and related concepts can also be a hidden mean for the protection of domestic producers when they are considered in the international trade setting. Differing national standards, technical regulations, and conformity assessment procedures generate frictions in international trade. They are thus collectively called the TBT which enforces additional costs on exporters to sell their products in countries where such measures exist. Imposing additional costs on producers, TBT reduce the welfare for both trading parties restricting them to reap the benefits stemming from free trade. In this respect, various attempts remove the frictions on free trade in both global and regional levels. This study explains the TBT phenomenon in Chapter 3.1.

After setting out the necessary framework on the subject, we focus on the regional level efforts in the EU (in Chapter 3.2), the Community level approaches in the removal of TBT together with Turkish approaches on the subject. Initially, the EU has proposed a total harmonization modality for some products or some product properties in a narrow sense, the Old Approach, in order to remove TBT among its members. In this approach of harmonization, conformity assessment procedures are detailed within harmonization directives and left to designated public

authorities of the EU member states. However, the inefficiencies faced within the legislation and application of the Old Approach led the EU to come up with a New Approach of harmonization. Instead of a total harmonization, the New Approach proposes harmonization of essential requirements of broad categories of products that foresee a greater flexibility for manufacturers to comply with these requirements. The New Approach also proposes an operative quality infrastructure that actively gives a place for the manufacturers' conformity assessment declaration as well as third-party conformity assessment organizations. Although the Old Approach and the New Approach regulations cover most of the products traded in the community market, some products are still left non-harmonized in the community level. For these products, countries are free to impose their own requirements as long as they mutually recognize each other's technical regulations and conformity assessment procedures. The EU perspective on the removal of TBT is addressed in Chapter 3.2.

Turkey has been involved in the EU approaches on the removal of TBT with the establishment of the CU in 1996 between Turkey and the EU. With this perspective, we turn our attention to the Turkish position on the subject. The establishment of the CU requires Turkey to harmonize all horizontal and vertical measures of the EU in the subject as well as to establish a standardization infrastructure that is parallel to that of the EU. However, the TBT subject has not been overcome among parties. In this respect, we evaluate the efforts of Turkey in the light of the CU requirements in Chapter 3.3.

Following, we address the harmonization measure in the EU, targeting a specific group of products. In this manner, we evaluate in Chapter 4 the structure of technical requirements under the new chemicals policy of the EU. In this chapter, we also assess Turkey's position on the subject matter.

For the final part of this study, we analyze and evaluate the Turkish trade vis-à-vis the EU-15,[1] referencing the trade values of other members of the EU-15, in the perspective of the EU measures of the removal of the TBT. We replicate and extend a previous study conducted by Brenton et al. (2001) for the case of Turkey with different regulatory and data sources. First, we recovered the importance of different approaches on the removal of TBT in the trade figures of EU-15 for Turkey. Then, we conducted a deeper analysis regarding a revealed comparative advantage (RCA) for the product groups that are subject to different EU approaches on the removal of TBT.

[1] The EU-15 member countries include Austria, Belgium, Germany, Denmark, Spain, Finland, France, Great Britain, Greece, Ireland, Italy, Netherlands, Portugal, and Sweden which are the EU members as of 1996.

CHAPTER 2

STANDARDS, CONFORMITY ASSESSMENT, AND MARKET SURVEILLANCE

Standards, in general terms, are regulatory norms that are widely approved. Standards provide homogeneity between different people, organizations, materials, and products, among others while making them meet on a common norm to apply. In this study, the term “standards” is considered in its economical meaning. From this perspective, a standard is defined as "a prescribed set of rules, conditions, or requirements concerning definitions of terms; classification of components; specification of materials, performance, or operations; delineation of procedures; or measurement of quantity and quality in describing materials, products, systems, services, or practices" by Breitenberg (1997).

In contemporary international economic conjecture, standards are necessary elements for the efficient operation of individual markets as well as smooth functioning of trade between different partners. However, the benefits associated with standards can be realized if their usage is complemented with proper conformity assessment, the procedures which evaluate and assess the compliance to products and processes to the standards in question. Because standards merely

would not be able to render their purposes without some degree of confidence on compliance of products or services for which they are designed (National Research Council, 1995). When standards and associated conformity assessment procedures are monitored and enforced with effective market surveillance operations by public authorities that guarantee convenient application of them, standards can promote information diffusion, competition, productive and innovative efficiency, quality and safety as well as can help protection of public welfare, exploitation of network effects.

2.1. Standards

All these functions of standards deserve a discussion. However, in order to set up a general framework on standards consideration, it is essential to differentiate them based on their purpose and judicial positions before discussing their functions.

Based on their purpose, standards can be classified under different titles. **Measurement standards** set up a common language, allowing agents in the economy to compare physical attributes of products and to convey explanatory technical information. **Product standards** describe measurable characteristics met by the product, while **process standards** specify requirements under which the process should be carried out. Similarly, **service standards** define requirements that apply while they are given to achieve the designated purpose of the service. **Test method standards** define the process and procedures to be used in conformity assessment procedures. Finally, **management system standards** are the norms regulating the different functions of enterprises subject to a proposed criterion such

as increasing quality, reducing environmental damage, or supplying occupational health and safety (Breitenberg, 1997).

Note that not all standards are mandatory in their usage. Standards that are imposed by public authorities and mandatory in usage are called **technical regulations**. In spite of the fact that standards, as a term, are generally used to encapsulate technical regulations; from the judicial view, standards differ from technical regulations. Noncompliance to a technical regulation prevents a product to be placed on the market in which that technical regulation is defined. However, not satisfying a standard does not lead a market ban on that product. Instead, the sales of that product may be influenced by customer preferences. Therefore, in general, standards may be classified as **voluntary standards** or **mandatory standards** (Togan, 2010). However, many times, voluntary standards gain mandatory status with their adoption by the governmental procedures (National Research Council, 1995).

2.1.1. Functions of Standards

Standards are generally formed to dissipate an inefficiency source in an economy. However, although targeting an aspect of inefficiency in the economy, Blind (2004) states that most of the standards serve more than one purpose and thus cannot be classified into a single category regarding their functions. Noting that, Blind (2004) followed by Guasch et al. (2007) classifies standards into four groups due to their functions since they consider such a distinction as important for theoretical reasons. According to Blind (2004) and Guasch et al. (2007), due to their functions,

standards can be classified as information and reference standards, variety-reducing standards, compatibility and interface standards, and minimum quality and safety standards.

Information and reference standards are the cluster of standards that define a common technical reference regarding the physical attributes of a product. For example a bolt, having a standard "M10 x 1.5-6g-S" in ISO 965-1 classification, is understood as a “metric fastener thread profile M, fastener nominal size (nominal major diameter) 10 mm, thread pitch 1.5 mm, external thread tolerance class 6g, and thread engagement length group S (short)”.

Variety-reducing standards define common characteristic for a product limiting them in terms of quality and measurement. For example, ISO 216 standard defines properties for paper formats (e.g., A3, A4, etc.) which are widely used throughout the world.

Compatibility and interface standards specify a physical or virtual relationship between different products in order to make them operate together. For example, 2.5 mm or 3.5 mm socket types are interface standards for earphones. A personal music player having a 3.5 mm socket type can only be used with an earphone having a 3.5 mm socket.

Minimum quality and safety standards determine some certain quality or safety properties for products. The EN 71-2 standard, which sets out non-flammability requirements for toys, can be given as an example for these kinds of standards. After making a classification on standards based on their functions, we can extend our discussion on them regarding their functions.

2.1.1.1. Reduction of Information Deficiency

Regardless of their types, all standards convey information about the characteristics of products. When a transaction on a product occurs between a seller and a buyer, many times one of the parties (generally the buyer's side) has deficient information about the product. The existence of standards conveys information between parties that decrease the search and transaction cost for the buyer's side and thus enhances efficiency in the market. The standards allow buyers to approach the products having the desired characteristics without additional search or independent testing (Guasch et. al, 2007 and WTO, 2005). Recall the earphone example, a consumer desiring to buy an earphone for her portable music player with a 3.5 mm socket can buy any earphone having the same socket without trying any other earphone in order to decide on the compliance of her player.

This information transfer is especially important when minimum safety standards are considered because these standards convey information for the buyer about the detrimental effects of products. This allows a buyer to beware of products that may have adverse effects and direct them to safer alternatives. Additionally, minimum quality standards can guarantee the existence of the products having high-level quality. Suppose a buyer is not informed about the quality of the product she intends to buy. Here, quality refers to any of the characteristics that may be measured in an objective perspective. For such a situation, a rational buyer will proceed to the cheapest available option. Assuming that supplying a product of higher quality is more costly, not being able to compete, the producers of the high quality products will vanish off the market either shifting to lower quality

production or becoming obsolete. What if there is a demand for high quality products or a certain characteristic of a product is crucial in terms of human health. Here, minimum quality and safety standards may operate to sustain high quality products to be in the market (WTO, 2005).

2.1.1.2. Technology Diffusion

Standards in general may be a vehicle in spillover of good technological approaches. If a particular technological approach is codified via standards, then virtually any agent can adopt it or use it to generate new ideas. In this perspective, a standardized innovation may yield increase of productivity throughout the industry via diffusion from its inventor to the other parties in the same industry. Moreover, the standardization process is information diffusive itself since standards are generally an outcome of a coordinated development process in which different parties interact and share information with each other (Guasch et. al, 2007).

2.1.1.3. Increasing Productive and Innovative Efficiency

The increasing productive efficiency is another type of function that is common for most standards. For example, variety-reducing standards directly decrease options for demands for a product type. Being aware of this phenomenon, a producer will supply a limited range of products. This specialization on some product categories and mass production will yield economies of scale with more homogenous production and lower unit cost. On the other hand, this concentration also allows manufacturers to allocate their resource to research and development efforts for a

limited number product, thus leading innovative efficiency as well (Guasch et. al, 2007).

Compatibility standards can likewise yield productive efficiency since producers will use compatible parts in their production. When a component is used in different final products, there is no need to produce or keep inventory of a variety of different components. Similar with variety-reducing standards, compatibility standards also restrict the producers' concentration on a limited number of options allowing them to allocate their efforts more efficiently in innovation. Additionally, minimum quality and safety standards may also derive producers to come up with more efficient designs and production methods to modify their products in order to meet these requirements (Guasch et. al, 2007).

2.1.1.4. Exploitation of Network Effects

Network externality is defined as the surplus benefit that an agent derives from consumption of a good when the number of agents that consumes the same good increases. However, this potential about a network would not be fully utilized with the existence of so many horizontal standards for the same kind of products. The potential here, in terms of welfare, may be far more above the market outcome due to the positive externalities created by network effects. However, different tastes of consumers, information deficiencies, and firms' actions in the market like promotions and advertisement may yield a market outcome where parallel standards exist for similar kinds of systems. In fact, the private benefit affects an individual's decision to join a specific system whereas social benefit is the

aggregation of private benefit that a newly joined individual derives and the marginal benefit of existing individuals in the system through the enlargement of network (WTO, 2005).

Compatibility and interface standards can be used to exploit network externalities in the system markets because a predetermined standard for compatibility of elements would solve coordination problem of producers. This in turn also solves the coordination problem among consumers ultimately yielding a more optimal social outcome. Because if all the products in a system market were compliant, then the consumers would naturally buy the products that are compatible with each other and they will be able to obtain the benefits that arise from the network structure of a market (WTO, 2005).

2.1.1.5. Increasing Competition

Approximating certain characteristics of products and thus making products closer substitutes to each other, standards increase the competition among different producers in general. Such competition benefits the consumers. For example, variety-reducing standards intensify the competition on a limited number of products, as they limit the variety of products to be introduced in a market. In the case of minimum quality and safety standards matching certain criteria, all firms harmonize their products on a single norm and compete more on prices with each other. Decreasing monopoly power and increasing competition ultimately yield a more optimal allocation of resources and thus introduce more efficiency to the economy (Guasch et al., 2007 and National Research Council, 1995).

2.1.1.6. Protection of Public Welfare

Standards can also be used as a means of promoting social objectives such as the protection of public health and safety as well as the environment. When the social dimension of the markets are considered, there may be some negative externalities in the market regarding products or associated production processes that are considered. For example, negative environmental externalities occur as a part of market failure because of misusage of environmental resources like air, water, and land in the production process of product or when the product is used. Similarly, a product that lacks safety may cause injuries or deaths, or a toxic product may cause diseases for people. In both cases, the associated negative externality is allocating more resources to medical operations.

In order to neutralize these negative externalities and to reach a more optimal social market outcome, governments may impose minimum quality and safety standards for the products in the market. In fact, most of the mandatory standards (technical regulations) are obligated by governments in this perspective. Mandatory safety and carbon emission requirements for motor vehicles as well as the requirements over the level of pesticide residues in food products can be given as examples to the promoting public welfare usage of standards.

2.1.2. Standards Formation

There are three different methods to form a standard. Some standards flourish within an industry due to uncoordinated processes in a competitive market setting. These standards are called **de facto standards**. If a specific set of product or process

specifications developed by a firm achieves a considerable market share acquiring high influence, then the set of specifications is considered as a de facto industry standard. De facto standards may be anonymous or may be patented on some individual or institution. A good example for anonymous standard would be QWERTY type keyboard layout which is a most commonly used keyboard layout type throughout the world. On the other hand, most of the industry standards are patented. A widely known patented de facto standard example would be Teflon, a material used in internal covering of frying pans.

Voluntary consensus standards arise from an intended, formal, and coordinated process in which major participants in the market or sector seek consensus with each other. The key participants may involve not only producers and designers but also consumers as well as corporate and government purchasing officials and regulatory authorities. The resulting standards are voluntary in usage, in this case. Voluntary consensus standards may be established within a market or may be a product of a formal formation mechanism. For example, a compact disc (CD) is a voluntary consensus standard developed by the consensus of two prominent industrial companies, Sony and Phillips, in the market level. On the other hand, all of the standards developed by national or international standardization organizations can be given examples for formal voluntary consensus standards. For instance, the International Standardization Organization (ISO) 9000 quality management standard developed by the ISO is a voluntary consensus standard. Note that since most of the voluntary standards are generated deliberatively and with compromise, they often become national or international standards through

their adoption by standardization organizations. For example, the CD standard is adopted by the ISO and now has international characteristics under the standard name, ISO 13490. However, this adoption does not require the usage of relevant standards in the commodities for which they are designed since they are voluntary in nature.

Finally, the standards, which are referenced by regulatory authorities, are simply called **mandatory standards**. They may be formed or adopted by public authorities for a specific purpose from convenient standards that already exist in the subject. In fact, any type of standard recognized and referenced by public authorities is mandatory in its usage. For example, a procurement standard is a mandatory standard specifying requirements used in government purchases to be met by suppliers. On the other hand, most of the mandatory standards clusters are intended to protect public welfare in terms of human safety and health, environmental or related criteria. For instance, in order to protect human safety, seat-belt equipage is mandatory for automobiles to be placed on the market in most of the countries (National Research Council, 1995).

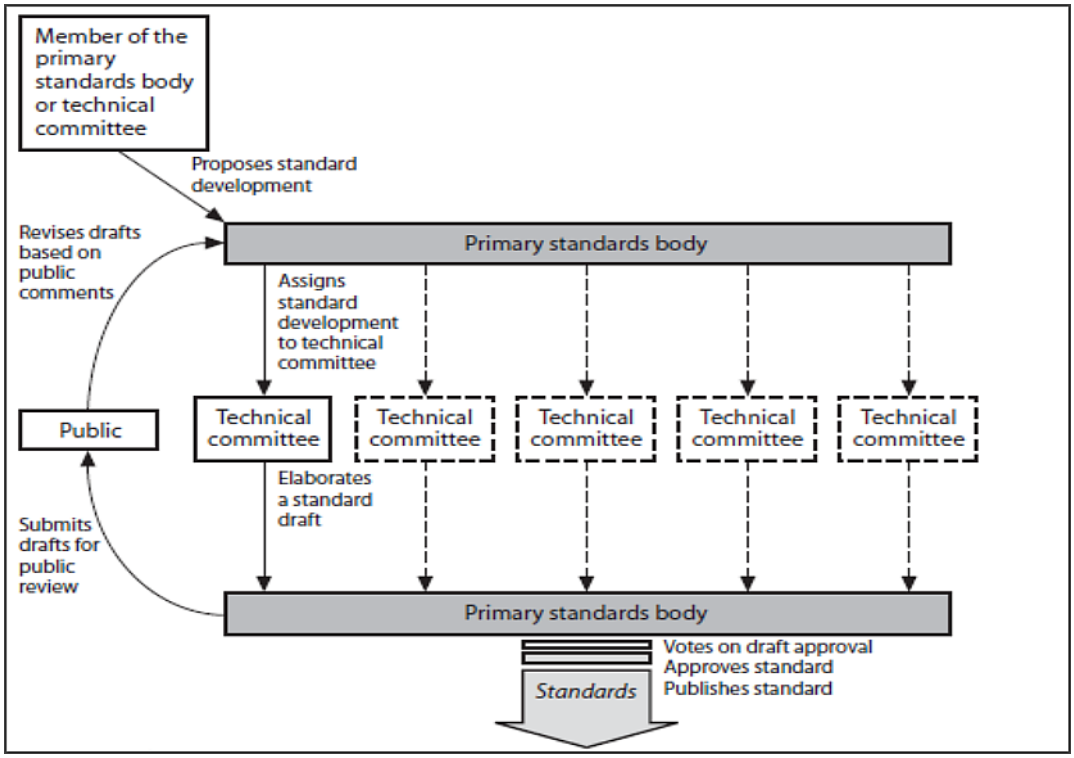
2.1.2.1. Role of Standardization Organizations

Standards vary among countries because of differences in consumer choices, levels and distributions of income, the sensitivity to natural concerns, technological advancement, or historical reasons. In a parallel manner, standard development activities also vary among countries. In some countries, a single central organization exists for the development of national standards, while in other countries, a variety

of institutions develop standards to meet the market requirements (Gausch et al., 2007).

As stated in the previous paragraph, standardization activities in some countries are gathered in a single central organization. For example, most of the EU member states have such a structuring in standardization. A national standardization organization (NSO) typically operates with work programs assigned to relevant technical committees in order to bring up standards in their specialty area. These technical committees consist of representatives from public authorities, industry, consumer associations, research institutions, and the academia. The standardization activities can be initiated by the members of the standards organization, the members of a technical committee, or other relevant parties outside of the NSO. If there is sufficient support for a plan in the standards organization, the technical committee begins to study and elaborate a standard. Once the technical committee has reached a consensus, a draft of the standard is submitted to a vote by members of the NSO. If approved, the standards body then subjects the draft to public enquiry. During the public review process, the draft is typically made available to the comments. Once the technical committee has revised the draft to incorporate public comments, the standards body finalizes, adopts, publishes, and distributes the standard. The resulting standard is adopted as a national standard (Gausch et al., 2007). Figure 2.1 illustrates a central standardization mechanism.

Figure 2.1. Illustration of a Centralized Standardization Mechanism

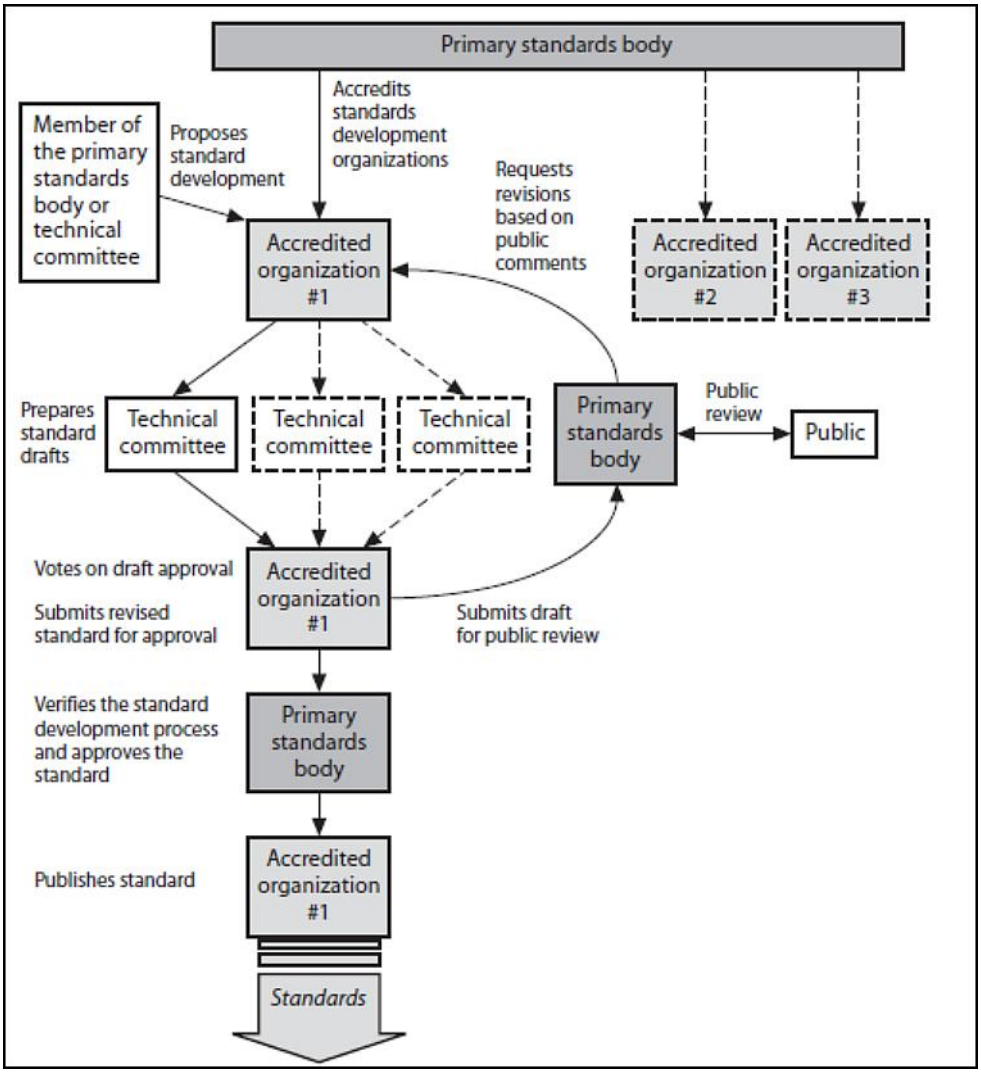


Source: Guasch et al. (2007)

On the other hand, in some countries standardization activities are organized in a more decentralized structure and more market oriented rather than a centralized manner. For example, in the United States of America (USA), the American National Standards Institute (ANSI) is appointed as the coordinating standardization body. However, neither ANSI nor another single standardization body operating in the USA develops the American standards. There are about 220 standardization entities including professional and technical organizations, trade associations, research, and testing institutions accredited by the ANSI. These individual bodies follow a standardization process similar to the aforementioned NSOs. Once they propose a standard, they capture public comments on the developed standard through their submission to the ANSI. Following public comments, the accredited standardization

bodies finalize their standards proposals. The ANSI assesses compliance with the approved development procedures. If the ANSI approves it, a standardization organization can publish a newly developed standard (Gausch et al., 2007). Figure 2.2 represents an illustration of a decentralized standardization mechanism within a country.

Figure 2.2. Illustration of a Decentralized Standardization Mechanism



Source: Guasch et al. (2007)

In order to provide homogeneity for standards in the regional and international level, standards organizations are also organized under regional and international standards setting organizations. At global level, three leading industrial standardization organizations exist: the ISO, the International Electrotechnical Commission (IEC), and the International Telecommunication Union (ITU). While the first two are independent nongovernmental organizations, the latter one is a division working under the United Nations (UN). The IEC is responsible for setting electrotechnical standards, while the ITU is responsible for setting telecommunication standards. The ISO covers all the range of standards that are beyond the scope of the IEC and the ITU. Those three organizations generally perform their functions in coordination. The ISO, the IEC, and the ITU are alike in two important ways. First, they have similar administrative structures with committees, subcommittees, and working groups directing the standards-setting process. Second, they all promote consensus for the final decision-making mechanism (National Research Council, 1995). Individual national standardization organizations are members of these organizations and actively participate on international standardization activities through their delegates. The resulting voluntary consensus standard is public for the usage of any interested party.

The standards formation within the ISO and the IEC are similar to centralized standardization mechanisms. For example, the standards creation mechanism in the ISO is as follows. There are three main phases in the ISO standards development process. The need for a standard is usually expressed by an industry sector, which communicates this need to a national member body. The latter proposes the new work item to the ISO as a whole. Once the need for an **international standard** has

been recognized and formally agreed, the first phase involves the definition of the technical scope of the future standard. This phase is usually carried out in working groups that comprise technical experts from countries interested in the subject matter. Once the agreement has been reached on which technical aspects are to be covered in the standard, a second phase is entered during which countries negotiate the detailed specifications within the standard. This is the consensus-building phase. The final phase comprises the formal approval of the resulting draft of the international standard. (The acceptance criteria stipulate approval by two-thirds of the ISO members that have participated actively in the standards development process, and approval by 75% of all members that vote.) The agreed text is published as an international standard (retrieved from www.iso.org on 05.09.2011).

On the other hand, the standardization mechanism inside the ITU differs a bit from the ISO and IEC. The standardization in the ITU is more market oriented. The standards developed by the ITU are referred to as "recommendations." The technical work, the development of recommendations of the ITU is managed by study groups (SGs). The people involved in these SGs are experts in telecommunications from all over the world. The SGs drive their work primarily in the form of study "Questions". "Questions" address technical studies in a particular area of telecommunication standardization, and are driven by contributions. Once an SG concludes that the work on a draft recommendation is sufficiently mature, the approval process begins. It is presented to members to solicit comments. If no comments are received on the draft, it is approved as a valid recommendation. Otherwise, following comments, the draft is revised during an SG meeting and

presented to members for approval. It is approved to be a recommendation unless more than one member state disapproves it, otherwise the adoption process returns to a draft preparation point (ITU, 2009).

2.2. Conformity Assessment Mechanisms

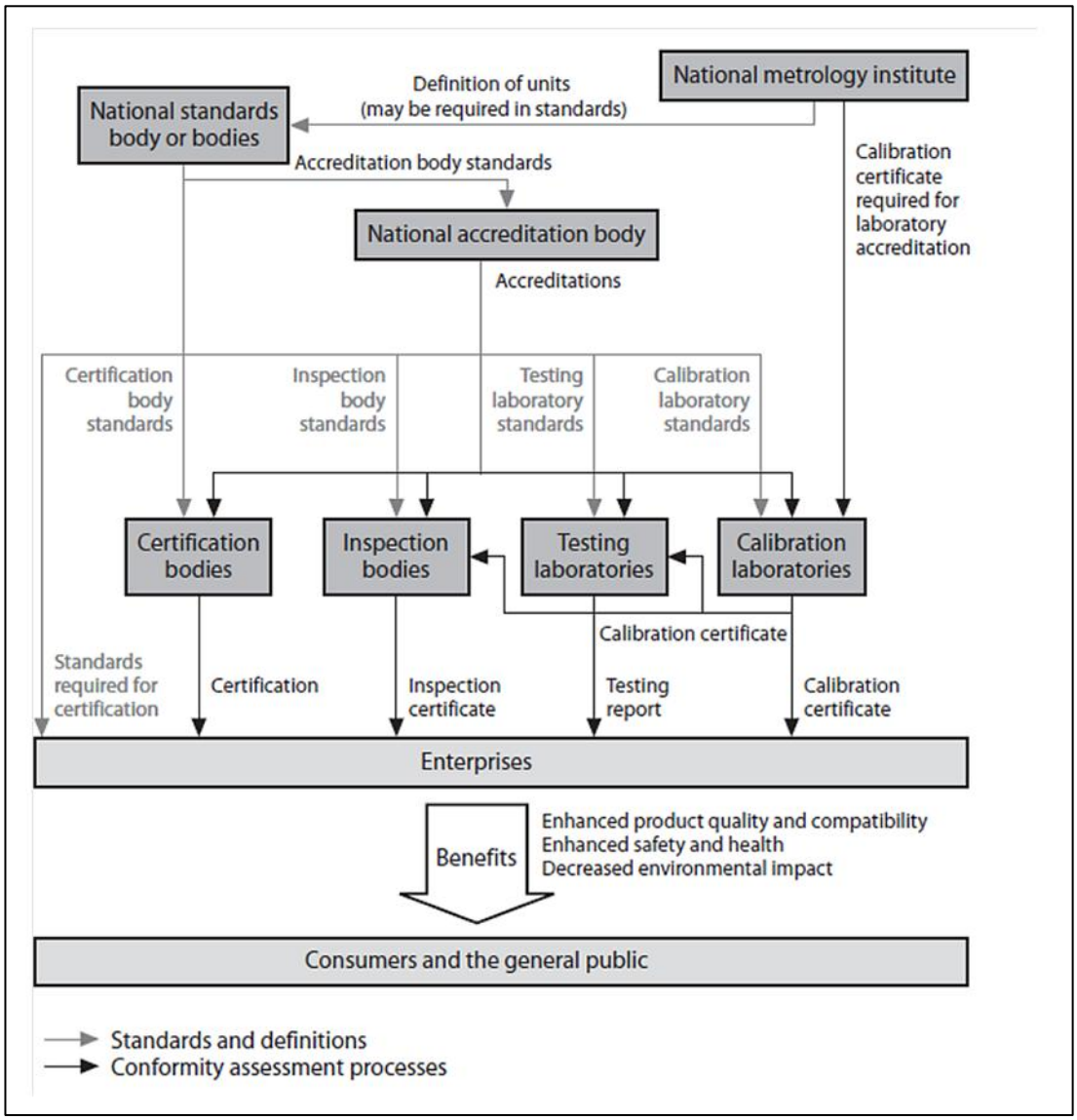
Conformity assessment is the comprehensive term for the procedures which evaluate and assess the compliance of products and processes to the standards in question. Conformity assessment is an essential aspect for the usage of standards because the mere existence of standards does not guarantee their proper diffusion in the absence of a mechanism for the validation of their usage. Standards contain technical specifications that can enhance safety, compatibility, quality, information diffusion, interchangeability, and information diffusion, among others. However, for the economy to reap these benefits, the producers must fully understand and comply with the standards. Therefore, in the context of many commercial and regulatory uses of standards, the measures to assess and ensure the conformity have as much or perhaps are more important than the sole standards (Guasch et al., 2007).

The usage of standards gains meaning with the appropriate conformity assessment mechanism. Because, in the case of many standards, especially for the quality and safety ones, self-enforcement incentives are low compared to gain by conforming a product or process to a standard. In above situations, producers may claim conformance to a standard for its product or process, even if it does not conform in reality. Moreover, the highly technical content of some standards may make it

difficult for producers to actually understand whether they have appropriately conformed to a standard or not. In the absence of a measure to differentiate the products in terms of conformity to a particular standards, having a limited usage, standards do not reach their objectives (Guasch et al., 2007).

The conformity assessment procedures may have multiple dimensions to determine a product's compliance to the measures specified in a given standard or technical regulation. Depending on the type specified by the conformity procedures related to a standard, the conformity assessment mechanisms may involve testing, inspection, and certification together with the manufacturer's self-declaration of conformity in a narrow sense. However, when considered in a wider scope, the conformity assessment mechanism encapsulates accreditation and metrology activities besides the ones earlier mentioned (WTO, 2005). Benefiting from the economic gains from standards requires a country to set up the necessary institutions that assess and acknowledge compliance with standards. This framework is completed with internationally recognized accreditation and metrology institutions in the top level which serves testing, inspection, certification, and calibration bodies that evaluate the conformance of products, processes, services, and organizations existing in the economy in the lower level (Guasch et al., 2007). Figure 2.3 shows a schematic representation of a national quality system as earlier mentioned.

Figure 2.3. Schematic Representation of a National Quality System



Source: Guasch et al. (2007)

2.2.1. Testing and Inspection

The basic technique for determining the characteristics of a product is the **testing** of specimens in individual or from samples according to a specified procedure. The performance of the product is assessed after testing results in the first step, and its conformity to the imposed requirements is then assessed based on its performance.

Testing requires specialized laboratories that possess sophisticated instruments to carry testing activities. The validity of testing results of the specimens concerning the whole batch depends on the rules specified in the conformity assessment measures for the standards. These rules may set levels for samples to be tested for a given quantity or other quantifiable measure. On the other hand, every individual item would be mandatory for testing, particularly the products that require high safety.

Another form of conformity assessment technique related to testing is **inspection**. Inspection is similar to testing but it relies on more simple instruments (such as scales) than testing, or it is usually carried by visual means. Inspection mostly relies on the expert's subjective adjudication ability in the area, while testing requires an objective and standardized procedure to be carried by educated staff. These two forms may be carried by the manufacturer's on-site facilities, regulatory authorities, or third party organizations depending on the requirements listed in standard or technical regulation (WTO, 2005 and Guasch et al., 2007).

In some cases, it may be sufficient for a supplier to give written assurance on the conformity of a product to the specified requirements. This is called **self-declaration of conformity**. Self-declaration of conformity does not require the testing and inspection to be carried at the supplier's own facilities. These evaluations may be well carried by third party bodies. However, the supplier (manufacturer, importer, or assembler—the party who is responsible for the products placement in the market) takes the full responsibility for the provisions related to conformance to set of required technical criteria. On the other hand, in many areas where safety,

health, and environmental concerns are high, self-declaration of conformity is not widely used. Instead, third party verification and certification is required. For instance, for the EU case, the electronic devices that operate under low voltage are all subject to self-declaration of conformity, as the risk associated with these kinds of products are relatively low. On the other hand, explosives for civil uses are all subject to intervention of a conformity assessment because these products are extremely sensitive. The associated risk to human health and safety with these products are relatively high (WTO, 2005).

2.2.2. Certification

Certification is the written assurance that a product, material, personnel, service, process, organization, or management system conforms to specific requirements that is given by authorized public or private third parties which are independent of the supplier or producer. The independence of certification bodies has a specific importance when parties desire to communicate compliance with standards to a larger public audiences or governmental authorities. Certification bodies generally specialize in specific areas and use various conformity assessment techniques to evaluate the manufacturers' product and systems. Besides their own technical facilities, certification bodies may employ the services of external laboratories and inspection resources as well. These organizations also carry on continuous surveillance regarding the certificates they issue. In the case of any deficiency in usage, they have right to withdraw the certificates they have already issued (WTO, 2005 and Guasch et al, 2007).

When the product level is considered, certification is generally based on type approval instead of testing whole products that are exposed to the market. For instance, the European Community (EC) Whole Vehicle Type Approval (ECWVTA) is based around the EC directives on automotive that provide the approval for whole vehicles, in addition to vehicle systems and separate components. This certificate is issued by designated approval bodies of each EU member state. However, a certification is widely used to evaluate systems. For example, the ISO 9000 certificate on quality management system requires an evaluation of conformance to the quality standard of a firm's management activities, whereas the ISO 14000 certificate on environmental management system is issued to firms that comply with certain environment-related criteria during their operations. The system certifications do not guarantee a product to comply with a specific technical specification; rather it is a quality measure regarding the environment where the product is made. In this context, the ISO 9000 certificate is a sign of proper quality control mechanisms and it is expected to reduce production errors and variations in product quality. Likely, a buyer knows that the process of manufacture of a product that is produced under ISO 14000 certificate gives less harm to the environment (WTO, 2005 and Guasch et al., 2007).

A certification conveys standardized information about the characteristic of a producer. The buyers benefit from it since it allows them to compare products or services regarding their desirable characteristics in terms of quality and safety, among others. It is a more reliable source than the sole confidence in the producer's reputation. Producers also benefit from certification since, as a sign of quality,

having a certificate distinguishes a producer from the ones that do not possess it (Guasch et al., 2007).

2.2.3. Accreditation

Accreditation is defined as the procedure by which an authoritative body gives formal recognition that an organization or person is competent to carry out specific tasks. Accreditation of an organization is a sign of its competence in its area. Therefore, it directly affects its reliability and validity of its assessments. Although accreditation bodies generally do not deal with verification of specifications itself, they must have upmost technical knowledge since they are in the position of assessing competence of certification and inspection institutions besides testing and calibration laboratories and technical experts. Accreditation institutions likewise carry out their tasks with compliance to a set of standards. Most of the accreditation institutions are accredited by upper level institutions to gain international recognition. Depending on the country, accreditation may be carried by specialized accreditation bodies or by a single institution. Accreditation is commonly considered as a governmental responsibility. The accreditation bodies are generally institutions that have a public character whereas inspection, testing, and certification are perceived mostly as commercial activities (WTO, 2005 and Guasch et al., 2007).

2.2.4. Metrology

Metrology is the complementary part for all conformity assessment activities. Establishing confidence in any measurement results as well as the capabilities of relevant laboratories requires calibration of testing or inspection instruments. Calibration (determination of metrological characteristics of an instrument through direct comparison to a standard) supplies traceability of results obtained by measuring instruments and allows them to operate within a specified level of uncertainties. Traceability involves a linkage from bottom to top level with calibrations to ultimate level of given metrological standard. This operation is carried through the national metrology institutes (NMIs) at the top level which are responsible to adjust measures used in calibration laboratories. Once they already have the precise measurement capability, calibration laboratories can make metrological assessment for the instruments used in the bottom level testing and inspection laboratories. On the other hand, the NMIs may increase their reliability and recognition by involving multilateral agreements with their counterparts in other countries (WTO, 2005).

2.3. Market Surveillance

Market surveillance is the final element for the efficient functioning of standards. It is carried by designated public authorities that monitor conformity of the products that are placed in the market with the required criteria laid down in specific standards and technical regulations. In order to enforce the technical requirements, these authorities take appropriate corrective actions in cases of nonconformity.

In order to perform their functions, market surveillance authorities must have sufficient financial resources to cover all areas within a country to reach products offered in every market with sufficient number of highly qualified experts and competent testing facilities. Market surveillance operations must be strictly separated by conformity assessment in order to provide impartiality and prevent a conflict of interests. However, in some cases, the surveillance authority may subcontract technical tasks (such as testing or inspection) to another body. In this case, the surveillance authority should retain its responsibility for its decisions and carefully consider possible interest conflicts that may arise from conformity assessment and surveillance activities of the hired external body (European Commission, 2000).

Efficient market surveillance needs its resources concentrated where high potential risks are anticipated, nonconformity occurs more frequently, or a particular interest is required. Scientific techniques using statistics and risk assessment measures should be used to be able to make above assessments. Market surveillance can be carried out by regular visits or random spot checks in markets or storage facilities for products and taking samples and subjecting them appropriate examination and testing. Although in principle, market surveillance does not involve controls in design and production stages. In cases of nonconformity, market surveillance must be capable of making these checks on-site in order to shed light on whether a constant error exists on the production process in a preventive manner for further nonconformance (European Commission, 2000).

CHAPTER 3

TECHNICAL BARRIERIS TO TRADE, AND THE EU AND TURKISH APPROACHES

Global integration of national markets through international efforts like successive rounds of the General Agreement on Tariffs and Trade (GATT) and the establishment of the World Trade Organization (WTO) has led the gradual elimination of at the border restrictions of trade barriers. However, free trade ideal is not attainable in a world where protective measures still exist. The elimination of border restrictions like tariffs and quotas has increased the relative importance of behind-the-borders measures which are stemmed from the differing domestic product regulations, namely standards, technical regulations, and conformity assessment procedures.

Differing standards, technical regulations and conformity assessment procedures among different countries are referred as **TBT** whenever a producer may have to alter its product to comply with importing partner country requirements for health, safety as well as environmental and consumer protection issues. These requirements can be imposed by both governments (technical regulations) and nongovernmental organizations (non-regulatory barriers, standards). In spite of

preventing both importer and exporter parties from reaping the welfare benefits associated with free trade, the impacts of TBT on international trade are more complicated and sometimes more restrictive than tariffs, quotas, or any form of trade barriers (Maskus et al., 2000 and Brenton et al., 2000). In fact, as previously stated, varying standards can reflect differences in consumer choices, levels and distributions of income, sensitivity to natural concerns, technological advancement, or historical reasons among countries. Technical regulations may also differ among countries because of national positions for the promotion of safety, health, and environment measures. Therefore, there may be a valid basis for not aligning standards, and technical regulations exist among trading countries (Gausch et al., 2007).

However, when standards and technical requirements are not justified by **legitimate** and **no more than necessary** level of health, safety, and environmental objectives, or they are not properly declared differing standards, technical regulations among countries create frictions to international trade by imposing additional cost figures on foreign firms or even deterring them to enter domestic markets. In many cases, even standards or technical regulations have been harmonized between countries or they both stem from the same international level measures. Not approving each other's conformity assessment procedures can also restrict the trade between parties because compliance to a standard or technical regulation is only useful when it is proved through conformity assessment procedures (Guasch et al., 2007).

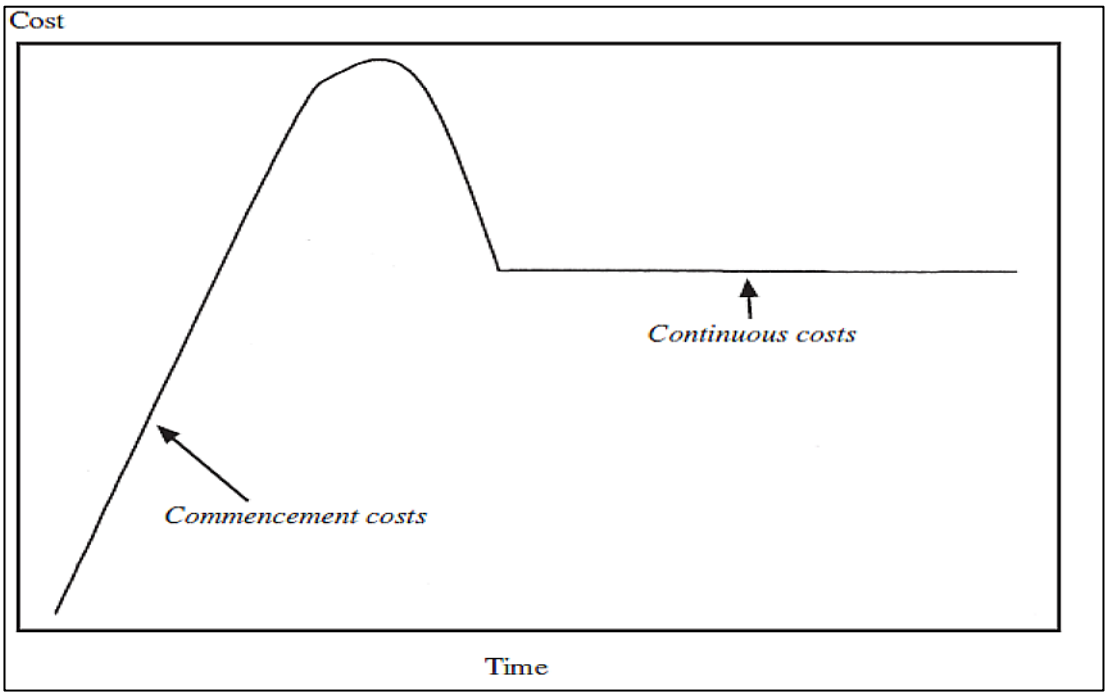
When at-the-border restrictions like tariffs and quotas are considered, they are more or less certain in terms of perception. Generally, they are imposed by a responsible public authority like national ministries of foreign trade and custom agencies. However, as a behind-the-border measure, technical regulations have different characteristics. They may be created, imposed, and examined by different national authorities due to their subject (Yılmaz, 2002).

In addition to their regulatory complexity, they are also complex in nature. That is, they may include environment, public safety, health, labor-related aspects, or a mixture of all these. The complexity associated with technical regulation creates an informational burden to the firms which are interested in exporting to that market. In order to comply with a given technical regulation, firms have to reach its content first and understand it clearly. However, when TBT exist in the export market, acquaintance to the requirements may not be easily attainable at all the times (Baldwin, 2000 and Yılmaz, 2002).

Besides the associated informational burden, physical compliance to a technical regulation has cost aspect in two dimensions. The first emerges at the production stage. In order to comply with foreign regulations, a firm would have to alter its production structure. Usually, firms have to redesign their products for compliance. This redesign may include a one-time fixed cost due to alteration of production (designing cost, buying new equipment, etc.) and a continuing variable cost. An element of continuing variable costs is a possible increase in the marginal production cost.

However, most of the recurring cost factor emerges in conformity assessment once a product is reshaped to comply with foreign regulations. It is common for importing party's authorities, not recognizing the conformity tests performed and certifications issued by foreign assessment bodies, and refusing conformity assessment to their own regulations (Baldwin, 2000 and Yılmaz, 2002). This situation yields multiple costs of certification and conformity assessment procedures for every market destination. Figure 3.1 summarizes the compliance cost profiles mentioned.

Figure 3.1. Compliance Cost Profile over Time



Source: Baldwin (2000)

In Figure 3.1, commencement cost encapsulates learning about the regulation and changes in the design of product, whereas continuous costs involves periodic conformity assessment costs and envisaged higher marginal variable cost (Baldwin, 2000). As a general assessment, countries may use standards, technical regulations,

and conformity assessment procedures to discourage foreign firms from entering the domestic market and thus protect home industries. However, their deterrent effect is not homogenous to all outside parties. Small firms are more affected than larger firms because larger firms can handle the associated cost burden largely due to economies of scale. On the other hand, developing countries are far more affected by TBT than the developed ones due to their lack of capacity for effective certification and accreditation of their testing facilities (Stephenson, 1997).

3.1. Elimination of Technical Barriers to Trade

In a global level, reducing the trade frictions that stem from TBT relies on the efforts of the GATT and later the WTO through the TBT Agreement. Historically, the TBT subject is first mentioned in the original GATT in 1947. However, the original GATT contains little explicit discipline on the TBT whose issue is taken into a work plan of the GATT during the Tokyo Round Negotiation between 1973 and 1979. The outcome of the TBT work in the Tokyo Round, the so-called Standards Code, extended the GATT 1947 disciplines on regulations to standards and conformity assessment procedures. Besides technical requirements, as its nature, the Standards Code has a plurilateral characteristic and only bound the Code signers.

The Standards Code later turned into the TBT Agreement as an integral part of WTO, during the Uruguay Round between 1986-1994. With the signature of all members, the TBT Agreement has strengthened and clarified the provisions of the Tokyo Round Standards Code. During the Uruguay Round, disciplines on food standards were split off from industrial goods and were combined in a manner, with the sanitary and phytosanitary (SPS) agreement (Baldwin, 2000).

The WTO-TBT Agreement lays down six common principles to be applied to preparation, adoption, and application of technical regulations. The **nondiscrimination** principle aims to ensure countries not to discriminate between similar domestically produced and imported goods due to the requirements they face. **Avoidance of unnecessary obstacles of trade** principle encourages countries to adopt measures in technical requirements only to fulfill a legitimate objective, e.g. national security, promotion of human health or safety, protection of environment etc., and to account of the risks non-fulfillment would create and should not be more trade restrictive than necessary. With the **harmonization** principle, members are encouraged to participate the international standardization[2] activities and use international standards if they are applicable.[3] **Equivalence** principles envisage members to accept other parties' regulation as equivalent even when they differ, provided that they fulfill the objectives of their own regulation. **Mutual recognition** principle encourages members to accept each other's conformity assessment results and to enter into negotiations for the conclusions of bilateral mutual recognition agreements (MRAs). Finally, **transparency** principle requires member states to notify WTO about the measures they are willing to adopt and to take into consideration the comments of other countries comments on the matter.

In spite of having a lead-in character, the WTO-TBT Agreement principles do not have an enforcement mechanism. This agreement provides the general framework. In fact, the frictions in international trade that stemmed from TBT can be overcome

[2] The international standardization bodies in this phrase refer to the ISO, IEC, and ITU.
[3] Exceptions to international standards are valid due to climatic factors, geographical factors, or technological problems.

by aligning differing technical requirements and conformity assessment procedures in different countries. These factors will not pose significant cost to producers in other countries.

The first method is the **harmonization** of technical regulations. Harmonization of technical regulations is converging into a consensus between parties and making them to adopt the same set of technical specifications. Harmonization can be achieved by either negotiation or through hegemonic enforcement. Harmonization by negotiation is generally a lengthy procedure, as it needs parties to compromise on exactly the same level of objectives. The negotiation is not an easy task especially when the initial level of political positions on the subject differs tremendously. Therefore, harmonization by negotiation is possible only when the parties have akin preferences and concerns. On the other hand, hegemonic harmonization arises when relatively small nations that are dependent on their larger partners unilaterally accept and legislate the measures of their partner as their own. Hegemonic harmonization is more attainable when compared to harmonization by negotiation.

The other alternative for overcoming TBT is the **mutual recognition of technical regulations** of involved parties. Mutual recognition is achievable when both parties believe that differing technical regulations serve a common objective even if they foresee different measures. The problem associated with the mutual recognition is that when a party has less stringent measures regarding the regulation, it may lead a race to bottom when firms find it more advantageous to comply with that party's specifications. In turn, parties may gradually lower their level of protections in mutually recognized area, to prevent their firms to lose their competitive position.

However, harmonization and mutual recognition are fully effective when the mutual recognition in the conformity assessment is also contracted between parties. MRAs are settlements between two parties (countries, groups, etc.) on which they agree to recognize the result of each other's testing, inspection, certification, or accreditation. MRAs reduce double conformity assessment procedures and have a special importance in international trade since they directly reduce costs of exporters which are reflected to the consumer's side as decreasing prices. To achieve these purposes, several international and regional systems of networks conformity assessment bodies have been set up to reduce bilateral coordination efforts. This network has upmost importance in the accreditation body level since when an agreement reached inside of the network of accreditation organizations, certificates from all certification bodies or test results from all laboratories accredited in one country are approved by the other countries without any need for bilateral agreement of individual countries (WTO, 2005). In the absence of MRAs, the firms in different parties may incur duplicate testing and certification costs even if they operate in the same set of technical regulations in their own country with another country (Baldwin, 2000).

3.2. The EU Approach to Technical Barriers to Trade

The problem of differing national legislations on product regulations has gained importance with the gradual integration of markets in the EC. The reducing efforts in technical barriers issue within the union had started before the Tokyo Round of the GATT by several years, and they had been addressed through several stages (Sykes, 1995). The removal efforts of TBT subject in the EU relies on Article 30-34 of

the Treaty of Rome (the EC Treaty) which prohibits quantitative restrictions on imports and all measures having equivalent effects. This principle was put into effect by the Commission Directive 70/50/EEC[4] which bans all measures that impose additional cost or restriction on imported goods. The 70/50/EEC lists 19 measures which constitutes barriers including uneven requirements for technical specification and testing favoring domestic products. However, Article 36 of the EC Treaty permits member states to apply exceptions in some specific cases on grounds of public morality, public order, public safety, and the protection of human or animal life or health, the preservation of plant life, the protection of national treasures of artistic, historical or archaeological value, or the protection of industrial and commercial property. Although Article 36 explicitly declares that such prohibitions or restrictions shall not constitute either a means of arbitrary discrimination or a disguised restriction on trade among member states. This article is open to exploitation of member states for trade protection purposes (Atkins, 1998 and Sabin, 1991).

Intra-community level frictions stemmed from differing national technical regulations which restrict free movement of goods leaded the EEC to come up with harmonization of technical regulations of different product groups. The primal efforts of harmonization, which started in 1970, consisted of issuing detailed directives relating to specifications and testing requirements of narrow product groups at the Community level. However, it was mostly time consuming since an

[4] Commission Directive 70/50/EEC of 22 December 1969 is based on the provisions of Article 33 (7), on the abolition of measures which have an effect equivalent to quantitative restrictions on imports and are not covered by other provisions adopted in pursuance of the EEC Treaty [OJ L 013 on 19.01.1970].

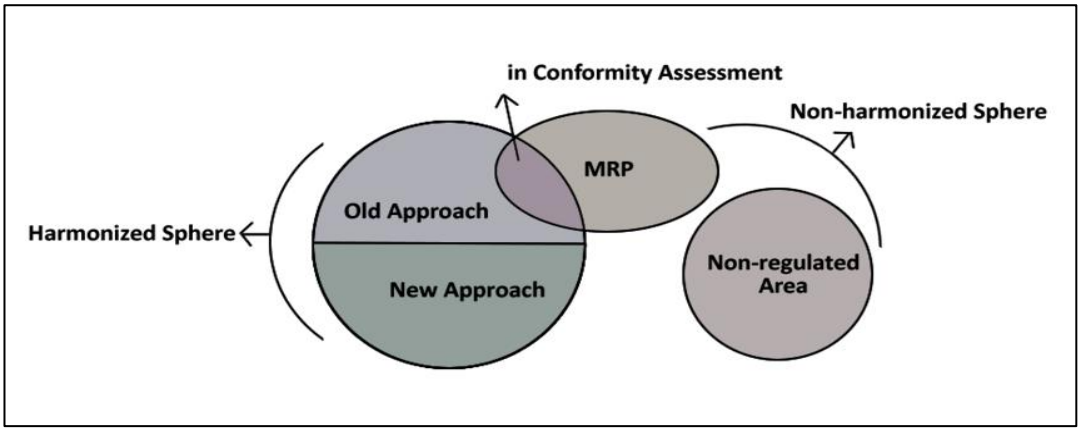
adoption of such a measure required the consensus of all members. Therefore this kind of detailed harmonization, called as Old Approach, proved itself inefficient and was abandoned since 1985. Although no Old Approach type of directives is issued for any newly harmonized areas and quitted for some of the regulated products, Old Approach directives persists to regulate areas which require specific health, safety, or environmental consideration like foodstuffs, chemicals, motor vehicles, labeling, and pharmaceuticals (Atkins, 1998).

The inefficient operation of Old Approach harmonization drove the Community to come up with a new type of harmonization technique, the New Approach, in 1985. The New Approach directives apply to groups of products which have similar characteristics where there used to be different technical regulations in all member states previously. However, the New Approach directives do not list detailed technical requirements of specifications and conformity. Instead, only essential requirements are listed. The European Standardization Organizations (ESOs) are charged to develop the European standards corresponding to these essential requirements. Compliance with these standards is voluntary for producers. They may use either these standards or any other measures to comply with the essential requirements as long as they prove their compliance (Atkins, 1998 and European Commission, 2000).

On the other hand, harmonization through the Old Approach and the New Approach at the community level does not encapsulate all of the traded products. In non-harmonized area, member states are free to impose their own technical regulations. However, they must approve equivalence of each other's technical

requirements and conformity assessment procedure. This is called the mutual recognition principle (MRP). However, not every product is regulated with technical legislation. Some product categories still lack regulating measures in the Community or national level (Atkins, 1998). Figure 3.2 illustrates the regulatory structure of products due to the EU approaches for the removal of TBT.

Figure 3.2. The Structure of Technical Regulations in the EU



Source: Author's own assessment

3.2.1. The Old Approach

In May 1969, the Council of Ministers adopted a General Program[5] on the elimination of TBT resulting from divergent national laws. The General Program based on Article 100 of the EC Treaty, gives authorization to the Council to harmonize the disparate laws of the member states by issuing directives. Once the council has issued a directive, a member state may no longer use Article 36 to justify a trade restriction in a harmonized area (Sabin, 1991). Four council resolutions and a framework decision constituted the General Program. The

[5] Council Resolution of 28 May 1969 drawing up a programme for the elimination of technical barriers to trade in industrial products which result from disparities between the provisions laid down by Law, Regulation or Administrative Action in Member States [OJ C 76 on 17.6.1969].

resolutions exposed a detailed timetable for a number of technical harmonization directives for some industrial products as well as for some foodstuff. In addition, the resolutions exposed the Council's intention to set up mutual recognition in the subject of conformity assessment and a procedure to amend technical directives that are subject to technological advancement (Baldwin, 2000). Every member requires incorporating harmonization directives into their national legislations and corresponding European standards into their national standards.

The Old Approach directives included detailed mandatory technical specifications for product-by-product, even component-by-component basis (as the ones for motor vehicles) written into annexes of each directive. The adoption of technical harmonization directives was based on unanimity[6] in the Council. As suggested by Ghelcke et al. (1990), the complex and fragmentary structure of the Old Approach directives and slow progress even made the directives outdated in the time of adoption. In other words, sometimes the adoption mechanism was so slow that technology corresponding to a product type advanced so much, making that directive invalid in reality. The Old Approach harmonization is a perfect example of harmonization by negotiation which takes lengthy a process to reach a common agreement. On this subject, Baldwin (2000) states that "10 years were required to adopt a directive on gas containers made of unalloyed steel, and the average delay for the fifteen directives adopted en masse in 1984 was 9.5 years." On the other hand, in order to obtain unanimity in the Council, traditional harmonization

[6] Unanimity requirement was replaced by a qualified majority with the adoption of Article 100A in 1987 (Ghelcke et al., 1990).

measures was more like an aggregation of individual national ideas rather than a balanced settlement between parties (Baldwin, 2000).

Conformity assessment procedures related to required technical specifications are also identified in the Old Approach directives. Although the Old Approach anticipates harmonization on technical regulations, the conformity assessment procedures remained not harmonized, that is, the conformity assessment procedures have been left to the official designated bodies of each member state. However, every member is required to recognize the conformity assessment results performed in any other member state as it is performed in their own country.

3.2.2. The New Approach

Although many groups of products were harmonized in the community with the Old Approach in about 600 directives, there were still many product categories where there is no harmonization of national legislations. The difficulties faced with the Old Approach dealing with TBT, led the European Commission (EC) to come up with a method that overcomes trade frictions caused by differing national technical product regulations. Ghelcke et al. (1990) mention that when the Court of Justice developed its Cassis de Dijon case law,[7] which called for mutual recognition of legislation and controls, the Commission realized the potential for progress in technical regulations. In the early 1980s, the Commission developed, based on the Court's case law, a new harmonization strategy which forms the core of its 1985

[7] European Court of Justice - Case 120/78

White Paper. The principles in the Council Resolution[8] of 1985 on the New Approach to technical harmonization and standardization are as follows:

- Legislative harmonization is limited to essential requirements that products placed on the Community market must meet, if they are to benefit from free movement within the Community.
- The technical specifications of products meeting the essential requirements set out in the directives are laid down in harmonized standards.
- Application of harmonized or other standards remains voluntary, and the manufacturer may always apply other technical specifications to meet the requirements.
- Products manufactured in compliance with harmonized standards benefit from a presumption of conformity with the corresponding essential requirements.

Differently from the Old Approach, the New Approach directives relies on short, simple rules setting essential health and safety requirement with which products must comply. ESOs are responsible for preparing detailed technical specifications and standards that show how to comply with these requirements with the request of the Commission. Member states have to transpose the New Approach directives by the deadline set by the directive into their national legislation and repeal any technical legislation on the subjected products in that directive. Member states are also required to transpose standards which are referred to in those directives into their national standards. For producers, compliance with harmonized standards

[8] Council Resolution of 7 May 1985 on a New Approach to technical harmonization and standards [OJ C 136 of 4.06.1985].

benefit from a presumption of conformity with the corresponding essential requirements. However, compliance with the referred standards in the New Approach directives is not compulsory for producers. Application of harmonized standards or other standards remains voluntary for the manufacturer as long as they meet essential specifications declared on the directives (European Commission, 2000). The New Approach directives are listed in Table 3.1. (see Appendix A).

3.2.2.1. Conformity Assessment

The New Approach for technical regulations is complemented by the Modular Approach, on the area of the conformity assessment procedures. The introduction of the Modular Approach has freed the conformity assessment procedures out of hegemony of official bodies for the product types inside of the New Approach sphere. This new technique in conformity assessment procedure proposed a modular approach, including eight basic modules for conformity assessments. Conformity assessment according to the modules is either based on a manufacturer's own declaration of conformity or with the intervention of a third party (notified body) and relates to the design phase of products and to their production phase or both (European Commission, 2000). The conformity assessment may be carried by the producer itself or with the intervention of a notified body (official or private) depending on the requirement of the module that corresponds to the product. Generally, the self-declaration is enough for low-risk

products where full quality assurance is required for high-risk product categories. The modules are summarized in Table 3.2.

The New Approach directives oblige the manufacturer to draw up technical documentation containing information to demonstrate the conformity of the product to the applicable requirements. The technical documentation must be kept for at least 10 years from the last date of manufacture of the product, unless the directive explicitly declares any other duration. The contents of the technical documentation are laid down, directive by directive, in accordance with the products concerned. As a rule, the documentation should cover the design, manufacture, and operation of the product. The details included in the documentation depend on the nature of the product and on what is considered as necessary, from the technical point of view, for demonstrating the conformity of the product to the essential requirements of the relevant directive (European Commission, 2000).

Once the conformity assessment is guaranteed with the corresponding module, the manufacturer or where the manufacturer is located outside of the Community, which the authorized representative established within, must issue an EC declaration of conformity as part of the conformity assessment procedure foreseen in the New Approach directives. The EC declaration of conformity should include all relevant information to identify the directives according to which it is issued, together with the manufacturer, the authorized representative, the notified body if applicable, the product, and where appropriate, a reference to harmonized standards or other required normative documents (European Commission, 2000).

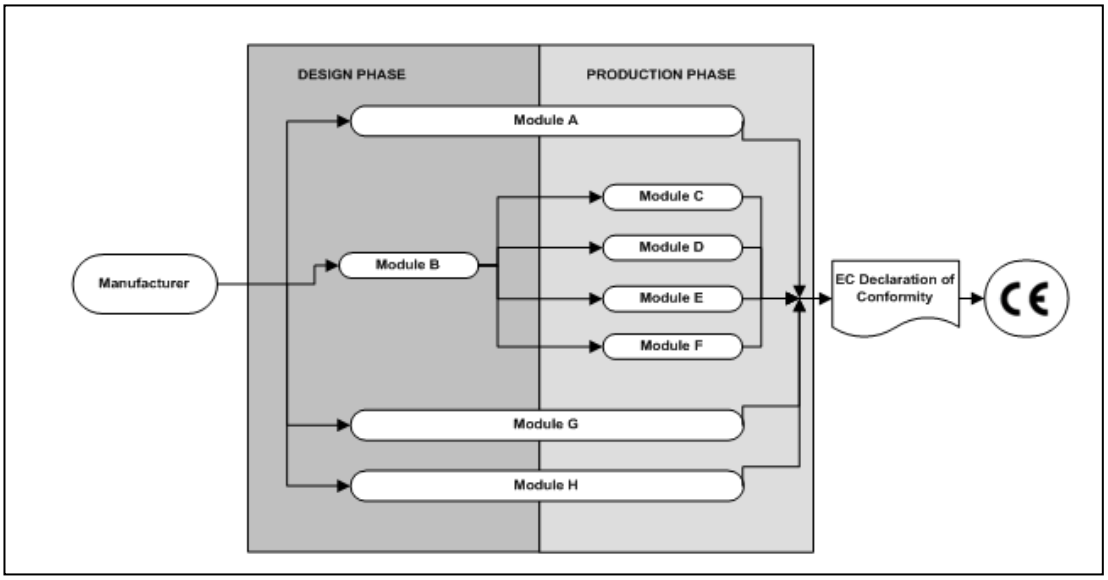
Table 3.2. Modules of Conformity Assessment in the New Approach

Module Number and Name	Description
A - Internal control of production	Covers internal design and production control. This module does not require a notified body to take action.
B - EC type-examination	Covers the design phase, followed up by a module providing for assessment in the production phase. The EC-type examination certificate is issued by a notified body.
C - Conformity to type	Covers the production phase and follows module B. Provides for conformity with the type as described in the EC-type examination certificate issued according to module B. This module does not require a notified body to take action.
D - Production quality assurance	Covers the production phase and follows module B. Derives from quality assurance standard EN ISO 9002, with the intervention of a notified body responsible for approving and controlling the quality system for production, final product inspection, and testing set up by the manufacturer.
E - Product quality assurance	Covers the production phase and follows module B. Derives from quality assurance standard EN ISO 9003, with the intervention of a notified body responsible for approving and controlling the quality system for final product inspection and testing set up by the manufacturer.
F - Product verification	Covers the production phase and follows module B. A notified body controls conformity to the type as described in the EC-type examination certificate issued according to module B, and issues a certificate of conformity.
G - Unit verification	Covers the design and production phases. Each individual product is examined by a notified body, which issues a certificate of conformity.
H - Full quality assurance	Covers the design and production phases. Derives from quality assurance standard EN ISO 9001, with the intervention of a notified body responsible for approving and controlling the quality system for design, manufacture, final product inspection, and testing set up by the manufacturer.

Source: European Commission (2000)

Once the conformity is declared by self-assessment or with the intervention of a notified body, the products that are subjected to the New Approach directives must carry CE[9] marking to circulate freely inside of Community borders. A simplified flow chart of conformity assessment until the affixation of CE markings is in Figure 3.3.

Figure 3.3. Simplified Flow Chart of Conformity Assessment Procedures under New Approach



Source: European Commission (2000)

3.2.2.2. Notified Bodies

In the New Approach, the notified bodies are chosen among the bodies (state-owned or private) that are competent in the requirements listed in the directives and the principles mentioned in Decision 93/465/EEC,[10] under their territories, and

[9]CE stands for Conformité Européenne, initials of "European Conformity" in French.
[10] 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 [OJ L 220 of 30.8.1993]

declared by member states. Here, competence encapsulates personnel and equipment availability, impartiality, and independence in relation with a concerned party with the product (designer, manufacturer, supplier, authorized representative etc.), technical capability of personnel in relevant conformity assessment procedure, maintenance of commercial privacy, and in cases where civil liability insurance is not carried by state, subscription to this insurance,[11] Note that member states designate notified bodies not only for a specific directive, but also limits them in product categories and procedures due to their capability.[12] Every notified body designated by a member state are reported to the Commission, and the Commission gives a single identification number to ensure consistent management of all listed notified bodies. The Official Journal of the European Communities regularly publishes the latest consolidated list of notified bodies together with directives and details of the product range covered, qualification criteria as well as a clear indication of the conformity assessment procedures for which the bodies are notified, and the expiry date for notification if their operations are limited in time. If a notified body ceases to fulfill its requirement or obligations, the member state by which the body is notified can withdraw its notification. Moreover, notified bodies can also be withdrawn by the Commission itself, if an infringement is detected of a given directive by a Member State at the end of an infringement procedure it is explored that the Member State's notification does not rely upon legitimate reasons. Therefore, Member States are responsible for

[11] Accreditation according to the EN 45000 series of standards is a support to the technical part of notification. Although it is not a requirement, it remains an important and privileged instrument for evaluating the competence, impartiality, and integrity of the bodies to be notified.

[12] A notified body can be designated for more than one directive each limited in terms of product groups and relevant procedures.

ensuring that notified bodies maintain their competence at all times and are capable of carrying out the work for which they are notified. The methods and means for this are left to member states' own initiatives. Member states may also prefer to establish time-limited notifications for bodies and renew notifications after they prove their competence (European Commission, 2000).

Notified bodies may also subcontract some of their works to other parties which may locate inside or outside of the Community. There is no requirement of notification of subcontractors. However, the notified body is responsible for providing proof of the compliance of its subcontractors according to the specifications settled in the relevant directive. Note that notified bodies have sole responsibility for all the activities covered by the notification regardless of whether they subcontract some of their works. Finally, notified bodies must keep their national notifying authorities informed of their activities either directly or via an authorized body. They must also be prepared to provide their notifying authorities all information concerning the proper implementation of the conditions under which they were notified, either at the request of their notifying authorities or of the Commission (European Commission, 2000).

3.2.2.3. The EU Quality Infrastructure

At this point, it is worth discussing the EU infrastructure in the areas of standardization, accreditation, and metrology. These elements are important especially for smooth functioning of the New Approach type harmonization since the notified body structure envisaged by the New Approach requires efficient

operation of the above elements. These elements conform to the requirement of the accredited notified bodies that have sufficient level of precision in their measurements through calibration by metrology institutions.

3.2.2.3.1. Standardization

The ESOs—the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI)—are the officially recognized standardization bodies for the EU. Similar to the worldwide ISO-IEC-ITU structure, CENELEC is responsible for setting electrotechnical standards, while ETSI is responsible for setting telecommunication standards. CEN covers all the range of standards that are out of the scope of IEC and ITU. These three organizations develop standards primarily to serve their members which are NSOs of EU members primarily. However, when mandated by the EU Commission, they are those deemed competent to develop or adopt the harmonized standards needed technically to achieve conformity to the EU New Approach and global approach directives (Rensberger et al., 1997).

The ESOs develop two kinds of standards in principle. A **European Standard (EN)** is a document that has been adopted by one of the three recognized ESOs. Directive 98/34/EC[13] defines European standards as technical specifications adopted by the ESOs for repeated or continuous application with which compliance is not compulsory. According to the internal rules of these organizations, European

[13] Council Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations. [Official.Journal L24, 21.7.1998].

standards must be transposed at a national level. This transposition means that the European standards in question must be made available as national standards in an identical way. All conflicting national standards must be withdrawn in a given period.

On the other hand, a **Harmonized standard (HD)** is a European standard, which is adopted by ESOs, prepared in accordance with the general guidelines, and agreed between the Commission and the ESOs. These follow a mandate issued by the Commission after consultation with the member states. HDs are published in the Official Journal of the European Communities and the compliance with them attributes the conformity presumption for the New Approach products. However, as previously mentioned, firms may well choose to comply with listed essential requirements in the New Approach directives. In fact, HDs are ENs that are referenced in the New Approach directives.

3.2.2.3.2. Accreditation

The European Co-operation for Accreditation (EA) is a non-profit organization established in 1997 resulting the merger of the European Accreditation of Certification and the European co-operation for Accreditation of Laboratories. Being a member of the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF), the EA is the European network of

authorized national accreditation bodies in the European region. Furthermore, the EA was appointed as the official accreditation infrastructure of the EC in 2009[14]

The EA is responsible for the accreditation of testing and calibration laboratories, inspection bodies, and certification bodies in the areas of quality and environment management system, products and services, persons, and auditing. As of 2011, the EA has 33 full members, each representing a European country. Most of these full members completed signature of multilateral agreements (MLA) all of the above mentioned five categories of accreditation. The MLA is an agreement signed between the EA and accreditation body members to recognize the equivalence, reliability and therefore acceptance of accredited certifications, inspections, calibration certificates and test reports. The MLA eliminates the need for suppliers of products or services to be certified in each country where they sell their products or services, and therefore provides a mean for goods and services to cross boundaries in Europe and throughout the world. It delivers confidence in the service supplied by accredited laboratories, inspection and certification bodies, thereby providing the framework for goods and services to cross borders in Europe and throughout the world.

In addition to its full members, the EA has signed a cooperation contract with 20 non-European accreditation bodies 11 of which also entered bilateral agreements[15] that leads recognition and mutual acceptance of these bodies with the EA (retrieved from www.european-accreditation.org on 10.08.2011).

[14] 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 [OJ L218/30 on 13.8.2008].

[15] This is the equivalent of the MLA designed for full members.

3.2.2.3.3. Metrology

In the EU metrology, area is split into two different organizations. Legal metrology is in the scope of the European Legal Metrology Cooperation (WELMEC) , while scientific metrology is in the responsibility of the European Association of National Metrology Institutes (EURAMET). WELMEC was first established in 1990 with the agreement of 13 EU and European Free Trade Association (EFTA) members in connection with the preparation and enforcement of the New Approach directives in legal metrology area. The member structure of WELMEC extended on new members of EU and other European countries in the form of associate membership. As of 2011, WELMEC has 30 members and 7 associate members. The principal aim of WELMEC is to establish a harmonized and consistent approach to the European legal metrology. WELMEC is concerned with the establishment, maintenance, and improvement of channels of communication between its members and associate members. It aims to develop mutual confidence through participation in common activities. WELMEC advises the European Commission and the Council regarding the application and further development of directives in the field of legal metrology, for example, the Measuring Instruments Directive and the Non-Automatic Weighing Instruments Directive (retrieved from www.welmec.org on 10.08.2011).

On the other hand, in scientific metrology area, EURAMET is the regional metrology institution of Europe. EURAMET serves the promotion of science and research as well as the European co-operation in the field of metrology. In particular, it coordinates the cooperation of NMIs of Europe in fields like research in metrology, traceability of measurements to the SI units, international recognition of national

measurement standards and related calibration and measurement capabilities of its members. Through knowledge transfer and cooperation among its members, EURAMET facilitates the development of the national metrology infrastructures.

EA and EURAMET signed a bilateral Memorandum of Understanding which aimed to support continuous cooperation between the two organizations. The management of specific calibration documents has been transferred from EA to EURAMET. In addition, EURAMET provides support to EA in the field of interlaboratory comparisons related to calibration (retrieved from www.euramet.org on 10.08.2011).

3.2.3. Mutual Recognition Principle

The harmonized sphere for technical regulations includes products, that there is a community legislation regulating that product. We have discussed two ways of community level harmonization: the Old Approach and the New Approach. Although harmonization efforts go on for non-harmonized products, the Old Approach and the New Approach directives do not cover all product categories. Nevertheless, this does not mean that all uncovered products are unregulated.

In non-harmonized sphere, every member state is free to impose its own legislation to regulate a product or product category as long as they notify the Commission of new regulations before they are adopted according to Council Directive 83/189/EEC[16] laying down a procedure for the provisions of information in the field

[16] Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations [OJ L 109 of 26.4.1983].

of technical standards and regulations. Both the Commission and other member states can object to the regulation and request modification on grounds of eliminating technical barriers. However, the possible problem of encountering TBT in this category is solved by the community with the invention of mutual recognition procedure.

Mutual recognition is the principle that a product that is lawfully produced or sold in one member state should be free to be sold in another member state. Therefore, in the non-harmonized sphere, virtually all member states have to recognize each other's standards and conformity assessment methods, although their own could differ. Note that the MRP also applies for products in the Old Approach harmonization in conformity assessment. Besides, the Old Approach directives do not always harmonize all aspects of a product. For some of the Old Approach products MRP clause also applies[17] (Atkins, 1998).

However, in application of MRP, some difficulties are encountered because member countries use inappropriate measures that block internal free movement of goods in a non-harmonized area (Atkins, 1998). Some difficulties are faced because of administrative practices in member states. For example, officials in importer parties may be reluctant to take responsibility for approving a product which is unfamiliar to them or certificates issued in languages which they do not know. Moreover, attitude in administrative practices are also enforced by mutual distrust between

[17] For example, there are three Old Approach directives laying down naming and labeling requirements for textile articles in the Community level. Member States are free to impose other requirements for those products.

trading member states. Issuing two communications[18], one resolution[19] and one regulation[20], the European Commission tries to overcome these difficulties in application and to ensure the operation of the MRP smoothly. Besides including a provision reminding the MRP, through issued Regulation (EC) No. 764/2008, EC requires each member state to establish product contact points to inform economic operators or competent authorities about the following terms, as stated in the Article 10:

- The technical rules applicable to a specific type of product in the territory in which those product contact points are established and information as to whether that type of product is subject to a requirement for prior authorization under the laws of their member state, together with information concerning the principle of mutual recognition;
- The contact details of the competent authorities within that member state by means of which they may be contacted directly, including the particulars of the authorities responsible for supervising the implementation of the technical rules in question in the territory of that member state;

[18] Communication from the Commission concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in Case 120/78 ('Cassis de Dijon') on 3 October 1980 and [OJ C 256 on 3.10.1980] and COM(1999)299 final on the application of the mutual recognition principle, based on a detailed analysis of the cases of incorrect application of mutual recognition handled by the Commission on 16.06.1999

[19] Council Resolution of 28 October 1999 on mutual recognition [OJ C 141 on 19.05.2000] later incorporated into European Economic Area Agreement in 2002 with Decision No. 15/2002

[20] Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC [OJ L218 on 13.08.2008]

- The remedies generally available in the territory of that member state in the event of a dispute between the competent authorities and an economic operator.

3.2.4. Market Surveillance

The general horizontal principles of market surveillance activities conducted in the harmonized area of the EU are laid down in Directive 2001/95/EC[21] (General Product Safety) and Regulation (EC) No. 765/2008.[22] According to these measures, market surveillance can be divided into two stages. The first stage is monitoring products that are placed in the market in order to control their compliance with the relevant regulations. The second stage is enforcement of taking action to assure conformity.

In general, market surveillance activities in the EU show a decentralized structure, that is, there is no common organization associated with the regulation of market surveillance activities in the Community. Market surveillance infrastructure is left to the member state's own choice as long as surveillance is conducted efficiently covering all of its territories. In this manner, member countries can allocate the responsibility of surveillance between different public authorities they desire. Member states need to inform the Commission about these authorities and their areas of competence (European Community, 2000). Moreover, they need to establish appropriate communication and coordination mechanisms between their

[21] Directive 2001/95/Ec Of The European Parliament and of the Council of 3 December 2001 on General Product Safety [OJ L11/4 on 15.1.2002]

[22] 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 [OJ L218/30 on 13.8.2008]

market surveillance authorities. For example, in Finland, the Finnish Consumer Agency is the central authority conducting surveillance and coordination activities while local authorities are also responsible for monitoring safety of consumer products placed in the market. In Sweden, the responsibility is shared between 15 public authorities while the Swedish Board for Accreditation and Conformity Assessment is appointed to ensure coordination of surveillance in both national and international level (Nordic Council of Ministers, 2005).

Efficient market surveillance requires concentration of resources where risks are more likely and non-compliance is more frequent. Regarding personnel resources, the designated authorities should have sufficient number of qualified and experienced staff possessing professional integrity. In order to guarantee the accurateness of test data, the testing facilities used by surveillance authorities should conform to the relevant EN 45000 standards (European Community, 2000). The New Approach directives give a special importance to market surveillance activities in order to protect the efficient functioning of this type of promoted harmonization. Note that the New Approach directives provide two different tools in order to enable surveillance authorities to receive information on the product. These are previously mentioned, EC declaration of conformity and the technical documentation related to product. These documents must be made available when requested by public authorities.

Surveillance authorities have the responsibility to take actions when they discover noncompliance with the requirements of directive regarding the product. In this respect, noncompliance would have two dimensions: non-substantial

noncompliance and substantial noncompliance. Non-substantial noncompliance arises when nonconformity regarding the product does not consist of a thread for public safety. For example, physically incorrect affixation of required markings like CE marking, non-availability of EC declaration of conformity when it is required may be good examples for this kind of nonconformity. On the other hand, noncompliance with the essential requirements declared in the relevant directive is a sign of substantial noncompliance. The corrective action taken by surveillance authorities to enforce conformity must be in accordance with the principle of proportionality (European Commission, 2000).

The authorities must collaborate with the relevant parties in their actions. When non-substantial noncompliance is detected, the surveillance authority should oblige the manufacturer or the authorized representative to make the product intended to be placed on the market and, if necessary, the product already on the market, complies with the provisions and to remedy the infringement. If no result is retrieved, further actions like restricting, prohibiting, or withdrawing the product placing on the market can be taken. On the other hand, more immediate measures are required for substantial noncompliance. Authorities shall restrict or prohibit the placing on the market and service of the product and ensure that it is withdrawn from the market. Unless the matter is urgent, authorities should consult the concerned parties in advance and provide information on available remedies to implement corrective actions before blocking the free trade. An example of this situation is in the case of the product that presents a serious and immediate danger to the health and safety of people. Detection of noncompliance requires informing people of the risk they are exposed to upon purchasing the same product or

product groups. The New Approach directives do not specify any penalty in cases of infringement. This allows member states to choose their level of sanctions to apply in these cases. The level of penalties must be proportionate and dissuasive (European Commission, 2000).

The New Approach directives propose a safeguard clause covering the products in their area. The application of the safeguard clause requires that the competent national authority decides to restrict or forbid the placing on the market and, possibly, the putting into service of the product, or has it withdrawn from the market. The contents of the decision should relate to all products belonging to the same batch or series. It must also have binding legal effect: it is followed by sanctions, if not respected, and can be subject to an appeals procedure.

The reason for invoking the safeguard clause may result, for instance, from differences or failures in the application of essential requirements, incorrect application of harmonized standards, or shortcomings in them. The surveillance authority can add or specify other motives (for example failure to comply with good engineering practice) when invoking the safeguard clause, provided that they are directly linked with these three reasons. Where non-compliance with harmonized standards that give a presumption of conformity is established, the manufacturer or the authorized representative in the Community must be requested to provide evidence of their compliance with essential requirements. The decision of the competent authority to take corrective action must always be based on an established non-compliance with the essential requirements invoking the application of the safeguard clause. When a member state invokes a safeguard

clause, they shall immediately send notification to the community regarding non-compliance to essential requirements. The relevant notification shall consists of information on nonconformity, name and address of manufacturer, declaration of conformity, notified body (if applicable), and detailed proof of nonconformity (including procedures, test methods, and results). After being notified, the Community forms an opinion about justification of the clause. If safeguard clause is justified, the Commission notifies other member states to take appropriate measures on the product; otherwise, the safeguard clause is revoked (European Commission, 2000).

Besides the proposed safeguard clause for the New Approach directives, The General Product Safety Directive provides a legal basis for an information exchange system for emergency situations for all products. Rapid exchange of information system (RAPEX) is a general and horizontal early warning and monitoring system designed to handle urgent situations caused by products presenting serious and immediate health and safety concerns. The safeguard clause procedures under the New Approach directives apply independently from the RAPEX. RAPEX aims to provide information to authorities of all Members States in order to make them to take immediate and appropriate action. When a serious and immediate risk has been identified, the authority consults, where possible and appropriate, the producer or the distributor to obtain product information and the nature of its hazard. This must make it possible to take measures and ensure consumer protection while minimizing interference with trade.

When a member state takes measures to eliminate a risk whose effects may extend beyond its territory, it must immediately inform the Commission. The information transmitted to the Commission contains details of identification of the product, description of the nature and severity of dangers involved, measures that have been adopted, and supply chain of the product. Every Friday, the Commission publishes a weekly overview of the dangerous products reported by the national authorities (the RAPEX notifications). This weekly overview gives consumers all information on the product, the possible danger, and the measures that were taken by the reporting country.

3.2.5. International Cooperation

In the international level to promote trade in regulated products, the EU has so far concluded MRAs in conformity assessment procedures with Canada, Israel, Japan, New Zealand, Australia, Switzerland, and the USA. MRAs are designed so that each party is required to accept reports, marks, and certificates that are issued by the other party's registered conformity assessment bodies in areas covered under an MRA. Note that, as previously mentioned MRAs in conformity assessment neither foresees harmonization nor means mutual recognition principles in terms of technical regulations. A product made in and certified in other party still requires conforming to the technical requirements imposed in the other one.[23] MRAs apply to one or more categories of products or sectors in the scope of the harmonization directives and, in certain cases, MRAs may involve the products or sectors that are

[23] As a general rule, MRAs are limited to products that have their origin on the territory of either party even MRAs concluded with Canada and the USA does not require rule of origin principle

not harmonized in the community level but are regulated by national laws. For example, the MRAs with the USA include recreational craft, electromagnetic compatibility, and telecommunication areas. The MRAs with Australia and New Zealand encompass electromagnetic compatibility, low voltage equipment, machinery, pressure equipment, medical devices, and telecommunications terminal equipment. The scope of the MRAs with Switzerland is large enough to cover 16 chapters of goods both from the Old Approach and from the New Approach. Note that MRAs in the New Approach allow non-European parties to designate notified bodies in the subject called "conformity assessment bodies."

3.3. Turkish Approach to Technical Barriers to Trade

Turkey-EU relations begin with the Turkey's application for associate membership to the European Economic Community (EEC)[24] in 1959. This application resulted in the formation of an association between Turkey and the EEC with the signature of Ankara Agreement between parties in 1963. The Ankara Agreement, endorsing the ultimate goal of membership, anticipated a progressive establishment of a CU between Turkey and the Community. The removal of TBT between parties is first mentioned implicitly in Article 10(2) of the Ankara Agreement within the scope of the CU: "the prohibition between member states of the Community and Turkey, of customs duties on imports and exports and of all charges having equivalent effect, quantitative restrictions and all other measures having equivalent effect which are designed to protect national production in a manner contrary to the objectives of

[24] The EEC, founded with Treaty of Rome in 1957, was renamed European Community (EC) in 1993 with Treaty of Maastricht and became one of the elements of the European Union (EU).

this Agreement." An additional protocol to the Ankara Agreement, which was signed in 1970 to be effective in 1973, sets out the timetable for the formation of the CU. Finally, the formation of the CU between Turkey and the EU was completed through Decision No. 1/95 of the EC-Turkey Association Council which came into force in 1996.

In order to conduct free movement of goods between parties, the Decision No. 1/95 proposes the elimination of tariffs, quantitative restrictions, and all other measures of having equal effects on industrial products and adoption of the EU's preferential agreements with third parties. Chapter I-Section II[25] of the Decision No. 1/95 particularly deals with the TBT subject between parties. Article 8(1) foresees a five-year period for Turkey to incorporate the Community instruments relating to the removal of TBT into its legal order. Moreover, Article 8(4) emphasizes the importance of effective cooperation between parties in the fields of standardization, metrology and calibration, quality, accreditation as well as testing and certification. The relevant community instruments on TBT that Turkey has to adopt are listed in Decision No. 2/97 of the EC-Turkey Association Council.

Eliminating all tariffs and quantitative restrictions on non-agricultural products, the formation of the CU was an important step towards free movement of goods between Turkey and the EU. The free movement of goods between parties is proposed to be achieved with the elimination of TBT by Turkey's unilateral harmonization of related Community instruments. The framework provided by Articles 8-11 of Decision No. 1/95 requires Turkey to adopt corresponding acquis on

[25] Chapter 1-Section II:Elimination of Customs Duties and Charges Having Equivalent Effect

the removal of TBT besides all other technical regulations. These articles also require Turkey to establish a standardization infrastructure that is parallel to that of the EU (USFT, 2008a). Although 16 years have passed since the formation of CU between Turkey and the EU, Turkey could not complete the required provisions under the requirements laid down in Decision No. 1/95 in order to remove the TBT between parties completely (Commission of European Communities, 2011). The legal alignment is evaluated as advanced regarding both horizontal and vertical measures. The transposition of the New Approach legislation is almost completed. The degree of harmonization on the Old Approach is also developed. However, regarding MRP Turkey is expected to issue the relevant legislation in the subject.

On the other hand, the improvements in Turkish infrastructure for standardization and conformity assessment issues are also appreciated. Nonetheless, the problems persist on TBT between parties mostly in the execution phase. The most prominent deficiencies are observed in market surveillance area. Thus, Turkey could not mount an efficient market surveillance system parallel to the EU requirements up to date. This subsection investigates the degree of harmonization that Turkey has attained with respect to these requirements laid down in Decision 1/95.

3.3.1. Legal Alignment

The vertical measures covering whole fields of technical harmonization in the EU are listed in Decision No. 2/97 to be adopted by Turkey. The Undersecretariat for Foreign Trade (USFT)[26] coordinates the transposition work of the vertical legislation

[26] In summer 2011, USFT was repealed, its responsiblities were incorporated in newly found Ministry of Economy

among more than 10 competent authorities in Turkey. The USFT is also responsible for transposing the horizontal legislation of the EU,[27] in particular those in the field of product safety. Moreover, the USFT is the primary institution responsible for all coordination activities regarding Chapter 1 - Free Movement of Goods of the EU acquis.

In this respect, the Framework Law, Law No. 4703[28] prepared by the USFT, was put into force in January 2002. The Framework Law has been prepared to transpose different elements of the horizontal EU technical legislation into the Turkish legal order. It describes the common principles in the areas of placing a product on the market, the responsibilities of the producer and the supplier, conformity assessment bodies and the notified bodies, and the market surveillance as well as provisions in violations and notification procedure to the European Commission, EU member states, and other EU organizations. Four implementing regulations of the Framework Law, as listed below, were put into force to support horizontal harmonization efforts with the EU. These four regulations are listed below. The Framework Law forms a basis and its implementing regulations provides legal infrastructure for the harmonization of the EU legislation in the subject.

- Regulation on the affixing and use of the CE conformity marking
- Regulation on conformity assessment bodies and notified bodies
- Regulation on market surveillance of the goods
- Regulation on the exchange of information on technical legislation on goods and standards between Turkey and the European Union

[27] Council of Ministries Decision No. 97/9196 on 15.1.1997

[28] Law No. 4703, the Law on the Preparation and Implementation of Technical Legislation on Products, [OJ No. 24459 of 11/7/2001]

On the other hand, transposing vertical legislation in harmonized area, Turkey has reached a high level of alignment regarding New Approach directives. In fact, all directives except Measuring Instruments Directive (2004/22/EC) are fully harmonized up to date (Commission of the European Communities, 2010). Harmonization works similarly go on in the Old Approach directives. The competent authorities have put approximately 210 technical legislations into force, out of approximately 280 technical legislations (USFT, 2008a). Further alignment was achieved in the areas of motor vehicles and from motor vehicle emissions, licensing and pricing of pharmaceuticals, pre-packaging and labeling of pharmaceuticals for human use, packaging waste, dangerous substances, and the inventory of chemicals and cosmetics. Nonetheless, TBT still exist, particularly in the areas of the Old Approach directives such as legal metrology, pharmaceuticals, chemicals, and foodstuff. Turkey is also expected to adopt the updates regarding Community acquis in the Annex II (community instruments to be harmonized) of the Decision 2/97 (Commission of the European Communities, 2008 and 2009).

Nominally, Turkey is subject to MRP in non-harmonized area with the EU according to Decision 2/97. An interpretative communication 2003/C 265/02[29] clarifies the implementation of the MRP and reminds the obligations of the EU member states towards Turkey. On the other hand, Turkey prepared a draft regulation on the mutual recognition in the application of the MRP in 2005. However, up to date it is not adopted. This factor prevents Turkey to benefit from the mutual recognition

[29] The Commission's interpretative communication on facilitating the access of products to the markets of other Member States, the practical application of mutual recognition [OJ C 265 on 04.11.2003]

since EU countries are reluctant to apply the principle in case of Turkish exports because of Turkish attitude on the subject (USFT, 2008a).

The draft technical regulations of the EU member states in the non-harmonized area are being notified by the European Commission to Turkey since year 2002 within a mechanism that is foreseen in the Directive No. 98/34/EC together with the relevant adaptations mentioned in the Decision No. 2/97. The USFT sends these notifications to relevant public authorities in Turkey. On the other hand, Turkey has been sending its draft technical regulations in the non-harmonized area to the EU member states via the European Commission as well. The notification procedure operates smoothly between parties (USFT, 2008a and Commission of the European Communities, 2010).

3.3.2. Standardization

Given the authority by law for every kind of standardization activities in Turkey, the Turkish Standards Institute (TSE) is the responsible organization for the harmonization of Turkish standards with the EU standards. TSE was first founded in 1954 within the organization of the Union of Chambers and Commodity Exchanges of Turkey (TOBB). TSE became a full member to ISO in 1955 and to IEC in 1956 to represent Turkey in these standardization organizations. In 1960, with Law No. 132,[30] TSE is turned into a public institution operating under the Ministry of Industry and Commerce that has its own legal personality. In 2002, given more autonomy, it is engaged under the Prime Ministry.

[30] Law No. 132 Regarding Establishment of TSE, published in O.J. No. 10661 on 18/11/1960

The TSE shows a centralized structure in standardization activities. However, ministries, public and private sector organizations, scientific organizations as well as consumers and users actively participate in standards development. Expert commissions prepare Turkish standards within the TSE. During the preparation stage of Turkish standards, these commissions take the views of all concerned parties (producers, consumers, universities, public institutions, nongovernmental organizations, etc.). Once a standard is prepared, it must be evaluated at the technical commission within the TSE. If the technical commission approves, it is published as an unprompted standard. However, if the application of a standard is considered as compulsory, it is presented to Commission of Ministers and published as a Turkish standard in the official gazette with the approval of Commission of Ministers.

As of November, 2010, there are 30,445 Turkish Standards in force issued by the TSE. In the same timeframe there exists 16,859 ENs issued by ESOs. TSE has harmonized 14,299 ENs into Turkish Standards. On the other hand, 10,167 International Standards (ISO/IEC) has been published as Turkish Standards by TSE (Yıldızeli, 2010). TSE is appreciated being in a synchronized position with EU standardization. (Commission of the European Communities, 2009). Besides, TSE also seeks cooperation with the ESOs having an affiliate status in CEN and CENELEC. Additionally, in order to extend its cooperation with the ESO, it applied for a full member status. (retrieved from www.tse.org.tr on 09.08.2011).

3.3.3. Conformity Assessment

3.3.3.1. Accreditation

Turkey showed a considerably great progress in terms of accreditation structure. In order to comply with CU requirements[31] on accreditation, the Turkish Accreditation Agency (TURKAK) was established in 1999 with Law No. 4457[32] as a legal entity that is subject to private law provisions and has financial and administrative autonomy connected under the Prime Ministry. TURKAK is the officially responsible authority in Turkey to accredit the local and international conformity bodies rendering laboratory, certification, and inspection services in order to ensure their operation in accordance with national and international standards.

In 2006, TURKAK has gained international recognition upon signing MLAs with the EA in the areas of calibration, inspection, testing, and system certification. In 2008, upon signing the remaining MLAs in the areas of personnel certification, EMS certification, and product certification, TURKAK became fully accredited by the EA. Following the full accreditation by the EA, TURKAK signed an MRA with ILAC in the areas of testing and calibration laboratories. In the screening report, (Commission of the European Communities, 2007a) provisions concerning conformity assessment and accreditation are aligned with EU norms. Turkey has proven its administrative and implementing capacity in this area for a sufficient level to operate in the single market of EU.

[31] Article 8 of Decision 1/95

[32] Law No.4457 on Establishment and Functions of TURKAK on 27.10.1999, [Official .Journal No.23866 on 4.11.1999]

3.3.3.2. Conformity Assessment

Decision No. 1/2006 of the EC-Turkey Association Council gives Turkey authority to designate notified bodies for conformity assessment procedures for the product groups covered in the New Approach directives. Decision No. 1/2006 stipulates that the results of the conformity assessment procedures carried out by Community bodies and by Turkish bodies are to be mutually recognized without repetition of these procedures or any additional requirements. TURKAK is formally appointed to assess candidate-notified bodies in Turkey. However, before TURKAK completes the signature of MLAs with the EA, Turkey has faced difficulties in the recognition of the appointed notified bodies by the EC. Upon TURKAK's completion of harmonization with the EA, Turkish notified bodies are recognized in the Community level. Accordingly, the USFT is a responsible authority in Turkey with regard to the notification process of these conformity assessment bodies.

Table 3.3. Number of Notified Bodies in the EU Member States

Member State	Number of notified bodies	Member State	Number of notified bodies
Austria	55	Italy	304
Belgium	52	Latvia	22
Bulgaria	36	Lithuania	20
Cyprus	4	Luxembourg	6
Czech Republic	36	Netherlands	68
Denmark	33	Poland	81
Estonia	12	Portugal	34
Finland	28	Romania	33
France	108	Slovakia	31
Germany	335	Slovenia	17
Greece	31	Spain	106
Hungary	28	Sweden	46
Ireland	4	United Kingdom	228

Compared to the EU members that have similar sizes (Table 3.3.), Turkey seems to lag behind regarding the number of notified bodies. However, the number of

notified bodies in Turkey is increasing ever since. In 2008, there were six notified bodies. The number of notified bodies rose up to 12 and 14 during 2009 and 2010, respectively (Commission of European Communities, 2008-2010). According to the New Approach, the Notified and Designated Organizations (NANDO) information system, as of 2011, there are a total of 19 bodies notified by Turkey in personal protective equipment, construction products, appliances burning gaseous fuels, hot-water boilers, lifts, pressure equipment, recreational craft, simple pressure vessels, medical devices, machinery equipment, and protective systems intended for use in potentially explosive atmospheres directives.

On the other hand, there is no explicit statement exists about equivalence of conformity assessment procedures between parties related to the Old Approach directives. Further efforts are needed in the harmonization of the Old Approach directives in order to remove frictions on free trade between Turkey and the EU.

3.3.3.3. Metrology

In Turkey, the metrology subject is divided into two different organizations. The Ministry of Industry and Trade Directorate General for Measurements and Standards is responsible for legal metrology. Having regional laboratories on metrology, provincial verification offices in every 81 provinces and verification bureaus in municipal level, MIT is responsible for inspection, verification, and issuance of type-approval certificates for the measuring instruments used. In legal basis, MIT is the authority in preparing the legislation for legal metrology.

On the other hand, the National Metrology Institute of Turkey (TUBITAK-UME) is semipublic organization which is responsible for scientific metrology activities. The national measurement standards are carried within TUBITAK-UME as well as their maintenance in accordance with international units. Calibration, training, and consultancy to industrial calibration laboratories are in the responsibility area of TUBITAK-UME. Note that TUBITAK-UME also serves as an industrial calibration laboratory itself. TUBITAK-UME contributes to research and development conducted on measurement techniques, calibration, and basic metrology in international level. Turkey is a full member of the Bureau for Weights and Measures (BIPM), International Organization of Legal Metrology (OIML), European Association of National Metrology Institutes (EURAMET) and an associate member of the European Cooperation in Legal Metrology (WELMEC).

The Commission of the European Communities (2007a) assesses that TUBITAK-UME has the adequate capability for metrology. However, to reach a wider calibration network through the country, Guasch et al. (2007) suggests that TUBITAK-UME should concentrate more on primary calibration activities and promote the works of other calibration activities rather than offer commercial calibration itself.

3.3.4. Market Surveillance

In Turkey, the legislative framework for market surveillance activities is established in Law No. 4703. It is supplemented by Market Surveillance of the Goods Regulation which provides the detailed principles for the surveillance activities in Turkey. Market surveillance system in Turkey is organized in a decentralized structure.

Accordingly, there are 10 public authorities operating on market surveillance activities. Each public authority designs and implements surveillance activities for the product under its scope. Table 3.4. shows the designated public authorities and product groups in their responsibility (USFT, 2008b).

Table 3.4. The List of Public Authorities Involved in Market Surveillance in Turkey

Designated Authority	Product Group
Ministry of Health	Cosmetics, toys, medical devices, medicinal products, detergents
Ministry of Industry and Trade	Machinery, explosives for civil use, motor vehicles, lifts, household Ministry of Industry and Trade appliances, gas appliances, pressure equipment, measuring instruments, cableway installations, electrical materials, textiles and footwear, other machinery, agricultural, or forestry tractors, etc.
Ministry of Agriculture and Rural Affairs	Foodstuffs, feed products, fertilizers, medicinal products
Ministry of Public Works and Settlement	Construction products
Telecommunications Authority	Radio and telecommunications terminal equipment
Ministry of Labor and Social Security	Personal protective equipment
Undersecretariat of Maritime Affairs	Recreational craft, marine equipment
The Tobacco and Alcohol Authority	Tobacco and tobacco products, alcoholic beverages, ethyl alcohol
Energy Market Regulatory Authority	Fuels, oil, gas
Ministry of Environment and Forestry	Dangerous substances

The coordination within the involved public authorities is provided by regional directorates and central units. Nominally, the central offices have the task of preparing the legislation, policy development, planning the surveillance activities, enforcement of measures, evaluation, and risk assessment, among others. On the other hand, the provincial offices have different executive tasks such as inspection and sampling of products and reporting of results, dealing with consumer complaints, and advising the public and business. The USFT has a coordinator role among these different public authorities heading the Coordination Board on Market

Surveillance that is responsible for overall coordination between these different public authorities. However, this board does not possess any executive power. In general, the legislation infrastructure concerning market surveillance is evaluated as advanced, yet implementing capacity is not developed at a sufficient level in Turkey. In this respect, Turkey has not achieved a high-level alignment in the execution phase of market surveillance. A number of problems persist according to progress reports by Commission of the European Communities (2011) and USFT (2008b).

First, the planning level has no central vision or policy concerning the product safety-related consumer protection observed for Turkey. There is not a common market surveillance policy (special target products, special groups to be protected rules for coordinated actions, plans, concentrated actions), or a common enforcement policy (rules for light and severe offences, instructions for warnings and fines, rules for proportionality, etc.). The surveillance activities are not planned and result oriented. These activities are not based on risk assessment either. In the surveillance activities, product safety requirements hardly play a role, neither centrally or regionally. Instead, market surveillance activities are mostly conducted based on conformity rather than on the safety for the consumer. Second, surveillance activities, a large part of non-harmonized products, are not at all a controlled market. Moreover, there are no surveillance activities concerning street vendors. In fact, these are the places where it is most likely that there are possible risks for the consumers because of the cheap and low quality products.

Additionally, the coordination mechanism between different units among responsible public authorities is weak. Besides, the coordination among different

public authorities also remains low. In this respect, The Coordination Board on Market Surveillance is not in a position to provide a steering operation and its operation is not very efficient. On the other hand, surveillance activities are rather biased towards import controls. For example, the USFT requires some of the products that are non-harmonized to be subject to mandatory Turkish standards. The conformity assessment for these products is required to be assessed by TSE[33]. Similarly, the USFT also requires conformity assessment of certain alcoholic and tobacco products to be controlled by the Tobacco and Alcohol Authority.[34] On the other hand, certain agricultural products are subject to mandatory standards prior their import.[35] The assessment of these products is conducted by import controllers of the USFT itself.

Turkey discriminates harmonized EU products over non-EU products. Although the products that carry CE marking should be subject to free movement within Turkey, some of the products that carry CE marking are subject to import control if they are imported by non-EU countries.[36] These kinds of import controls create TBT when importing into Turkish market besides being in contradiction with the market surveillance activities (USFT, 2008 and Commission of European Communities, 2011).

In execution level, the financial and human resources allocated to market surveillance are not in sufficient levels. In general, the market surveillance activities are financed centrally (personnel, buildings, and labs). There are no separate

[33] The USFT Communique No. 2011/1
[34] The USFT Communique No. 2011/9
[35] The USFT Communique No. 2010/2
[36] The USFT Communique No. 2011/10, 2011/11, 2011/14, 2011/16, 2011/19

allocations in the budget regarding planned surveillance activities. There is no separate budget for samples or for lab analyses either. Only occasionally, a limited amount of additional money is allocated for samples. In fact, sampling or laboratory research for assessing conformity remains very limited. This situation prevails up to now. According to (USFT, 2011), only 2% of the total surveyed products are scientifically tested. On the other hand, most of the public authorities do not possess their own testing facilities and generally employ TSE to carry out tests relevant to surveillance. TSE's active involvement in the market surveillance system creates controversies since TSE itself also has functions related to conformity assessment commercially.

Regarding personnel resources, more full-time, specialized inspectors are needed in particular. Although, the employees in relevant authorities are fairly well educated and being continuously trained, there are no clear specializations. In many cases, too many tasks are centered in one single person, which slows down progress. In fact, there is no staff exclusively dedicated to market surveillance and enforcement. Surveillance activities are conducted on a part-time basis. In particular, more full-time, specialized inspectors are needed. On the other hand, no harmonized method for data gathering has been achieved. The reporting and accounting are mainly done by filling out forms by hand. This situation creates difficulties in the consolidation and analysis of surveillance data. There was no central data registration system. There is no database linking accidents and injuries to products either. An EU Twinning Project, the “Reinforcement of Institutional Capacity for Establishing a Product Safety System in Turkey (TR05-EC-01)” funded by the EU, was launched in January 2007 to set up an information exchange system similar to

RAPEX. This project has been completed and a central database on product safety is formed. However, neither it is effectively working nor integrated with RAPEX. In this respect, the visibility of market surveillance activities remains low (USFT, 2008 and Commission of European Communities, 2011).

On the other hand, some progress can be reported. Some public authorities published revised regulations on the method and principles of their market surveillance systems. The USFT issued legislation to lay down a common template for market surveillance reports and notifications. Since 2005, the USFT publishes yearly reports on market surveillance activities. It is a major step towards a systematic collection of comparable surveillance data, even though a number of authorities were unable to contribute basic data. It is observed that market surveillance activities have continued to increase over time. The data for 2008-2010 retrieved from yearly surveillance reports of the USFT is presented in Table 3.5. Additionally, the USFT also issued a national surveillance strategy for 2010–2013 emphasizing the improvement of legal and financial framework, empowerment of execution infrastructure, improvement of training activities, and increasing the awareness and visibility of market surveillance activities. However, further efforts are needed in Turkey to empower market surveillance according to the Commission of European Communities (2010).

Table 3.5. Surveillance Activities in Turkey (number of inspected products)

Designated Authority	2008	2009	2010
Ministry of Health	19,499	29,842	34,289
Ministry of Industry and Trade	12,929	22,756	81,137
Ministry of Agriculture and Rural Affairs	371,423	363,762	392,749
Ministry of Public Works and Settlement	328	710	1,505
Telecommunications Authority	877	764	755
Ministry of Labor and Social Security	304	409	624
Undersecretariat of Maritime Affairs	96	258	379
The Tobacco and Alcohol Authority	64,776	46,951	34,472
Energy Market Regulatory Authority	4049	N/A	84,218
Ministry of Environment and Forest	10082	N/A	N/A

Source: USFT (2008-2010)

CHAPTER 4

REACH

The chemicals policy of the EU initiated in the 1960s with a 1967 directive on classification, packaging, and labeling of chemical substances as Dangerous Substances Directive (DSD).[37] Since then, the cluster of the legislation on chemicals has been extended with numerous amendments to early directives and issuing new directives on restrictions, chemical preparations, and waste. On the other hand, some of those directives targeted a specific group of chemicals such as pharmaceuticals, cosmetics, food additives, and pesticides (Eriksson et al., 2010).

To sum up, the legislation cluster in the EU before REACH and CLP[38] had five directives. Directive 1967/548/EEC and Directive 1999/45/EC regulated the classification, packaging, and labeling schemes of dangerous substances and preparations. In 1979, the sixth amendment on the DSD, introduced a differentiation between the chemicals traded in the EC market. In this respect, 100,106 "existing" substances placed in the EC market before 18.09.1981 were

[37] Council Directıve 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [OJ 196 on 16.08.1967]

[38] CLP regulation is not explained in detail in the scope of this study. The relevance between REACH and CLP is adressed in subsection 4.1.1.1.

taken into European Inventory of Existing Commercial Substances (EINECS). The substances placed on the market for the first time after 18.09.1981 are considered as “new” and required a notification mechanism and are added to European List of Notified Chemical Substances (ELINCS). Directive 76/769/EEC consisted of restriction provisions on the supply and usage of dangerous articles. Directive 91/155/EC introduced provisions on the supply of SDSs as a mean for hazard communication with the downstream users. Finally, Directive 1993/67/EC included provision regarding risk assessment procedures for notified substances.

However, the regulation on existing chemicals required a trustful cooperation between the state authorities and industry. Thus, the regulating authorities and the regulated manufacturers are mutually dependent on each other within systems of co-operative chemical policy. The authorities do not have the power to generate on their own all the information needed for the risk assessment on their own. As a consequence, manufacturers are entitled to have an influence on evaluation and the outcome of decisions that are drawn from that process. Existing procedures are time consuming and cannot accelerate the risk evaluation process. Moreover, different rules applied to new and existing substances, so many "existing" chemicals that have been on the market for some time have never been properly tested. At the same time, the different rules applying to new and existing chemicals meant that employers were often discouraged from introducing new substances on the market and instead would be more likely to use existing untested chemicals which

might actually be more dangerous. All these factors drove the EU to come up with a new regulatory policy on chemical substances[39] (Foth and Hayes, 2008).

Replacing about 40 previous directives[40] and regulations on industrial chemicals and dissolving the regulatory distinction between "existing" and "new" substances, REACH (Registration, Evaluation, Authorization and Restriction of Chemicals)[41] regulation is the new harmonizing measure regarding chemical substances[42] in the EU. This provides a high level of protection on human health and environment with the promotion of alternative methods for assessment of hazards of substances besides ensuring free movement of goods in the Community. Covering 849 pages and taking seven years to pass from the Commission, it is regarded as being one of the most complex legislations in the EU (Foth and Hayes, 2008).

REACH requires all manufacturers or importers of chemical substances into the EU to register these substances if their manufacture or import exceeds 1 ton per year to the European Chemicals Agency (ECHA,[43] referred to as the Agency herein after). REACH legislation covers substances, substances in mixtures as well as substances in finished articles. However, it requires the registration of substances themselves, not their mixtures and articles there are used in. When used in mixtures, each individual substance exceeding 1 ton/year requires a registration separately. On the

[39] Note that the directives targeting a specific groups of chemicals as well as Directive related to waste is not handled with REACH provisions.
[40] The total number of directives including amending directives, interpretation directives etc.
[41] REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [OJ L 396/1 on 30.12.2006]
[42] Chemicals that are encapsulated by REACH are explained in section 4.1.
[43] Established by the REACH regulation

other hand, substances used in articles may be potentially subject to registration.[44] In this context, the REACH legislation binds not only chemical manufacturers but also other producers using chemical substances in their products. Therefore, when considered in a wider scope, the REACH regulation may affect many sectors like textiles and electronics that use chemical substances in their products.

The REACH legislation holds any element in the supply chain including manufacturers, importers, and downstream users responsible for the efficient functioning of REACH. However, it is enough for an element in the supply chain to register a substance. On the other hand, REACH does not allow extra-community firms to register products in their behalf. Therefore, extra-community firms may register their products with either appointing a sole representative from natural or legal person established in the Community, or registering their product via their importers residing in the Community.

Besides registration, REACH foresees an authorization and restriction procedure in order to regulate the manufacture, placing on the market, or use of certain substances, either on their own or in mixtures or articles within the EU territory given that these substances impose potential harms to human health and the environment. In order to limit the usage of substances of very high concern (SVHC) and subsequently to replace them with suitable alternatives, REACH proposes an authorization mechanism for these substances. Once identified and placed in REACH regulation, articles containing the listed SVHC substances cannot be placed on the market or used after a date to be set unless the company is granted an

[44] This requirement is necessary if substances are intended to be released from articles.

authorization by the Agency. Besides the authorization requirements, there are some other substances[45] which have been already banned totally or restricted extensively in usage. Such substances pose unacceptable risk to health or the environment.

REACH regulation falls within the scope of the Old Approach. Since registration to the Agency is a prerequisite for market access, the registration process regarding REACH is a technical regulation itself. Unregistered substances are not allowed in the EU market. Conformity assessment of the registrations is provided by the Agency through evaluation of registration dossiers. On the other hand, the control and assessment of substances themselves are performed by competent authorities of member states (MSCAs). Enforcement of REACH regulation is carried through the designated authorities of member states in the framework that is previously mentioned EU market surveillance system. In order to conduct a coordination mechanism among these authorities, REACH establishes a subunit within the Agency, named as the Forum for Exchange of Information on Enforcement, within the Agency.

This chapter gives information about the REACH regulation while shedding light on its requirements, conformity assessment procedure, and surveillance mechanism. in order to demonstrate how a harmonizing measure of the EU in order to reduce TBT from differing national regulations works in a detailed manner. The REACH regulation itself together with its amendments and the guides that are published by the Agency as envisaged in REACH are used throughout this chapter. Since these

[45] These are listed in Annex XVII of REACH.

resources are used in a highly crossed manner, the references for these sources are not given separately through the text but available in the bibliography. Additionally, the last subsection of this chapter addresses the harmonization efforts with the EU measures in Turkey in the EU chemicals policy.

4.1. Registration

REACH envisages the registration of chemicals exceeding 1 ton/year that are produced in or imported into the EU by its manufacturer or importer. These chemical substances may be imported or produced individually in mixtures or in articles. In any case, if the sole existence of a substance exceeds 1 ton/year, then it requires registration. Note that not all substances need to be registered. There are some exceptions laid down within the REACH directive.

The first category that does not need registration, besides any other provisions, encapsulates the substances that are out of the scope of REACH. These substances are radioactive substances regulated by Council Directive 96/29/Euratom, substances under customs supervision waiting in free zones or free warehouses for transportation or re-exportation, substances that are used in the interest of national defense requirements of Member States given that they are covered by national exemptions, waste as defined by Directive 2006/12/EC and non-isolated intermediates.[46]

[46] According to REACH definition, these are the chemicals that are not intentionally removed from the equipment in which the synthesis takes place.

The second category that does not need registration encapsulates the substances that are mainly regulated in other Community measures. Substances used for food and feed production within the scope of Regulation (EC) No 178/2002 and in medicinal products within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC are exempted from registration. However, note that this exemption does not cover all uses of that substance. It covers these substances only if they are manufactured or used for the aforementioned purposes. Suppose a substance is produced and sold to two different downstream[47] users. One of the downstream users utilize this substance as a food additive and the other one uses it to produce any other substance, mixture, or article that is not exempted. In this case, the substance part used by the second downstream user must be registered if it exceeds 1 ton/year.

On the other hand, the substances listed in Annex IV are exempted by registration for all uses since there exists sufficient information regarding those in order to consider them to cause minimal risk to human health and the environment. In fact, most of these substances have a natural origin. For example natural oils retrieved from soybean or sun flower can be given as examples for this category. Additionally, substance categories that are in scope of the listed 13 categories of Annex V are also exempted from registration. For example, substances that are formed due to a chemical reaction with the incidental exposure of a natural factor on another substance are exempted from registration. REACH also does not require registration

[47] Downstream user is defined in REACH as any natural or legal person established within the Community, other than the manufacturer or the importer who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. Note that consumers are not downstream users.

of polymers since polymer molecules generally do not raise any concern on human health and the environment because of their high molecular weight. Recycled or recovered substances and re-imported substances are also exempted from registration if these substances have been already registered before. Finally, substances used for the purpose of product and process-oriented research and development (PPORD) are exempted from registration but requires a notification to the Agency.

The final types of substances that do not need registration are the ones that REACH assumes as already registered. These are active substances and co-formulants manufactured or imported for use in plant protection and substances that were previously notified within the mechanism laid down in Directive 67/548/EEC.

4.1.2. Registration Procedure

REACH distinguishes substances due to their production or placement on the internal market before REACH legislation came into force. The substances that are already produced or placed in the internal market before REACH are classified as **phase-in** substances. Phase-in substances cover three types of substances:

- The substances listed in the EINECS which virtually cover all substances in the community market on 18 September 1981.
- The substances that are produced by any current member states, at least once after 31 May 1992, without being placed on the actual EU market by the manufacturer or importer if the manufacturer or importer has documentary evidence of this.

- Finally, substances that are called as no-longer polymers and are placed on the current EU market between 18 September 1981 and 31 October 1993 if the manufacturer or importer again has documentary evidence.

The substances that do not enter the definition of phase-in substances are classified as **non phase-in** substances.

REACH proposed a preregistration period for phase-in substances that passed on 1 December 2008. The preregistration should have involved name and classification (due to EINECS and Chemical Abstracts Service [CAS] number) of substance in question together with name and address for contact person, envisaged registration time and tonnage band. Every producer/importer that has already placed substances on the market exceeding 1 ton/year was required to preregister their substances in order to benefit from following the extended registration deadlines for phase-in substances.[48]

Once preregistered, REACH envisages three extended deadlines for registration due to quantities and risk levels of considered phase-in substances. The first registration period passed on 1 December 2010. It was required for chemicals that were produced or exported over 1000 tons/year, for R 50-53[49] substances exceeding 100 tons/year and for CMR[50] substances exceeding 1 ton/year. The second registration period expires on 1 June 2013 for all substances in tonnage band of 100-1000

[48] The manufacturers or importers of a substance in quantities of 1 ton or more for the first time after 1 December 2008 can also benefit from extended registration periods. They only need to preregister in six months after the manufactured or imported substances exceed 1 ton/year and preregistration occurs before the extended deadlines.
[49] These are classified as very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment (R50-53) in accordance with Directive 67/548/EEC.
[50] These are classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548/EEC.

tons/year and final registration deadline is 1 June 2018 for every substance exceeding 1 ton/year.

The nonpreregistered phase-in substances and non phase-in substances are subject to a different registration procedure. For above substances, an **inquiry** process is required before the registration step. If several potential registrants have made an inquiry with respect to the same substance, the Agency shall inform all potential registrants without delay of the name and address of the other potential registrants. If no registration is recorded within the system previously, the potential registrants may register their products according to the rules in 4.1.3 subsection, independently or with other potential registrants, on the same substance if there is any. Otherwise, the data sharing procedure required for registration is explained in 4.1.4.1. subsection before a registration shall occur.

Note that a company needs not to interrupt its activities for preregistered substances if they meet the registration procedures. On the other hand, activities regarding nonpreregistered and non phase-in substances must be suspended until the registration is completed. For these substances, there is also a three-week waiting period after a valid registration before manufacturing or importing can start again.

4.1.3. Registration Requirements

Registration of substances in scope of REACH is carried through **registration dossiers** submitted to the Agency electronically through REACH-IT interface. As specified in Annex VI, a registration dossier shall consist of information on the

identity of registrant (manufacturer or importer), identity of substance, classification and labeling of substance, registrant's identified uses of substance, and guidance of safe uses of substance.

The registration dossier must also have information about the required provisions' related intrinsic properties. An intrinsic property of a chemical substance is a characteristic of the substance which can be used to determine its fate or to identify potential hazards. In REACH, the required intrinsic properties are categorized into endpoints under the areas of physicochemical, toxicological, and ecotoxicological information. An endpoint is an observable or measurable inherent property of a chemical substance. For example, it can refer to a physicochemical property like vapor pressure, or to degradability or a biological effect that a given substance has on human health (toxicological) or the environment (ecotoxicological). Examples of this include carcinogenicity, irritation, and aquatic toxicity. REACH categorizes the data on the intrinsic properties of a substance into endpoints and lists those endpoints in Annexes VII-X. The information for endpoints under REACH are summarized in Table 4.1.

Table 4.1. Listed Endpoints in REACH under Annexes (VII-X)

	ANNEX VII	ANNEX VIII	ANNEX IX	ANNEX X
Toxicological Information	• Skin irritation or skin corrosion (in vitro) • Eye irritation (in vitro) • Skin sensitisation • Mutagenicity • In vitro gene mutation study in bacteria • Acute toxicity (by oral route)	• Skin irritation (in vivo) • Eye irritation (in vivo) • Mutagenicity (in vitro, cytogenicity mammalian cells or micronucleus) • Mutagenicity (in vitro, gene mutation mammalian cells) • Acute toxicity (inhalation) • Acute toxicity (dermal route) • Repeated dose toxicity (28 days, one species) • Reproductive toxicity (screening, one species) • Toxicokinetics (assessment from available information)	• Repeated dose toxicity (28 days,one species)* • Repeated dose toxicity (90 days,one species, rodent) • Reproductive toxicity (pre-natal development, one species) • Reproductive toxicity (two generations, one species)	• Reproductive toxicity (developmental, one species) • Reproductive toxicity (two generations, one species)* • Carcinogenicity study
			*These studies have to be carried out if they have not been completed for the lower tonnage band because of waiving	
Ecotoxicological information	• Aquatic toxicity (short term, invertebrates) • Aquatic toxicity (short term, aquatic plants) • Degradation (biotic, readily biodegradability)	• Aquatic toxicity (short term, fish) • Aquatic toxicity (activated sludge respiration, inhibition testing) • Degradation (abiotic, hydrolysis function of pH) • Fate and behaviour in the environment (adsorption/desorption screening)	• Aquatic toxicity (long term, invertebrates) • Aquatic toxicity (long term, fish) • Degradation (biotic, surface water) • Degradation (biotic, soil) • Degradation (biotic, sediment) • Degradation (biotic, identification of degradation products) • Fate and behaviour in the environment (bioaccumulation, aquatic species) • Fate and behaviour in the environment (further information on adsorption/desorption) • Effects on terrestrial organisms (short term, invertebrates) • Effects on terrestrial organisms (soil micro-organisms) • Effects on terrestrial organisms (short term, plants)	• Degradation (biotic, further testing) • Fate and behaviour in the environment (further information) • Effects on terrestrial organisms (long term, invertebrates) • Effects on terrestrial organisms (long term, plants) • Effects on sediment organisms (long term) • Effects on birds (long term or reproductive)
Physico-chemical properties	• State of the substance at 20°C and 101.3 kPa • Melting/freezing point • Boiling point • Relative density • Vapour pressure • Surface tension • Water solubility • Partition coefficient n-octanol/water • Flash-point • Flammability • Explosive properties • Self-ignition temperature • Oxidising properties • Granulometry		• Stability in organic solvents and identity of relevant degradation products (if substance stability is considered to be critical) • Dissociation constant • Viscosity	

Source: REACH directive

The content of the required endpoints information encapsulates results of conducted tests as study summaries, robust summaries if required, under Annex I, and testing proposals if specified in Annexes IX and X. Note that at the specified registration time, some properties of substances may not be fully available in order to assess its hazard status. For these cases, the registrants must provide testing proposals and timeline for the proposals when required in certain conditions set in the Annexes IX and X. The requirements for test procedures will be explained in subsection 4.3.1.

The extension of required information of intrinsic properties depend on the tonnage band (1-10 tons/year, 10-100 tons/year, 100-1000 tons/year, and more than 1000 tons/year) of substance for registration in question. For substances falling within the scope of 1-10 tons/year, exposure information as specified in Section 6 of Annex VI is required. Information specified in Annex VII as a whole also shall be submitted for non phase-in substances and for phase-in substances meeting criteria specified in Annex III. For phase-in substances that do not enter scope of Annex III, submitting information regarding only physicochemical information requirements listed in Annex VII is sufficient. For each tonnage band above 10 tons/year, information requirements gradually increase. For registration in tonnage band of 10-100 tons/year, information listed in Annex VII and Annex VIII is required. Whereas for tonnage band 100-1000 tons/year information listed Annex IX is also required. Finally, for tonnage band of more than 1000 tons/year, information listed in Annex X enters to the list of requirements. Requirements of information listed in Annexes are shown in Table 4.2., with respect to the stated tonnage bands.

Table 4.2. The Requirements for Registration Dossier Under REACH

Requirements	Tonnage Band				
	1-10 tons		10-100 tons	100-1000 tons	>1000 tons
	non phase-in and phase-in listed in Annex III	other			
Annex VI	required	required (ex. sec. 6)	required (ex. sec. 6)	required (ex. sec. 6)	required (ex. sec. 6)
Annex VII	required	only physiochemical information required	required	required	required
Annex VIII	not required	not required	required	required	required
Annex IX	not required	not required	not required	required	required
Annex X	not required	not required	not required	not required	required

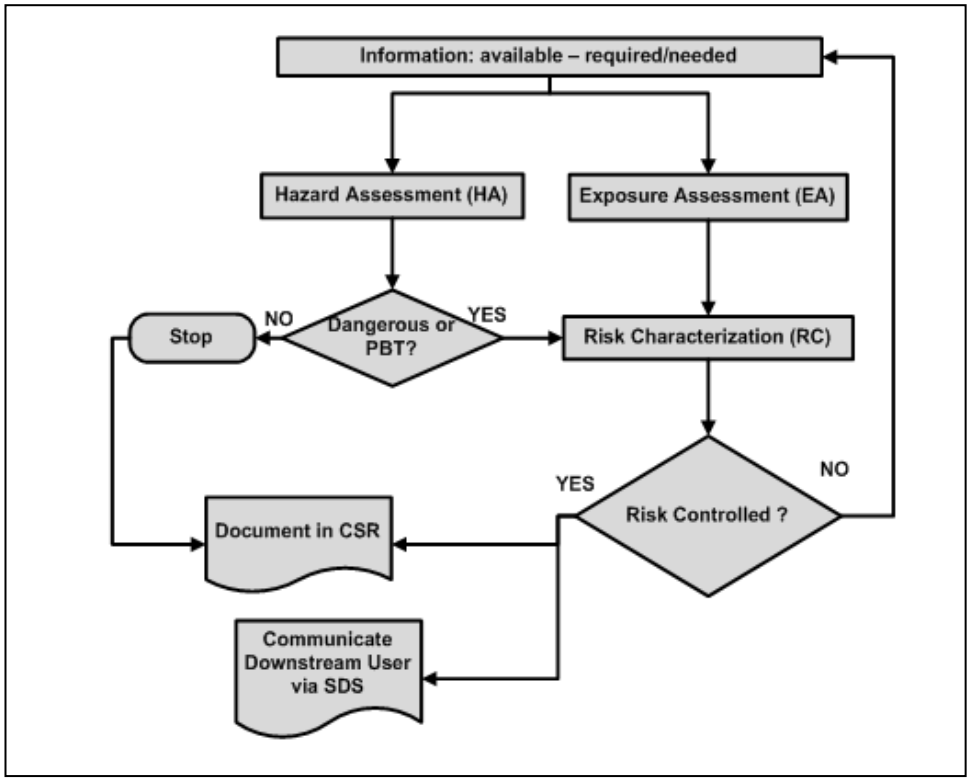
Source: REACH directive

For the substances registered in quantities more than 10 tons/year a separate document, chemical safety report (CSR), as specified in Annex I, should be included in the "registration dossier." CSR represents chemical safety assessment (CSA) of substances which is the assessment of risks related with their manufacture and/or use in order to guarantee their adequate control. CSR is composed of human health hazard assessment, physicochemical hazard assessment, environmental hazard assessment and persistent, bioaccumulative and toxic (PBT), as well as very persistent and very bioaccumulative (vPvB) assessment. If the substance in question is classified as dangerous,[51] PBT or vPvB,[52] the CSR associated with it must be supplemented with a proper exposure assessment, containing generation of exposure scenarios or the identification of relevant use and exposure categories if appropriate, and relevant exposure estimation and risk characterization. An exposure scenario is a set of conditions that describes how a substance (including in mixtures and articles) is manufactured or used during its life cycle (encapsulating its

[51] As defined in Directive 67/548/EEC
[52] The condition for PBT and vPvB are defined in Annex XIII.

transportation and disposal) and how the manufacturer or importer or downstream user controls or recommends controlling exposure of humans and the environment. Note that the development exposure assessment is an iterative process. If it is estimated that a risk may not be sufficiently controlled, then further efforts regarding refinement of either the exposure assessment (eventually including modifications of the operational conditions or risk management measures put in place and described in the exposure scenarios) or of the hazard assessment might be needed until the risks to the environment and the human health are adequately controlled. The CSR must include the final exposure scenario output of this iterative process. This iterative process is illustrated in Figure 4.1.

Figure 4.1. Flow Chart of the Iterative Process of Exposure Assessment



Source: ECHA (2008)

In order to minimize burden of testing requirements required by registration to the REACH system, regarding registration of same substance by different identities, REACH has common provisions to apply in registration process for same substances to be registered by different entities. In registration, each registrant shall supply identity of registrant, identity of substance and information on the registrant's identified uses of substance and relevant exposure information for registrations falling within the scope of 1-10 tons/year, independently. However, the other information requirements are submitted by a **lead registrant** registering the substance. The follower entities should refer to lead registrant's submit of information regarding classification and labeling as well as information on intrinsic properties including study summaries, robust study summaries, and proposal for testing.

On the other hand, CSR and guidance of safe uses may be submitted individually or jointly. However, in jointly required areas, a registrant may use different information set other than the lead registrant's, if it would be disproportionately costly for him to submit this information jointly. Submitting the information jointly would lead to disclosure of information which he considers being commercially sensitive and is likely to cause him substantial commercial detriment, or he disagrees with the lead registrant on the selection of this information. In fact, if a registrant uses above clauses to send different information, he has to explain the underlying reasons. The mechanism of data sharing is explained in the following subsection.

Note that a registrant should complete all required areas and send its registration in IUCLID format via REACH-IT in order to register its substance since an automated

procedure checks the format and completeness of a registration entry. Also, note that after conducted conformity assessment procedures, which will be explained in relevant subsection, a registration may need to be updated. Registrations and registration updates should be accompanied with a fee paid to the Agency in order to be validated. The amount of fees to be paid by registrants that are set out in Regulation (EC) No 340/2008 together with deadlines for payment.

4.1.4. Data Sharing Mechanisms

In order to reduce unnecessary duplication on tests required by REACH legislation and to minimize the tests conducted on vertebrate animals, REACH obliges data sharing across different entities that have to register the same substance. However, the procedure differs for preregistered phase-in substances and nonpreregistered phase-in substances, and non phase-in substances.

4.1.4.1. Preregistered Substances

For preregistered phase-in substances in REACH, the mechanism for data sharing is established by the formation of Substance Information Exchange Forums (SIEFs). Besides, their duties regarding data sharing SIEFs are also responsible for agreement of its members regarding classification and labeling of the substances.

In principle, one SIEF is formed up for every preregistered substance. SIEFs are composed of both potential registrants who have not registered their substances, and the parties that have already registered their substances while the membership is mandatory for these types of parties. Other stakeholders like manufacturers or

importers of same substance, who do not have registration obligation due to their amount (less than 1 ton/year), downstream users, and other third parties that hold information on the substance may also participate in SIEFs. All SIEFs will be operational until 1 June 2018, the latest deadline for registration.

SIEF participants shall provide other participants with existing studies and react to requests by other participants for information. Specifically, the parties that have already registered their substances have obligation to share their test data with other parties in return of financial compensation or admit penalization. Other stakeholders may also share their data on voluntary basis in return for financial compensation.

In any case, before conducting a required test to obtain relevant data, members of SIEF are obliged to consult each other about the availability of test data. Because data sharing mechanism envisaged in REACH across SIEF, members are required to share information with each other. Using a previous study conducted by another identity requires the permission of its owner. If a relevant study involving tests on vertebrate animals is available within the SIEF, a participant of that SIEF shall request that study. On the other hand, if a relevant study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study.

The provisions differ for tests on vertebrate animals and other test types. If a requirement imposes a test on vertebrate animals, a SIEF member that has already conducted test imposed to share its test data for a financial compensation. REACH encourages negotiations between parties in order to ensure this cost sharing

operates in a fair, transparent, and non-discriminatory way. One way of doing this is to follow cost sharing guidance developed by the Agency. However, if no agreement is reached, the applicant is supplied the test data by the Agency for a compensation of equal sharing of this test data provided that the study owner has proved its study to the applicant and regarding cost burden to the Agency. Otherwise, the Agency penalizes the test owner, blocking it to register until it provides information to other members.

The Agency permits other members to register without required test data on vertebrate animals. However, the Agency requires the relevant test to be conducted in 12 months. If no test data within a SIEF is available regarding usage of vertebrate animals, then a member can be chosen by SIEF before the announced deadline or can be assigned by the Agency if it is not chosen within the SIEF. This is done in order to conduct the test on behalf of the members and it is equally compensated by other members of the SIEF.

On the other hand, where the test not including usage of vertebrate animals are considered, the owner of data may optionally refuse sharing of such data accepting penalization foreseen by the Agency. In this case, SIEF participants may proceed to register as if no test data are available on the subject. If the data owner agrees to share its data, then the SIEF members may register using that data and cost sharing procedure applies for all SIEF members. If no data within a SIEF is available regarding a test not including usage of vertebrate animals, then the applicants may proceed to registration as if no study is available on the subject. The data sharing procedure for preregistered substances is shown in Figure 4.2 (see Appendix B).

4.1.4.1. Nonpreregistered and Non Phase-in Substances

As previously stated, nonpreregistered and non phase-in substances must follow an inquiry process before the registration step. Prior to registration, the first step is for these substances to send an inquiry to the Agency with his identity, full identity of the substance, and which information requirements would require new studies involving or not involving vertebrate animals. If there are previous registrations on the substance in question, the following data sharing mechanisms apply.

If the substance has been registered for more than 12 years, the Agency informs relevant summaries or robust study summaries that are already available for the substance without requiring any fee. The applicant may use this information in registration with performing new test if it is required.

On the other hand, the Agency informs potential registrants about previous registrants' name and contact details and informs previous registrants about the name and contact details of applicant if the same substance has previously been registered less than 12 years. If a relevant study involving tests on vertebrate animals is available in the registration of the previous registrant, the potential registrant shall request for that study. On the other hand, if a relevant study not involving tests on vertebrate animals is available in the registration of the previous registrant, the potential registrant may request for that study in order to register. In this phase, REACH encourages potential and previous registrants to negotiate on the costs of sharing. The information is determined in a fair, transparent, and non-discriminatory way. If they cannot reach an agreement, they can also direct the cost sharing allocation to the arbitration board. If this is the case, they must approve the

arbitration order. If the matter is not directed to the arbitration board, the potential registrant ultimately retrieves the permission for usage of required information paying proportionate share or an equal share in case of full study reports. In this phase, the parties may apply to the arbitration board or appeal against the Agency about the decision. The procedure for data sharing in case of a previous registration exists less than 12 years, as shown in Figure 4.3 (see Appendix B).

4.2. Other Requirements and Limitations under REACH

In order to provide full protection on the human health and on environment, besides registration requirements which are already mentioned, REACH imposes the formation of Safety Data Sheets (SDSs). These will convey information through a supply chain, notification of articles that contains SVHC substances, authorization regarding the substances having revealed SVHC properties and restriction of some substances that impose an unacceptable level of concern.

4.2.1. Safety Data Sheet

Besides ensuring manufacturers and importers to have sufficient information on the use of their substances, REACH also aims to guarantee downstream users who also have the relevant information about the substances they use. The information flow between these actors about the safe use of the substances in question is provided by REACH through SDSs prepared in the official language of the member state where it is placed on the market. Actually, SDSs are not a new concept in the European regulatory system. They were already covered by the SDSs Directive

(91/155/EEC) for dangerous products before REACH comes into force. REACH repeals this directive extending its scope. Regardless of its tonnage level, for every registered substances classified as dangerous, PBT or vPvB or mixture of substances that contain dangerous, PBT or vPvB substances for a specified threshold, a SDS must be prepared according to rules laid down in Annex II.

The SDSs establishes a mechanism for transmitting appropriate safety information on classified substances and preparations down to the supply chain. SDSs basically includes the following information: identification of the substance/preparation and of the company/undertaking, hazards identification, composition/information on ingredients, first-aid measures, fire-fighting measures, accidental release measures, accidental release measures, handling and storage, exposure controls/personal protection, physical and chemical properties, stability and reactivity, toxicological information, ecological information, disposal considerations, transport information, regulatory information, and other information.

If SDSs are prepared for substances that also require CSR in registration, the information provided in SDSs must be in line with the CSRs. Moreover, the relevant exposure scenarios developed for CSRs must be placed into annexes of corresponding SRSs with references under the relevant headings. This procedure is necessary for informing downstream users about the risk management measures that are implemented or recommended for safe uses of the substance.

Note that SDSs must be updated whenever new information is revealed on corresponding hazards which in turn might affect proposed risk management measures. The SDSs must also be updated if an authorization is granted or refused,

or if a restriction is imposed on that substance. SDSs must be provided free of charge on paper or electronically. It is an obligation for manufacturers and importers to keep all relevant information about a substance. Besides, downstream users are also responsible for keeping SDSs and any other relevant document of the substances they use for a period of at least 10 years after they last used the substance in question. These agents should provide all information or make it available immediately upon request to any competent authority of the member state in which he is established or to the Agency.

4.2.2. Notification Requirements

Notification to the REACH is a similar process to registration but requiring comparably small information. REACH legislation envisages notification for two cases of registration exemptions which are explained below. Additionally, in order to create a community level inventory of classification and labeling a third type of notification also laid down in REACH.

REACH provisions exempt substances used with the intent of product and process orientated research and development (PPORD) by importer or manufacturer himself or in cooperation with listed customers from registration for five years in first step. However, a notification including the identity of the manufacturer or importer of articles, the identity of the substance, the classification of the substance, the estimated quantity and the names and addresses of referred customers. In order to ensure that the notified PPORD substances will be transported by the notifier or its customers in controlled conditions, respecting the

protection of workers and the environment and will not be used commercially and the remaining quantities will be disposed, evaluating notification dossier the Agency may impose additional conditions and request more information regarding the notification.

The first five years of exemption may be prolonged by the Agency for a maximum of five years or for a maximum of ten years in the cases of development of medicinal products, or for unmarketed substances upon the request if it is properly justified by the scope of the research and development process.

Another notification requirement applies to article producers and importers. Given that the substances used in articles are not registered by another entity for usage in articles and included in the SVHC Candidate List as well as its exposure from the article cannot be excluded, any article manufacturer or importer shall notify the Agency if the substance exist in those articles in quantities exceed 1 ton/year and the substance is present in those articles above a concentration of 0.1% by its weight. The notification must include the following information: the identity and contact details of the producer or importer, identity and classification of substance of the substance, a brief description of the uses of the substances in the article, and the tonnage band of the substance.

The final type of the notification is required by all substances that are subject to registration (but are not yet registered) and dangerous substances that are out of scope of the registration requirement in[53] order to set up a community level inventory of classification and labeling. This notification requires information

[53] For example, they might be manufactured or imported under 1 ton/year or used within purposes of PPORD.

regarding identity of manufacturer or importer, identity, hazard classification, hazard labeling of the substance, the hazard classification and specific concentration limits (where applicable).

The first two types of notification require a fee as specified in Regulation (EC) No. 340/2008, whereas classification and labeling notification is not subject to a fee.

4.2.3. Authorization and Restriction

Besides registration, REACH foresees an authorization and restriction procedure in order to regulate the manufacture, placing on the market, or use of certain substances, either on their own or in mixtures or articles within the EU territory given that these substances impose potential harms to human health and environment. In REACH nomenclature, SVHC are the substances either enters the scope of CMR, PBT, vPvB or there is "scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern." These substances are identified gradually on a case-by-case basis. Being a SVHC does not immediately lead an authorization or a restriction on that substance.

The European Commission or one of the member states may declare a concern on a substance and prepare a proposal for the identification of a substance as SVHC.

In order to control risks arising from the usage of SVHCs and to ensure subsequent replacement of SVHCs with economically and technically applicable alternatives REACH proposes an authorization mechanism for these substances. This authorization may be specified for all uses or for certain uses of that substance.

The procedure for a substance to be placed in authorization list on Annex XIV of REACH is as follows. The first step is identification of concerned substances to be included in the SVHC Candidate List for Authorization for eventual inclusion in the list in Annex XIV. The Commission may ask the Agency to prepare a dossier for a substance, or a member state may prepare a dossier and submit it to the Agency for a according to rules established in Annex XV. When a dossier is prepared, it is announced by the Agency and opened for public comment. If a member state or the Agency does not make any comment on the proposal, the substance in question is listed in the SVHC Candidate List. Otherwise, the proposal is forwarded to a member state Committee. If a unanimous agreement reached over the proposal substance in question is included in the candidate list, otherwise, the Commission amends the draft and the final decision on the subject is given by the European Council.

Note that the substances included in the candidate list is taken into work program of the Agency and eventually listed in Annex XIV by amendment of REACH. Once a substance is listed in Annex XIV, it requires authorization granted to the importer or manufacturer in order to be used or produced in the Community, after the indicated deadline.

On the other hand, REACH also proposes a restriction mechanism for some SVHCs. The restriction may be in form of a total ban on a substance or limitations on their certain usages. The restricted list of substances is listed in Annex XVII of REACH regulation. The extension of restriction list may be demanded by the Community or any member state. Additionally, this procedure may also be initiated for the

substances listed in Annex XIV that are subject to authorization following the deadline mentioned above paragraph. For above cases a proposal dossier should be prepared according to rules laid down in Annex XV. The Agency shall keep up a list of these proposal dossiers. At this step, these proposals are opened for public comment. Considering public comments, two committees under the Agency shall form an opinion on the proposals. The committee for risk assessment forms an opinion about the appropriateness of suggested restrictions for reducing the risks on human health and on the environment. The committee for socioeconomic analysis forms an opinion on the proposed restrictions regarding their socioeconomic effects. These opinions are forwarded to the Commission and the Commission prepares a draft amendment to Annex XVII. The final decision on the subject is taken by the Commission itself. Once a substance is listed in Annex XVII it is restricted for indicated certain uses or banned totally.

4.3. Evaluation

REACH legislation envisages a very high-level protection of human health and environment in the community level controlling many chemical substances. The main tool for the attainment of these objectives is to retrieve information about the substances through registrations. Having more information on a substance allows the Community to identify possible risks that may arise from the usage of the substance better. When these risks can be estimated, they can be controlled via authorization requirements and restrictions proposed under REACH legislation.

On the other hand, registering a substance via REACH requires its manufacturer or importer to reach a high level of awareness through identification and classification of the substance in question as well having more information on its intrinsic properties and possible consequences of these properties when this substance is used. This situation together with requirements of self-control if a possible risk exist makes the manufacturers and importers of the chemical substances them to come with more efficient solutions in order to minimize the associated hazard of the product. REACH also promotes an information flow through the base in the supply chain with the instruments like SDSs.

In order to attain above objectives, REACH requires registration of the substances in order to be produced or imported in the community market. However, the conformity of these registrations with the provisions declared under REACH is also important for the efficient functioning of the system. The mechanism for conformity assessment is called as evaluation in REACH jargon. This subsection explains the technical requirements under REACH and relevant conformity assessment mechanisms.

4.3.1. Technical Requirements

All procedure related with registration of a substance consist of a technical regulation for a manufacturer or importer, since registration itself is obligatory in order to put that substance, a mixture of that substance or an article that consists of that substance into internal market of the EU. However, the entries in the registration themselves are subject to some sort of standards laid down in REACH.

The requirements for classification and labeling as well as the requirements for testing procedures are explained in the following subsections.

Also, note that in order to make available when requested by the MSCAs and the Agency, each manufacturer, importer, or any downstream user shall keep all information regarding his registration or usage of the substances under REACH for at least 10 years after he last manufactured, imported, or used the substance respectively.

4.3.1.1. Testing Requirements

Registrations require more information regarding the properties of a substance. This information is mostly retrieved by conducting specialized test procedures. Where tests on substances are required to generate information on intrinsic properties of substances, they must be conducted in accordance with the test methods laid down in Regulation (EC) No. 440/2008 or in accordance with other international test methods recognized in Regulation (EC) No. 440/2008. On other hand, when tests and analyses in order to reveal ecotoxicological and toxicological properties are considered, these tests and analyses must be carried out in compliance with the principles of good laboratory practice (GLP) laid down by the EU with Directive 2004/10/EC or other international standards recognized as being equivalent by the Agency or the Commission and with the provisions of Directive 86/609/EEC, if applicable. Accreditation of testing facilities with GLP is important for the validity of these studies especially for ecotoxicological and toxicological tests and analyses presented in the registrations.

However, REACH does not require conducting new tests in every case. In some cases, conducting new tests is not necessary scientifically. Annex XI lists the cases where a new test may not be conducted with the requirements for applicability if this is the case. The relevant data retrieved from existing studies may be used. Results of qualitative or quantitative structure-activity relationship (QSAR) may also be used instead of testing. On the other hand, some properties of the substances can be revealed by read across approach from the other substances whose physicochemical, toxicological, and ecotoxicological properties are similar with the substance in question.

Additionally, in some cases testing for a specific endpoint may well be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the substance: e.g. very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion or the radio-labeling of the substance required in certain studies may not be possible. Testing can also be omitted for endpoints under the titles of repeated dose toxicity and reproductive toxicity based on the exposure scenario(s) developed in CSA.

4.3.1.1. Classification and Labeling Requirements

Substances that are registered under REACH, besides other chemical substances are subject to provisions of classification, labeling, and packaging laid down in CLP (Classification, Packaging, Labeling) Regulation. The EU CLP Regulation harmonizes the EU classification, labeling and packaging schemes with the global approach developed by United Nations (UN) under name GHS (Globally Harmonized System

of Classification and Labeling of Chemicals). CLP Regulation replaces provisions of two directives, the Dangerous Substances Directive 67/548/EEC (DSD) and the Dangerous Preparations Directive 1999/45/EC (DPD), in a stepwise approach; where these directives will finally be repealed on 1 June 2015. REACH legislation[54] requires CLP provisions apply to identification and classification required for registration dossiers and SDSs supplied to users under REACH provisions.

4.3.2. Conformity Assessment

Conformity assessment activities regarding application of REACH are the responsibility of the Agency and the MSCAs. The conformity assessment activities have two pillars in the first step: dossier evaluation and substance evaluation. Dossier evaluation is further divided into two independent evaluation mechanisms for compliance check and examination of testing proposals. Dossier evaluation is conducted in order to assess conformance of registrations to the REACH provisions whereas substance evaluation is a precautionary step to identify potential risks associated with a substance. Substance evaluation may yield change in status of a substance regarding its classification or may alter the requirements of assessments regarding test data.

[54] This requirement is incorporated into REACH with Commission Regulation (EU) No. 453/2010 since the original REACH precedes the CLP regulation.

4.3.2.1. Dossier Evaluation

In principle, dossier evaluation is conducted by the Agency itself whereas the MSCAs play a role in dossier evaluation process, commenting on draft decisions. As stated above, dossier evaluation has two independent steps.

4.3.2.1.1. Examination of Testing Proposals

The main objective of the examination of testing proposals is to investigate whether the information requirements according to REACH are fulfilled, and if the proposed studies are appropriate and will increase the knowledge of the dangerous properties of chemicals in order to protect human health and the environment, while at the same time preventing unnecessary testing costs and animal testing.

All registration dossiers are subject to the examination of testing proposals. However, the immediacy factor differs for phase-in and non phase-in substance registrations. In case of a registration of a phase-in substance, a decision upon proposal should be drafted within two years following the first deadline, three years following the second deadline, and four years following the third deadline. On the other hand, the non phase-in substance registration requires more immediacy where a decision has to be drafted within 180 days of registration. Besides, the examination of testing proposals will be subject to a priority ordering. Priority will be given to registrations concerning dangerous, PBT, vPvB, and CMR substances as well as substances registered for a quantity level over 1000 tons/year.

The examination of testing proposal concerns two aspects: justification and adequacy. In order to assess justification of considered testing proposals, the

Agency investigates submitted registrations examining relevant sections of the dossier regarding testing proposals (and CSR when available). The proposals are evaluated with the information requirements laid down in Annexes IX and X of REACH regulation regarding physicochemical, toxicological, and environmental (ecotoxicological and environmental fate) properties. The justification of a test proposal is provided if it is found appropriate for fulfillment of a necessary information regarding clarification of a suspected hazard, setting of classification, and refining the risk assessment. The Agency also assesses adequacy of testing proposal, decides the completeness of testing proposal, and identifies if a modification or additional testing is needed.

Note that since it is possible to have multiple registration entries regarding the same substance, it is expectable having several testing proposal to identify a specific endpoint. However, not all of these tests may be required to reach objective information. It is advisable that all testing proposals submitted for the same substance should be examined at the same time in order to prevent redundant testing requirements. If the Agency decides, then only one of the considered tests will be conducted actually. If this is the case, the Agency has to convey this information on the registrants to make them form a consensus on the test method.

Following its evaluation of testing proposal in a registration, the Agency publishes a draft decision regarding its assessment. The draft decision may adjudge one of the following provisions:

- Acceptance of the testing proposal in the way it is stated
- Acceptance of testing proposal with a requirement of performance of one or more simultaneous tests
- Acceptance of testing proposal with modified conditions under which the testing is proposed
- Acceptance of testing proposal with modified conditions under which the testing is proposed and one or more additional tests need to be performed
- Rejection of testing proposal with one or more additional tests need to be performed
- Rejection of testing proposal

The bureaucratic procedure for a draft decision can be explained as follows. Following the preparation of a draft decision, the registrant(s) are notified in order to collect their comments on it. The Agency may amend the draft decision considering the feedback supplied by the registrant(s). After that, the draft decision is notified to the MSCAs together with comments made on it. The MSCAs propose amendments to the draft. The Agency may modify the draft decision considering amendments and pass the draft decision to the Member States Committee including the proposed amendments by the MSCAs. At this step, the registrant(s) are allowed to make comments on the draft decision once more. Then, a conclusion is drawn by the Member States Committee. Following this, the Agency finalizes the

decision considering proposed amendments and conclusion. The decision is notified to the registrant(s) allowing them to submit required information accordingly. In the final step, the Agency notifies the Commission and the MSCAs of the obtained information and any drawn conclusion.

4.3.2.1.2. Compliance Check

Compliance checking is the evaluation of quality and adequacy of declared elements in registration with respect to the criteria laid down in REACH. The Agency does not check all registrations for compliance. In order to ensure this assessment mechanism to operate efficiently and for compliance checking, the Agency selects a percentage (no lower than 5% of total) of registration dossiers for each tonnage band. The selection procedure may be random or the Agency may also give priority for some registrations. The priority shall be given to joint registrations that declare different information which must be common among them. The registrations that have missing elements for information requirement in Annex VII and registrations belong to substances in Community Rolling Action Plan.

Note that compliance check is not necessary for all information for a registration in question. The Agency may also introduce efficiency to the process that is only checking on specific points or sections instead of the whole registration coverage. If this is the case, regular checking should be followed by any occurrence of nonconformity. Compliance checking may be conducted in any area of registration. It may target technical dossier, CSR, or explanations where separate submits are made for the same substances.

The technical dossier evaluation needs assessment of given information with the CLP requirements when identification and classification is considered. In order to assess validity of test data, study summaries and robust summaries should be carefully inspected and their compliance with the testing requirements (like GLP) should be verified. If standards methods are not used in testing, during the compliance check it should be checked whether reported adaptations follow the instructions. If adaptations for a defined endpoint are not in accordance with the guidance, these adaptations have to be evaluated for their applicability on a case-by-case basis.

When compliance checking for CSRs, the very first thing to do is to verify the completeness of CSRs regarding Annex I since automatic procedure checking completeness of registration entries does not specifically control the elements of CSRs. The adequacy of exposure scenarios is also important since it directly affects human health and other environmental elements. Another point that needs specific care is the calculations risk assessment values evaluated with the exposure scenarios to verify the safety of a substance in consideration.

After compliance, checking the Agency prepares a draft decision requiring registrant to submit information in order to bring its registration in compliance with the provisions. The bureaucratic process for draft decision is similar to one that is considered in testing proposal evaluation section.

4.3.2.2. Substance Evaluation

Substance evaluation aims at the clarification of a concern for human health or the environment. It is conducted on the substances placed on the Community Rolling

Action Plan formed for 3 years considering hazard and exposure information of a substance, where these elements pose a serious consideration regarding human health and environmental safety and total tonnage of substances. Community Rolling Action Plan allocates the evaluation of substances in consideration to the MSCAs basically on voluntary basis. Community Rolling Action Plans are formed by the Agency following feedbacks from Member States. Currently no Community Rolling Action Plan exists in the Community. The first Community Rolling Action Plan will be drafted on 1 December 2011.

Substance evaluation is closely related with compliance checks since the evaluations regarding compliance checks form a basis for substance evaluation. However, compliance check is not mandatory for substance evaluation. In order to facilitate the substance evaluation process, substances listed in the Community rolling action plan should be given priority for compliance. However, if the dossier has not yet undergone a compliance check, the MSCA conducting the substance evaluation should check the reliability and relevance of the data used within the substance evaluation before commencing with the substance evaluation. The information presented in registration dossiers may not be sufficient to determine the status of a substance. MSCAs may also use scientific publications, international assessments, environmental surveys, consumer product information, occupational health reports, and information on exposure and risk management measures, compliance supplied by the other elements of supply chains.

Within 12 months following its assignment by Community Rolling Action Plan, the MSCA should draft a decision regarding its assessment on a substance. Once the MSCA prepares a draft on the evaluation on a substance, it requires a bureaucratic

procedure similar to one defined for evaluation testing proposal section. Three types of outcomes are possible in this draft decision.

After its inspection, the MSCA may remove its concern from the substance in question. If this is the case, the results of the data review and the conclusions shall be documented so that others can benefit from the work done. In these cases, if new information has been found having insufficient weight to carry on with the substance evaluation process, but is considered relevant for the registrants (e.g., because it affects the validity of their risk assessments), the evaluating MSCA should consider bringing this information to the attention of the registrant(s) with an encouragement to update the registration dossiers.

The second possible outcome is the follow-up procedure for the inspected substance. After the evaluation, if the concern is not removed for that substance, the MSCA may go on preparing a proposal dossier under the requirements laid down in Annex XV. Accordingly, this dossier may propose a change in the classification and labeling schemes. It may suggest for the identification of the substance in question in the candidate list for SVHC or it may suggest a restriction for the substance. Additionally, the proposal may propose further actions in national or community level outside of the scope of REACH to handle the substance or may request voluntary actions by registrants and downstream users.

The third possible outcome arises if the existing data is not sufficient for determining status of the substance in question. In this case, stating its justification, the MSCA may request for further information if appropriate, including information that is not listed in relevant annexes from registrants, obliging the registrant to submit further information and setting a deadline for its submission.

4.4. Surveillance

There is no community level measure specific to enforcement of REACH requirements. Legally, the general provisions laid down in Regulation (EC) No. 765/2008 also applies for the scope of REACH regulation. Market surveillance and enforcement activities under REACH are carried by responsible authorities of member states under the coordination of the Forum for Exchange of Information on Enforcement (Forum) working within the Agency. Specifically, the Forum is recognized by the REACH regulation in Article 77(4) in order to conduct good practice in enforcement, proposal and coordination of harmonized enforcement activities, identification of enforcement strategies, and development of an electronic information exchange mechanism. With the adoption of CLP regulation, the duties of the Forum regarding enforcement of REACH also extended to the CLP regulation.

The Forum has shown a relatively active performance so far in completing a joint enforcement project (REACH-EN-FORCE-1) including about 1600 companies with manufacturers, importers, sole representatives, or downstream users in the Community during 2009. Noncompliances are detected at about a 20% level while necessary corrective actions are taken. The Forum also published two advisory guidance documents for member states regarding inspection and strategies for enforcement regarding REACH and CLP. Moreover, the Forum organized an event "to train the CLP enforcement trainers." In order to regulate its organizational duties, the Forum adopted an internal regulation defining its management structure and functions. Accordingly, the Forum defined its first work program to cover the

tasks, as described in the REACH and CLP regulations for the interval of 2011-2013, to be reviewed yearly. The work program divides related activities into three work packages as forum coordinated enforcement projects, enforcement of REACH and CLP, and forum organizational and general administrative issues while the latter work package is maintenance of the work plan itself.

Forum coordinated enforcement projects work package includes projects that have already started and proposed to be initiated in the years of its scope. Currently, two projects are ongoing. REACH-EN-FORCE-1 project is decided to be prolonged by a number of member states in order to collect more data and to raise awareness amongst responsible entities. REACH-EN-FORCE-2, similar to REACH-EN-1 is initiated targeting inspection of specific downstream users. Another enforcement project, including cooperation with custom authorities, is in proposal stage.

Regarding the enforcement work package, two previously mentioned guidance documents were revised. Following the completion of the abovementioned enforcement projects, a more specific guidance defining methods and practices is proposed to be prepared. A study is initiated in order to clarify interlinks among the Agency, MSCAs, and enforcement authorities of member states. Accordingly, an information exchange mechanism is proposed to be implemented. Moreover, a separate information exchange system is also completed for the direct access of enforcement authorities to the REACH-IT portal. Refinement procedures continue in this level. Furthermore, in order to establish the electronic information exchange system as envisaged in REACH regulation, requirements are defined by the Forum. The studies for this are ongoing to prepare a final decision for this system. On the

training issues, the Forum completed a training event for enforcement trainer separately for REACH and CLP regulations. A program for exchange of inspectors between member states is seriously taken into consideration. The other issues considered in this work package are on the subjects of improving dialogue with international stakeholders, cooperation with other enforcement networks in the EU, and general assessment of penalties in case of infringement.

4.5. Harmonization of the EU Chemicals Policy in Turkey

Previously, the chemicals policy corresponding to the EU legislation (Directive 1967/548/EEC, 1999/45/EC Directive, 1993/67/EC Directive and 91/155/EEC Directive 76/769/EEC) in Turkey was regulated by the regulation on dangerous chemicals (OG No: 21634, 1993). However, this regulation differed a lot from its EU counterparts. In order to establish the necessary system, institutional structure, the institutional capacity and the legal framework and to strengthen the regulatory cycle for implementation of the EU Chemicals Directives in Turkey a program on Technical Assistance for Strengthening the Institutional Structure and Capacity in the Field of Chemicals Turkey (TeaCH) with the aid of the EU was completed in Turkey in 2008.

Accordingly, four by-laws issued by the Ministry of Environment and Forest as a result of TeaCH project are published on 26.12.2008 in Official Gazette No. 27092. These four by-laws are:

- By-law on the classification, packaging, and labeling of dangerous substances and preparations

- By-law on the restriction of market supply and the usage of some dangerous substances, preparations, and articles
- By-law on inventory and control of chemicals
- By-law on the preparation and distribution of the safety data sheets related with dangerous substances and preparations

In this framework, the by-law on the classification, packaging, and labeling of dangerous substances and preparations incorporates Directive 1967/548/EEC and Directive 1999/45/EC into Turkish legislation. The by-law on the preparation and distribution of the safety data sheets related with dangerous substances and preparations harmonizes Directive 91/155/EC. The by-law on the restriction of the supply on the market and the usage of some dangerous substances, preparations, and articles harmonizes Directive 76/769/EEC to some extent. Finally, the by-law on inventory and control of chemicals harmonizes Directive 1993/67/EC. In this respect, a database regarding notifications of existing chemicals produced or imported into Turkey was established similar to REACH.

However, all Turkish by-laws harmonize the old measures on the European chemicals policy since the EU replaced its policy with REACH and CLP regulations during the execution phase of this project. In fact, the Directive 1993/67/EC, 76/769/EEC and Directive 91/155/EC are repealed with REACH regulation and incorporated into REACH. Accordingly, related Turkish legislation in the subject incorporated some provisions of REACH either. On the other hand, Directive 1967/548/EEC replaced with CLP regulation in 2010 and Directive 1999/45/EC will be replaced with the provisions in the CLP regulation in 2015.

In this respect, Turkish chemicals legislation can be viewed as a transitionary phase to harmonize the new chemicals policy of the EU. In fact, two separate projects started to harmonize the new EU chemical policy fully. In order to incorporate REACH into Turkish legislation, the REACH Chemicals Project (TR0802-02) started in June 2010 and expected to be finalized by June 2012. On the other hand, the project on the harmonization of CLP regulation (TR070228-01) started in January 2011 and finalized by May 2011. Besides, in order to increase the awareness for REACH and CLP at the industrial level, a project was completed in April 2011 together with a project on the enforcement of regulatory capacity for REACH and CLP is expected to be completed on October 2011. The full harmonization with REACH and CLP regulations are proposed to be completed in 2013 (Dağ, 2011). If Turkey fully complies with REACH and CLP regulations, the TBT regarding REACH provisions between Turkey and the EU would be overcome.

CHAPTER 5

TECHNICAL BARRIERS TO TRADE BETWEEN THE EU AND TURKEY

Following the study conducted by Brenton et al. (2001) and extending it for Turkey with different data and regulatory sources, in the empirical part of this study we analyze the importance of the removal approaches of TBT for the EU and Turkey. As a result, we find that the imports of EU-15 from other countries as well as from other EU-15 members may be affected by the presence of technical regulation to a great extent. In fact, about 96% of Turkish exports into EU-15 may be affected by the existence of technical regulations. Although there are variations between different countries regarding the share of product groups clustered under the scope different methods of the removal of TBT in the EU, we observe that the Old Approach is the most widely used method in the imports of the EU-15. This phenomenon is valid for Turkey since 37.58% of Turkish exports into the EU-15 are covered by the Old Approach lately. On the other hand, we find that the share of harmonized (New Approach and Old Approach) products is increasing over time since the formation of the CU between parties.

Additionally, we also recovered the number of product groups where Turkey has a revealed comparative advantage. We observe that the number of product groups

where Turkey has the RCA in harmonized area is increasing over the period. In this manner, we can claim that the overall competitiveness of Turkey regarding its trade with the EU-15 has increased since the formation of the CU.

5.1. Data and Methodology

Brenton et al. (2001) analyze the importance of TBT for Central and Eastern European (CEEC) Accession Countries[55] by finding the shares of different approaches for the removal of TBT in the EU, in these countries' trade figures with the EU-12 countries and exposing the number of sectors that have the RCA subject to these different approaches. In order to identify the sectors that are subject to the EU approaches of removal of TBT, they use a previous study conducted by Atkins (1998) to review of the impact of the single market in the EU. Atkins (1998) study provides information of regulatory measures (e.g., New Approach, Old Approach, mutual recognition, and no regulatory barrier) of about 120 manufacturing sectors at 3-digit NACE-CLIO classification. Accordingly, Brenton et al. (2001) use external trade data retrieved from COMEXT for 3-digit NACE classification sectors in order to identify the positions that the CEECs possess in those different approaches for the years 1988 to 1998.

Brenton et al. (2001) find that there is a considerable diversity among the CEECs regarding the importance of sectors subject to technical regulations in the EU. For example, the Old Approach sectors are of great importance for Estonia and Latvia

[55] The analyzed CEEC countries are Czech Republic, Poland, Hungary, Slovakia, Slovenia, Estonia, Latvia, Lithuania, Bulgaria, and Romania. These countries became members with the EU enlargement in 2004 and 2007.

while these sectors do not account considerably for Bulgaria and Romania. Similarly, for Czech Republic and Slovenia, sectors that are subject to the New Approach harmonization accounts the higher share of their exports in the EU-12, whereas the New Approach sectors possess less importance in exports of Bulgaria, Romania, and Lithuania. On the other hand, Brenton et al. (2001) also find that in general, the CEECs generally do not show significant RCA in the Old Approach sectors when compared to existing EU members. Regarding the New Approach sectors, this picture improves slightly for all CEECs while Czech Republic and Poland shows the RCA in considerably high number of sectors.

Regarding the analyses conducted in this study, we use the EUROSTAT data for intra-EU-15 trade and trade of the EU-15 with other parties in Combined Nomenclature (CN) at an 8-digit level for the years 1996 to 2010. We select the year 1996 as of our initial point because the CU came into force between Turkey and the EU at the time. We choose the CN 8-digit level external trade classification since it provides the most detailed information about the traded product. Note that the CN has a one to one correspondence up to the 6-digit codes with a harmonized system (HS) nomenclature. It is defined by the World Customs Organization (WCO) and which comprises about 1600 commodity groups which are identified by a 6-digit code and arranged according to a legal and logical structure based on fixed rules. The CN also comprises additional 8-digit subdivisions and legal notes specifically created to address the needs of the Community.

Using the above data sources, we assign the trade values at CN 4-digit level into five categories: New Approach (NA), Old Approach (OA), New Approach and Old

Approach (NAOA), mutual recognition principle (MRP), and sanitary and phytosanitary standards (SPS) with respect to their regulatory regime.

We start analyzing the products at the CN 8-digit level. For all CN 8-digit products, we reveal the technical regulations they are subject to. Writing a programming script, we retrieve the technical requirements for these products, from the Export Helpdesk website[56] created by the External Trade Division of the European Commission. There exists total of 129 requirement types for export into the EU as listed by Export Helpdesk. The next step is to identify these requirement types due to regulatory regime they are subject to. We browse inside these requirements and analyzed the relevant EU regulations and directives. The requirements and relevant legislation is listed in Table 5.1 in Appendix C.

Although some processed agricultural products are regulated under Old Approach harmonization, we exclude both raw and processed agricultural products (CN 01-CN 24) from the Old Approach cluster since it is quite complex to differentiate between raw and processed agricultural products even at the most differentiated CN 8-digit level. These products are represented under the SPS subclass. Note that this approach may yield a little unfavorable bias towards the assignments into the Old Approach category.

Using the information presented in European Commission (2000) for New Approach and European Commission (2010) and Annex of Decision No. 2/97 for Old Approach, we set correspondences with those requirements and the harmonized regulatory regime they are part of. For example, "Technical standards for toys" requirement

[56] See http://exporthelp.europa.eu/thdapp/index_en.html.

refers to New Approach Directive on Toys Safety (Council Directive 88/378/EEC). Therefore CN 8-digit products that are subject to this requirement are assigned as New Approach (NA) products. "Marketing requirements for dangerous chemicals, pesticides, and biocides" requirement refers to REACH and CLP legislations. Corresponding products that are subject to this requirement are clustered as the Old Approach (OA) products. Note that for some products even at CN 8-digit level, it is not possible to differentiate their regulatory regime as the New Approach or the Old Approach since these products may be either subject to the New Approach or subject to the Old Approach depending on their usage. This situation is encountered mostly for metallic products. For instance, "bars and rods of high-speed steel, hot-rolled, in irregularly wound coils" (CN 72271000) articles are subject to the New Approach legislation construction products directive if they are used for constructional purpose. However, these articles may also be subject to the Old Approach legislation relating to motor vehicles if they are used in motor vehicles. In order to aggregate these products precisely, we clustered them as being subject to both the new and the Old Approach (NAOA).

On the other hand, we identify MRP products using the information presented on the EU website on mutual recognition.[57] Here, products that are subject to MRP are listed in CN 8-digit level. For example, there is no community level harmonization measure on "padlocks of base metal" (CN 83011000). Therefore, it is listed by the EU for MRP to be applied. Finally, we assigned the products that are not subject to the New Approach, the Old Approach, the new and Old Approach, or the MRP clauses are categorized as the unregulated (NOR) products.

[57] See http://ec.europa.eu/enterprise/intsub/a12/index.cfm?fuseaction=a12.menuproducts#.

In order to simplify the analysis[58] after identifying product-based regulations, we moved to a more sectoral level aggregation. We clustered CN 8-digit level products into CN 4-digit aggregate level. However, for some CN 4-digit level product groups, the corresponding CN 8-digit level subproducts are subject to different types of harmonization measures. In such cases, we assigned regulatory sphere to CN 4-digit level products considering the most used regulatory type. This type is found by calculating the total share in EU-15 trade (intra-EU-15 imports, EU-15 imports from the rest of the world, and EU-15 exports to the rest of the world) of each regulatory type and picking the regulation type, which has the highest share.

Once, the regulatory approaches are assigned across product groups, we analyzed their recent incidence in EU-15 imports from EU-15 countries besides Turkey. Specifically, we detailed the evolution of Turkish trade with EU-15 regarding those regulatory approaches. Then, for the countries in our sample, we identified the number of product groups where these countries have the RCA in the breakdowns of regulatory approaches. After that, we analyzed the evolution of the products groups where a comparative advantage is revealed for Turkey.

The RCA concept flourishes from one of the most prominent trade theories of economics literature, the Hecksher-Ohlin (H-O) theory. According to the H-O theory, a country's comparative advantage is determined by its relative factor scarcity (i.e., its factor endowment ratios, relative to the rest of the world or a set of countries). However, measuring the comparative advantage and testing the H-O theory have some difficulties since measuring factor endowments is not possible for every

[58] There are about 15,000 products listed in total at CN 8-digit level covering 1996-2010 period. On the other hand, at CN 4-digit aggregate level, the number of products (sectors) is about 1250.

instance. Based upon this, Balassa (1965) suggests that it may not be necessary to include all components affecting a country's comparative advantage. Instead, he suggests that comparative advantage is "revealed" by observed trade patterns. In this manner, he comes up with the RCA concept, extracting comparative advantage from observed data in which it is revealed. In practice, this is a commonly accepted method in analyzing trade data. Balassa (1965) derives the RCA index (also called as the Balassa Index) that measures a country's comparative advantage (Seymen and Utkulu, 2004).

Given a market, Balassa index (RCA) is defined as follows:

$$RCA_{i,M}^{j} = \frac{\frac{X_{i,M}^{j}}{X_{i,M}^{k}}}{\frac{X_{n,M}^{j}}{X_{n,M}^{k}}}$$

Where:

$X_{i,M}^{j}$: Country i's export of product (industry) j into market M

$X_{i,M}^{k}$: Country i's total export of product (industry) group k into market M

$X_{n,M}^{j}$: Set of countries'(n) total export of product (industry) j into market M

$X_{n,M}^{k}$: Set of countries'(n) total export of product (industry) group k into market M

A comparative advantage is revealed by country i in set of countries n, in product (industry) j among set of products (industries) k, in the market M, if $RCA_{i,M}^{j} > 1$.

Note that in this study the market, M corresponds to the EU-15 market. An industry j corresponds to relevant CN 4-digit sector. Set of countries corresponds to the

whole world and set of products (industries) k corresponds to all products traded into EU-15. In this respect, for example Turkey's RCA in "Ferro-Alloys" (CN 7202) is found as:

$$\text{Turkey's RCA in "Ferro} - \text{Alloys"} = \frac{\frac{\text{Turkish Exports of "Ferro} - \text{Alloys" into EU} - 15}{\text{Total Turkish Exports of all products into EU} - 15}}{\frac{\text{Total EU} - 15 \text{ imports of Ferro-Alloysfrom the whole world}}{\text{Total EU} - 15 \text{ imports of all products from thewhole world}}}$$

5.2. Results

5.2.1. Incidence of Technical Regulations in EU-15 Trade

In this subsection, we analyze the incidence of technical regulations and the different approaches to their removals. Table 5.2 shows the breakdown of EU-15 imports from Turkey, individual EU-15 countries, extra EU-15,[59] and intra EU-15[60] in 2008-2010 average values.

[59] Extra EU-15 refers to all countries in the world except EU-15 countries in total.
[60] Intra EU-15 refers to countries in the EU-15 in total.

Table 5.2. Coverage of EU-15 Imports in Different Approaches on TBT (2008–2010 average)

	REGULATORY APPROACHES					
COUNTRY/GROUP	**NA**	**OA**	**NAOA**	**MRP**	**SPS**	**NOR**
Turkey	15.95%	37.67%	33.38%	0.99%	7.55%	4.46%
Austria	27.03%	31.55%	19.54%	4.72%	8.45%	8.70%
Belgium	13.80%	56.12%	14.12%	2.84%	9.66%	3.45%
Germany	22.83%	43.40%	15.76%	2.80%	7.16%	8.05%
Denmark	20.72%	30.99%	18.07%	2.40%	22.61%	5.21%
Spain	13.01%	46.16%	16.37%	3.42%	17.00%	4.05%
Finland	30.98%	26.32%	19.24%	5.77%	1.90%	15.79%
France	16.03%	41.39%	14.37%	3.43%	14.01%	10.78%
Great Britain	19.97%	50.65%	10.69%	3.39%	7.34%	7.96%
Greece	12.98%	32.71%	20.62%	2.30%	27.01%	4.38%
Ireland	25.84%	52.25%	3.52%	0.99%	13.20%	4.21%
Italy	20.39%	33.50%	25.71%	2.13%	10.35%	7.91%
Netherlands	26.76%	42.89%	8.65%	3.82%	14.84%	3.04%
Portugal	15.73%	34.02%	24.35%	6.51%	10.95%	8.44%
Sweden	24.98%	39.39%	14.23%	7.49%	4.59%	9.33%
Intra EU-15	20.91%	43.37%	14.79%	3.31%	10.78%	6.85%
Extra EU-15	25.38%	40.42%	13.28%	5.58%	6.50%	8.84%

Table 5.2 shows that a very large proportion of imports into EU-15 is affected by the technical regulations. In fact, only 6.85% of intra EU-15 trade and 8.84% of imports from other countries into EU-15 countries is not affected by technical regulations. On the other hand, the presence of technical regulations varies for individual countries for their exports into EU-15. The presence of technical regulations is most important for Netherlands and Belgium constituting about 97% of their exports into other countries in EU-15. On the other hand, the significance of technical regulations has the least importance for Finland and France covering their exports about 84.21% and 89.22%, respectively. On the other hand, affecting 96.54% of Turkish exports, the technical barriers also challenge Turkish exports into EU-15 to a great extent.

There is also a remarkable variation among the different approaches of the removal of TBT for the countries analyzed in the sample. The realized coverage of the New Approach is 20.91% for intra EU-15 trade and 25.38% for imports of EU-15 from outside parties. The New Approach harmonization seems to have the highest importance for Finland covering about 31% exports into other EU-15 member states, followed by Austria, Netherlands, and Ireland covering about more than 25% of their exports. On the other hand, this approach regulates about 13% of Belgian, Spanish, and Greek exports into EU-15. Note that the share of the sole coverage of the New Approach lags behind the EU-15 averages since this value is realized about 16% in the case of Turkish exports.

When we analyze the data, we observe that although the Old Approach harmonization is abandoned for new products, it conserves its place as the most prominent type of harmonization for the EU-15 trade. In fact, 43.37% of the intra EU-15 trade and 40.42% of the EU-15 imports from the rest of the world are regulated merely by the Old Approach. The share of products falls under the Old Approach measures accrues most respectively for Belgian, Irish, and British external trade covering more than 50% of their exports. Still being the harmonization measure that has the highest coverage among analyzed countries, the Old Approach regulates the least proportion of exports of Finland and Denmark. The Old Approach is also very important for Turkey, since about 38% of Turkish exports into EU-15 are regulated by these measures.

The shares for products that are subject to the New Approach or the Old Approach (NAOA) harmonization show an unusually interesting breakdown. The internal trade

and imports of EU-15 from other parties are realized as to cover 14.79% and 13.28%, respectively. On the other hand, the incidence at the exports of individual EU members varies in the range from 3.52% (for Ireland) to 25.71% (for Italy). For Turkey, the exports falling under the scope of this cluster has much more share than it has in any other country in the sample. In fact, 33.38% of Turkish exports into EU-15 are regulated by the new or the Old Approach depending on the product type.

On the other hand, the MRP regulates 3.31% of trade of EU-15 with each other. The products under this cluster constitute 5.58% of imports of other parties into EU-15. Having a share of 0.99% in total, mutual recognition principles apply the least for Irish exports. The other EU-15 countries also benefit from the MRP to the extent to 7.49% as for Sweden case. Covering only 0.99% of its exports into EU-15, the MRP products account the lowest share for Turkey, besides Ireland among the analyzed countries.

Trade in agricultural (raw and processed) products constitutes about 10.78% of intra EU-15 trade and 6.50% of EU-15 imports from non-EU-15 countries. Greece and Denmark seem to have a partly agriculture-driven economy since the share of agricultural products for these countries are about in the band of 25%. Turkish exports in agricultural products have a share of 7.55% in total. Note that trade of EU-15 in agricultural products is a little biased towards EU countries since the EU restricts the trade of some of those products with strict preferential agreements and country of origin requirements.

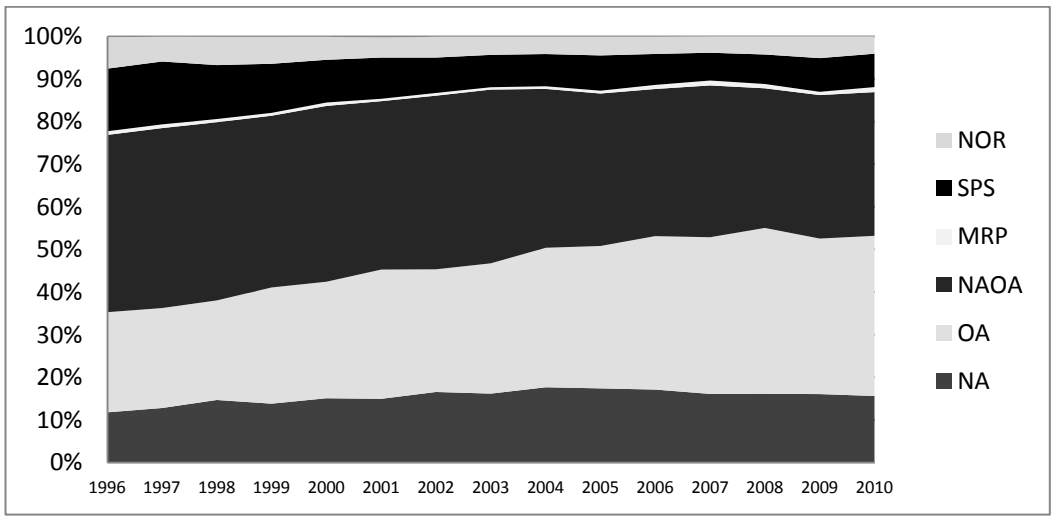
At this point, we analyze the coverage of different EU approaches on the removal of TBT on Turkish trade with EU-15 from 1996 to 2010. The fractions that these

approaches cover are presented for Turkish exports in Table 5.3 and Figure 5.1, and Turkish imports in Table 5.4 and Figure 5.2.

Table 5.3. The Importance of Different Approaches to TBT: Coverage of the EU-15 Imports from Turkey

	REGULATORY APPROACHES					
YEAR	NA	OA	NAOA	MRP	SPS	NOR
1996	11.79%	23.50%	41.60%	0.86%	14.68%	7.36%
1997	12.81%	23.46%	42.22%	0.87%	14.75%	5.82%
1998	14.69%	23.36%	41.81%	0.75%	12.65%	6.64%
1999	13.83%	27.27%	40.30%	0.67%	11.52%	6.32%
2000	15.10%	27.34%	41.25%	0.80%	10.02%	5.40%
2001	14.96%	30.33%	39.51%	0.56%	9.68%	4.60%
2002	16.57%	28.79%	40.74%	0.63%	8.31%	4.89%
2003	16.19%	30.57%	40.76%	0.56%	7.59%	4.27%
2004	17.67%	32.74%	37.28%	0.62%	7.56%	4.07%
2005	17.42%	33.41%	35.77%	0.66%	8.28%	4.40%
2006	17.13%	36.01%	34.52%	0.96%	7.26%	4.05%
2007	16.12%	36.76%	35.62%	1.15%	6.53%	3.83%
2008	16.14%	38.92%	32.76%	1.02%	6.92%	4.24%
2009	16.08%	36.50%	33.67%	0.76%	7.91%	5.09%
2010	15.63%	37.58%	33.72%	1.18%	7.83%	4.06%

Figure 5.1. The Evolution of Different Approaches to TBTs: Coverage of EU-15 Imports from Turkey

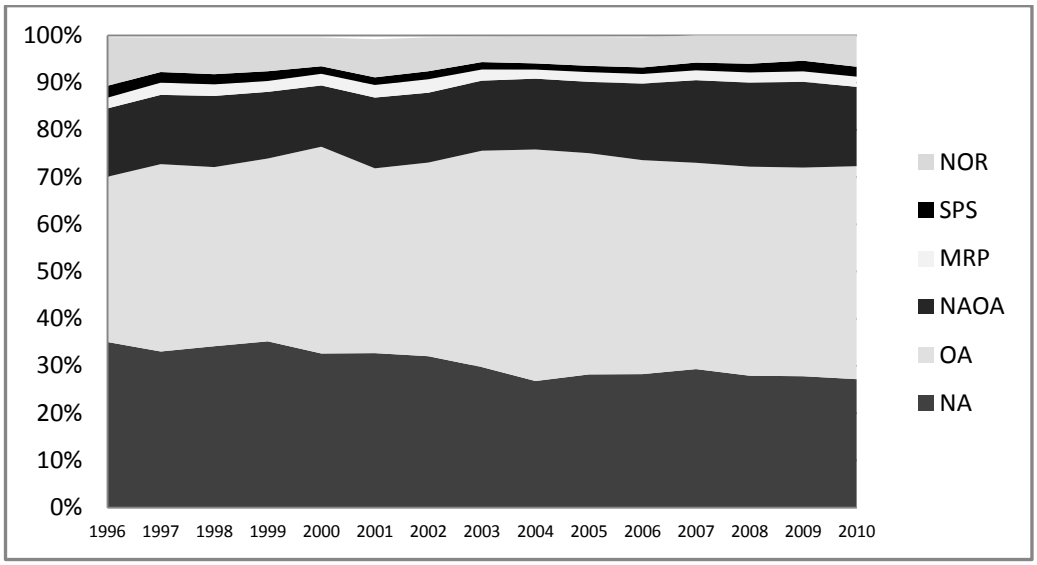


For Turkish exports, in the considered timeline we observe that the New Approach and the Old Approach products have increased their individual shares while the cluster (NAOA) that covers both these harmonization measures has decreased in the total share. The increase in shares of the New Approach products has realized around 4% while this value is more visible for the Old Approach product being around 14%. On the other hand, the clusters that cover both the New Approach and the Old Approach products decreased its share around 8%. Therefore, we can conclude that the total share of Turkish exports to EU15 in harmonized area (NA and OA) has been increased since the formation of the CU. On the other hand, the increase in the share of harmonized area products is compensated mostly from the decrease in the share of agricultural products (SPS). Additionally, the products that are not subject to any form of technical regulation have lost some importance for Turkey.

Table 5.4. The Importance of Different Approaches to TBT: Coverage of EU-15 Exports to Turkey

	REGULATORY APPROACHES					
YEAR	NA	OA	NAOA	MRP	SPS	NOR
1996	35.06%	34.99%	14.47%	2.26%	2.53%	10.29%
1997	33.04%	39.68%	14.67%	2.59%	2.25%	7.32%
1998	34.16%	37.93%	15.07%	2.45%	2.15%	7.77%
1999	35.20%	38.72%	14.11%	2.30%	2.07%	7.16%
2000	32.62%	43.79%	12.98%	2.46%	1.60%	6.10%
2001	32.70%	39.14%	14.98%	2.67%	1.62%	8.08%
2002	32.04%	41.01%	14.79%	2.85%	1.70%	7.17%
2003	29.75%	45.82%	14.84%	2.36%	1.57%	5.28%
2004	26.79%	49.04%	14.99%	1.92%	1.31%	5.63%
2005	28.19%	46.85%	15.10%	2.06%	1.33%	6.09%
2006	28.25%	45.31%	16.21%	2.04%	1.38%	6.36%
2007	29.31%	43.69%	17.50%	2.08%	1.64%	5.77%
2008	27.92%	44.27%	17.79%	2.16%	1.85%	6.02%
2009	27.81%	44.19%	18.15%	2.22%	2.26%	5.38%
2010	27.18%	45.10%	16.81%	2.15%	2.10%	6.65%

Figure 5.2. The Evolution of Different Approaches to TBTs: Coverage of EU-15 Exports to Turkey



When we consider Turkish imports from EU-15 countries, we observe a decrease in the share of the New Approach products about 8% in total while the share of the Old Approach products seem to increase about 10% in total. Moreover, we observe a slight increase in the share of products that are covered both by the New Approach and by the Old Approach. The shares of products that are subject to MRP and SPS show a rather stable pattern while the share of unregulated (NOR) products also decreased since 1996. Note that in general, Turkish imports from EU-15 show a relatively constant pattern when compared to Turkish exports to EU-15. Turkish exports structure seems to converge to its import structure.

5.2.2. The Revealed Comparative Advantage Analysis

At this point, we evaluate the product groups in which Turkey shows the RCA regarding different approaches in the removal of TBT. First, note 1,221 product

groups are in CN 4-digit classification which is distributed under different approaches, as presented in Table 5.5.

Table 5.5. Distribution of CN 4-digit Product Groups due to Regulatory Approaches

Regulatory Approaches	NA	OA	NAOA	MRP	SPS	NOR	TOTAL
Number of Prodcut Groups	236	413	174	128	167	103	1221

Table 5.6. Number of RCA (>1) Product Groups in EU-15 Imports

	REGULATORY APPROACHES						
Countries	**NA**	**OA**	**NAOA**	**MRP**	**SPS**	**NOR**	**Share of RCAs**
Turkey	45	109	73	20	36	23	85.48%
Austria	105	99	64	38	29	29	75.81%
Belgium	59	197	58	48	55	23	73.11%
Germany	162	195	97	59	40	58	70.47%
Denmark	69	78	55	24	60	22	76.99%
Spain	63	150	87	46	81	41	68.46%
Finland	51	60	34	22	6	17	80.47%
France	67	140	73	49	83	37	64.66%
Great Britain	65	141	39	54	30	23	60.84%
Greece	27	59	48	12	50	15	85.44%
Ireland	26	44	10	9	33	8	86.61%
Italy	123	155	120	38	50	47	71.25%
Netherlands	50	128	23	29	94	22	70.40%
Portugal	61	125	78	34	52	35	78.18%
Sweden	76	73	53	28	16	27	72.63%

Table 5.6 presents the number of product groups in which Turkey and individual EU-15 countries show the RCA in different approaches in the removal of TBT together with the share of the RCA product groups in their total exports into EU-15 in 2010. Note that the findings in Table 5.6 are consistent with the theory. Most of the countries in our sample export over 70% of their products in the product groups have the RCA. Also, note that among all countries in the sample, Ireland has the least number of the RCA product groups in all regulatory approaches except

agricultural products. Regarding agricultural products only having six, Finland has the least number of the RCA product groups.

Regarding the New Approach, having 45 product groups, Turkey lags behind most EU-15 countries in terms of the number of the RCA product groups. In this cluster Germany has the most diversified structure in its New Approach products revealing a comparative advantage possessing 163 RCA product groups. For the Old Approach having 197 RCA product groups, Belgium has the highest number of product groups followed by Germany which has 195 RCA product groups in this cluster. With 109 product groups where a comparative advantage revealed in the Old Approach, Turkey ranks in an average level considering EU-15 countries. Turkey's position is similar in NAOA product groups. In this cluster with 120 product groups, Italy is the country that has the most number of product groups where the RCA is shown.

On the other hand, when the MRP is considered, Germany has the highest number of the RCA product groups with 59 over 128 product groups. Germany is followed by Great Britain with 54 product groups. Turkey shows the RCA in only 20 product groups regulated by the MRP. In agricultural products, the Netherlands has the most number of product groups where the RCA is shown. The Netherlands shows a comparative advantage in 94 of 167 product groups in the SPS cluster. The Netherlands is followed by France and Spain which have 83 and 81 RCA groups, respectively. The number of RCA products is limited to 36 for Turkey regarding agricultural products. Finally, regarding unregulated product groups, once again Germany has the most number of RCA products with 58 over 107. In this cluster, Germany followed by Italy and Spain which respectively have 47 and 41 product

groups revealing a comparative advantage. On the other hand, Turkey shows the RCA in 23 products groups in this cluster.

Table 5.7. Number of RCA (>1) Product Groups in EU-15 Imports from Turkey

	REGULATORY APPROACHES					
YEAR	NA	OA	NAOA	MRP	SPS	NOR
1996	30	82	49	21	40	16
1997	25	85	55	18	43	18
1998	24	89	56	16	37	16
1999	31	92	53	17	40	17
2000	34	98	56	20	42	16
2001	37	96	60	14	40	16
2002	36	101	59	17	38	18
2003	38	100	59	19	38	16
2004	38	96	65	17	35	17
2005	43	95	63	20	36	18
2006	42	104	63	19	33	19
2007	49	104	64	24	33	22
2008	57	110	61	21	31	21
2009	46	109	66	20	35	22
2010	46	112	73	20	36	23

Table 5.7 shows the evolution of number in product groups as Turkey shows the RCA in EU-15 market in breakdowns for different approaches in the removal of TBT. In Table 5.7, we observe that the number of product groups that Turkey shows the RCA in EU-15 market has increased in both the New Approach and the Old Approach product groups, besides the product groups regulated by both the new and the Old Approach. The number of product groups where a comparative advantage is revealed is rather steady for MRP cluster while in agricultural trade the number of RCA product groups seems to decrease a little in Turkish exports into EU-15. Finally, we observe a slight increase in number of unregulated product groups where a comparative advantage is revealed. The top 10 product groups of Turkish

exports that have the highest RCA values (2008-2010 average) in the EU-15 market are presented in Table 5.8 (See Appendix D).

CHAPTER 6

CONCLUSION

The study sheds light on the TBT subject within the EU perspective and analyzes the degree of harmonization that Turkey has achieved regarding the requirements laid down in Decision No. 1/95 that establishes a CU between Turkey and the EU.

There has been 16 years passed since the formation of the CU between the EU and Turkey. However, Turkey is unable to complete the required provisions under the requirements laid down in Decision No. 1/95 in order to remove the TBT between parties completely. The legal alignment is evaluated as advanced regarding both horizontal and vertical measures. The transposition of the New Approach legislation is almost completed. The degree of harmonization on the Old Approach is also developed. However, regarding MRP, Turkey is expected to issue the relevant legislation on the subject. On the other hand, the improvements in Turkish infrastructure for standardization and conformity assessment issues are also appreciated. Thanks to the TURKAK's completion of signature of MLAs with the EA, Turkey can designate notified bodies in the New Approach for the sake of Decision No. 1/2006.

However, the problems persist on TBT between parties mostly in the execution phase. The most prominent deficiencies are observed in the market surveillance area. Thus, Turkey is unable to mount an efficient market surveillance system parallel to the current EU requirements. In spite of ongoing efforts, Turkey has not achieved a complete harmonization of technical measures with the EU as specified in the Decision No. 1/95.

Additionally, this study analyzes the incidence of technical regulations in Turkey's exports into EU-15 regarding different approaches on the removal of the TBT comparatively with the EU-15 member states. In this manner, we find that about 96% of the Turkish exports into the EU-15 may be affected by the presence of technical regulations. However, the composition of the share of technical regulations regarding different approaches varies. Most of the Turkish exports into EU-15 are affected by the harmonized EU approaches on the removal of the TBT. On the other hand, about 1% of Turkish exports into the EU-15 are affected by non-harmonized measures, namely MRP and about 8% of Turkish exports into EU-15 are agricultural products subject to SPS measures. The shares of those different approaches also evolve in time. The product groups regulated by harmonized measures seem to gain importance since the formation of the CU.

On the other hand, we also investigate the number of product groups that Turkey reveals a comparative advantage in the EU-15 market. Although lagging behind most of the EU-15 member states in terms of the product groups that Turkey shows an RCA, Turkey increases the number of product groups revealing a comparative advantage, especially in harmonized area since 1996. This situation indicates that

Turkey's competitiveness in the EU-15 market has been increasing after the formation of the CU.

There is still room for Turkey to extend its competitiveness in the EU market as a whole. In this respect, Turkey should accelerate its harmonization with the EU in the TBT subject in order to benefit from a smoother trade with the EU member states. The obstacles on the free trade are disposed in the New Approach. Harmonizing its measures completely and establishing an efficiently operating market surveillance system, Turkey should also seek to remove trade barriers regarding the Old Approach and MRP areas.

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APPENDICES

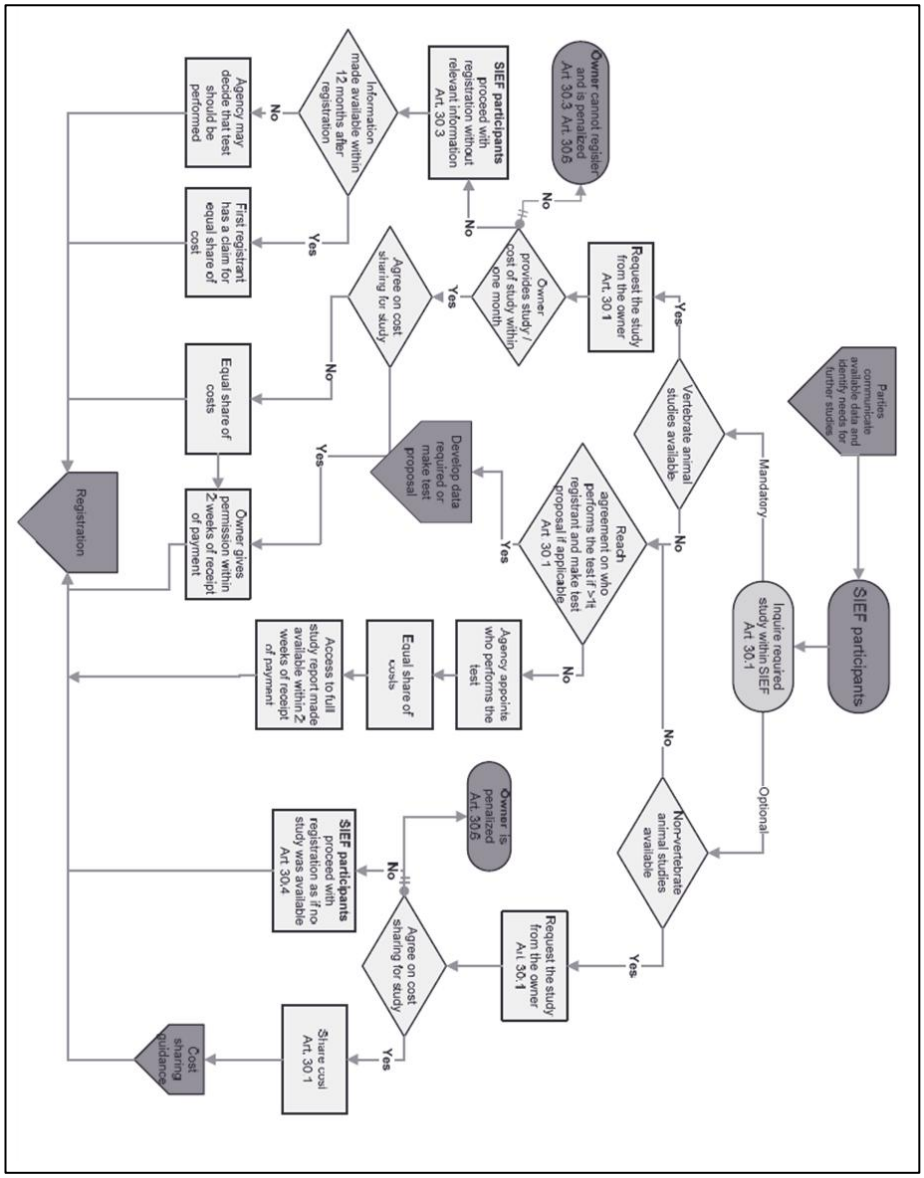
APPENDIX A

Table 3.1. The List of EU New Approach Directives

Directive	Subject
90/385/EEC	Active implantable medical devices
90/396/EEC	Appliances burning gaseous fuels
2000/9/EC	Cableway installations designed to carry persons
89/106/EEC	Construction products
2004/108/EC	Electromagnetic compatibility
94/9/EC	Equipment and protective systems in potentially explosive atmospheres
93/15/EEC	Explosives for civil uses
90/396/EEC	Gas appliances
98/79/EC	In vitro diagnostic medical devices
95/16/EC	Lifts
2006/95/EC	Low Voltage Equipment
2006/42/EC	Machinery safety
2004/22/EC	Measuring instruments
93/42/EEC	Medical devices
90/385/EEC	Medical devices: Active implantable
98/79/EC	Medical devices: In vitro diagnostic
92/42/EEC	New hot-water boilers fired with liquid or gaseous fluids
90/384/EEC	Non-automatic weighing instruments
94/62/EC	Packaging and packaging waste
89/686/EEC	Personal protective equipment
97/23/EC	Pressure equipment
1999/5/EC	Radio and telecommunications terminal equipment
94/25/EC	Recreational craft
87/404/EEC	Simple pressure vessels
88/378/EEC	Toys safety

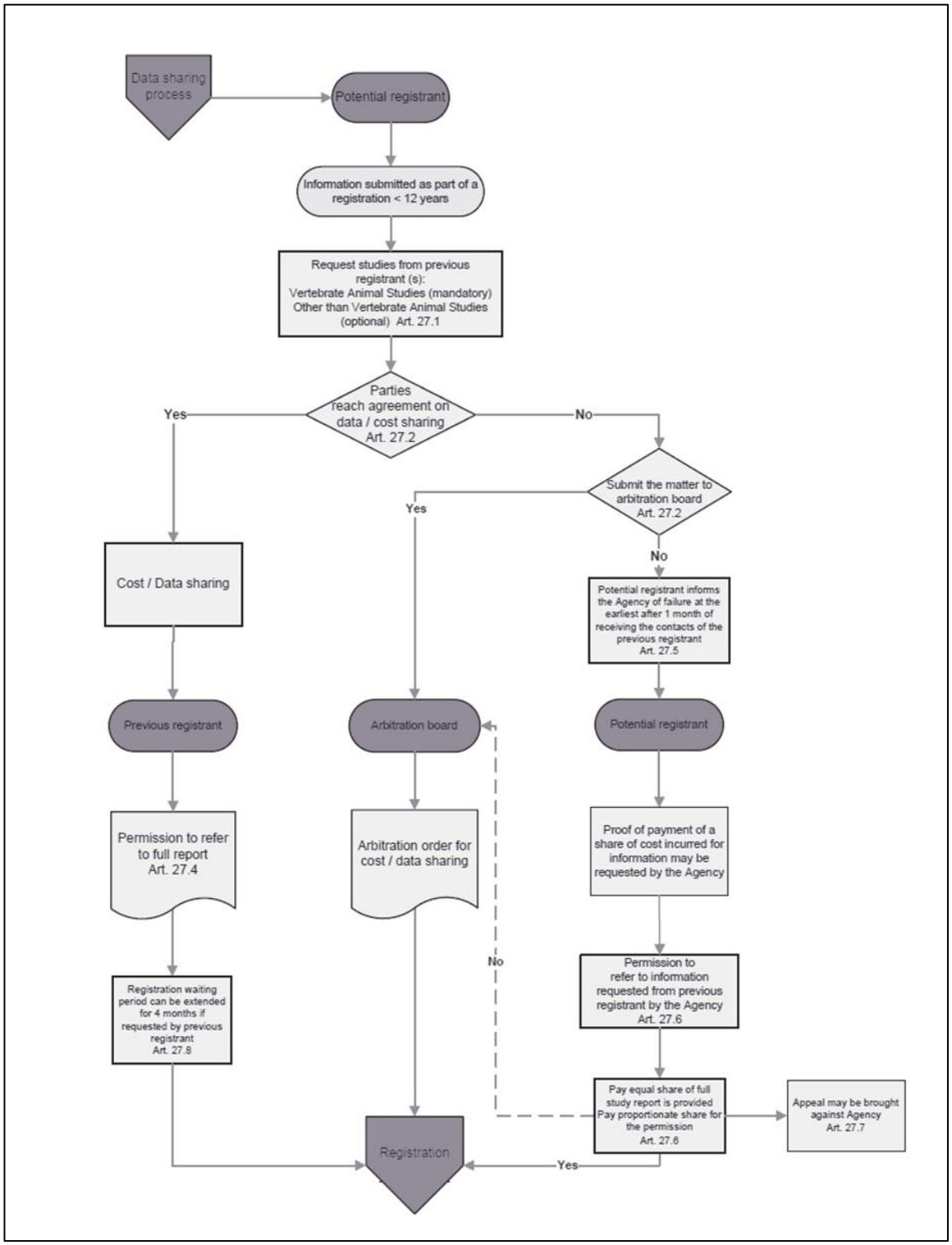
APPENDIX B

Figure 4.2. Data Sharing Mechanism within a SIEF



Source: ECHA (2011b)

Figure 4.3. Data Sharing Mechanism for Non Phase-in Substances and Nonpreregistered Phase-in Substances



Source: ECHA (2011b)

APPENDIX C

Table 5.1. The EU Requirement List for Export

LISTED REQUIREMENT	REGULATORY TYPE	REFERENCED REGULATION
Catch documentation scheme for bluefin tuna	Documentation/Not classified	Regulation (EU) No 640/2010
Catch documentation scheme for Dissostichus spp.	Documentation/Not classified	Council Regulation (EC) No 1035/2001
Certificate and analysis report for wine,grape juice and must	Certificate/Not classified	Council Regulation (EC) No 1234/2007
CITES - Endangered Species Protection	Restriction/Not classified	Council Regulation (EC) No 338/97
Control of contaminants in foodstuffs	SPS	Council Regulation (EEC) No 315/93, Commission Regulation (EC) No 1881/2006
Control of drugs precursors	OA	Council Regulation (EC) No 1277/2005
Control of persistent organic pollutants	Prohibition/Restriction/ Not classified	Regulation (EC) No 850/2004
Control of pesticide residues in plant and animal products intended for human consumption	SPS	Regulation (EC) No 396/2005
Control of residues of veterinary medicines in animals and animal products for human consumption	SPS	Council Directive 96/23/EC
Control of trade in dangerous chemicals	Notification	Regulation (EC) No 689/2008
Control on illegal fishing	Documentation/Not classified	Council Regulation (EC) No 1005/2008
Ecodesign requirements for external power supplies	NA	Commission Regulation (EC) No 278/2009
Ecodesign requirements for household refrigeration appliances	NA	Commission Regulation (EC) No 643/2009
Ecodesign requirements for non-directional household lamps	NA	Commission Regulation (EC) No 244/2009
Ecodesign requirements for simple set-top boxes	NA	Commission Regulation (EC) No 107/2009
Ecodesign requirements for standby and off mode electric power consumption of electrical and electronic household and office equipment	NA	Commission Regulation (EC) No 1275/2008
Ecodesign requirements for televisions	NA	Commission Regulation (EC) No 642/2009
Ecodesign requirements for tertiary lighting equipment	NA	Commission Regulation (EC) No 245/2009
Eco-label for all purpose cleaners and cleaners for sanitary facilities	Voluntary	Commission Decision 2005/344/EC
Eco-label for bed mattresses	Voluntary	Commission Decision 2009/598/EC
Eco-label for copying and graphic paper	Voluntary	Commission Decision 2002/741/EC
Eco-label for detergents for dishwashers	Voluntary	Commission Decision 2003/31/EC
Eco-label for dishwashers	Voluntary	Commission Decision 2001/689/EC
Eco-label for footwear	Voluntary	Commission Decision 2009/563/EC
Eco-label for growing media	Voluntary	Commission Decision 2007/64/EC

Eco-label for hand dishwashing detergents	Voluntary	Commission Decision 2005/342/EC
Eco-label for hard coverings	Voluntary	Commission Decision 2009/607/EC
Eco-label for laundry detergents	Voluntary	Commission Decision 2003/200/EC
Eco-label for light bulbs	Voluntary	Commission Decision 2002/747/EC
Eco-label for lubricants	Voluntary	Commission Decision 2005/360/EC
Eco-label for paints and varnishes	Voluntary	Commission Decision 2009/543/EC
Eco-label for personal computers	Voluntary	Commission Decision 2005/341/EC
Eco-label for portable computers	Voluntary	Commission Decision 2005/343/EC
Eco-label for soaps%2C shampoos and hair conditioners	Voluntary	Commission Decision 2006/799/EC
Eco-label for soil improvers	Voluntary	Commission Decision 2006/799/EC
Eco-label for televisions	Voluntary	Commission Decision 2009/300/EC
Eco-label for textile floor coverings	Voluntary	Commission Decision 2009/967/EC
Eco-label for textile products	Voluntary	Commission Decision 2009/567/EC
Eco-label for tissue paper products	Voluntary	Commission Decision 2009/568/EC
Eco-label for wooden floor coverings	Voluntary	Commission Decision 2010/18/EC
EU Eco-label for wooden furniture	Voluntary	Commission Decision 2009/894/EC
General product safety	Not classified	Directive 2001/95/EC
Health and labelling control of tobacco products	OA	Directive 2001/37/EC
Health and marketing conditions for cosmetic products	OA	Council Directive 76/768/EEC
Health control of articles in contact with food products	OA	Regulation (EC) No 1935/2004
Health control of feedingstuffs of non-animal origin	SPS	Regulation (EC) No 178/2002, Regulation (EC) No 183/2005
Health control of fishery products intended for human consumption	Certificate/Not classified	Commission Decision 2003/858/EC
Health control of fishery products not intended for human consumption	Certificate/Not classified	Regulation (EC) No 183/2005
Health control of foodstuffs of non-animal origin	SPS	Regulation (EC) No 178/2002
Health control of live animals	Certificate/Not classified	Directive 91/496/EEC
Health control of products of animal origin for human consumption	Certificate/Not classified	Directive 91/496/EEC
Health control of products of animal origin not intended for human consumption	SPS	Regulation (EC) No 178/2002,Regulation (EC) No 183/2005
Health control of semen, ova, and embryos	Certificate/Not classified	Directive 94/28/EC
Import licence for agricultural products	Licence/Not classified	Commission Regulation (EC) No 376/2008
Import licence for textile products	Licence/Not classified	Council Regulation (EEC) No 3030/1993
Import requirements for medicinal active substances	OA	Regulation (EC) No 726/2004
Import requirements for medicinal products for human use	OA	Directive 2001/83/EC
Import requirements for seal products	SPS	Regulation (EC) No 1007/2009
Import requirements for veterinary medicinal products	OA	Regulation (EC) No 726/2004
Import requirements for weapons and warlike material	No information/Not classified	
Import restrictions for rough diamond - Kimberley Scheme	Restriction/Not classified	Council Regulation (EC) No 2368/2002
Labelling for fishery products	SPS	Council Directive 2000/13/EC
Labelling for foodstuffs	SPS	Council Directive 2000/13/EC
Labelling for footwear	OA	Directive 94/11/EC
Labelling for household appliances	Not classified	Council Directive 1992/75/EEC

Labelling for textiles	OA	Directive 96/73/EC
Marketing of products containing fluorinated greenhouse gases	Labelling/Not classified	Regulation (EC) No 842/2006
Marketing requirements for batteries and accumulators	Not classified	Directive 2006/66/EEC
Marketing requirements for dangerous chemicals%2C pesticides and biocides	OA	Regulation (EC) No 1907/2006
Marketing requirements for detergents	OA	Regulation (EC) No 648/2004
Marketing requirements for electrical and electronic equipments	Not classified	Directive 2002/96/EC
Marketing requirements for fertilisers	OA	Regulation (EC) No 2003/2003
Marketing requirements for seeds and plant propagating material	SPS	Council Directive 2000/29/EC and a number of directive specific to plant types
Marketing standards for eggs	SPS	Commission Regulation (EC) No 589/2008
Marketing standards for eggs for hatching and farmyard poultry chicks	SPS	Commission Regulation (EC) No 617/2008
Marketing standards for fishery products	SPS	Council Regulation (EC) No 2406/1996
Marketing standards for fresh fruit and vegetables	SPS	Council Regulation (EC) No 1234/2007
Marketing standards for hemp	SPS	Council Regulation (EC) No 507/2008
Marketing standards for hops	SPS	Commission Regulation (EC) No 1850/2006
Marketing standards for olive oil	SPS	Commission Regulation (EC) No 1019/2002
Marketing standards for petrol, diesel fuels, gas oil, and heavy fuel oil	Not classified	Directive 98/70/EC
Marketing standards for poultry meat	SPS	Commission Regulation (EC) No 543/2008
Marketing standards for preserved sardines	SPS	Council Regulation (EEC) No 2136/1989
Marketing standards for preserved tuna and bonito	SPS	Commission Regulation (EEC) No 1536/1992
Ozone-depleting products	Ban	Regulation (EC) No 1005/2009
Ozone-depleting substances	Ban	Regulation (EC) No 1005/2009
Packaging	OA	Council Directive 94/62/EC
Plant health control	SPS	Council Directive 2000/29/EC
Presentation and labelling of wine and certain wine products	Not classified	Commission Regulation (EC) No 607/2009
Prior community surveillance for iron and steel products	Not classified	Commission Regulation (EC) No 76/2002
Products from organic production	SPS	Council Regulation (EC) No 834/2007
Prohibition of products containing fluorinated greenhouse gases	Prohibiton/Not classified	Regulation (EC) No 842/2006
Prohibition of toys made of soft PVC	Prohibiton/Not classified	Commission Decision 1999/815/EC
Prohibition on imports of cat and dog furs and products containing such fur	Prohibiton/Not classified	Regulation (EC) No 1523/2007
Prohibition on imports of fresh blood	Prohibiton/Not classified	Council Directive 92/118/EEC
Radioactive products	OA	Council Directive 96/29/Euratom
Statistical monitoring of trade in bigeye tuna and swordfish	Not classified	Council Regulation (EC) No 1984/200
Technical standards for above medium accuracy weights	OA	Directive 2009/34/EC
Technical standards for alcoholometers and alcohol hydrometers	OA	Directive 76/765/EEC
Technical standards for automatic checkweighing and weight grading machines	NA	Directive 2004/22/EC
Technical standards for cableways for the carriage of passengers	NA	Directive 2000/9/EC
Technical standards for civil aircrafts	Not classified	Regulation (EC) No 1592/2002

Technical standards for components of the rail system	NA	Directive 2008/57/EC
Technical standards for construction products	NA	Council Directive 89/106/EEC
Technical standards for electromagnetic compatibility	NA	Directive 2004/108/EC
Technical standards for explosives for civil use	NA	Council Directive 93/15/EEC
Technical standards for fishing vessels	Certificate/Not classified	Council Directive 97/70/EC
Technical standards for hot water boilers	NA	Council Directive 92/42/EEC
Technical standards for household gas appliances	NA	Directive 2009/142/EC
Technical standards for implantable medical devices	NA	Council Directive 90/385/EEC
Technical standards for in vitro medical devices	NA	Directive 98/79/EC
Technical standards for lifts	NA	Directive 95/16/EC
Technical standards for low voltage electrical equipment	NA	Directive 2006/95/EC
Technical standards for machinery and safety components	NA	Directive 2006/42/EC
Technical standards for marine equipment	NA	Council Directive 96/98/EC
Technical standards for material measures of length	OA	Directive 2004/22/EC
Technical standards for medical devices	NA	Council Directive 93/42/EEC
Technical standards for medium accuracy weights	OA	Council Directive 71/317/EEC
Technical standards for meters	NA	Directive 2004/22/EC
Technical standards for motor vehicles	OA	Directive 2007/46/EC,Directive 2002/24/EC,Directive 2003/37/EC
Technical standards for non automatic weighing instruments	NA	Directive 90/384/EEC
Technical standards for passenger ships	Certificate/Not classified	Directive 2009/45/EC
Technical standards for personal protective equipment	NA	Council Directive 89/686/EEC
Technical standards for pressure equipment	NA	Directive 87/404/EEC
Technical standards for radio and telecommunication terminal equipment	NA	Directive 1999/5/EC
Technical standards for recreational crafts	NA	Directive 94/25/EC
Technical standards for simple pressure vessels	NA	Directive 87/404/EEC
Technical standards for toys	NA	Council Directive 88/378/EEC
Technical standards for tyre pressure gauges for motor vehicles	OA	Council Directive 86/217/EEC

Source: http://exporthelp.europa.eu/thdapp/index_en.html

APPENDIX D

Table 5.8. Top 10 Turkish RCA Product Groups in Exports to the EU-15

CN 4-digit Code	Regulation Type	Average RCA (2008-2010)
	New Approach (NA)	
2529	Feldspar; leucite, nepheline and nepheline syenite; fluorspa...	227.55
2515	Marble, travertine, ecaussine and other calcareous monumenta...	30.01
7413	Stranded wire, cables, plaited bands and the like, of copper...	23.05
7322	Radiators for central heating, non-electrically heated, and ...	13.52
6802	Monumental or building stone, natural (excl. slate), worked,...	12.16
8450	Household or laundry-type washing machines, incl. machines w...	10.26
4203	Articles of apparel and clothing accessories, of leather or ...	9.59
8307	Flexible tubing of base metal, with or without fittings	9.02
6801	Setts, curbstones and flagstones, of natural stone (excl. sl...	7.86
8528	Monitors and projectors, not incorporating television recept...	7.52
	Old Approach (OA)	
5203	Cotton, carded or combed	122.18
6305	Sacks and bags, of a kind used for the packing of goods, of ...	111.77
5511	Yarn of man-made staple fibres, put up for retail sale (excl...	98.27
5701	Carpets and other textile floor coverings, of textile materi...	61.78
5202	Cotton waste, incl. yarn waste and garnetted stock	39.32
2840	Borates; peroxoborates "perborates"	36.61
5406	Man-made filament yarn, put up for retail sale (excl. sewing...	36.41
5204	Cotton sewing thread, whether or not put up for retail sale	34.84
2810	Oxides of boron; boric acids	32.77
6302	Bedlinen, table linen, toilet linen and kitchen linen of all...	32.45
	New Approach and Old Approach (NAOA)	
6106	Women's or girls' blouses, shirts and shirt-blouses, knitt...	32.74
6109	T-shirts, singlets and other vests, knitted or crocheted	27.1
6208	Women's or girls' singlets and other vests, slips, pettico...	26.16
6207	Men's or boys' singlets and other vests, underpants, brief...	24.09
6115	Pantyhose, tights, stockings, socks and other hosiery, incl....	22.05
6104	Women's or girls' suits, ensembles, jackets, blazers, dres...	18.79
6105	Men's or boys' shirts, knitted or crocheted (excl. nightsh...	13.6
6206	Women's or girls' blouses, shirts and shirt-blouses (excl....	13.44

6103	Men's or boys' suits, ensembles, jackets, blazers, trouser...	13.26
6205	Men's or boys' shirts (excl. knitted or crocheted, nightsh...	12.76
	Mutual Recognition (MRP)	
2610	Chromium ores and concentrates	23.14
2506	Quartz (excl. natural sands); quartzite, whether or not roug...	20.76
2603	Copper ores and concentrates	8.96
501	Human hair, unworked, whether or not washed or scoured; wast...	7.35
1401	Vegetable materials of a kind used primarily for plaiting, e...	7.03
9607	Slide fasteners and parts thereof	6.42
9706	Antiques of > 100 years old	5.04
2502	Unroasted iron pyrites	4.9
9206	Percussion musical instruments, e.g. drums, xylophones, cymb...	4.05
5807	Labels, badges and similar articles, of textile materials, i...	4.02
	Agricultural (SPS)	
802	Other nuts, fresh or dried, whether or not shelled or peeled...	29.71
813	Dried apricots, prunes, apples, peaches, pears, papaws "papa...	26.48
2001	Vegetables, fruit, nuts and other edible parts of plants, pr...	22
812	Fruit and nuts, provisionally preserved, e.g. by sulphur dio...	14.44
909	Seeds of anis, badian, fennel, coriander, cumin or caraway; ...	14.39
806	Grapes, fresh or dried	12.49
1106	Flour, meal and powder of peas, beans, lentils and other dri...	11.54
713	Dried leguminous vegetables, shelled, whether or not skinned...	11.49
2401	Unmanufactured tobacco; tobacco refuse	11.39
2008	Fruits, nuts and other edible parts of plants, prepared or p...	11.21
	Unregulated (NOR)	
8902	Fishing vessels; factory ships and other vessels for process...	57.15
8904	Tugs and pusher craft	20.35
8901	Cruise ships, excursion boats, ferry-boats, cargo ships, bar...	7.52
9305	Parts and accessories for weapons and the like of heading 93...	4.9
7113	Articles of jewellery and parts thereof, of precious metal o...	3.31
9401	Seats, whether or not convertible into beds, and parts there...	2.95
2508	Clays, andalusite, kyanite and sillimanite, whether or not c...	2.75
9303	Firearms and similar devices which operate by the firing of ...	2.65
4114	Chamois leather, incl. combination chamois leather (excl. gl...	2.15
4115	Composition leather with a basis of leather or leather fibre	2.03