

INTERNATIONAL DEVELOPMENT IN PRACTICE

Turkey

QI Toolkit Case Studies

Martin Kellermann

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Abbreviations

CAC	Codex Alimentarius Commission
CE	Conformité Européenne
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CMC	calibration and measurement capabilities
EA	European co-operation for Accreditation
EC	European Commission
EN	European standard
ETSI	European Telecommunication Standards Institute
EU	European Union
EURAMET	European Association of National Metrology Institutes
GDP	gross domestic product
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
OECD	Organisation for Economic Co-operation and Development
PTB	National Metrology Institute of Germany (Physikalisch-Technische Bundesanstalt)
QI	quality infrastructure
SMEs	small and medium enterprises
TS	Turkish standard
TSE	Turkish Standards Institute (Türk Standardlari Enstitüsü)
TÜRKAK	Turkish Accreditation Agency (Türk Akreditasyon Kurumu)
UME	National Metrology Institute (Ulusal Metroloji Enstitüsü)

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Abstract: Turkey reengineered its quality infrastructure (QI) as a result of the customs union established between it and the European Union (EU) in 1995 and as a precursor to EU membership later on. This major reengineering was to fundamentally change the technical regulation regime, which was based on mandatory standards and the concomitant product certification into the EU system based on the New Approach Directives for technical regulation and the Global Approach Directives for conformity assessment. The Turkish Standards Institute (TSE) and the National Metrology Institute (UME) existed but were modernized, and the Turkish Accreditation Agency (TÜRKAK) was established and gained international recognition.

EXECUTIVE SUMMARY

In 1995, a customs union was established between Turkey and the European Union (EU). The free movement of goods between these two entities became a significant driver for the socioeconomic development of Turkey. However, major differences in standardization and, especially, technical regulation practices existed between these two trading partners, leading to significant barriers to trade. Therefore, Turkey had to align its standardization and technical regulation regime with the EU's. In addition, once Turkey indicated it wished to become an EU member, Turkey had to demonstrate full compliance with the *acquis communautaire*, the body of EU legislation.

Turkey's standardization and technical regulation regime developed over many years to serve the needs of the Turkish political level and the internal market. By 2000, two public sector quality infrastructure (QI) entities—the Turkish Standards Institute (TSE) and the National Metrology Institute (UME)—had been operational for quite some time, but both needed to be modernized. A national accreditation body did not exist. The major challenge, however, was the technical regulation regime, with over 1,500 mandatory standards developed by TSE, and for which TSE operated a mandatory testing and certification scheme.

Although some efforts to reengineer the QI were made from 1995 onward, it was only after 2000 that Turkey started to dramatically reengineer its QI and its technical regulation regime. The Undersecretariat for Foreign Trade in the Prime Ministry was given overall responsibility for this massive undertaking. The reengineering of the QI and the technical regulation regime was a mixture of (a) Turkish government interventions; (b) technical support from the EU and its member countries in a variety of projects; and (c) the active involvement of the Turkish private sector in advocacy, upgrading products, meeting quality requirements, and establishing private sector conformity assessment services. Areas that required attention included the following (table 1):

- Before 1995, the TSE published national standards in accordance with national interests. Some were adoptions of international standards; many were not. By 2011, the TSE had adopted almost 99 percent of the European (EN) standards recognized by the EU. Many of the EN standards were translated into Turkish; otherwise, they were published with a Turkish cover page and an English text.
- By 1995, the UME had moved into new buildings with 21 laboratories that had appropriate environmental controls, supported by a computer center and workshops. Whereas the UME had provided much of Turkey's calibration services before 1995, private sector calibration laboratories were established thereafter and were accredited, with the result that, by 2010, UME could focus much more on research and development and the maintenance of national measurement standards.
- At the end of the 1990s, Turkey's system for controlling weights and measures was dysfunctional. Some of the national and provincial authorities were notionally responsible for market surveillance, but little of this function was in place. Personnel were trained in general legal metrology practices through a German-supported project that ran from 2006 to 2008, and some of the authorities' directorates were reorganized in 2008 to ensure a better focus on legal metrology matters. Coordination between the national and provincial authorities remained a problem, and the authorities' understanding of the EU's Legal Metrology Directives remained a challenge.
- Before 1995, accreditation in Turkey was not considered an important QI service. The TSE and the UME provided some accreditation services for testing and calibration laboratories, respectively, but these services were neither internationally recognized nor acceptable to the EU. The Turkish Accreditation Agency (TÜRKAK) was established in 1999. The accreditation activities of the TSE and the UME were transferred to TÜRKAK. TÜRKAK benefited from a German-funded technical cooperation project implemented by the National Metrology Institute of Germany (PTB) that ran from 2000 to 2005. TÜRKAK became a full member of the European co-operation for Accreditation (EA) within three years, and gained international recognition through ILAC and IAF soon afterward.

The most profound reengineering took place in the technical regulation domain. Before 1995, Turkey relied heavily on a system of mandatory standards coupled with mandatory testing and certification. About 1,500 mandatory standards had been developed by the TSE over the years, and for many of them TSE was responsible for premarket inspection, testing, and certification

TABLE 1 Snapshot of quality infrastructure (QI) reform in Turkey

BEFORE REFORM	AFTER REFORM
The TSE, as the national standards body, develops and publishes national standards in accordance with its own system. Some standards are adoptions of ISO and IEC standards, but many are not.	The TSE standards development and publication system is fully aligned with the European system, and the TSE participates actively therein. EN standards developed and published by CEN, CENELEC, and ETSI are adopted in full as Turkish national standards.
No national accreditation body exists. Two accreditation bodies linked to the TSE and the UME provide accreditation services, but these are not internationally recognized.	TÜRKAK is established as the national accreditation body, and all other accreditation work is incorporated. TÜRKAK is accepted within three years as a full member of the EA and thereafter by ILAC and the IAF, providing Turkey with internationally recognized accreditation services.
Metrology has a long history in Turkey but did not keep up with international developments after World War II.	The UME was established as the new national metrology institute, new laboratories were built, modern measuring equipment was installed, and the UME's calibration and measurement capabilities (CMCs) were listed in the Key Comparison Database of the BIPM, thereby providing for the recognition of Turkey's metrology system at the international level.
Mandatory standards constituted the system of choice of implementing technical regulation, with the TSE responsible for mandatory testing and certification as a precondition for marketing products. More than 1,500 mandatory standards are in force.	Turkey implemented the EU technical regulation system, with the EU Directives containing essential requirements, supported by harmonized EN standards that remain voluntary. Conformity assessment is provided by accredited and designated service providers known as "notified bodies." Mandatory standards are largely withdrawn.

Note: BIPM = International Bureau of Weights and Measures; CEN = European Committee for Standardization; CENELEC = European Committee for Electrotechnical Standardization; EA = European co-operation for Accreditation; EN = European standard; ETSI = European Telecommunications Standards Institute; EU = European Union; IAF = International Accreditation Forum; IEC = International Electrotechnical Commission; ILAC = International Laboratory Accreditation Cooperation; ISO = International Organization for Standardization; TSE = Turkish Standards Institute; TÜRKAK = Turkish Accreditation Agency; UME = National Metrology Institute.

of the relevant products. This system was anathema to the EU and would have to change dramatically before Turkey complied with the EU's New Approach and Global Approach Directives. Reengineering activities included the following:

- All ministries had to reexamine all mandatory standards within their own domains and implement EU Directives in their place.
- The Ministry of Industry and Trade was responsible for about 80 percent of the mandatory standards, and it established a major program in 2004 to deal with the issue.
- The Undersecretariat for Foreign Trade allocated the responsibility for specific EU Directives to particular ministries to ensure that no overlaps or gaps developed.

In 2002, there were still 1,250 mandatory standards in operation. By the end of 2006, the number had fallen to 261, some of which had no EU Directive counterparts and most of which were used only for import controls.

By 2010, Turkey had reengineered its QI and technical regulation regime to comply with the EU's requirements. This was a major reengineering exercise that took 15 years, the last 10 years with major development partner interventions. Even though some challenges remained (particularly in legal metrology), the pre-1995 system was totally changed. It was especially the mandatory standards system—with its premarket approvals through mandatory testing and certification by the TSE—that had been replaced by a technical regulation system fully compliant with the EU Directives, EN-harmonized standards, notified bodies, and market surveillance based on risk assessments.

COUNTRY CONTEXT

General background

Turkey is a Eurasian country—located mainly in Western Asia, with a smaller portion consisting of East Thrace in southeastern Europe—with a land mass of nearly 780,000 square kilometers. Turkey is bordered by eight countries: Bulgaria to the northwest; Greece to the west; Georgia to the northeast; Armenia, Azerbaijan, and the Islamic Republic of Iran to the east; and Iraq and the Syrian Arab Republic to the southeast. The Mediterranean Sea and Cyprus are to the south, the Aegean Sea is to the west, and the Black Sea is to the north. The Sea of Marmara, the Bosphorus, and the Dardanelles demarcate the boundary between East Thrace and Anatolia; they also separate Europe and Asia.

Turkey has a population of nearly 79.4 million (2016 estimate). Ethnic Turks make up the majority, estimated at 70–75 percent; Kurds are the second-largest ethnic group, estimated at 18 percent. The largest city, Istanbul, has over 13 million inhabitants; Ankara, the capital, has 4.3 million; and five other cities have populations exceeding 1 million.

Turkey has become increasingly integrated with the West through membership in organizations such as the Council of Europe, the North Atlantic Treaty Organization (NATO), the Organisation for Economic Co-operation and Development (OECD), the Organization for Security and Co-operation in Europe (OSCE), and the Group of Twenty (G-20) major economies. Turkey began full membership negotiations with the EU in 2005, having been an associate member of the European Economic Community since 1963 and having joined the EU Customs Union in 1995. Turkey has also fostered close cultural, political, economic, and industrial relations with the Middle East, the Turkic states of Central Asia, and the African countries through membership in organizations such as the Turkic Council, Joint Administration of Turkic Arts and Culture, Organization of Islamic Cooperation (OIC), and the Economic Cooperation Organization (ECO).

The economy

During the first six decades of the republic, between 1923 and 1983, Turkey mostly adhered to a quasi-statist approach with strict government planning of the budget and government-imposed limitations over private sector participation, foreign trade, flow of foreign currency, and foreign direct investment. However, in 1983 it initiated a series of reforms designed to shift the economy from a statist, insulated system to a more private sector, market-based model. Turkey gradually opened up its markets by reducing government controls on foreign trade and investment and the privatization of publicly owned industries. The liberalization of many sectors to private and foreign participation has continued amid political debate.

The reforms, combined with unprecedented amounts of foreign loans, spurred rapid economic growth. However, this growth was punctuated by sharp recessions and financial crises in 1994, 1999 (following the earthquake of that year), and 2001—resulting in average gross domestic product (GDP) growth of 4 percent per year between 1981 and 2003. Lack of additional fiscal reforms, combined with large and growing public sector deficits and widespread corruption, resulted in high inflation, a weak banking sector, and

increased macroeconomic volatility. Since the economic crisis of 2001 and the reforms initiated by the finance minister of the time in view of the looming membership negotiations for EU membership, inflation has fallen to single-digit numbers, investor confidence and foreign investment have soared, and unemployment has fallen.

GDP growth from 2002 to 2007 averaged 7 percent, which made Turkey one of the fastest-growing economies in the world during that period. However, growth slowed to 1 percent in 2008, and in 2009 the Turkish economy was affected by the global financial crisis, with a recession of -5 percent. The economy was estimated to have returned to 8 percent growth in 2010. By 2015, Turkey had the world's 17th-largest GDP by purchasing power parity (PPP) and the 18th-largest nominal GDP.

Key sectors of the Turkish economy are banking, construction, home appliances, electronics, textiles, oil refining, petrochemical products, food, mining, iron and steel, machine industry, and automotive. Turkey has a large and growing automotive industry, ranking as the 6th-largest producer in Europe (behind the United Kingdom and above Italy) and the 15th-largest producer in the world. Turkey is also one of the leading shipbuilding nations: in 2007 the country ranked 4th in the world (behind China, the Republic of Korea, and Japan) in terms of the number of ordered ships, and also 4th in the world (behind Italy, the United States, and Canada) in terms of the number of ordered megayachts. Tourism in Turkey has experienced rapid growth in the past 20 years and constitutes an important part of the economy.

BACKGROUND OF QI ISSUES

The free movement of goods played a special role in the case of Turkey because of the Customs Union between it and the EU that was established in 1995. After 1985, European legislation concerning product safety and integrity was expressed in its New Approach and Global Approach Directives.¹ The modalities of these Directives included the definition of essential requirements, compliance with which was underpinned by harmonized European standards (EN standards) and conformity assessment by designated conformity assessment bodies. The latter are known as “notified bodies,” their “notification” being based on their technical competency and legal accountability in Europe.

The situation in the Turkish home market, however, was equally important, because this had to be fully aligned with EU practices before mutual recognition could be achieved. Standardization and metrology have traditionally played an important role in trade issues and were therefore important elements in the accession negotiations between Turkey and the EU.

The Undersecretariat for Foreign Trade (under the Prime Ministry) was given the oversight responsibility for the whole system. It promulgated the “Ministerial Decree on the Regime of Technical Regulations and Standardization for Foreign Trade” and its supplementary legislation, with the aim of providing transparency in the reform of the standardization and technical regulation regime—thereby assembling all the dispersed regulations regarding standardization policies in Turkey and establishing a legal base for the harmonization of Turkish legislation with that of the EU. The developments in this regard started in 1995 and intensified during the next decade as Turkey sought to comply fully with the *acquis communautaire* of the EU.²

PROJECT OBJECTIVES AND COMPONENTS

The EU requirements were the major driver for the more recent developments in the Turkish national QI and technical regulation regime. The *acquis communautaire* of the EU regarding standardization and technical regulation had to be implemented in full before EU accession could take place. The development of the QI and the regulatory reform of the mandatory standards system was a mixture of Turkish government interventions and technical support from foreign development partners.

The development of the QI is a continuing process, and hence the narrative in this case study must of necessity be limited to a specific period, largely reflecting the changes during 2000–10. The narrative is to some extent therefore out of date, but it provides ample evidence of the major changes that were implemented in that period. Further developments will also be influenced in part by the evolving political dynamic of the relationship between the EU and Turkey.

Standards

Institutional changes

Standardization has a long tradition in Turkey. It started in 1930, when provisions controlling the quality of export products were put into force. The Turkish Standards Institute (TSE), the national standards body of Turkey, was established in 1954 as an autonomous institute affiliated with the state. The TSE is the only organization in Turkey that is authorized to develop and publish national standards.

The TSE's status was changed in 1960 by Organization Law 132, which gave it the status of a legal entity administered under the provisions of civil law. Organization Law 132 was later amended to ensure that the TSE's structure, responsibilities, and activities meet the membership requirements of the European standardization bodies, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC). The amended law gave the TSE a more flexible organizational structure that is administratively, financially, and technically independent. The TSE had to establish new technical committee structures to achieve a balance among members from the public sector, related industry sectors, and academia. The necessary separation between standardization activities and conformity assessment, as required by the EU, was also ensured.

The TSE is an active member of the world standardization community, with full membership in the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) since 1956, and in CEN and CENELEC since 2012.

Standards development and publication

Before 1995, the TSE published national standards in accordance with national interests. Some of these were adoptions of international standards; others were more of an indigenous nature. Once the decision had been made to negotiate accession to the EU, the focus changed dramatically.

Since 1995, as in all EU member countries, the TSE has focused first on EN standards development, next on international standards, and last on national

standards, even though Turkey is not a full member of the EU. The methodology is contained in a TSE Quality Manual that also regulates the establishment of national technical committees and national mirror committees.³ The previous custom of paying sitting fees to committee members was abolished in view of EU requirements. As of June 2011, 71 national mirror committees covering 20 sectors were actively involved in the work programs of 183 international and European technical committees and their subcommittees.

The TSE circulates the European drafts for inquiry when they are circulated in Europe and creates the country comment in the relevant national mirror committee. Although the TSE will only gain voting rights in CEN and CENELEC if Turkey becomes an EU member, it started to register dummy votes, which are kept for future evidence. After the publication of the EN standard, the TSE adopts the EN within six months (just like full CEN or CENELEC members) without asking the stakeholders again. At the same time, the TSE withdraws national standards of similar scope to promote technical harmonization and to remove technical barriers to trade, a procedure generally welcomed by both industry and regulatory authorities.

As of mid-2011, approximately 99 percent of the EN standards had been adopted as Turkish standards, and conflicting national standards were withdrawn. By then the TSE had adopted nearly 16,300 EN standards as Turkish (TS EN) standards. Of these, 45 percent had been translated into Turkish; the rest had a Turkish cover page with the document in English. The aim was to have all the EN standards translated in the future. If no EN standard is available, the adoption of international standards may be contemplated, but EN standards have priority.

Stakeholder awareness

A standards information service, fully compliant with the requirements of the 1998 revision of the EU New Approach Directive for technical regulation,⁴ is operational within the TSE's Standards Preparation Centre. The TSE also acts to raise awareness among national stakeholders on the importance of participation in standardization work. In addition, ministries have created central information points between the respective bodies for the fields under their responsibility. These points are responsible for the dissemination of information within the ministries and for providing draft technical regulations to the Undersecretariat for Foreign Trade for notification to the World Trade Organization (WTO).

Standardization requires balanced representation between the various actors. It is therefore important that it be representative of all interested parties. Technical ministries and big companies deal fairly well with normative information and hence also with their participation in standardization work. This is not necessarily the case for consumer organizations, which are not really involved in the standardization process; small and medium enterprises (SMEs); and professional organizations, especially those representing SMEs. The difference between voluntary standards and technical legislation was not well known among SMEs by 2011, and the issue would need to be addressed through heightened awareness campaigns. Hence, SMEs and consumers were not yet well integrated into the standardization system by 2011.

Metrology

Scientific metrology

The Ottoman Empire was one of the 20 founding states of the Metre Convention in 1875.⁵ There were, however, no significant developments in metrology in Turkey until the promulgation of the Law on Weights and Measures in 1931. After World War II, the need for an integrated system of metrology was felt strongly, but major investments had to wait until the 1980s, leading to the establishment of the National Metrology Institute (UME) in 1992 under the Scientific and Technical Research Council of Turkey (TÜBİTAK). The UME moved to new buildings in January 1994 with 21 laboratories, a computer center, an electronic workshop, conference and seminar rooms, and offices. Each laboratory has environmental controls, and all the parameters—such as temperature, humidity, and air pressure—are measured and recorded by a fully automated, computerized environmental control center. The most sensitive laboratories are underground, and special precautions are taken to minimize vibrations.

UME operations were already recognized in 2003 to be fully compatible with European practices, and subsequent progress has seen the UME developing even more. As an institute under TÜBİTAK, the UME has changed its scope from being a service provider to becoming a research and development institute. The UME has redefined its mission to be a scientifically based metrology institute with responsibility for all measurement standards except those related to ionizing radiation. This also means that the UME will gradually stop delivering services that are not directly related to scientific metrology, and these services will be devolved to capable accredited laboratories (for example, the calibration department of the TSE and private sector calibration laboratories).

The single biggest new activity that the UME has taken up is in chemistry. This has been done after extensive hearings and in collaboration with the European Commission's (EC) metrology laboratory at its Joint Research Centre. In the chemical community, there was still some skepticism toward the UME's engagement in metrology in chemistry by 2010 that the UME needed to overcome. In general, though, there was respect for the UME's high technical competence and its international engagement. The UME also planned to become a major supplier of certified reference materials (CRMs) in the future.

Consistent with its new mission, the UME had intensified and broadened the scope of its training activities, and it had made several important strategic alliances to increase the impact of metrology in Turkish society. For example, the Turkish Atomic Energy Authority (TAEK) became the designated institute for metrology within ionizing radiation. Hence, TAEK participates in the Mutual Recognition Arrangement of the International Committee for Weights and Measures (CIPM-MRA), which has responsibility for ionizing radiation.

The national metrology system, represented by the UME and including TAEK, is therefore well positioned regionally and internationally, with the UME fully compliant with European practices and an active member of the European Association of National Metrology Institutes (EURAMET). Furthermore, Turkey's calibration and measurement capabilities (CMCs) are listed in the International Bureau of Weights and Measures (BIPM) Key Comparison Database (KCDB), thereby facilitating acceptance of the Turkish metrology system at the international level.

Legal metrology

Despite the substantial work on improving legal metrology in Turkey, progress up to 2006 was limited, and it was in a less favorable position than scientific metrology. The EU Measuring Instruments Directive⁶ was foreseen to be difficult to handle, with its new concepts for notified bodies and for market surveillance by the Ministry of Industry and Trade. This turned out to be true, as was also manifested by the lack of national notified bodies for legal metrology.

To initiate change, the relevant ministries received general training on market surveillance, and the Ministry of Industry and Trade started working on the existing law (Law No. 3516, “Metrology and Measurement,” promulgated in 1989) to incorporate EU Directives. Thereafter, the Directorate General for Measurements and Standards was reorganized in 2008. (For example, tasks other than legal metrology were transferred to the Directorate General for Industry to provide a better focus on legal metrology.) In addition, new experts were appointed at the Directorate General for Measurements and Standards.

By 2011, revised legal metrology legislation was promulgated, and market surveillance had been implemented in 10 authorities (including six ministries) responsible for this activity. But the implementation varied from authority to authority, and there was a lack of common understanding of what market surveillance really is. There was still no notified body designated for the EU Measuring Instruments Directive, but at least one candidate body had applied to the Ministry of Industry and Trade for designation and was ready for notification to the EU by the Undersecretariat for Foreign Trade.

Producers of measuring instruments in Turkey therefore expressed concern about the lack of public infrastructure for legal metrology. They were concerned that when the transition period for the EU Measuring Instruments Directive expired in 2016, foreign competitors would overrun the Turkish market because of the lack of legal metrology knowledge in the country. With no up-to-date legislation on legal metrology and no notified bodies, Turkey would appear as a weak supporter of its otherwise successful measurement industry. Eventually, the public’s faith in Turkish consumer protection could be at stake. To deal with this situation, legal metrology became the subject of a specific EU-supported development project after 2016.

Calibration

By 2008, a complete data set for the calibration activities in Turkey did not exist, but with the big increase in number of accredited laboratories, it was expected to be a growing market. The market situation in calibration benefited specifically from a new policy of the Small and Medium Enterprises Development Organization (KOSGEB). According to this policy, it was possible for SMEs to get support to consult accredited laboratories for calibration, testing, and product development, provided that these SMEs had been listed in the KOSGEB database.

New calibration laboratories emerged in such diverse fields as the environment, aflatoxin in dried food, and medical instrumentation. The calibration laboratories in the newer fields such as chemistry and microbiology were less developed, as was also the case in Europe. Here, traceability was more difficult to establish, and uncertainties were more difficult to calculate, because consideration of metrology was not yet routine. When the measurements were

performed on food or the environment, the problem of sampling occurred, and none of the laboratories had yet fully integrated sampling in the measurement process.

Accreditation

Turkish Accreditation Agency (TÜRKAK)

The Turkish Accreditation Agency (TÜRKAK) was established in 1999 as the sole accreditation body for all accreditation activities in Turkey. Its legal framework is provided in Law No. 4457/1999 (on Establishment and Tasks of TÜRKAK) and a number of supporting regulations. Turkey notified the EC that TÜRKAK is the national accreditation body, and as a consequence it was listed in the EC's list of national accreditation bodies—but not before its technical capabilities were extensively developed under a project implemented by the National Metrology Institute of Germany (PTB) from mid-2000 through 2005. The PTB project invested just over €1 million in consultancy, training, and advocacy in the public and private sectors.

The law provides that TÜRKAK operates on a not-for-profit basis and that it neither offers any activities or services that conformity assessment bodies provide nor provides consultancy services to, owns shares in, or otherwise has a financial or managerial interest in any conformity assessment body. The Turkish government ensured that TÜRKAK had the appropriate financial and personnel resources for the proper performance of its tasks, especially during the first years of operation.

TÜRKAK has been a full member of the EA since 2006, actively participating in its scheme-specific activities. It is a signatory to multilateral agreements of the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) for testing, calibration, inspection, personnel, and quality management system and product certification schemes—most of those agreements also since 2006. Signing the EA Multilateral Agreement with the EA changed the public perception on accreditation significantly. Accreditation is operated on a voluntary basis—that is, provided when conformity assessment bodies so request.

TÜRKAK has business relationships for assessment and accreditation with several neighboring countries: Albania, Azerbaijan, Georgia, Kazakhstan, the Kyrgyz Republic, Turkmenistan, and Uzbekistan. Applications for accreditation have also been received from countries in the Middle East like Lebanon, Saudi Arabia, and Syria, but by 2008 they had not yet been processed. When accepting and processing applications from abroad, TÜRKAK observes the cross-frontier policies of ILAC and the IAF.⁷ In spite of the provision in the amended Law No. 4457, TÜRKAK does not consider establishing branches abroad.

By the end of the German project, in 2005, TÜRKAK had accredited 33 testing laboratories, 17 calibration laboratories, 17 management system certification bodies, 11 inspection bodies, 2 product certification bodies, and 3 personal certification bodies—a total of 83. By mid-2016, the numbers increased to 730 testing laboratories, 120 calibration laboratories, 18 medical laboratories, 165 inspection bodies, 53 product certification bodies, 81 management system certification bodies, 81 personal certification bodies, and 4 proficiency testing providers—a total of 1,204 bodies, some with more than one accreditation. This was remarkable growth by any measure.

By 2007, over and above the conformity assessment bodies accredited by TÜRKAK, many were still operating in Turkey that had been accredited by foreign accreditation bodies. These did not seem in a hurry to obtain TÜRKAK accreditation. The main reason stated was the significant difference in financial obligation implied by TÜRKAK accreditation (UNIDO 2013). Competition with European accreditation bodies ended in the wake of EU Regulation No. 765/2008 (to regularize accreditation across EU member states),⁸ and TÜRKAK was able to take over all accreditations granted by these bodies to Turkish conformity assessment bodies. Competition continued with other national accreditation bodies, such as those from the East Asia and Pacific region, but it was kept notionally within the framework of the ILAC and IAF cross-frontier policies (IAF 2016).

Notified bodies

According to EC Regulation No. 768/2008, conformity assessment procedures can be performed by authorities, manufacturers, or conformity assessment bodies. In case authorities decide not to perform conformity assessment themselves, they may delegate this task to conformity assessment bodies, but must notify such delegation to the EC. This is what Turkey has also been practicing. TÜRKAK's role in the notification process is to assess applicant-notified bodies and report the results to the relevant ministry. By 2007, the EC had accepted three notified bodies from Turkey, and others were pursuing notification.

The Undersecretariat for Foreign Trade publishes the complete list of notified bodies, as do some ministries for their specific sectors. When the designation process started in Turkey, it was possible for a candidate conformity assessment body to apply directly to the ministry in charge without being accredited. The ministry reviewed the application and documents, and then submitted the file to TÜRKAK for evaluation. In this case, TÜRKAK's evaluation concentrated only on the conformity assessment body's competence in assessing conformity with essential requirements, which is less than an accreditation against the reference criteria plus the directive requirements. By 2008, this approach was no longer possible because the EU had changed its rules, but some remnants of the old dispensation still had to be cleared.

Mandatory standards

General

Until the early 2000s, Turkey relied heavily on the imposition of mandatory standards (which were a form of technical regulation) to control the integrity of products in the marketplace. Because of Turkey's plans to become an EU member, these had to be withdrawn in totality to meet the EU requirements. Hence the number of mandatory standards decreased considerably over the years. For example, in import controls, the number decreased from 1,250 to 261 in five years (2002–07), and a further 220 were abolished by the beginning of 2009. The remaining ones used for customs control were a mixture of TS EN standards and some national TS standards, such as gas cartridges for liquefied petroleum gas, child articles, fire protection, lighters, and roller bearings.

Mandatory application of standards is the responsibility of the concerned ministry. Therefore, each ministry had to make the necessary arrangements to withdraw the mandatory standards within its jurisdiction. The Ministry of

Industry and Trade was in charge of coordinating all information on this matter and informing the stakeholders. The TSE facilitated this process by informing the relevant ministry that the standard under mandatory implementation was revised and replaced by a European standard. Additionally, at the TSE website, superseded Turkish standards under mandatory implementation were shown as “withdrawn” with an “Important Notice” stating, “The standard is withdrawn even if it is in mandatory implementation.”

European Directives

By 2007, the responsibility for implementation of the EU Directives had been officially allocated to specific ministries, for example:

- *Ministry of Industry and Trade* is responsible for directives in the fields of motor vehicles, agricultural and forestry tractors, legal metrology, electrical risk and electrical equipment, pressurized equipment, and other manufactured product groups.
- *Information and Communication Technologies Authority* is a member of the European Telecommunication Standards Institute (ETSI) and the International Telecommunication Union (ITU). All ETSI standards are transposed and published by the TSE as TS ETS standards.
- *Ministry of Health* is responsible for the harmonization of the following directives (both old and New Approach): safety of toys, medical devices, cosmetic products, detergents, chemicals and their safe use, and ionizing radiation.
- *Ministry of Agriculture and Rural Affairs* is in charge of Codex Alimentarius Commission (CAC) standards. The Turkish Food Codex is prepared by the National Food Codex Commission and its subcommittees. As soon as the specifications prepared by the Codex Alimentarius are adopted by the Turkish Codex Committee, they are made applicable to the market.
- *Undersecretariat for Maritime Affairs* is in charge of directives on recreational crafts, marine equipment, and noise and exhaust emission measurement of the same.
- *Ministry of Public Works and Settlement* is responsible for the implementation of the directive on construction products. This, however, has not been fully implemented—and approximately 40 mandatory standards are still in place.
- *Ministry of Labour and Social Security* is in charge of the directive on personal protective equipment and on the protection of the health and safety of workers from the risks related to chemical agents. Most standards in use are ISO and EN standards.

Import inspection

Inspectors of the Directorate General Standardization, a directorate of the Undersecretariat for Foreign Trade, dealt with quality control of more than 140 agricultural produces and products such as fresh fruits and vegetables, edible oils, dry and dried produces, and pulses. The inspectors were conducting inspections of these commodities according to 80 TS standards. These standards were mandatory on both the export and import levels. They corresponded, for example, to the United Nations Economic Commission for Europe (UNECE) or CAC standards for fresh fruits and vegetables as well as dry and dried products, and the inspections were performed in accordance with OECD Scheme recommendations. These were to be withdrawn once the EU Directives were established.

Market surveillance

With the transition from the existing system of mandatory standards to the new system of EU technical legislation combined with voluntary standards, the Ministry of Industry and Trade, among others, was confronted with some new and challenging tasks. Implementation of mandatory standards was basically a premarket control system, whereas EU technical legislation relies heavily on in-market surveillance to check the compliance of products with essential requirements. The ministry's organization had to be restructured so that its responsibilities and tasks related to the transposition, preparation, and implementation of technical legislation were in line with European and international requirements. A "twinning project" between the German Federal Ministry of Economic Affairs and Technology (BMWi)⁹ and the Turkish Ministry of Industry and Trade was implemented to address these challenges (BMWi 2008).

The most serious deficiency probably concerned the lack of experienced and qualified staff equipped with the necessary means and tools. New and existing personnel in both the central and provincial offices had to be trained. The training needs varied from technical assistance to consultancy on the administrative and practical issues of implementing the *acquis communautaire* of the EU. Coordination and cooperation between the Ministry of Labour and the Ministry of Industry and Trade in the field of inspections of industrial enterprises was another issue that was worked out in the short run. Furthermore, a proactive market surveillance policy and improved coordination between the various directorates general of the ministry were needed.

Conformity assessment

By 2008, conformity assessment—as a means of demonstrating that only safe products are put on the market—was slowly being appreciated by the business community in Turkey. Council Decision No. 1/2006 to implement the final phase of Turkey's Customs Union with the EU,¹⁰ which permitted the designation of notified bodies from Turkey, opened up opportunities to trade with the EU. The number of notified bodies had increased since 2006, but Turkey still lagged behind small nations such as Romania. Despite this progress, there were still many gaps; for example, there were no notified bodies for the EU's Low Voltage Directive or Electromagnetic Compatibility Directive. The scope of coverage also needed to be increased.

A conformity assessment body needed accreditation from TÜRKAK based on the relevant accreditation standards as well as the relevant ministry's approval before it could be designated and notified to the EC and other member states. However, in some sectors, conformity assessment bodies felt TÜRKAK did not have the competence to assess them against the directives, and hence relevant ministries assisted TÜRKAK in the technical aspects. It was felt that TÜRKAK should be able to engage independent expertise, rather than giving the impression of a governmental group conducting the assessment.

Certification marks

By 2010, two other product certification marks besides the regulatory *Conformité Européenne* (CE) marking—the G mark and the TSE mark—were still in common use in Turkey. This led to confusion, and the two marks were in some cases applied

in conflict with European law, which states that only the CE marking is legally required to indicate conformity with the essential safety requirements of products.

- *The CE marking* is the demonstration of compliance with the appropriate EU Directive in terms of standards and conformity assessment procedures, and it is affixed by the manufacturer or supplier once all conformity assessment requirements stated by the relevant directive have been fulfilled.¹¹
- *The G mark* (the Gulf Mark used in Gulf Coordinating Council [GCC] member countries) on construction products was introduced by the Ministry of Public Works and Settlements in 2008 as a national, compulsory safety mark for products that were not in the harmonized area or where CE marking could not be applied. Once the EU Construction Products Directive was implemented, the G mark should have been abolished where the directive applied. On the other hand, in a nonharmonized area, there may be a use for a national mark. However, the situation in Turkey gave rise to confusion among both conformity assessment bodies and end users, and the Turkish authorities were under pressure to present convincing arguments for the continued use of the G mark.
- *The TSE mark* is a quality mark given by TSE Certification that enjoyed considerable visibility and respect in Turkey. In this respect, the TSE mark is similar to the multitude of national marks that prevail in European markets. However, it was not clarified even by the TSE how the scope of the TSE mark differed from, especially, the CE marking. The EC is quite clear that there should be no confusion with the CE marking. Other marks are permissible as long as they do not purport to be equal to the CE marking. The TSE still had some public enlightenment to conduct in this regard.

Laboratories

By 2008, there was an extensive network of laboratories to cater to the needs of most industrial and food products. However, there were tensions between the private sector laboratories and the relevant ministries. The authorities showed a preference for the work to be done in their own laboratories, even when they were stretched to accommodate the testing. The private laboratories claimed that they were just as competent as the public laboratories, if not more so. They had highly qualified and trained staffs who are well versed in the necessary testing procedures. The staffs respected confidentiality and impartiality, and the testing was done independently of any knowledge of the source of the sample. Their equipment was modern, and they had the capacity. The laboratories invariably had TÜRKAK accreditation. Despite these credentials, they felt left out or picked up disproportionately less work.

System certification

Quality management system certification, especially ISO 9001 (“Quality Management Systems—Requirements”), was in place in Turkish society.¹² However, public procurement rules emphasizing ISO 9001 may have, perhaps unintentionally, opened up the market to low-quality certificates being awarded, with certified entities not in full conformity with the requirements. Authorities needed to become more vigilant in their selection of certification bodies. Environmental management system certification to ISO 14001 (“Environmental Management Systems—Requirements with Guidance for Use”)¹³ and occupational health and safety via OHSAS 18001 (“Occupational Health and Safety Management”)¹⁴ were commonly in use in major enterprises but not so widespread in SMEs. These needed to be promoted.

PROJECT DESIGN AND IMPLEMENTATION

Not all the outcomes were the result of specific projects supported through outside interventions. Quite a few successes were achieved by Turkish efforts within the relevant ministries. This section details some of the main projects as facets of an overall approach coordinated by the Undersecretariat for Foreign Trade.

Standards

To support Turkey, and in particular the TSE, the EU funded a technical assistance project through a grant from EuropeAid's Mediterranean Countries and the Middle East (MEDA) program, named Support to Standardisation Activities in Turkey, with the following objectives:

- *Provide technical assistance to the TSE* to contribute to the progressive alignment of national legislation and to implement the European requirements
- *Provide training to TSE staff* to enable them to become familiar and conversant with internal regulations and procedures of the European organizations CEN and CENELEC
- *Provide training of trainers* to a small team of TSE staff and some selected external consultants to enable them to work independently and train their colleagues after the completion of the project (transfer of know-how).

The project had a budget of €750,000, ran from 2005 to 2007, and was implemented by a consortium of four EU national standards bodies: the French Standardization Association (AFNOR), the Spanish Association for Standardization and Certification (AENOR), the German Institute for Standardization (DIN), and the Austrian Standards Institute (ÖN).

Mandatory standards

In 2000, the situation regarding mandatory standards was of real concern for Turkey's EU accession plans in several ways:

- The number of mandatory standards was high, but it was difficult to obtain precise statistics, and the number of mandatory standards differed according to sources (the ministries or the TSE).
- These standards existed in many sectors, including those covered by the EU New Approach Directives.
- The standards were perceived as the main technical obstacle to importing industrial products from foreign countries, particularly European countries.
- The TSE bore a large responsibility for the situation because the Technical Board of the TSE recommended to the ministries concerned the standards to be promulgated as mandatory. The TSE was also responsible for verifying conformity with mandatory standards for import control.

To address the situation, the Undersecretariat for Foreign Trade decided the following:

- The ministries concerned should reexamine all mandatory standards within their fields of competence in order to withdraw or maintain them, depending on the developments in progress—such as implementation of a New Approach Directive, obsolescence of the standard, revision of the TS standard following

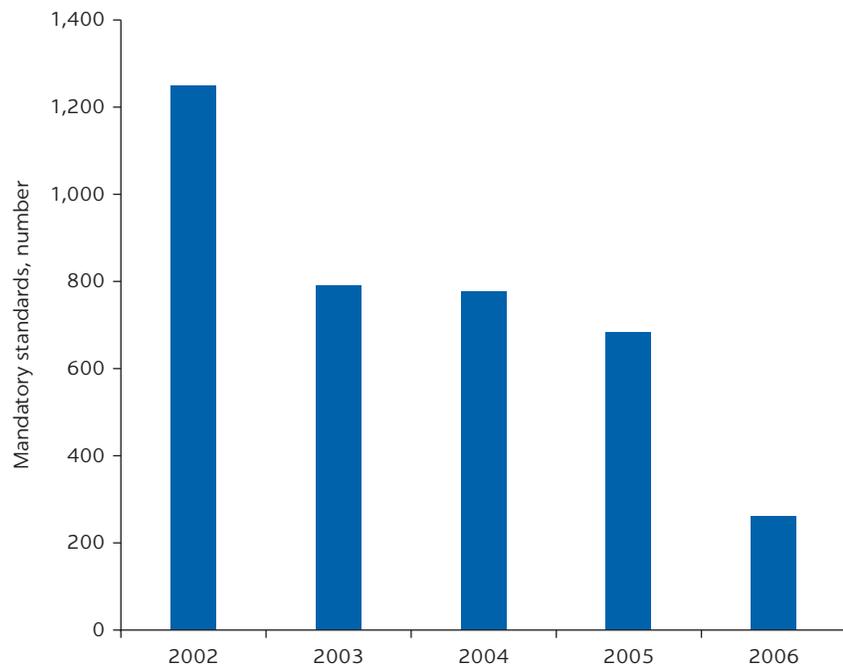
the approval of the corresponding EN or ISO standard, and so on. The Ministry of Industry and Trade, which was in charge of approximately 80 percent of the mandatory standards, set up a working group at the end of 2004 in cooperation with the TSE and prepared a plan for withdrawal of mandatory standards within its field of competence.

- The TSE Technical Board would no longer give any opinion on the mandatory application of a standard. Only the ministry in charge would have the responsibility for both the possible initiative and the decision, and the TSE would be excluded from the decision-making process.
- The list of mandatory standards—as established every year by the Undersecretariat for Foreign Trade in liaison with the other ministries for import control—would serve as a reference for the follow-up of all relevant actions.

The application of these decisions resulted in an important reduction in the number of mandatory standards (figure 1). Generally speaking, the trend for reduction was continuous—from 1,250 in 2002, to 777 in 2004, 683 in 2005, and finally a drastic cut in 2006, to 261. In the New Approach sectors, 29 standards were still mandatory toward the end of 2006. The Undersecretariat for Foreign Trade envisaged that these standards would be deleted from the list at the beginning of 2007. Hence, the situation concerning mandatory standards at the end of 2006 was as follows:

- *In the food sector*, 69 standards were still mandatory. These standards dealt with fruit and vegetables for which no European standards existed. Moreover, the national TS standards transposed the specifications of the Codex Alimentarius.

FIGURE 1
Number of mandatory standards in Turkey, 2002–06



Source: CEN 2007.

- *In the other sectors*, there were 163 mandatory standards. Of these, 108 standards were more or less old and purely national, whereas 55 standards were the transposition of European or ISO/IEC standards. These standards dealt with a lot of sectors: industrial equipment, automotive, road, and electrical equipment.

A study involving ministries to determine the sector distribution of remaining mandatory standards and to facilitate the repeal of the mandatory application of these standards was thereafter launched. In general, all of these changes were accepted by the relevant ministries, and suppliers got a year to change to the new TS EN standard. In special circumstances this could be extended to up to three years. The ministry inspectorates ensured that the new standards were met by the suppliers.

Market surveillance

A twinning project between the BMWi and the Turkish Ministry of Industry and Trade was initiated to strengthen the Turkish ministry's capacity to establish an effective market surveillance system for the implementation of relevant EU Directives. The project was implemented from September 2006 to May 2008, with an investment of €1.297 million from the German side.

Project objectives

The main purpose of the project was to strengthen the capacity of the Ministry of Industry and Trade for market surveillance in the areas of textiles, civil explosives, protective equipment used in explosive environment, appliances burning gaseous fuels, nonautomatic weighing instruments, legal metrology and prepackaging, new hot boilers, and elevators in relation to the relevant EU Directives (BMWi 2008). The project was subdivided into three components.

Project inception (Component 1). After a public workshop with stakeholders to describe the project, an intensive benchmark study was conducted within the relevant directorates general of the Ministry of Industry and Trade to determine the available resources and deficiencies. The benchmark study led to far-reaching recommendations in four areas:

- *Organization:* (a) Reorganization of the ministry's structure to align it with responsibilities and better market surveillance; (b) establishment of a formal coordination system between the central and provincial offices; and (c) inspector identity cards to identify them during their inspections
- *Procedures:* (a) Communication of annual reports on the ministry level to the public; (b) extensive coordination of ministry resources; (c) revision of strategy and annual plans on the basis of inspection data; (d) development of specialized sectoral checklists to help inspectors in their daily work; (e) strengthening of relations with Customs; (f) precise definition of the competence of inspectors; (g) definition of decisions on critical issues like banning sales or withdrawing or stopping operation; (h) establishment of a procedure to subcontract laboratories; and (i) establishment of a cooperative method of inspection, including awareness and information (imposing a fine should always be the last step)
- *Equipment:* (a) Provision of required information technology (IT) equipment, cameras, and other tools for inspectors; and (b) establishment of a database for proper communication.

- *Special sector recommendations*: Recommendations regarding the inspection of elevators, civil explosives, and legal metrology, despite the understanding that the EU Measuring Instruments Directive would take some time to be transposed and implemented in Turkey. Legal metrology at that stage was rather weak and would become the subject of later EU-funded development projects.

Training (Component 2). The training component of the project consisted of four subcomponents: (a) identifying the training needs and designing the “train the trainers” program, (b) training the trainers, (c) designing the training program for inspectors, and ultimately (d) training the inspectors.

Initially 40 trainers were scheduled to participate, but this number was increased to 74 at the request of the beneficiary. The training of the trainers was provided on a directive-by-directive basis. These included civil explosives, gas appliances, elevators, and textiles. Training in a general sense was also provided for legal metrology, but detailed training in this area was not possible because the ministry’s organizational structure was not yet supportive of the implementation of the EU Measuring Instruments Directive.

The project provided for 400 inspectors to be trained. In the end, a total of 656 inspectors participated in a program that dealt with each of the relevant directives separately. The trainers who had been previously trained instructed the inspectors under the watchful eyes of German experts. In this way, the efficacy of the trainers could also be evaluated. The training was not confined to theoretical training but continued at a practical level in the marketplace.

Enhanced enforcement of relevant EU Directives (Component 3). To ensure the sustainability of the project, the main activities carried out were the following:

- *Establishment of cooperation between the market surveillance and conformity assessment bodies* to strengthen the position of national manufacturers. This was an activity that would have to be advanced through the sectoral committees set up by the Ministry of Industry and Trade after the project.
- *Seminars to raise awareness* were a precursor to the future transposition and implementation of the General Product Safety Directive, which applies in the absence of specific European regulations on safety of certain product categories. Seminars were held in Ankara and Istanbul to explain the differences between this directive and the others focused on specific products.
- *Study tours to demonstrate market surveillance activities* as they were implemented in Germany were organized in 2007 and 2008, again organized on a directive-by-directive basis. Among the German entities visited were ministries, metrology and standards bodies, governmental bodies, producers, traders, users of equipment, and trade fairs.

Project outcomes

During the 18-month implementation period of the project, significant progress was realized in the effectiveness of market surveillance activities.

The Ministry of Industry and Trade had transposed and implemented all relevant European Directives covered by the project except the Measuring Instruments Directive. For the latter, transposition studies were initiated. Changes in the organization of the Directorate General Measurements and

Standards—changes that were proposed by the project—were implemented, namely moving the related responsibilities of the directives other than those on legal metrology from the Directorate General Measurement and Standards to the Directorate General Industry and the Directorate General Consumer Protection.

The capacity of the ministry and the provincial offices was raised considerably, leading to more effective market inspections, with a clear focus on conformity of products with the relevant EU Directives. The issue of product safety became central to market surveillance activities rather than mandatory product certification. This not only enhanced the protection of consumers and users but also improved the competitiveness of industry, which is encouraged to market only safe products.

The most significant change in practical inspections was the shift from document-based inspection to product safety inspection, clearly focusing on product properties. Taking samples and subcontracting laboratories for evidence were procedures that inspectors were trained in to enable them to better assess the risk arising from nonconformities.

The project implementation went smoothly because of the active engagement of the Ministry of Industry and Trade staff and the high commitment of both the external experts and their Turkish counterparts. Changes of key staff did not have a negative effect the overall project implementation because of the high qualifications and commitment of their successors, who easily integrated themselves into the existing project structures and took the necessary steps to ensure the fulfillment of the key outcomes. The three-month extension proved to be useful to regain lost ground resulting from initial delays in getting activities started during the first year. Because of the concerted effort of both the German and Turkish sides, the project was able to be completed within the envisaged time frame, and all the benchmarks were reached, in many cases even exceeding initial expectations.

Accreditation

To participate in international markets and for its envisaged accession to the EU, Turkey had to establish an internationally recognized accreditation body. This was of specific importance for the SME sector to access European markets. A project funded by Germany and implemented by PTB was agreed to in 1999 between the German Federal Ministry of Economic Cooperation and Development (BMZ) and the Turkish Undersecretariat for Foreign Trade. The project was worth €1.023 million and was planned for a period of five years, which at the end was extended by six months. The main objective of the project was to establish TÜRKAK as a fully operational national accreditation organization with increased use of accredited testing, calibration, and certification bodies by both the public and private sectors as a direct outcome thereof.

One of the major risks identified during the inception phase was the fact that TÜRKAK was not yet established, and there was initially some doubt as to whether the Turkish parliament would promulgate the necessary legislation in a timely manner. But the Turkish private sector actively pressured the politicians through Turkish business councils, and this effort, combined with impending EU accession negotiations, motivated the parliament to promulgate the necessary legislation in record time.

Project output and indicators

The overall project goal was a Turkish accreditation system established in accordance with international requirements and used extensively by economic operators. From the beginning of the project—initially coordinated by the Undersecretariat for Foreign Trade and later by the Ministry of Industry and Trade—several ministries and institutions were involved in the development of TÜRKAK. The project consisted of subprojects that were closely aligned, many of which were implemented in parallel:

- Revision and implementation of the TÜRKAK legislation
- Establishment of TÜRKAK steering committees and working groups
- Training and qualification of personnel
- Accreditation system rendered operational
- Advocacy in the public and private sectors
- International recognition.

The establishment of the accreditation system had a wide reach and affected civil servants; authorities; and interested parties from industry, trade, and consumer protection—over and above the many individuals in TÜRKAK, steering committees, and the personnel of organizations seeking accreditation.

The establishment and capacity building of TÜRKAK largely followed the agreed-upon planning. The project was initially overseen by a steering committee established by the Undersecretariat for Foreign Trade, but after the promulgation of the TÜRKAK legislation and the first meeting of the TÜRKAK General Assembly, the project’s oversight was handed over to TÜRKAK. Two other accreditation bodies, the Accreditation Body in TSE (KAMK) and the Calibration Accreditation Body in UME (TKS), transferred their accredited entities to TÜRKAK, enabling it to become the sole accreditation body operating in Turkey. The project activities included consultancy regarding the organizational arrangements, recruitment and training of personnel, establishment of a pool of assessors, and application for EA membership, as well as support for organizations seeking accreditation—all of which were aligned with the urgent needs of the Turkish industry’s calibration, testing, and certification requirements.

Project results

An increased understanding in the public and private sectors as well as by consumers and the media regarding the QI’s role in economic development and consumer protection showed positive changes at a qualitative level. TÜRKAK was consistently seen as a “good for country” presence owing to an informative website, discussion forums, and a functioning complaints system. A wide range of stakeholders were reached through sector specific workshops, such as “Accreditation in the Medical Sector,” “Systems, Standards, and Certification in Global Trade,” and “CE-marking.” The full support of important business and industry councils, with their large and wide-ranging memberships at various levels, provided TÜRKAK with a useful platform in the private sector. The looming EU accession negotiations also pushed political decision makers to instigate countrywide information campaigns with respect to the QI, consumer protection, and market surveillance.

In 2003, three years after the German-funded PTB project began, TÜRKAK became a full member of the EA and relevant EU structures. For the rest of the project, TÜRKAK’s profile in these entities continued to increase.

This was an extraordinary achievement, because TÜRKAK did not even exist at the beginning of the project, and all its personnel had to be appointed and properly trained and qualified. A challenge regarding TÜRKAK's independence, due to the potential for political interference in its decision-making processes, was dealt with through an interim governmental directive. This interim directive was to be incorporated into the TÜRKAK legislation during its next revision.

The requests for accreditation from testing and calibration laboratories, management system certification bodies, and inspection bodies increased slowly at the beginning, but thereafter accelerated. Only the accreditation of product certification bodies did not fulfill expectations. In the first year of the project, a total of 7 entities were accredited; in the second year, 20; and in the third year, 56—a total of 83. By the end of the project in 2005, this number had risen to 118 accredited entities. This was ample evidence of the increased relevance of accreditation in the marketplace, but it also placed additional pressures on the available capacity of TÜRKAK.

STAKEHOLDERS AND THEIR ROLES

Many stakeholders, especially public sector entities, were involved in the alignment of the Turkish QI and technical regulation system with EU requirements as a precursor to more intense negotiations for Turkish accession to EU membership.

Undersecretariat for Foreign Trade

At the political level, the Undersecretariat for Foreign Trade in the Prime Ministry was the most important entity driving and coordinating change. Early on, it was given the overall responsibility for the implementation of the EU Directives relating to trade, which included those dealing with the QI and technical regulation. It was therefore mindful of the requirements Turkey had to fulfill. It promulgated the necessary legislation to initiate and facilitate this process, and it was responsible for the notification of conformity assessment bodies to the EC. It therefore used its powerful position in the Turkish government's organizational hierarchy to good effect to get other relevant ministries and QI organizations to cooperate and initiate far-reaching organizational reform where necessary.

Ministry of Industry and Trade

The Ministry of Industry and Trade bore the brunt of the demise of the mandatory standards system and the implementation of the EU Directives. It had to reengineer its own organizational structure quite decisively to align it with new realities while also overseeing similar reengineering programs in the public standards and accreditation bodies. The support from ministry personnel was generally considered to be very high by development partners, and even when staff moved around, their replacements were of a high caliber and picked up the necessary knowledge and skills quite quickly.

Public sector QI institutions

The TSE underwent two major changes: its standards development system was totally reengineered, and its function as a regulatory authority with respect to mandatory standards disappeared.

As for the UME, it was established already in 1992, even though metrology had a long history in Turkey going back to 1875 as a founding signatory to the Metre Convention. The UME moved into new laboratories in 1994. By 2002, it was already considered to meet EU requirements. Thereafter the UME broadened its activities to also include metrology in chemistry. All of these developments indicated a high engagement of its management and metrologists.

TÜRKAK, the third fundamental of the QI, was established in 1999. Thereafter things moved quickly during the 2000–05 German support project. Within only three years, TÜRKAK had achieved recognition in Europe through the EA and internationally in ILAC and the IAF. Again, this progress indicates high commitment by management and personnel.

Private sector entities

The private sector was very much aware of the need to align the QI and the technical regulation system with EU requirements because Turkish trade within the common market depended heavily on this. Hence, when the public sector was still dallying a bit regarding the development and promulgation of the necessary legislation, the private sector, through its influential business associations, was able to pressure politicians to move much more quickly. Likewise, the private sector embraced the liberalization of the conformity assessment business; as a result, many private sector laboratories and certification bodies were established and accredited after 1995, as indicated by the growing number of accredited facilities in the years since TÜRKAK's establishment in 1999—reaching 730 by mid-2016.

The broader alignment of the Turkish QI with the EU requirements would also not have happened if the private sector had not implemented formal quality management systems and had their products tested and certified on an increasing scale to enter the European markets. Therefore, the success story of the major reengineering and modernization of the Turkish QI and technical regulation system would not have been possible without the active participation of the private sector in pushing for reform as well as implementing its outcomes.

RESULTS ACHIEVED AND OUTCOMES

The outcome of the decade of QI and technical regulation reform can be considered in two domains, albeit closely intertwined. The first is the modernization of Turkey's QI; and the second, even more profound, is the total reengineering of its technical regulation system.

Modernization of the Turkish QI

Standards. In the development and publication of standards, Turkey had to align its practices with those of the EU. The TSE became a member of the CEN, CENELEC, and ETSI committee structures, and the EN standards progressively

replaced the indigenous Turkish standards. From 1995 to 2008, more than 90 percent of the EN standards had been adopted; that is, nearly half of the approximately 35,000 Turkish national standards were full adoptions of the EN standards.

The TSE also participated fully in the voting procedures of CEN, CENELEC, and ETSI even though Turkey was not yet an EU member; and although the Turkish vote did not count in the final approval of the EN standards, the country's votes were kept on record as evidence of its active participation. The TSE technical committee structures were also fully reengineered to provide for mirror committees to the CEN, CENELEC, and ETSI technical committees.

Accreditation. As for accreditation, Turkey established the national accreditation body, TÜRKAK, and gained European acceptance for it through the EA within less than five years, in 2006. This led to TÜRKAK's international recognition through ILAC and the IAF that same year. TÜRKAK was also able to increase the number of accredited facilities from only 7 in its first year of operation to 83 in its third year, growing to over 700 by 2016. Accreditation was therefore firmly established as a fundamental of Turkey's QI, and TÜRKAK was seen as an established and prominent accreditation body in the EU.

Metrology. As the third fundamental of the QI, development of the metrology system had a mixed result. As noted earlier, scientific metrology had a long tradition in Turkey, the country (then the Ottoman Empire) having been one of the original signatories to the Metre Convention in 1875. But after World War II, it had failed to keep up with developments until the 1990s.

The UME of Turkey was established in 1992, and by 1994 it moved into new buildings with ample space for laboratories. By 2003, the UME was already considered to meet EU requirements and became a member of EURAMET. The country's CMCs were progressively listed in the Key Comparison Database of the International Bureau of Weights and Measures (BIPM), ensuring international recognition of Turkey's metrology system. Metrology in chemistry was developed, and the UME is planning to become a major supplier of certified reference materials.

As for legal metrology, some progress had been achieved, but much still needed attention before it would be considered to be at the same level of development as scientific metrology. It was especially the new EU Measuring Instruments Directive that was still poorly understood and for which the technical and market surveillance infrastructure was still to be established.

Reengineering of the technical regulation system

Before 1995, the Turkish technical regulation system was typical of systems that developed over time without policy guidance; in other words, each ministry developed and implemented technical regulations as it saw fit. Worse, the Turkish system was based largely on mandatory standards, a system that operated on a premarket approval system for products falling within the scope of these mandatory standards. This system, although favored by many low- and middle-income countries because of its simplicity from an operational perspective, became a major stumbling block to trade.

Anecdotal evidence would suggest that the regulatory authority, usually the national standards body, is prone to rent-seeking practices—for example, payment by suppliers is secured by law through a levy and for the mandatory product certification scheme, without the regulatory authority necessarily providing proper service. Other negatives of this system include (a) the propensity of the standards body to pursue the development of standards to be used as mandatory standards, rather than providing standards according to the actual needs of industry; and (b) the retesting of especially imported products in order to keep the laboratories of the national standards body busy.

Turkey, as a precursor to its negotiations on EU membership, had to reengineer the system of mandatory standards in its totality. The mandatory standards had to be replaced by the EU Directives, in which the technical regulation provides for essential requirements only. The technical requirements are provided for in harmonized EN standards that remain voluntary, and conformity assessment services can be offered by a number of designated technically competent bodies—the “notified bodies.”

This reengineering had a profound impact on the finances of the national standards body, the TSE, which lost the income from mandatory testing and certification and had to compete in the marketplace with other notified conformity assessment bodies. In all, nearly 1,500 mandatory standards were withdrawn and replaced by EU Directives, and the mandatory premarket product certification system was totally replaced by an in-market surveillance system.

PROBLEMS ENCOUNTERED: CHALLENGES AND ISSUES

It is difficult to move from a system of absolute control to a system whereby the market is allowed to play an important part in the QI, and especially in the technical regulation regime. The propensity of some state organs that wished to control everything therefore led to most of the problems or challenges that were encountered.

Draft law for creating TÜRLAK, potentially weakening TÜRKAK

A project that started as an inventory of public laboratories soon morphed into one that sought to control all laboratories. Initially a database of just over 1,000 public sector laboratories was established, and work was started to increase the efficiency of public service conformity assessment bodies. This project changed direction, and a draft law was circulated whereby all laboratories, public or private, wishing to operate in Turkey would have to be registered by the to-be-established Turkish Laboratory Agency (TÜRLAK), even if they had been accredited by TÜRKAK. The functions of TÜRLAK in many instances duplicated those of TÜRKAK.

If this draft law had been allowed to pass the parliament, it would have set up an organization that would have been in direct competition with TÜRKAK on the Turkish market. Furthermore, the law would have given TÜRLAK powers that would have allowed it to act as an accreditation body without meeting the requirements of international standards. This would have damaged not only TÜRKAK but also the whole Turkish conformity assessment system that had

taken so much time and energy to build, and it would have confused a market that had only started learning the EU rules properly. The draft law was shelved after EU interventions.

Push needed to expedite accreditation legislation

At the start of the German project to build capacity in accreditation, TÜRKAK had not even been established by law. Parliament was rather lax in considering the draft legislation, and all indications were that it would take a few years to promulgate it. The business community, however, was able to harness its powerful lobbies and create enough pressure for parliament to consider and promulgate the accreditation legislation in record time.

Lack of capacity in legal metrology

The responsibilities for legal metrology are decentralized, with public entities at both the national and provincial levels responsible. Coordination of such a decentralized system is always challenging. Over and above the coordination issues, further uncertainty stemmed from a lack of metrology skills, generally lax oversight over the implementation of the requirements in the market, and the imminent transposition and implementation of the Measuring Instruments Directive of the EU. This directive's approach to legal metrology differed from the classic weights-and-measures controls practiced by most countries, and its modalities were not understood by the relevant authorities in Turkey.

The results were great uncertainty and a lack of progress in spite of much effort invested to streamline legal metrology—so much so that the private sector became alarmed that Turkey would be overrun by other European-based legal metrology notified bodies once the directive finally replaced all national systems by 2016, to the detriment of the local metrology industry. A major support program funded by the EU was planned, and it was hoped that this would alleviate the situation to large extent.

KEY SUCCESS FACTORS AND LESSONS LEARNED

The major success factors and lessons learned throughout both Turkish and foreign project implementation came down to one overarching lesson: it takes leadership to attain success (figure 2).

Political leadership. The undeniable driver of the profound QI and technical regulation system reengineering in Turkey was obviously Turkey's quest to become an EU member. This meant the full-scale, demonstrable adoption and implementation of the *acquis communautaire* of the EU. The Turkish government allocated the overall coordination and responsibility for this activity regarding the QI and technical regulations to the Undersecretariat for Foreign Trade in the Prime Ministry. This was key to the success of the whole endeavor because this undersecretariat was a governmental heavyweight able to ensure that ministries and other public sector entities implemented the radical changes as required. It is doubtful whether the Ministry of Industry and Trade, or any other ministry, would have been able to do so as successfully as the Undersecretariat for Foreign Trade.

FIGURE 2

Timeline of the Turkish QI development and notable milestones, 1995–2011



Note: AENOR = Spanish Association for Standardization and Certification; AFNOR = French Standardization Association; DIN = German Institute for Standardization; EA = European co-operation for Accreditation; EU = European Union; ÖN = Austrian Standards Institute; PTB = National Metrology Institute of Germany; QI = quality infrastructure; TÜRKAK = Turkish Accreditation Agency; UME = National Metrology Institute.

Private sector involvement. The private sector, as one of the main beneficiaries of Turkey's entry into EU markets, got involved by putting pressure on government bodies to expedite important measures such as the promulgation of relevant legislation. It did so through its powerful business associations, which politicians listened to. Later, the private sector was at the forefront of implementing the necessary requirements to satisfy EU regulatory authorities regarding product integrity, making full use of the standards, metrology, and accreditation infrastructure that was established. The private sector also made full use of the liberalization of the conformity assessment environment and established many calibration and testing laboratories as well as certification bodies. The state, except for the TSE, was no longer the main provider of such services.

Skilled and dedicated personnel. A successful QI and technical regulation system depends heavily on skilled personnel. And if they are also dedicated, things get done properly and quickly. This was certainly the case in Turkey in many instances. It was especially the donor community that commented favorably on the commitment and skills of the people involved from the Turkish side, even though they were moved around quite a bit within public entities because of the overall government reengineering exercises. New staff were mostly well educated, highly skilled, and committed to get on board quickly.

CONCLUSION

Turkey made significant progress in the decade from 2000 to 2010 toward establishing a modern, market-based technical regulation regime to facilitate its accession to the EU and other international markets. Turkey has a functioning QI in place, comprising the Turkish Standards Institute (TSE), the Turkish Accreditation Agency (TÜRKAK), the National Metrology Institute (UME), and

a fair number of testing and calibration laboratories as well as certification and inspection entities. Quality awareness among Turkish firms seems to be improving, as shown by the increasing growth rate of quality certificates, although in absolute terms Turkey is still far from other relevant comparator countries. The country had replaced almost all national standards with EN and international standards, and had significantly reduced the number of mandatory standards. The recently created accreditation body, TÜRKAK, has been accepted to the EA Multilateral Agreement (EA-MLA) for quality management systems, testing, calibration, and inspection. The UME is well equipped, has highly qualified staff, and already offers the reliable measurement traceability essential for the proper functioning of the Turkish QI.

Notwithstanding this progress in the period up to 2010, policy and institutional changes were needed to further improve Turkey's QI and foster implementation of quality standards at the company level. Furthering international recognition of the main institutions of the QI would be crucial to remove remaining constraints faced by Turkish producers and exporters. The UME, for example, should participate in more international intercomparisons of measurements, and TÜRKAK should broaden its participation in the recently signed EA-MLA by applying to also become a signatory in the areas of product certification and environmental management systems certification (which TÜRKAK achieved after 2010). Revisiting legislation regulating the functioning of these institutions could clarify responsibilities, increase flexibility, and facilitate the adoption of more efficient and transparent practices with increased participation of the private sector. Finally, it would be important to increase requests for accreditation and certification by Turkish laboratories and companies, respectively.

NOTES

1. The EU New Approach Directive for technical regulation (Council Directive 83/189/EEC of March 28, 1983) and Global Approach Directive for conformity assessment (Council Directive 90/683/EEC of December 13, 1990) have both been revised continuously and extensively over the years.
2. The *acquis communautaire* is the accumulated legislation, legal acts, and court decisions that constitute the body of EU law. The term is French—*acquis* meaning “that which has been acquired or obtained,” and *communautaire* meaning “of the community.”
3. Mirror committees are established as the national counterpart of either regional or international technical committees, and their objective is to develop a consolidated national position to be presented in the discussions at the regional or international level. They are also an important conduit for transferring knowledge to the national level, that is, to sensitize national stakeholders to the developments at the regional or international level at an early stage, thereby giving national stakeholders a chance to adapt more quickly.
4. Council Directive 98/34/EC of June 22, 1998.
5. The Metre Convention, an international treaty signed in 1875 that created the International Bureau of Weights and Measures (BIPM), established the metric system and addresses the base units of scientific metrology.
6. The Measuring Instruments Directive (Council Directive 2004/22/EC of March 31, 2004) set the implementation date for November 2006, with a 10-year transition period. National implementations of the new legislation started only thereafter.
7. The cross-frontier policies of ILAC and the IAF endeavor to limit competition between accreditation bodies that could be detrimental to the quality of accreditation (IAF 2016; ILAC 2012).
8. “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”: <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF>.
9. The BMWi is now known as the Federal Ministry for Economic Affairs and Energy (Bundesministerium für Wirtschaft und Energie).
 10. 2006/654/EC: Decision No. 1/2006 of the EC-Turkey Association Council of May 15, 2006.
 11. The CE marking is placed on the product or packaging by the manufacturer or supplier once all the requirements of the relevant EU Directive have been fulfilled, denoting that the manufacturer or supplier takes full responsibility for the compliance of the product with specified requirements. These may involve third-party conformity assessment service providers (that is, notified bodies) depending on the new directive, but the manufacturer or supplier is not licensed by a product certification body or anybody else to affix the CE marking on the product; it is done totally on that manufacturer’s or supplier’s own responsibility.
 12. ISO 9001:1987, titled “Quality Systems—Model for Quality Assurance in Design /Development, Production, Installation and Servicing,” has been revised five times. The current standard is ISO 9001:2015, “Quality Management Systems—Requirements”: <https://www.iso.org/standard/62085.html>.
 13. ISO 14001:2015, “Environmental Management Systems—Requirements with Guidance for Use”: <https://www.iso.org/standard/60857.html>.
 14. OHSAS 18001, “Occupational Health and Safety Management” (see <https://www.bsigroup.com/en-US/OHSAS-18001-Occupational-Health-and-Safety/>), is in the process of being replaced by ISO 45001:2018, “Occupational Health and Safety Management Systems—Requirements with Guidance for Use”: <https://www.iso.org/standard/63787.html>.

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