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Technical Barriers to Trade: Reducing the Impact of Conformity Assessment Measures

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ABSTRACT

Conformity assessment, consisting of such activities as certification, testing and inspection, is frequently required by government regulators to ensure that firms' products and production processes meet minimum health and safety standards. Although conformity assessment systems achieve important economic and societal goals, they may also serve as significant technical barriers to trade. Such barriers may emerge from the need for exporting firms to have their products tested overseas, adjust to diverse conformity assessment requirements, undergo duplicative testing, face lengthy approval times, or overcome discriminatory requirements in overseas markets. As the costs of conformity assessment activities and their effects on trade have increased, manufacturers, trade officials, and regulators have pursued approaches that they hope will ensure that safe products are placed on global markets promptly and in the least trade restrictive manner possible to ensure compliance with the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT agreement). Some of the approaches for reducing the impact of conformity assessment have included mutual recognition agreements among trading partners, unilateral recognition by a country of another country's conformity assessment results, and increased acceptance of a supplier's declaration of conformity (SDoC). When conformity assessment is mandatory, businesses have increasingly come to prefer SDoC over third-party conformity assessment. Supporters of SDoC point out its benefits, including flexibility and nondiscriminatory treatment for firms in choosing where to have their products tested, decreased uncertainty associated with mandatory testing by designated testing bodies based in foreign countries, high compliance levels, and lower administrative costs. The challenge to industry and trade officials is convincing regulatory authorities that alternatives such as SDoC will not compromise regulators' obligations to assure the safety of workers and consumers.

[1] This paper represents solely the views of the author and is not meant to represent the views of the U.S. International Trade Commission or any of its commissioners. The invaluable assistance of Laura Polly, Deb McNay, Monica Reed, and Wanda Tolson is gratefully acknowledged. Please direct all correspondence to Christopher Johnson, Office of Industries, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, telephone: 202-205-3488, fax: 202-205-2018, email: christopher.johnson@usitc.gov.

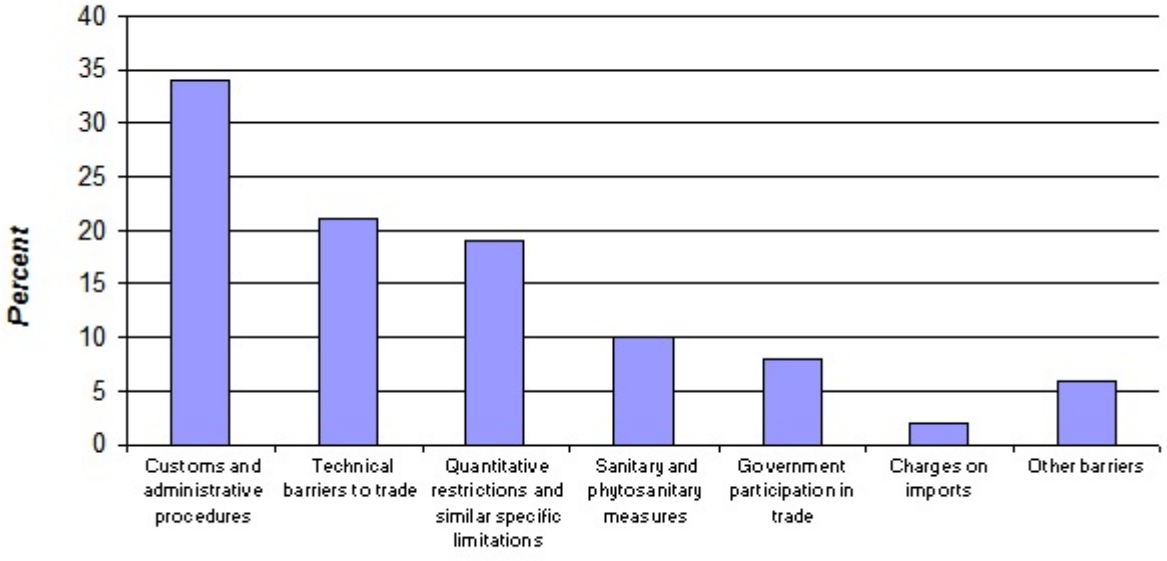
Technical Barriers to Trade: Reducing the Impact of Conformity Assessment Measures

Introduction

Conformity assessment measures, including activities such as certification, testing, and inspection, are important tools used by nations' regulators, manufacturers, and consumers to ensure product quality and provide protection against threats to human and animal health and safety, and to the environment. However, with the increasing importance of international trade, differences in conformity assessment requirements across global markets can serve as technical barriers to trade (TBTs) by increasing manufacturers' costs and reducing their access to important foreign markets.

TBTs represent one of the leading categories of nontariff barriers (NTBs) notified by members of the World Trade Organization (WTO) in the WTO Non-Agricultural Market Access (NAMA) negotiations taking place in connection with the Doha Round (figure 1). Such barriers include standards, technical regulations, and conformity assessment procedures (box 1) that are discriminatory, create unnecessary trade obstacles, or are more trade restrictive than necessary (Popper, Greenfield, Crane, and Malik 2004, xiii). Conformity assessment requirements have been troublesome to manufacturers, and may present the largest technical barriers to trade by making it difficult for them to obtain product approval in overseas markets (Maskus, Otsuki, and Wilson 2001, 19). In fact, of the TBTs notified by WTO members in the example noted above, over one-half pertained to conformity assessment (Fliess and Schonfeld 2006, 8) (figure 2).

FIGURE 1 NTB notifications in Doha Round NAMA negotiations, by NTB category, 2005



Source: Compiled from WTO, *Non-Tariff Barrier Notifications: Secretariat Compilation of the Various Barriers Notified in TN/MA/W/46*, November 22, 2005.

BOX 1 Definitions of important terms in the WTO Agreement on Technical Barriers to Trade

Standard: document approved by a recognized body that provides for common and repeated use, rules, guidelines, or characteristics for products or related processes and production methods, with which compliance is not mandatory (i.e., voluntary standards).

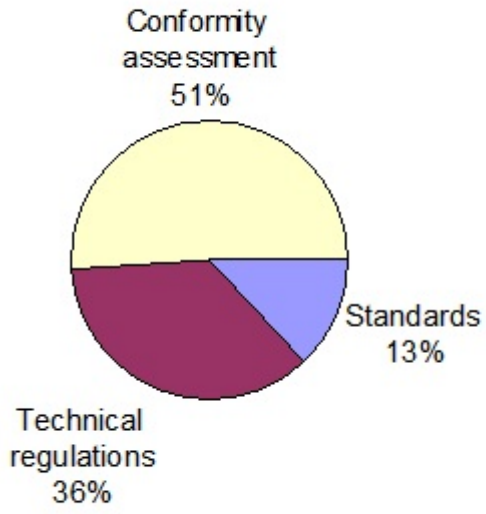
Technical regulation: document approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is mandatory (i.e., government mandated standards, or standards referenced in regulations).

Conformity assessment procedure: Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Conformity assessment consists of such activities as certification, testing, quality system registration, and inspection. Conformity assessment procedures include, inter alia, procedures for sampling, testing, and inspection; evaluation, verification, and assurance of conformity; and registration, accreditation, and approval; as well as their combinations. Conformity assessments may be either voluntary, such as those conducted by private or nonprofit testing bodies assessing conformity of products requested of or by a private (nongovernment) party, or government-mandated, such as government regulations to ensure that given technical regulations are met.

Source: WTO Agreement on Technical Barriers to Trade, Annex 1, Terms and Their Definitions for the Purposes of this Agreement.

FIGURE 2 WTO Doha Round NAMA TBT notifications, by type of TBT, 2005



Source: Compiled from WTO, *Non-Tariff Barrier Notifications: Secretariat Compilation of the Various Barriers Notified in TN/MA/W/46*, November 22, 2005.

This paper illustrates, in practical terms, how conformity assessment measures impede trade and raise costs in specific industries and examines different approaches for addressing them. The paper begins with a summary of WTO TBT provisions as they relate to conformity assessment procedures. It then briefly describes how such procedures can serve as TBTs. After outlining the three major types of conformity assessment, the paper looks at the impact of conformity assessment barriers on exporters. To illustrate more concretely some of the ways that conformity assessment measures affect firms, four separate industries are examined: the information technology (IT), medical device, automobile, and consumer products industries.

The paper concludes with a discussion of the relative advantages and disadvantages of several alternatives for reducing the impact of conformity assessment barriers to trade: mutual recognition agreements (MRAs) among trading partners, unilateral recognition by a country of another country's conformity assessment results, and increased acceptance of a supplier's declaration of conformity (SDoC). It finds that when conformity assessment is mandatory, companies often favor SDoC over third-party conformity assessment as it provides them with greater flexibility, nondiscriminatory treatment, and lower costs when entering overseas markets. The challenge to supporters of SDoC is convincing regulatory authorities that it will not compromise regulators' obligations for reducing risks to human and animal health and safety, or to the environment.

Relevant WTO TBT Provisions

The WTO Agreement on Technical Barriers to Trade (TBT agreement) aims to ensure that standards, technical regulations, and conformity assessment procedures do not constitute unnecessary barriers to trade. It is important to note that the agreement's provisions do not apply solely to discriminatory practices. While government regulatory authorities are not to discriminate against foreign individuals or countries, they also are prohibited by the TBT agreement from having technical regulations or conformity assessment procedures that are more trade restrictive than necessary to meet their legitimate regulatory objectives. Further, members are to ensure, whenever possible, that results of another member's conformity assessment procedures are accepted, even when they differ from their own, provided that the procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures.[2] Moreover, WTO members are encouraged to support global harmonization of conformity assessment procedures on as wide a basis as possible. Finally, the TBT agreement contains strict transparency provisions to enable members to understand, as well as have an opportunity to influence, the proposed adoption by another member of technical regulations and conformity assessment practices that could affect international trade.[3]

Conformity Assessment Systems

Conformity assessment systems include activities such as certification, testing, inspection, and assessment of quality manufacturing systems that can provide customers and regulatory officials with needed confidence that a product or process meets appropriate standards or requirements (National Research Council 1995, 65 and Shortall 2007, 1–5). As such, they ensure product quality and provide protection against threats to human and animal health and safety, or to the environment. They also provide competitive advantages to manufacturers by allowing them to differentiate their products from those of competitors that do not meet certain levels of safety, quality, or reliability (Fliess and Schonfeld 2006, 31). For example, products that have obtained conformity assessment to voluntary electrical safety

[2] WTO TBT article 6.1.
[3] TBT articles 5.6.1–5.6.4, and 10.1.

standards by a recognized body, such as Underwriters Laboratory, can obtain a competitive advantage over products that have not done so.

However, conformity assessment systems can also serve as TBTs. Technical trade barriers may emerge from the need for exporting firms to (1) have their products tested overseas, (2) adjust to diverse conformity assessment requirements in different foreign markets, (3) undergo duplicative testing to the same standards, (4) face longer than usual approval times in certain foreign markets, or (5) overcome discriminatory requirements. For example, when foreign regulatory officials do not accept product test results or certifications previously obtained in the exporter's home market, the exporter often faces the costly process of having to undergo testing and certification again in the foreign market. Meanwhile, differences in conformity assessment requirements across global markets increase costs for producers that sell in multiple markets because they must adjust to the unique requirements in each market (Sykes 1995, 46). Further, when each country maintains its own separate procedures for sellers to follow in securing approval of their products, a duplication of effort will exist across markets even if the technical regulations and testing and certification procedures are identical or similar (Shortall 2007, 23). In some markets, regulatory approval times for products requiring certification and testing are much longer than in other countries, resulting in opportunity costs for firms that are unable to sell their goods until approvals are received. Finally, discrimination against foreign-made products in terms of certification and testing requirements can provide a competitive advantage to domestic producers over foreign companies that forgo revenues because their products do not have fair access to the market in question.

Major Types of Conformity Assessment

There are three major types of conformity assessment: first-party conformity assessment conducted by the supplier; second-party conformity assessment conducted by the customer; and third-party conformity assessment conducted by independent third parties, including government agencies and designated private testing bodies (table 1). First-party and third-party conformity assessment may be required of sellers by either customers or by government authorities to ascertain that their products meet required specifications or standards, and second-party conformity assessments are completed primarily by way of arrangements between buyers and sellers in the market place.

First-party conformity assessment, or a supplier's declaration of conformity (SDoC),[4] is used by many manufacturers, especially large firms. SDoC is a procedure by which a manufacturer, importer, distributor, or other supplier provides written assurance of the conformity of its goods or services to specified requirements (figure 3). The declaration identifies the party responsible for making the declaration of conformity and for the conformity of the product itself. The assessment may be undertaken by the supplier's own internal test facility, or the supplier may contract out to independent testing bodies, to ensure that its products conform to standards or technical regulations with regard to quality, safety, and interoperability of its goods. Conformity claims may be made by the manufacturer through labels on the product, on its packaging and in its advertising, or through documentation provided to government regulatory agencies.

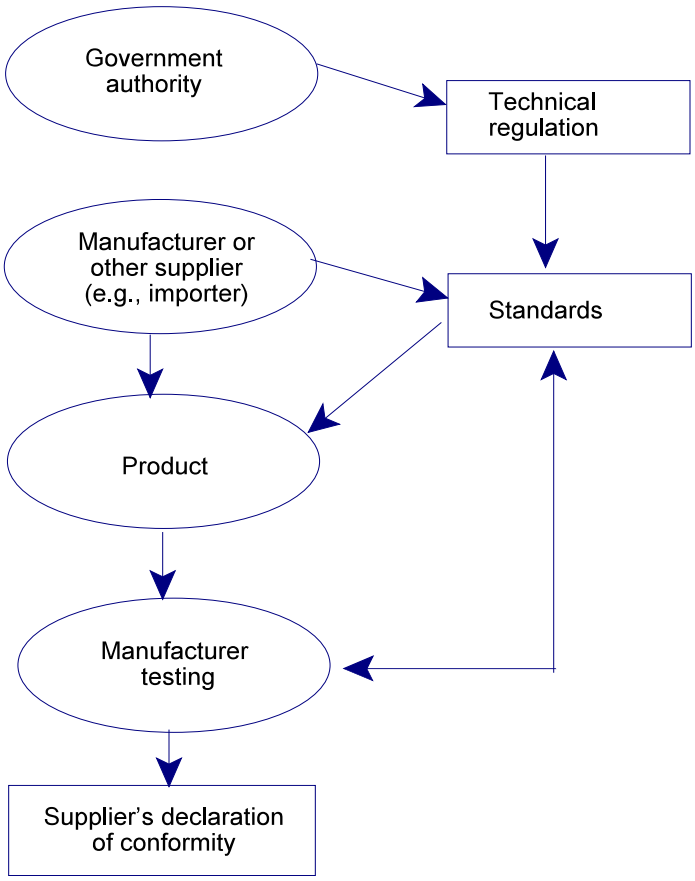
[4] SDoC is also referred to as manufacturer's declaration, first-party certification, or self certification.

TABLE 1 Conformity assessment types

Item	**First party** (also known as supplier's declaration of conformity, or SDoC)	**Second party**	**Third party**
Conformity assessment party	Manufacturer, importer, or other supplier.	Customer	Regulatory body or independent testing body.
Description	Procedure by which the manufacturer, importer, or distributor provides written assurance of the conformity of its products to specified requirements.	Buyer requires and certifies that the products it wishes to purchase from suppliers meet one or more standards. Purchaser's own inspectors usually perform the assessment of the supplier's products.	Conformity assessment by technically competent body not under control of either buyer or seller. Assessment undertaken in government laboratories or by accredited third-party bodies.
Industry examples	Testing and certification by automobile manufacturers and importers demonstrating their vehicles' compliance with mandatory government safety or environmental standards. Certification by petroleum producers that motor oil conforms to selected voluntary Society of Automotive Engineering Standards (SAE), (i.e., SAE 10W-40W).	Certification and testing by aircraft manufacturers of parts and components produced by their suppliers to assure conformance to their specifications.	Regulatory authorities, or accredited third-party testing organizations, assess compliance of new pharmaceuticals with mandatory health and safety standards.

Sources: NIST, *ABC's of the U.S. Conformity Assessment System.*

FIGURE 3 First party conformity assessment system



Source: Compiled by USITC staff from NIST, *ABC's of Conformity Assessment*, 2007.

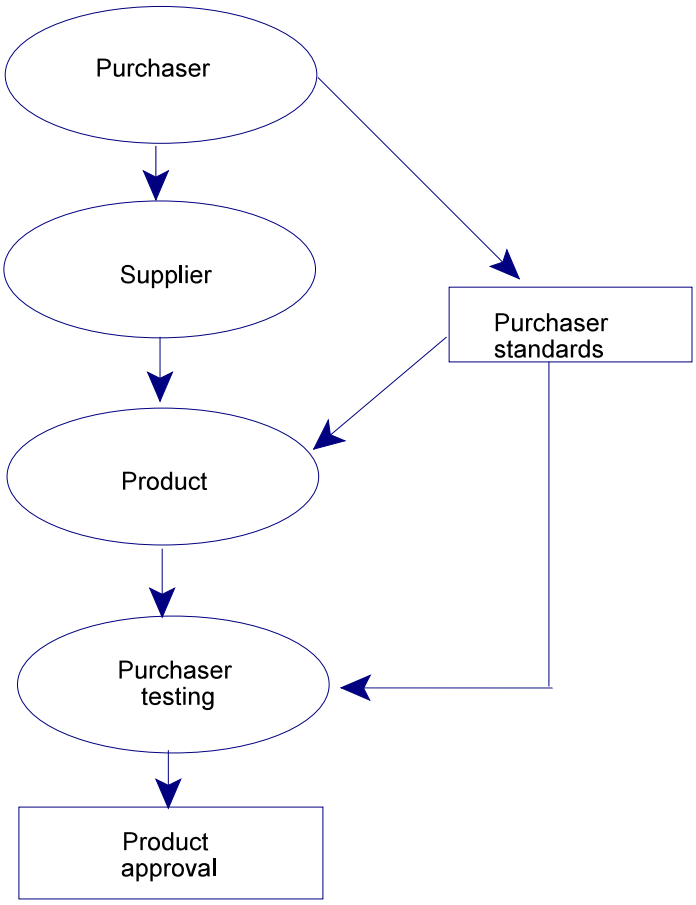
SDoC is used predominantly in product sectors that involve a low to medium level of risk to health, safety, and the environment (Shortall 2007, 23–24). For example, the U.S. Federal Communications Commission (FCC) has adopted rules that permit recognition of a supplier's declaration for demonstrating that personal computers and peripherals meet required electromagnetic compatibility standards, provided that supporting test results are obtained from an accredited laboratory. However, SDoC may sometimes be used in product sectors that are considered to be medium or high risk, such as electrical products and automobiles. For instance, despite the high potential risk to safety of automobiles, the motor vehicle industry in the United States is able to use SDoC because of a well developed U.S. automotive regulatory system, including an effective postmarket surveillance system to monitor products' safety and performance after they reach the market. Thus, use of SDoC is not exclusively guided by a risk analysis approach, but also on the regulatory and legal infrastructure existing in the sector.

In its simplest form, SDoC requires no test reports or certificates and no specified form of documentation beyond the declaration of conformity itself. However, SDoC regimes are frequently more complex, requiring, for example, suppliers to use test reports prepared by competent third parties rather than conducting tests in-house, or to register their products through an organization located in the export market. In fact, complex types of SDoC may approximate what usually is considered to be third-party conformity assessment (OECD, forthcoming).

In some instances, a purchaser or customer wants a stronger guarantee of conformity than that provided by the supplier. In second-party conformity assessment, the purchaser's own inspectors perform the assessment on its supplier's products (figure 4). For instance, when large manufacturers, such as aircraft manufacturers, purchase large volumes of parts from suppliers, purchase contracts with their suppliers stipulate formal specifications or standards that are verified by the purchaser. By inspecting the supplier's production line, manufacturing processes, and samples or batches of parts, a purchaser can gain confidence in the supplied products and reduce potential delays in its own production line caused by non-conforming products. Unlike first- or third-party conformity assessment, second-party assessment has not been the subject of trade discussions since its use is limited to cases involving requirements between buyers and sellers in the marketplace and not national or government-mandated requirements.

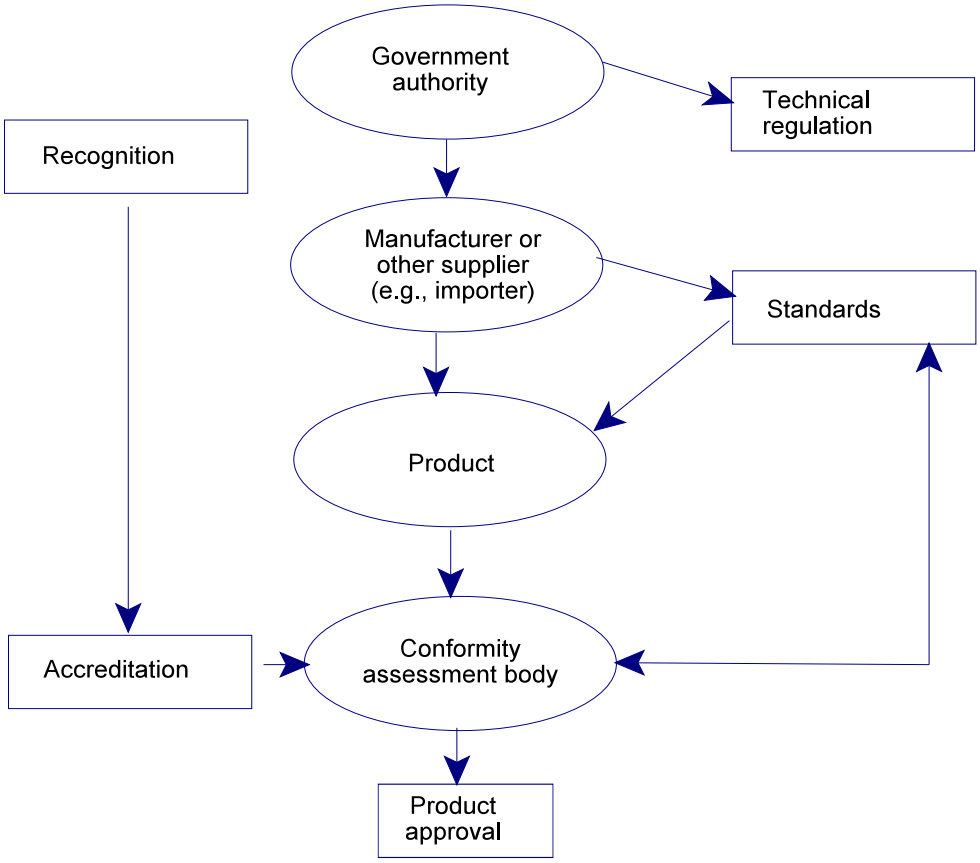
Sometimes concerns about the health, safety, or environmental impact of a product are deemed too important to be left to the manufacturer's or supplier's own assessment, or too expensive or technically difficult for the customer to perform itself (National Research Council 1995, 69). For these products, government regulators may require third-party assessment to verify product safety. Third-party conformity assessment often is undertaken in government laboratories or by accredited third-party bodies recognized and accredited by regulatory authorities (figure 5). In heavily regulated product sectors, government authorities often require competent, prior assurance of conformity to relevant mandatory standards or technical regulations before a product is sold or used. Medical device safety and efficacy certification required by the U.S. Food and Drug Administration (FDA) is an example of the use of third-party conformity assessment.

FIGURE 4 Second-party conformity assessment system



Source: Compiled by USITC staff from NIST, *ABC's of Conformity Assessment*, 2007.

FIGURE 5 Third-party conformity assessment system



Source: Compiled by USITC staff from NIST, *ABC's of Conformity Assessment,* 2007.

Impact of Conformity Assessment Barriers on Exporters

While conformity assessment procedures are important tools for achieving such societal goals as protecting consumers' health and safety, and the environment, such procedures can also act as trade barriers by raising exporters' costs unnecessarily when they are applied in a duplicative, inefficient, or discriminatory manner. Although recent surveys suggest that the economic effects and costs of conformity assessment barriers and other TBTs may be considerable, such costs or trade effects have been difficult to quantify (box 2) (Popper, Greenfield, Crane, and Malik 2004, 105; Maskus, Otsuki, and Wilson 2001, 10–57; and Fliess and Schonfeld 2006, 3–36). Unnecessary conformity assessment costs arise from (1) the need for exporters to comply with burdensome certification and testing requirements in multiple markets; (2) sales foregone due to delays in products' time-to-market because of lengthy conformity assessment procedures; (3) excessive fees for laboratory testing and certification bodies, including fees unrelated to the direct cost of testing; (4) lack of transparency in conformity assessment requirements; and (5) the need to collect information on different conformity assessment requirements, hire additional regulatory affairs expertise, and redesign products to meet different countries' conformity assessment standards and requirements.

BOX 2 Challenges in quantifying the effects of conformity assessment and other technical barriers to trade

TBTs, including unjustified conformity assessment requirements, are among the most difficult NTBs to measure (Deardorff and Stern 1998, 52). Because they are neither taxes nor quotas, they are hard to measure directly, and less amenable to application of price-based approaches to measuring NTBs (Maskus, Otsuki, and Wilson 2001, 43). Instead, they are complicated specifications of "such characteristics as minimum quality, maximum toxicity, ambient characteristics in production environment, along with rules for demonstrating conformity" (Maskus, Otsuki, and Wilson 2001, 43).

An important task in the quantification process is to try to "extract credible assessments of [conformity assessment and other TBT] costs from experts in the affected industries," and only if that approach does not work should price-based approaches to measuring barriers be attempted (Deardorff and Stern 1998, 52). However, as a practical matter, data on compliance costs may be hard to obtain. Firms may not maintain such data or may be reluctant to give up proprietary information (Popper, Greenfield, Crane, and Malik 2004, 105), and even if they are willing to provide such information, their reports may be subject to bias.

Another complicating factor in analysis of the effect of TBTs is the fact that standards, technical regulations, and conformity assessment procedures offer benefits to both consumers and importers that can counterbalance costs incurred to meet certification and testing requirements in the target market (Ganslandt and Markusen 2001, 95). For example, adherence to such requirements can reduce the risks and costs of unsafe products being placed on the market for consumers and society writ large. Further, if conformity assessment certifies a product as meeting safety, health, or environmental goals, such certification can raise consumer demand for imports that are certified to meet such requirements and increase the profits of their foreign suppliers. Thus, both the cost of the measures and any positive impact they may have on the demand for a product must be taken into account when quantifying the effects of the TBT.

Even when standards and technical regulations for specific products are identical for many countries, demonstration of conformity to such standards may be required for each market that exporters want to enter, thereby multiplying a firm's costs unnecessarily by the number of additional markets for which they must conduct the same or equivalent tests (Shortall 2007, 23). A 2006 OECD survey completed by 110 exporters in 2006 indicated that a significant source of conformity assessment costs "is the geographical dispersion of tests among several export markets," which the exporters perceived as "technically unnecessary and economically inefficient" (Fliess and Schonfeld 2006, 33–36). The 2006 OECD survey respondents questioned why regulators in one country cannot accept certifications and tests conducted by competent bodies in another market to demonstrate compliance to commonly held safety or other regulatory objectives (Fliess and Schonfeld 2006, 33–36). Further, they pointed out that even where the technical regulations or required standards differ from country to country, such differences are often within the capability of an internationally recognized third-party testing organization, such as Underwriters Laboratory, BSI Product Services, or the German-based TUV, to certify (Fliess and Schonfeld, 36; and OECD official, written communication to Commission staff, April 8, 2008). As such, the additional costs incurred by firms to undergo multiple conformity assessments are unnecessary. Exporters also point out that nonacceptance by countries of foreign testing or certification results is incongruent with WTO TBT agreement principles that encourage members to accept the results of conformity assessment procedures, even when they differ from their own, provided that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures.

Manufacturers of high-technology products with short product life cycles are especially disadvantaged by unusually lengthy approval times. Often the most significant costs resulting from such delays are opportunity costs incurred by firms during the time their products are under review and thus not generating sales revenues (Sykes 1995, 46 and Shortall 2007, 23). Excessive fees for conformity assessment or large expenses incurred when further clinical testing data are required—even when such data have previously been generated in testing to another country's conformity assessment requirements—represent another unnecessary cost imposed on exporting firms. The lack of transparency in a country's regulatory process makes it difficult for exporters to ascertain the certification, testing, and other conformity assessment rules and requirements for attaining product approval in that market. Constantly changing regulations or arbitrary application of conformity assessment requirements or procedures without adequate explanation or justification make it particularly difficult for a company to get its products approved and sold in some foreign markets (Fliess and Schonfeld, 33–37). According to U.S. industry officials, such transparency deficiencies appear to be inconsistent with provisions of the WTO TBT agreement requiring notification and publication of new conformity assessment rules potentially affecting trade.[5] Moreover, industry officials question whether countries violate the TBT requirement that conformity assessment procedures not be more trade restrictive than necessary to meet legitimate regulatory objectives when approval procedures with similar regulatory objectives take significantly longer in certain countries.[6]

When conformity assessment requirements differ across markets, or if countries' regulations are not transparent, companies often need to expend significant administrative resources to obtain such information, thereby increasing their costs significantly. Sometimes companies selling in multiple markets with complex and changing regulatory approval requirements must establish whole new departments devoted principally to regulatory affairs. Other times, firms may need to redesign their products to meet requirements in different markets, at much cost to them. When firms' conformity assessment expenses exceed their expected returns for marketing in a particular country, they may give up completely on their plans to export to that market, resulting in significant opportunity costs. Small-

[5] TBT article 2.9.1.

[6] U.S. industry officials, telephone interviews by Commission staff, February 8, 2008.

and medium-sized firms with fewer resources to overcome regulatory barriers may be affected most by onerous and costly conformity assessment practices. Finally, in some markets, U.S. and other foreign goods face stricter or more burdensome certification and testing requirements than do domestic products, increasing the relative costs for foreign firms compared to domestic ones (National Research Council 1995, 109 and USTR 2007, 94, 96, 213, 225, 322, and 494).

Case Studies Illustrating Impact of Conformity Assessment Barriers in Selected Industries

Because of the difficulty of empirically assessing the costs of conformity assessment and other technical trade barriers on industry, some economists suggest that in order to understand such costs, detailed description and micro-level analysis is required in which individual firms are investigated (Maskus, Otsuki, and Wilson 2001, 29–57). The following industry case studies are used to illustrate the use of conformity assessment in the United States and selected foreign countries and how differences in conformity assessment may impact costs and trade. The industries selected include the IT, medical device, automobile, and consumer products industries.

Information Technology Industry

For most computer hardware, telecommunications equipment, and other IT product manufacturers, the most significant technical barrier in terms of cost is the need to undergo multiple conformity assessment procedures to meet duplicative government technical regulations based on the same international standards. These redundant requirements result in technical barriers to trade (USTR 2008a, 14).

Conformity assessment barriers to trade are particularly costly to U.S. computer, telecommunications, and other IT equipment manufacturers.[7] Unnecessary conformity assessment costs arise from the need for exporters of IT equipment to comply with similar or identical conformity assessment requirements in multiple markets that result in excessive fees being charged to them for laboratory testing and certification. Manufacturers of IT equipment also face conformity assessment delays in many markets that cause them to forego sales in important markets while they await approval of their products. Even though regulatory officials in some advanced countries appear to be trying to address the encumbrances and costs of multiple conformity assessments for the IT industry, the proliferation of duplicative standards and conformity assessment requirements and testing fees in rapidly growing IT markets, such as Brazil, India, and China, are worrisome to U.S. industry officials.[8]

[7] The costs of conformity assessment affect other technologies as well. Investigating non-tariff barriers to trade in seven sectors of environmental technology, a recent multi-country OECD survey of 136 exporters finds product testing and certification of apparent concern to firms from both developed and developing countries and most frequently described as causing major or prohibitive obstacles to exporting (Fliess and Kim 2007, 13–19).

[8] U.S. industry officials, telephone interviews by Commission staff, June 2, 2008.

The IT industry is characterized by relentless competition, continually declining profit margins, global supply chains, and rapid obsolescence. Thus, cost management and speed to market are critical competitive factors that make IT producers exceptionally vulnerable to conformity assessment and other TBTs that increase IT manufacturers' relative costs and delay market entry.[9]

> [IT] Industries are particularly concerned about delays in market introduction as the speed of innovation in IT products and shortening product cycles are being accelerated. Currently, as the life cycle of the typical IT product has already been shortened to between 12 to 18 months, even a one month delay in putting a new product on the market has a significant impact by reducing sales revenues, which should compensate increasingly high research & development costs (OECD 2002, 7). (Also see Whitmer and Rubel 2007, 8–9).

The IT industry is global in nature, with production of commodity electronic components and final product assembly largely performed in multiple countries, particularly in rapidly emerging Asian economies. IT producers cut costs and enhance competitive positions by securing high quality products and components internationally at the lowest possible prices, setting up foreign production and sales facilities, and entering into strategic alliances. Because of the number of countries involved and borders crossed in various stages of IT production and marketing, conformity assessment barriers have a particularly significant impact on the costs and competitiveness of globally oriented IT firms (Beers 2005, 171–185).

Most countries' principal technical regulations related to IT products are based on the same international standards and are used for the same general purposes: to provide for worker safety and to minimize the effects of electromagnetic interference generated from IT and electrical products on nations' telecommunications networks and radio spectrums. For example, certain regulations related to electrical safety and electromagnetic compatibility adopted by regulatory agencies in the United States, EU, Canada, and a number of other countries are based on the same international standards, IEC 950 and CISPR 22, respectively (box 3), though with some slight variations known as national deviations.[10]

Despite their similar standards, these countries have implemented redundant conformity assessment requirements and procedures to test to those standards. Although telecommunications equipment regulations in China, Mexico, and Brazil are all harmonized to IEC 950 and CISPR 22, the three countries require conformity assessment to be completed domestically to those same standards, even if they have been previously tested and certified to equivalent standards by other accredited labs or certification bodies in the United States or other countries. For example, in order to obtain China's unique compulsory certification (CCC) mark of approval, IT products require testing in a designated Chinese laboratory (DiBiase 2008, 3). Such redundancies in conformity assessment requirements result in TBTs.

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[9] For further information on IT industry characteristics making it vulnerable to conformity assessment and other technical barriers to trade, see U.S. International Trade Commission 1998, 4-1─4-9; and Canavan, Carr, and Johnson 2002, 3─7.

[10] National deviations to international standards are often necessary to address countries' social, geographical, climactic, or infrastructure differences. For example, greater use of materials such as wood in U.S. construction led to the incorporation of flammability tests in electrical safety standards in the United States, while they were not included in electrical safety standards in Europe, where construction materials consisted of materials such as stone, brick, and plaster. However, over time, through participation in the international standards-development process, many national deviations are eventually adopted into the body of the international standard and the national deviations can be withdrawn. Thus flammability test requirements that were national deviations in the principal standard used in the United States for electrical safety, Underwriters Laboratories (UL) 1950, are now contained in the body of international standards for electrical safety, IEC 950. Underwriters Laboratories, Inc., telephone interview by Commission staff, June 19, 2008.

BOX 3 Important International Standards Affecting IT Products

International Electrotechnical Commission (IEC) 950: This standard applies to information technology equipment, including computer equipment, with a rated voltage not exceeding 600 V. IEC 950 specifies requirements intended to ensure safety for the operator and layman who may come into contact with the equipment and, where specifically stated, for service personnel.

International Special Committee on Radio Interference (CISPR) 22: This electromagnetic compatibility (EMC) standard is used to ensure that any equipment does not harm telecommunications networks or other equipment in the same environment. The standard indicates the maximum allowable electromagnetic emissions either radiated or conducted in various frequencies. The purpose of the standard is to establish uniform requirements for the radio disturbance level of equipment, including fixing disturbance limits, describing methods of measuring disturbance, standardizing equipment operating conditions, and interpreting measurement results.

Many countries have adopted these standards as a basis for the technical regulation of IT equipment; however, it is difficult to measure exactly what additions or deviations occur at the national level for each of these standards. Some examples of countries that have adopted these standards include the following:

- **United States:** The requirements for electrical safety are based on American National Standards Institute (ANSI) standards harmonized to IEC 950. The requirements relating to eletromagetic interference are contained in U.S. Federal Communications Commission rules. However, suppliers also have the option of using CISPR 22.

- **EU:** European harmonized standards for electrical safety and EMC are harmonized to IEC 950 and CISPR 22, respectively.

- **Canada, Brazil, Mexico, Korea:** These countries have mandatory regulations for electrical safety and EMC, which are harmonized to IEC 950 and CISPR 22, respectively.

- **Australia and New Zealand:** The Australian/New Zealand standard for electrical safety, A-NZS 3260, is harmonized to IEC 950 and the A-NZS 3548, the standard for EMC, is harmonized to CISPR 22.

- **Japan:** The Japanese technical regulation on electrical safety does not cover IT equipment. There is only a voluntary scheme for EMC.

- **China:** China's mandatory IT equipment standard is equivalent to IEC 950 and its EMC standards (GB9254-1998 and GB/T17618-1998) for IT products are equivalent to CISPR22.

Sources: International Electrotechnical Commission, International Special Committee on Radio Interference, Information Technology Industry Council, OECD 2002, 17–18, and NIST.

U.S. industry continues to identify conformity assessment procedures relating to IT equipment as a significant barrier to trade, focusing in particular on electromagnetic compatibility (EMC) and electrical safety testing and certification. Particular mandatory certification requirements maintained by China, Mexico, and Brazil (especially EMC), as well as [electrical safety] requirements maintained by China, Thailand, and Malaysia that equipment be tested domestically, can lead to redundant testing, particularly where a product is required to undergo testing to the same standard in both the exporting and importing country (USTR 2008b, 14).

U.S. and other foreign IT equipment exports to countries requiring conformity assessment to be completed domestically may face not only increased fees for redundant testing required but also delays in getting their products to market, if the countries' approval systems are inefficient. For example, according to U.S. IT industry officials, China's test cycle for approval of telecommunications equipment can take up to 13 weeks, compared to 30 days in the United States and Japan (ITI 2005, 5). Because of the short product life cycle, above average approval times in China "can seriously affect production cycles, time-to market, and revenue flows" (ITI 2005, 5 and DiBiase 2008, 3). The refusal to accept foreign test reports, and overly burdensome and redundant IT conformity assessment requirements in Brazil and India, have reportedly led to similar difficulties for U.S. and other foreign IT manufacturers (ITI 2005, 2 and USTR 2008, 14).

Because of the global supply nature of IT production, duplicative conformity assessments and testing requirements raise particular challenges for this industry. Empirical analysis conducted for a 2006 World Bank research study on the impact of standards on export success showed that IT and other manufacturers that typically outsource components are more challenged by duplicative conformity assessment and other technical requirements than those that do not outsource (Chen, Otsuki, and Wilson 2006, 22–24). This is particularly true for those markets whose technical requirements differ from the international EMC and electrical safety standards. This is purportedly because when the inputs are produced, their ultimate destination is unknown and consequently may not meet the technical regulations imposed in the market of the final products. The World Bank paper concluded that importing inputs from numerous locations, which are not likely to be produced to the standards in the ultimate product destination(s), makes the demonstration of conformity increasingly difficult as multiple assessments must be performed on identical or similar inputs, differing only in their origin.[11]

There is some evidence that regulatory officials in some advanced countries are trying to address the burden and cost of duplicative conformity assessments in the IT industry. For example, regulatory authorities in the United States, Japan, the EU, and other OECD countries have begun to accept test reports from accredited labs or certification bodies, a process that should prove faster than testing by regulatory authorities themselves. This is expected to reduce certification and testing costs for companies serving multiple foreign markets. Some countries are also allowing designated certification bodies to grant approval without the involvement of regulatory authorities (OECD, forthcoming). On the other hand, industry and trade officials find the continued proliferation of duplicative standards and conformity assessment requirements in large emerging IT markets such as Brazil, India, and China to be troubling (DiBiase 2008, 3).

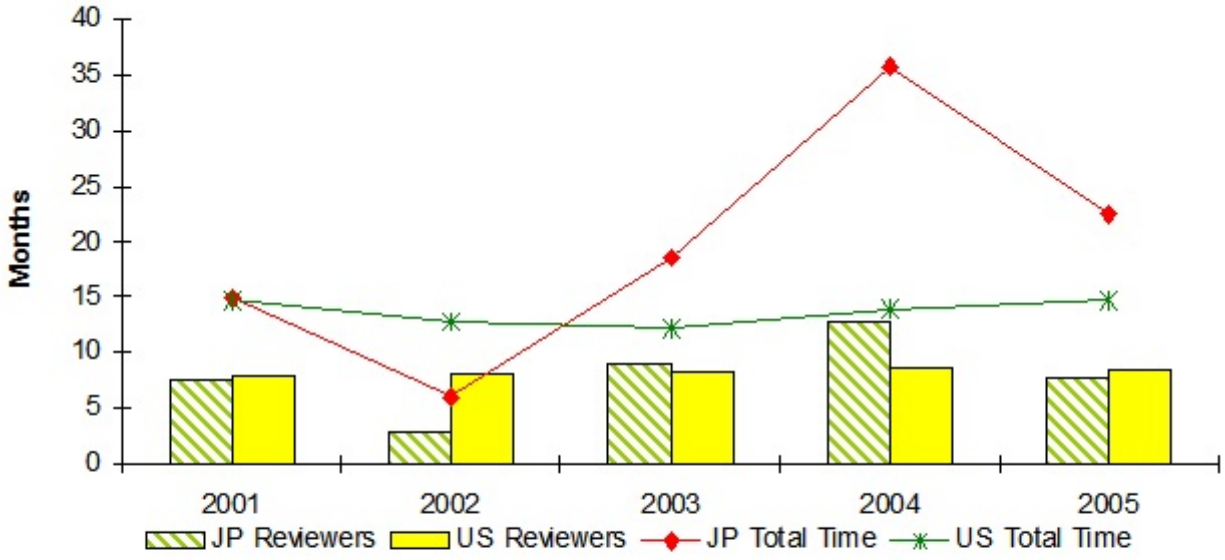
[11] For the empirical estimation results, see Chen, Otsuki, and Wilson 2006, 23.

Medical Device Industry

Conformity assessment delays, duplication in testing, and excessive data requirements constitute the most significant technical barriers to trade in the medical device industry. The amount of time it takes to gain regulatory approval in various markets can have a significant impact on the sales success of manufacturers in this industry, especially producers of advanced technology medical devices that have relatively short product life cycles. Meanwhile, requirements that clinical testing of devices be repeated even when identical testing has been completed previously to gain approval in other foreign markets often result in unnecessary costs for medical device manufacturers. Finally, excessive information and data requirements and nontransparency of such requirements can create costly burdens and delays for medical device firms.

Lengthy conformity assessment approval times may especially affect the sales of advanced technology medical devices with short product life cycles. A study completed in 2007 by the U.S. International Trade Commission (USITC) assessed competitive conditions, including regulatory conditions, affecting U.S. sales and trade of medical devices in Japan and other principal foreign markets from 2001 through 2005 (USITC 2007, 6-1–6-34). An examination of conformity assessment approval times for new medical devices showed that such times were much lengthier in Japan than in the United States and the EU. For example, the estimated length of the approval process for medical devices was found to average 3–10 months in the United States, 6 months in the EU, and anywhere from 1–3 years in Japan (FDA 2006 and JETRO 2004, 6–40). A comparison of official data from the U.S. Food and Drug Administration (FDA) and the Japanese Pharmaceuticals and Medical Devices Agency confirms the significant differences in total approval times in the United States and Japan for the most strictly regulated products, which include a high proportion of innovative, high-technology devices (figure 6).

FIGURE 6 Comparison of new medical device review times between the United States and Japan, 2001-05



Sources: Compiled by Commission staff from official data of the Japan Pharmaceuticals and Medical Devices Agency and the U.S. Food and Drug Administration.

Note: After completion of the USITC study, Japan's PMDA reported that medical device approval times in Japan declined by 12 percent, from 22.4 months to 19.7 months in 2006 (PMDA 2008, 64-66). However, even with the decline in approval times in 2006, the average length of time it took PMDA to complete its reviews of medical devices in that year continued to be significantly higher than that of the FDA, which took an average of 11.1 months to complete its reviews in 2006 (FDA 2008, 27).

The study concluded that, although the Japanese conformity assessment system does not discriminate in its treatment of of domestic and foreign-made medical devices, because U.S. medical device firms are the leading developers and exporters of advanced medical technology, they likely are disproportionately affected by the slower Japanese approval times given their relatively short product life cycles. The study also found that Japan's conformity assessment system raised costs by requiring duplicative testing before approving advanced medical technology (USITC 2007, 6-1–6-34).

Although the lack of industry pricing data or consistent cost information precluded empirical measurement by the USITC of the effects of Japan's conformity assessment procedures, a study contracted by a major U.S. medical device trade association estimated Japan's conformity assessment system cost U.S. firms $350 million from 2002-2005 and that U.S. firms will incur an additional $1.2 billion in compliance costs from 2006–2010 (Agress 2006, and AdvaMed/ACCJ 2005, 15).

U.S. industry and trade officials are also concerned about new registration requirements in Brazil for medical devices (USTR 2008, 2). They indicate that many of Brazil's conformity assessment requirements relate to what are perceived to be excessive information and data requirements.[12] For example, companies seeking to register a medical device must (in addition to providing what U.S. officials concede are legitimate safety data) submit manufacturers' pricing data, anticipated company sales volumes, estimated expenses for sales and advertising efforts, and a list of substitute products available in the Brazilian market, along with their corresponding prices. According to U.S. industry and trade officials, such information and data requirements do not appear to be related to a regulator's analysis of the safety or efficacy of medical devices, and appear to be excessively burdensome and intrusive.[13] Not only are such data not publicly available, but other requested information, such as forecast sales volumes and expected marketing costs, are highly sensitive business proprietary information and the new rules do not provide assurance that such information will remain confidential. Finally, Brazil's new registration requirements have substantially lengthened its approval process to over 6 months to register new medical devices (USTR 2008, 2).

Global medical device producers argue that Japan's and Brazil's conformity assessment procedures are inconsistent with WTO TBT obligations that members (1) apply their conformity assessment procedures in such a manner that they are no more trade restrictive than necessary to meet legitimate health and human safety objectives, and (2) ensure, whenever possible, that results of conformity assessment procedures are accepted, even when they differ from their own, provided that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures.[14]

Automobile Industry

The global automobile industry is an example of a sector that, while gradually moving toward harmonization of its standards and technical regulations, continues to face two distinct approaches to conformity assessment in major markets for the testing and certification of automobiles and parts. The two approaches to conformity assessment include SDoC and type testing (McDonald and Malone, 2005, 24). The different conformity assessment approaches reportedly increase costs for automakers wishing to sell in multiple countries by requiring them to either redesign their vehicles to meet different conformity assessment requirements or incorporate features in their vehicles that enable them to demonstrate

[12] U.S. industry and trade officials, interviews by Commission staff, Washington, DC, June 17, 2008.
[13] U.S. industry and trade officials, interviews by Commission staff, Washington, DC, June 17, 2008.
[14] TBT articles 5.1.2 and 6.1.

conformity assessment in multiple markets.[15] Diverging technical regulations related to safety, environmental protection, energy efficiency, and anti-theft in various markets for automobiles can also affect conformity assessment to such regulations. This case study will primarily focus on conformity assessment and applicable technical regulations related to automobile safety (McDonald and Malone, 2005, 24).

The extent of government regulatory involvement in the initial approval of automobiles is determined by the particular approach to conformity assessment used in the country or region. The United States and several other nations, including Canada, use SDoC (commonly referred to as self certification in the automobile industry), whereas the EU, Japan, and most other countries require some form of type testing and premarket approval by regulatory authorities (Popper, Greenfield, Crane, and Makik 2004, 73–74). Under self certification (table 2), an automobile or parts manufacturer certifies compliance to the regulatory agency's technical regulations before vehicles and parts are placed on the market. In the type approval system, manufacturers must obtain a certificate of type approval from a government agency or accredited testing organization indicating they meet applicable technical regulations before an automobile or component can enter the market (Popper, Greenfield, Crane, and Makik 2004, 73–74). To obtain this approval, the manufacturer must submit a representative sample of each new product to a government accredited testing organization for testing and receive certification that it meets the required technical regulations (McDonald and Malone 2005, 24). The following examples demonstrate how self certification and type approval are used in the United States and EU, respectively.

In the United States, the National Highway Traffic Safety Administration (NHTSA[16] is responsible for setting and enforcing safety performance standards and regulations for motor vehicles and motor vehicle equipment (NHTSA 2007b, 103). NHTSA does not test and approve the safety of motor vehicles and parts before they are placed on the market.[17] Instead, it places responsibility on manufacturers and importers to self certify that all motor vehicles and parts placed on the U.S. market comply with all applicable Federal Motor Vehicle Safety Standards (FMVSS) in effect as of their date of manufacture (NHTSA 2007a, 1–3). The original manufacturer is required to provide its certification on a label permanently affixed to the vehicle, indicating that the vehicle complies with such FMVSS. Manufacturers are not required to submit any additional compliance information to NHTSA in this regard. Certification requirements of imported motor vehicles that conform to required FMVSS are identical to those of domestically produced vehicles and do not require additional regulatory approval.

[15] According to the Congressional Research Service, automotive safety standards are one example of how different regulatory approaches in the United States and the EU increase costs. For example, if U.S. and German automakers' standards were recognized by both the United States and EU, "they could reduce their costs by not having to produce two different automobiles. The European Commission has estimated that further transatlantic liberalization of these kinds of regulatory barriers could lead to permanent gains of 3 to 3.5 percent in per capita gross domestic product on both sides of the Atlantic." Congressional Research Service 2008, CRS-6.

[16] NHTSA is an agency under the U.S. Department of Transportation (DOT).

[17] Although not required to do so, NHTSA may test motor vehicles and equipment before they are placed on the market.

TABLE 2 Self certification vs. type approval in conformity assessment of automobiles

	Self certification	**Type approval**
Description	Under self certification, an automobile or parts manufacturer itself certifies compliance to the regulatory agency's technical regulations without the need for formal regulatory approval before the products are placed on the market.	Under type approval, regulatory approval is required of each new type of automobile or part to ascertain whether it meets mandatory technical regulations. Conformity assessment is required by regulatory or third-party testing bodies and, if satisfactory, the government regulatory authority issues a type approval certifying compliance.
Countries where applicable	United States, Canada.	EU, Japan, Korea, China, Mexico, and most other countries.
Estimated share of world auto production	22 percent.	78 percent.
Major differences	No third-party conformity assessment required.	Third-party conformity assessment required.
Pros	Manufacturer may avoid costly certification and testing fees and administrative delays associated with formal regulatory approval.	Manufacturers less susceptible to large civil liability and criminal judgements if automobiles have previously obtained type approval by regulatory authorities.
Cons	Manufacturers face potentially high civil and criminal penalties and susceptibility to large civil liability judgements if products cause injury or other damage.	Manufacturer may have less control over costs and length of time it takes for approval related to third-party certification and type approval by regulatory authorities.

Sources: International Organization of Motor Vehicle Manufacturers 2007; NHTSA 2007a; NIST 1997; and Popper, Greenfield, Crane, and Makik 2004.

After a self-certified product enters the U.S. market, NHTSA may test any vehicle or equipment for compliance with one or more of the FMVSS. In addition, manufacturers are responsible for collecting and furnishing information on after-sale performance to NHTSA to ensure that the vehicle or part performs to the specified technical regulations. If either the supplier or NHTSA determines that the product does not comply with any FMVSS, the supplier must notify the product's owner and remedy the non-compliance at no cost to the owner. Failing to meet the requirements can lead to expensive recalls for the manufacturer. In addition, the self certification system in the United States places liability on manufacturers, making them potentially subject to civil law suits (Popper, Greenfield, Crane, and Malik 2004, 73–74).

Under the type-testing approval in the EU, mandatory standards, or technical regulations, established by transportation authorities in EU member states, determine design specifications to be fulfilled by the manufacturer (Popper, Greenfield, Crane, and Malik 2004, 73–74). To ascertain whether an automotive product meets the specifications, a producer is required to undergo conformity assessment by an EU accredited third-party testing organization. When testing is completed, the manufacturer submits the test results to an appropriate transportation authority in one of the EU member states, which decides whether to issue a type approval certifying that the product meets required technical regulations (Popper, Greenfield, Crane, and Malik 2004, 73–74). If it does, the manufacturer may place the product on the market in any EU member state. Type approval is also required in Japan, Mexico, China, India, and most other countries. Unlike self certification, where the manufacturer is liable for all injuries or other damages incurred by an automobile after it is marketed, under the type approval system, the third-party conformity assessment body shares a much greater degree of responsibility with automobile manufacturers for unsafe vehicles entering the market.

Differences in the two principal approaches to conformity assessment, as well as divergences in countries' and regions' technical regulations to which the conformity assessments apply, make it expensive for automobile manufacturers, which must obtain both U.S. self-certification and foreign type-testing conformity assessment approvals to one another's technical regulations. As a result, manufacturers wanting to sell in global markets produce vehicles in three versions: North American, rest-of-world left-hand-drive (LHD), and rest-of-world right-hand drive (RHD). A U.S.-EU automotive industry conference held in 1996 concluded that the cost of designing and developing different versions of a particular automobile model in order to satisfy differing conformity assessment requirements could add as much as 10 percent to the cost of a vehicle (USDOC 1996, 1–3). However, difficulties in meeting automotive regulations throughout the world are expected to gradually ameliorate as U.S. and European technical regulations approach each other as the result of a substantial effort to harmonize automotive technical regulations in major producing countries (box 4). Nevertheless, as long as two different approaches continue to exist in conformity assessment procedures, the costs of serving multiple markets will remain significant.

BOX 4 1998 Global Agreement on Technical Regulations for Wheeled Vehicles, Equipment, and Parts

Efforts to harmonize motor vehicle technical regulations worldwide resulted in a draft Agreement Concerning the Establishing of Global Technical Regulations for Wheeled Vehicles, Equipment and Parts (the Global Agreement), which was presented to the United Nations Economic Commission for Europe Working Party 29 (UNECE WP.29). The agreement, negotiated by the United States, EU, and Japan, established a global process for developing new global technical regulations for motor vehicles where standards do not exist, harmonizing existing technical regulations, and ensuring high levels of safety, energy efficiency, and environmental protection. Among the signatories to the agreement are most automobile producing countries, including the United States, Canada, Japan, France, Germany, Italy, South Africa, and Russia.

With the support of at least one-third of the members, a member can enter a standards proposal in a compendium of candidate technical regulations. A consensus on the proposal makes it binding, but the agreement does not obligate members to adopt a regulation into its own laws. However, if a contracting party votes to establish a technical regulation in the domain of the consensus standard, it must initiate domestic procedures to adopt the consensus standard for its regulation.

On November 14, 2005, the parties to the agreement agreed on the first global technical regulation, regulating performance of door locks and door retention components. Work is progressing on 14 other rules related to, among other things, motorcycle and automobile brakes, window safety glazing, child safety seats, head restraints, and vehicle emissions.

Sources: UNECE, 1998 Agreement on Global Technical Regulations [for Wheeled Vehicles], 1;Garcia 2005, 1-3; U.S. Department of Commerce 1996, 1; USITC 2002, 30–31; and Popper, Greenfield, Crane, and Malik 2004, 73–74.

Consumer Product Industry

Growing concerns in the United States, the EU, and Japan with respect to the safety of imported products from less developed countries have led them to reassess their own consumer product safety regimes while insisting that problematic counties, such as China, significantly strengthen their safety controls over exports of consumer products. However, U.S. industry officials worry that new, stronger conformity assessment policies adopted by the less developed countries to address such concerns could be used instead to discriminate against consumer products of the United States and other advanced countries. While U.S. government and industry officials stress the importance of China and other emerging countries rigorously addressing their safety issues, they expect them to do so in the least trade restrictive manner necessary to meet their health and safety objectives. By engaging in discriminatory and non-transparent policies with respect to the sale of foreign-made products, less developed countries could create technical trade barriers affecting imports of consumer products made in the United States and other advanced countries.

In the United States and other major countries, consumer products were traditionally subjected to less stringent conformity assessment schemes than other regulated sectors. Until recently, this has worked relatively well, given firms' reluctance to suffer significant losses resulting from bans, recalls, and substantial civil liability claims stemming from unsafe products. However, in 2007, after major concerns were raised in the United States and other advanced economies regarding the safety of imported consumer products from China, including children's toys, major governments were criticized for not being proactive in protecting the safety of their citizens (Nord 2007, 1). Proposed new rules in the United States, the EU, Japan, and China would require more independent testing of toys, ban lead and other substances in toys and other consumer products, and increase resources allocated to consumer product safety. The challenge for all countries will be to improve consumer safety without creating new technical trade barriers.

Generally, governments in advanced countries have regulated consumer product safety through SDoC and postmarket monitoring to identify defective or potentially defective products once on the market and worked with manufacturers to ban or recall products when necessary. In the United States, the Consumer Product Safety Commission (CPSC) is the federal regulatory agency responsible for protecting the public from unreasonable risks of injury and death associated with consumer products (box 5).[18] The CPSC is responsible for developing voluntary safety standards with industry; issuing and enforcing mandatory standards; banning consumer products if no feasible standard would adequately protect the public; arranging the recall or repair of products by manufacturers; conducting research on potential product hazards; informing and educating consumers through the media, local and state governments, and private organizations; and responding to consumer inquires (CPSC 2005, 1 and CPSC 2007b, 1) (figure 7).

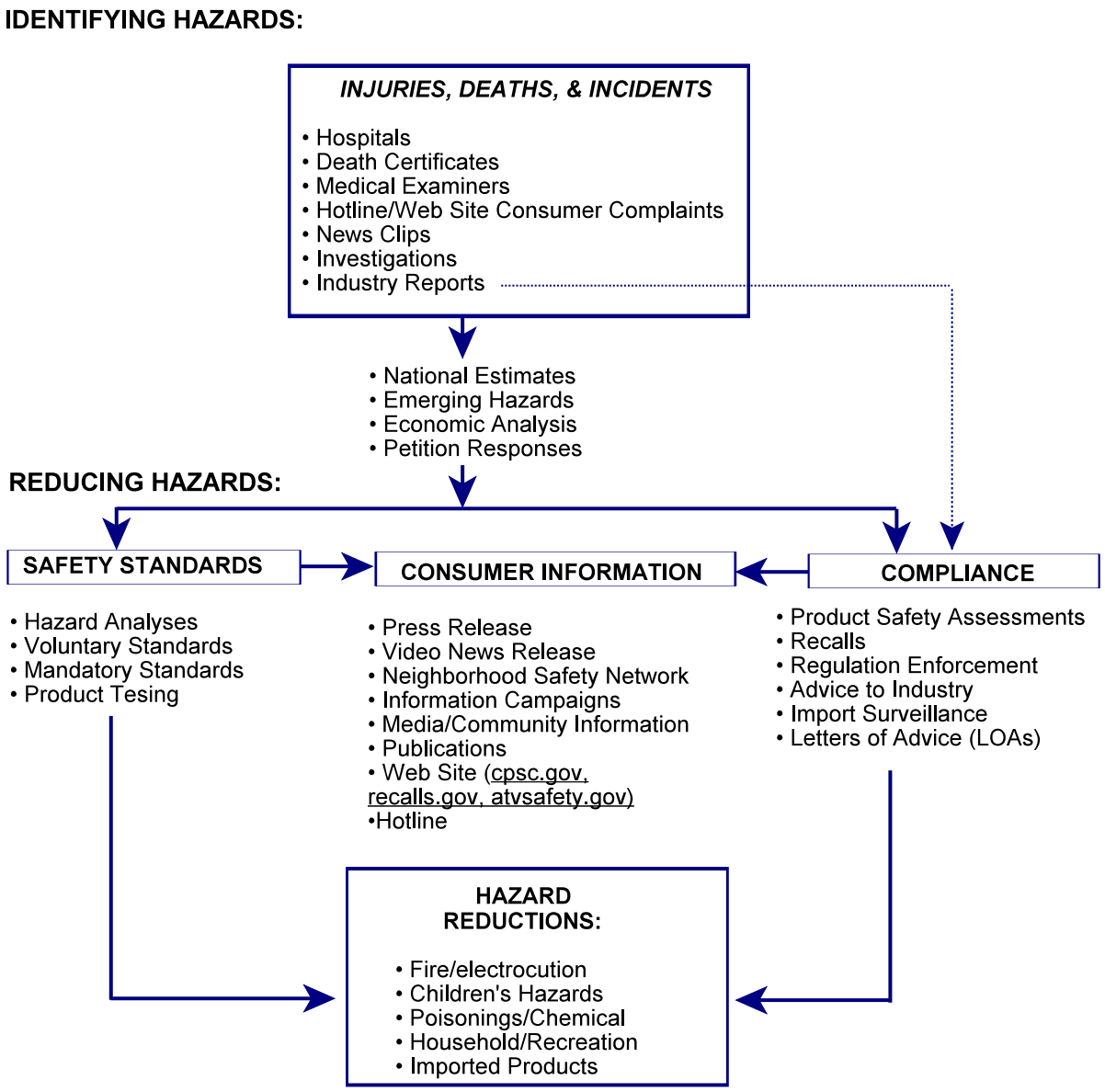
BOX 5 The Consumer Product Safety Act

The 1973 Consumer Product Safety Act of 1972 (15 U.S.C. § 2051 et seq.) requires manufacturers, importers, distributors, and retailers to report information to the CPSC about potentially hazardous products. Generally a firm must notify the CPSC if it obtains information that suggests that one of its products contains a defect that could create a substantial product hazard, presents an unreasonable risk of serious injury or death, or violates a mandatory standard issued under the act. The CPSC negotiates almost all recalls with consumer product manufacturers, distributors, and retailers. Since it was established in 1973, it has recalled more than 1,500 consumer products, and 220 million units. During the same time, manufacturers, distributors, and retailers recalled another 2,300 products, or 168 million units, that violated CPSC standards.

Source: CPSC 2005.

[18] The CPSC has jurisdiction over 15,000 types of consumer products used in or around homes and schools, and in recreation, including toys, household appliances, furnaces, and sporting equipment. The CPSC generally does not have jurisdiction over motor vehicles, foods, drugs, cosmetics, pesticides, medical devices, and boats, which are regulated by other federal agencies.

FIGURE 7 Consumer Product Safety Commission approaches to product safety.



Source: *CPSC 2007 Performance & Accountability Report.*

With respect to mandatory standards, the CPSC allows firms to use SDoC to indicate that they comply with required technical regulations either through the firms' own testing facilities or through use of an independent third-party testing organization.[19] Specifically, the Consumer Product Safety Act (CPSA), the principal legislation under which the CPSC operates,[20] requires manufacturers, importers, and private labelers of consumer products subject to a consumer product safety standard to issue a certificate stating that the product complies with all applicable consumer product safety standards.[21] The CPSA also requires that the certificate of compliance must be based on a test of each product or upon a reasonable testing program.[22] Up until the present time, however, the CPSC has permitted firms to choose between self certification or use of an independent testing body to assure conformance to required safety standards.[23] Significantly, new legislation recently enacted in the United States makes testing of toys by third-party testing laboratories mandatory.[24] According to industry officials, mandatory testing could lead to higher costs in the United States.[25]

Similar to the United States, EU regulation of toys sets high standards of protection for consumers.[26] However, while the EU generally allows manufacturers of consumer products such as toys to choose between self-verification (i.e., SDoC) or third party-certification (European Commission 2007, 1), in cases where standards do not demonstrate that essential toy-safety requirements are met, third-party certification is mandatory.[27] Under mandatory third-party certification in the EU, the manufacturer submits a model of the product as well as a design document to a qualified independent testing body, known as a notified body.[28] If the notified body determines that the manufacturer complies with the essential requirements, it affixes the CE marking on each product or its packaging. Under mandatory third-party certification, U.S. industry officials report that suppliers of consumer products to the EU have less control

[19] According to the CPSC, the term certification under the Consumer Product Safety Act has a different meaning than it does in recent international usage. Certification under the CPSA is more like a "supplier's declaration of conformity" (i.e., SDoC).

[20] Other statutes administered by the CPSC are the Federal Hazardous Substances Act, the Flammable Fabrics Act, and the Poison Prevention Packaging Act.

[21] 15 U.S.C. § 2063(a).

[22] 15 U.S.C. § 2063(b).

[23] Section 14 of the CPSA requires that suppliers certify by SDoC that consumer products conform to all applicable consumer product safety standards, and state the name and issuer of the SDoC, including the date and place of manufacture of the products. Each certificate must be based on a test of each product or a reasonable testing program. Any test or testing program may be conducted by a qualified, independent third party, but the CPSC cannot require third-party testing. Section 17 of the CSPA states that a product offered for importation "shall be refused admission" if it is not accompanied by a certificate. Under pending legislation (see next footnote), expansion of mandatory certification legislation is likely and may make certification requirements applicable to an expanded list of products, especially toys. Mullan 2007, 1; and Shin 2008, A1.

[24] The President signed the Consumer Product Safety Improvement Act of 2008 into law on August 14, 2008. (Shin 2007, D1–D5; Nord 2007, 1; and Abrams 2008, A8).

[25] U.S. industry officials, telephone interviews by Commission staff, July 28, 2008.

[26] In the EU, the Council directive of 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys, amended by Council Directive 93/68/EEC of 22 July 1993, specifies essential requirements for safety that toys must meet during their manufacture and before they are placed on the market. The safety criteria cover general risks such as protection against health hazards or physical injury, and particular risks, such as physical and mechanical, flammability, chemical properties, electrical properties, etc. The degree of risk has to take into account the ability of the user. If appropriate, the toy must contain labeling that specifies a minimum age.

[27] EU official, telephone interview by Commission staff, April 24, 2008.

[28] Notified bodies are organizations designated by EU member states on the basis of common evaluation criteria, and notified to the European Commission and the other member states. These are the functional equivalent of independent testing organizations in the United States. Several notified bodies–including UL, BSI, and TUV– have global operations.

over the costs and length of time it takes for approval related to third-party certification than in the United States.[29] Nevertheless, they indicate that the EU approach is generally fair.[30] The consumer product safety legislation of the other major trading partner of the United States, Japan, is considered to be less strict than that of the EU and is not believed to constitute a trade barrier.[31]

The effectiveness of these various approaches to consumer product safety was called into question in the summer of 2007, after a number of U.S., EU, and Japanese imports of toys from China, including painted toys and jewelry, were found to contain lead. As a result, each of those countries' respective regulatory agencies established cooperative programs with China to try to address the problems. In the United States, where over 70 percent of toys sold are manufactured in China, the CPSC worked with U.S. businesses to recall such toys already in the market and prevent others from entering the United States. In September 2007, the CPSC reached an agreement with its counterpart agency in China, the General Administration of Quality Supervision and Quarantine (AQSIQ), for the Chinese government to take immediate action to eliminate the use of lead paint in Chinese-manufactured toys exported to the United States.[32] Japan and the EU have concluded similar agreements with China.

U.S. government and industry officials stress the importance of China addressing its safety issues rigorously, but using the least trade restrictive means necessary to meet its health and safety objectives. A major concern of toy companies is that China could, for protective purposes, significantly strengthen its safety certification system in a manner that could make it more difficult for foreign companies (including those based in countries that have traditionally had strong consumer product safety) to gain product certification of their consumer products in China's market, thus creating technical trade barriers.[33]

Industry officials are concerned that the current consumer product safety climate could also encourage other countries to discriminate against imported goods in favor of their own domestic consumer product industries. A WTO complaint lodged against Brazil in April 2007 alleged that its administrative rule on toy safety testing, requiring that all imported toys be tested in accredited laboratories in Brazil, constituted a technical barrier to trade ("EU Accuses Brazil of Imposing Technical Barriers to Imported Toys" 2008, 1). The new rule was justified as a security measure needed to protect Brazilian consumers against toys with lead paint and other hazardous qualities. The primary complaint of Brazil's trading partners is that the testing requirements are not the same for both imported and domestically manufactured

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[29] U.S. industry officials, telephone interviews by Commission staff, June 15–16, 2008.

[30] The European Commission has also proposed new legislation to address perceived problems of the safety of imported products, by replacing and modernizing the previous legislation on toys (Proposal of the Parliament and of the Council on the Safety of Toys, January 25, 2008 (COM 2008)9 Final). The European Commission is currently in discussions with the European Parliament and the Council of Ministers with a view towards adoption of the legislation. European Commission 2008, 1; and "EU Proposes Stricter Toy Safety Rules" 2008, 1.

[31] In Japan, the Ministry of Economics, Trade, and Industry (METI) and National Institute of Technology and Evaluation, Life and Welfare Technology Center (NITE) work together to assure consumer product safety. NITE is a quasi-governmental body that investigates and reports final conclusions to METI on various areas of consumer product safety through accident data collection; market surveillance; and on-site inspection, testing, and analysis. On an annual basis, NITE collects accident information related to human damage, property damage with a high probability of causing human damage, and defects in consumer products that can cause human damage, such as defects in home electrical appliances, combustion appliances, vehicles, leisure items, and baby products. NITE reports this information to METI, which monitors consumer product compliance with relevant Japanese regulations but does not require third-party certification. Ozawa 2007, 1.

[32] AQSIQ agreed to (1) increase inspections of toy manufacturers; (2) take concrete steps to assist the CPSC in tracing imported products with safety problems to Chinese toy manufacturers and suppliers; (3) exchange technical personnel with the CPSC; (4) establish regular and systematic exchanges of information with the CPSC concerning emerging safety issues identified in China; and (5) attend CPSC-sponsored training programs on U.S. product safety standards and the importance of adhering to such standards. CPSC 2007a, 1.

[33] U.S. industry officials, telephone interviews by Commission staff, February 25, 2008.

products and, therefore, are discriminatory. Further, lack of transparency in Brazil's regulations reportedly make it difficult for U.S. and other foreign manufacturers to understand the new requirements, making it difficult for them to comply with them.[34] Importers reported that the measure increased the average time it takes to import consumer products into Brazil from 60 days to about 140 days, and increased their costs substantially ("EU Accuses Brazil of Imposing Technical Barriers to Imported Toys" 2008, 1).

According to toy manufacturers, while they understand the need for governments to update their consumer product safety legislation, they indicate that they need to do so in ways that ensure high levels of safety without compromising commercial and trade interests.[35] Toy producers point out that because of the tremendous amount of resources required, precertification of every consumer product before it is placed on the market could tax national regulatory budgets and significantly increase consumer prices, without improving the public safety.[36]

Reducing Conformity Assessment Barriers to Trade

Manufacturers and regulators are pursuing new approaches, such as establishment of mutual recognition agreements (MRAs) among trading partners, unilateral recognition by a country of another country's conformity assessment results, and increased acceptance of SDoC, to address the increasing costs and challenges of conformity assessment on trade. Such costs have become more apparent with the greater globalization of production and markets and the increasing adoption of product regulation in developing countries. The implementation of these measures may improve the ability of manufacturers and regulators to ensure that safe products are placed on global markets quickly, and in the least trade restrictive manner possible, while achieving legitimate regulatory objectives.

MRAs

The establishment of MRAs may reduce firms' conformity assessment costs for demonstrating compliance to requirements in multiple markets (box 6). MRAs allow product testing and approval in the home country for compliance with other countries' technical regulations. For example, under the Asia Pacific Economic Cooperation (APEC) telecom MRA between the United States and Singapore, a cellular phone tested and certified in the United States may meet Singapore's technical requirements and be shipped and marketed throughout Singapore without the need for any further testing or approvals (NIST 2007, 1).

A number of policy experts state that such agreements between governments to recognize one another's national conformity assessment mechanisms can facilitate trade. An empirical study investigating the trade effects of MRAs found that "MRAs have a positive influence on both export probabilities and

[34] U.S. industry officials, telephone interviews by Commission staff, February 26–27, 2008.
[35] U.S. industry officials, telephone interviews by Commission staff, February 25, 2008.
[36] U.S. industry officials, telephone interviews by Commission staff, February 26–27, 2008.

BOX 6 Important Mutual Recognition Agreements (MRAs) Concerning Conformity Assessment

U.S.-EU, EU-New Zealand, EU-Australia, and EU-Canada MRAs

The MRAs are framework agreements under which EU and partner country exports are facilitated through mutual recognition by partners of the agreements of one another's third-party product test results, inspections, and certifications to address conformity assessment and market access barriers in the respective markets. The U.S.-EU MRA covers conformity assessment related to the medical device, pharmaceutical, telecommunications equipment, and recreational craft industries; and horizontal issues related to electrical safety and electromagnetic compatibility. The EU MRAs with the other countries have similar coverage with some variations.

Australia-New Zealand MRA

The key principle in this MRA is that a good which has been approved for sale in one of these countries may legally be sold in the other country without having to meet further regulatory requirements. However, this principle only applies in instances in which technical regulations and standards are harmonized or mutually accepted as equivalent in terms of regulatory requirements.

Asia Pacific Economic Cooperation (APEC) MRA for Conformity Assessment of Telecommunications Equipment

This MRA covers conformity assessment of regulations on fixed and radio telecommunications equipment, but as a model and not as a legally binding arrangement. Under the MRA, interested APEC member economies may, but are not required to, conclude individual arrangements among one or more other members to accept conformity assessment certification and testing reports among themselves. A country may also designate foreign conformity assessment bodies on the basis of reciprocity. For instance, the United States has designated foreign conformity assessment bodies based on this approach, most recently with Japan in 2007. Hong Kong and Singapore have unilaterally recognized certification and testing bodies in other APEC member countries without reciprocity with respect to telecommunications equipment under the MRA.

Sources: U.S. Department of Commerce, Office of the United States Trade Representative, European Commission, U.S. Federal Communications Commission; and portions adapted and extracted from OECD 2002, 31.

trade volumes for partner countries" (Baller 2007, 1).[37] With MRAs, firms are not subjected to multiple testing and certification of their products; products can undergo conformity assessment before being exported and can enter foreign markets directly without having to face duplicative procedures (Lesser 2007, 13–14). Other benefits of MRAs may include simplified and less expensive conformity assessments and decreased time to market, which is especially important for firms that manufacture products with shorter product life cycles (FCC 2007, 1–3 and NIST 2007, 1–3). Benefits accruing to regulators may include a reduction in regulatory resources required for certification and testing of products; opportunities to reapportion certification costs to other areas administered by the regulatory bodies; and the ability for regulators to learn and benefit from cross-country cooperation. Consumers may profit from increased product safety from more consistent certification and testing policies in national and foreign markets, increased access to a wider range of technology, and faster access to products at lower prices. MRAs appear to be most effective for industries that experience a high level of government regulation in partner countries, such as the telecommunications equipment, medical device, and pharmaceutical industries. However, MRAs may be less effective in reducing technical barriers to trade in traditionally less regulated industries, because MRAs may require countries with less stringently regulated systems to introduce more regulation than they believe to be necessary, and require regulatory authorities in both parties to cooperate. This is of particular importance to U.S. industries because less regulation tends to be more common in the

[37] The empirical assessment applied a two-stage gravity estimation and investigated sectoral effects of regional TBT liberalization on parties to the MRA as well as excluded industrialized and developing countries.

United States compared to other countries, especially in sectors such as electrical products. For example, the major electrical products trade association in the United States has opposed the negotiation of MRAs with respect to electrical equipment generally, because much of that sector is only required to comply with voluntary safety and other standards through certification by independent organizations such as Underwriters Laboratories (UL); in most other countries, manufacturers must meet mandatory technical regulations.[38] However, the same trade association has supported MRAs with respect to electromedical equipment, because such products are already under strict U.S. government regulation.[39]

MRAs can entail significant costs for countries that are not included in the MRAs, as well as reduce economic efficiencies even for those that are. A recent empirical model shows that MRAs can harm the exports of countries excluded from MRAs as a result of trade diversion (Amurgo-Pacheco 2007, 1). That is, exporters from non-MRA countries may become relatively less competitive in a foreign market where MRA partner countries meet less restrictive and less expensive regulatory requirements than those that are excluded. Developing countries particularly have opposed MRAs between developed countries, which due to product safety concerns are only willing to enter into MRAs with countries that have well established regulatory systems, and these tend to be other developed countries.

Many economists believe that MRAs also adversely affect economic efficiency in the partner countries since they limit import competition from those economies that are not party to the agreements and consequently face more restrictive regulatory barriers. Moreover, MRAs are often time and resource intensive because of the need for regulators to cooperate extensively to gain confidence in one another's regulatory regimes and complete the negotiations of the MRA. For example, the MRA between the United States and the EU, which contained four sectoral and two horizontal annexes, took over 5 years to complete and at considerable costs to the regulatory agencies involved.[40] Finally, the extent to which MRAs concluded and implemented are used by exporting firms is unclear because data on MRA-based certificates are not readily available.

Unilateral Recognition

A less costly and less trade restrictive alternative to MRAs is unilateral recognition. The TBT agreement calls on members to "accept unilaterally the results of the conformity assessment procedures in other [m]embers whenever possible."[41] Such acceptance could contribute to the reduction of unnecessary barriers to trade associated with duplicative testing and certification. Upon a finding of equivalent competence of a foreign conformity assessment body compared to domestic conformity assessment bodies, foreign test reports and certifications may be recognized unilaterally by regulators. To provide assurance of equivalence to regulators, conformity assessment bodies may seek accreditation under recognized international accreditation systems or prove their competence by other means (WTO 2000, annex 5). Governments may also designate specific conformity assessment bodies located outside their territories to undertake conformity assessment to their own regulations.

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[38] Except in the workplace, where the Occupational Safety and Health Administration (OSHA) administers mandatory health and safety standards, the U.S. government has found that, because the market demands safety in electrical and selected other products posing hazards, almost, if not all, electrical manufacturers voluntarily obtain certification by independent bodies such as UL in order to meet consumer demands. For example, consumers in the United States have traditionally looked for the UL mark on potentially risky products to assure themselves of the safety of the product. This system is believed to have worked as well or better than systems imposing regulatory authorities in other countries, at less cost to business and government.

[39] U.S. industry official, telephone interview by Commission staff, February 26, 2008.

[40] U.S. government officials, telephone interviews by Commission staff, December 3–21, 2007.

[41] TBT article 6.1.

Acceptance of SDoC

When conformity assessment is mandated by the government, businesses have increasingly come to prefer first-party, or SDoC, over third-party conformity assessment. The WTO, in a review of the TBT agreement, found that "[r]eliance on a supplier's declaration of conformity could also be a cost-saving and efficient tool for regulators to ensure that regulatory requirements and legitimate policy objectives were met " (WTO 2000, 7). Supporters of SDoC point out its benefits, including flexibility and nondiscriminatory treatment for the firm in choosing the location to have a product tested, decreased uncertainty associated with mandatory testing by designated testing bodies based in foreign countries, high compliance levels, and lower administrative costs (Industry Canada 2001, 1 and WTO 1998, 1). For example, with SDoC the manufacturer may avoid costly certification and testing fees and opportunity costs resulting from administrative delays associated with formal third-party regulatory approval.

According to one economist, because SDoC "is surely the cheapest form of conformity assessment, it is to be preferred except when it cannot be trusted" (Sykes 1995, 134). For SDoC to work, however, the supplier must have incentives to be honest and accurate in certifying its goods, i.e., suppliers must face a deterrent penalty for incorrect certifications. Critics, meanwhile, question the ability of SDoCs to hold manufacturers accountable and ensure safety to the public (Sykes 1995, 134).

To increase adoption of SDoC, this regulatory regime generally should be supported by rigorous product liability laws that ensure that anyone suffering injury from a defective product can claim damages against the supplier of the product; such laws provide an incentive to suppliers to put only safe products on the market in order to avoid liability costs. Governments have found that such a regime must also be underpinned by an effective market surveillance regime. Market surveillance consists of verifying in the market the actual conformity of products with existing laws and regulations. The government may do this by taking samples, reviewing complaints, investigating adverse incidents such as injuries, making spot checks, or using customs inspections. The investigative role of the government also may be triggered by legislated reporting requirements imposed directly on the manufacturers and importers (Industry Canada 2001, 7–8). Sometimes remedial actions, such as product recalls, required replacement or repair, or penalties for false or misleading declarations are used to increase the effectiveness of market surveillance activities.

Under SDoC, the investigative powers of the relevant government authority are often crucial in detecting product defects not covered by existing standards. In the automotive industry, for example, because any motor vehicle product safety defect has to be reported by the manufacturer or importer to the surveillance body, defects that are not specifically covered by the related standards are often revealed (Industry Canada 2001, 7–8).

> The governing legislation evident in the case of SDoC for American automobile manufacturers places very broad public protection responsibility on the manufacturer, thereby enhancing testing and reporting results. These results may not arise from a pre-market testing system where the product is not tested beyond what is required for government certification to a given standard (Industry Canada 2001, 7–8).

Thus, SDoC differs from traditional third-party premarket approval processes in that it requires less pre-market involvement from regulators. As such, under an effective postmarket surveillance system, SDoC may not only be less trade restrictive than other conformity assessment systems but could result in greater safety by identifying product safety defects that would not otherwise have been discovered by a premarket approval process.

Conclusion

Although conformity assessment requirements serve important economic and societal goals by ensuring that products meet appropriate quality and safety standards, such requirements may also serve as significant trade barriers. Conformity assessment barriers have been shown to increase manufacturers' costs, which result from requirements that manufacturers have their products tested overseas, adjust to diverse conformity assessment requirements, undergo duplicative testing, face lengthy approval times, or overcome discriminatory requirements in overseas markets.

As the costs and trade effects of conformity assessment have multiplied, manufacturers, trade officials, and regulators have tried different approaches to ensure that products are safely placed on global markets promptly and in the least trade restrictive manner possible. These approaches have included MRAs, unilateral recognition by a country of another country's conformity assessment results, and increased acceptance of SDoC. When conformity assessment is mandatory, companies often favor SDoC over third-party conformity assessment as it provides them with greater flexibility, nondiscriminatory treatment, and lower costs when entering overseas markets. The challenge to supporters of SDoC is convincing regulatory authorities that it will not compromise regulators' obligations for reducing risks to human and animal health and safety, or to the environment.

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