Volume 7 Number 2 2007

Dave HANSON
Jan Napoleon SAYKIEWICZ
Duquesne University

The Agreement on Technical Barriers to Trade: is it working for business?

Abstract: International differences in technical requirements, product standards and conformity assessment procedures create major barriers to international trade. The Agreement on Technical Barriers to Trade is intended to reduce the impact of these differences on trade. The major emphasis has been on promoting the convergence of national requirements through mutual notifications. This has not been an especially effective approach since governments and businesses often have major commitments to existing requirements and procedures. A more effective approach would be to promote international acceptance of a rebuttable presumption that the various sets of national product requirements, although different, provide equivalent levels of protection.
Keywords: free trade, standards, non-tariff trade barriers, Technical Barriers to Trade Agreement.
JEL codes: F13.

1. Introduction

National differences in product requirements can lead to some of the most troublesome barriers to international trade (Organization for Economic Cooperation and Development: 2000: Chen, Otsuki and Wilson, 2006). Exporters often have to develop products to meet at least two different, and potentially incompatible, sets of requirements. Manufacturers often start by developing products for their home markets. Exporters have to make sure that their products are also compatible with their destination market requirements. Exporters often have to make a choice between modifying their domestic market products to meet foreign market requirements or developing different products for different markets. Both options can be difficult and expensive to implement. John Bruton, EU ambassador to the US, pointed out that: "New models of motor cars have to be crashed twice, once to comply with the EU standards and again to comply with the US standards.

We simply cannot afford to load more costs on the shoulders of our customers or to place more restrictions in the way of our business if we are to beat our global competitors" (Bounds, 2007).

Bonay (1983) lists some of categories of national technical requirement which can affect products and trade. They include; a) health and safety regulations, b) pharmaceutical control regulations, c) product design requirements, d) industrial standards, e) size and weight regulations, f) packaging and labeling regulations, g) package marking regulations, h) regulations affecting product use, i) intellectual property rules, j) trademark regulations. The documentation requirements may include design analyses and the processes of product development (Hanson, 2005; Hanson and Manchego, 2006).

The total costs of meeting product design, manufacturing and documentation requirements can be significant for smaller and medium manufacturers that are interested in developing export markets. (Organization for Economic Cooperation and Development n.d). The costs of complying with technical requirements and standards constitute a capital cost, expenditures are largely independent of the quantity sold. Smaller manufacturers may be reluctant to fund the up front costs for product modification and documentation that may be required before they can export their first orders to test the potential of foreign markets.

The globalization of the supply chain presents additional arguments for the international coordination of standards. Manufacturers exporting products generally want to purchase components that comply with foreign market requirements. US suppliers who are not exporting now find that they must satisfy the requirements of a foreign government if they want to sell components to manufacturers who are exporting.

The impact of national differences in product requirements has been increasing with the emergence of new technologies and the development of new standards and technical requirements. Protectionist interests often seem to play a role in the development of these national standards and requirements. (Hanson 2005; Egan, 2001).

2. Considering standards

A "standard" is defined as a "document approved by a recognized body that provides for common and repeated use, rules, guidelines and characteristics for products or related processes and production methods, with which compliance is not mandatory" (World Trade Organization, 2007, Technical Barriers to Trade Agreement, Annex I, article 1). Product standards can be developed to address a wide range of issues, including classifying product characteristics, ensuring product compatibility,

and promoting product quality, durability and safety. These standards are essential in a modern industrial society; they are the building blocks for product development (US Office of Technology Assessment, 1992).

The WTO defines a "conformity assessment procedure" as "any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled." These may include product sampling, testing and inspection procedures, the evaluation, verification or assurance that these procedures are properly implemented, and the registration, accreditation or other forms of approval for the assessment procedures (World Trade Organization, 2007, Technical Barriers to Trade Agreement, Articles 5.2.3 and 5.2.6).

Virtually every developed country has one or two "standards development organizations" that take the lead in developing national standards and the associated conformity assessment procedures. These organizations are generally in the private sector. The American National Standards Institute has the lead role in the United States. ISO, the International Standards Organization, and IEC, the International Electrotechnical Commission, are the lead international non-governmental organizations charged with developing "international" standards.

Standards are usually developed in partnership with industry groups. Under the ISO/IEC Code of Good Practices (International Standards Organization, 2004), standards development organizations are charged with supporting "technical committees" that develop drafts of new standards and revisions to old ones. The committees are staffed by volunteers from business and other interested groups. After the end of a mandatory public comment period, the members of the standards development organizations can vote to approve or reject the technical committee drafts.

A "technical requirement" is defined as a "document which lays down product characteristics or their related process and production methods, including the applicable administrative provisions, with which compliance is mandatory" (World Trade Organization, 2007, Technical Barriers to Trade Agreement, Annex I, article 1). The distinction between a standard and a technical requirement is often blurred in practice. It is increasingly common for governments to use (voluntary) product standards as the basis for (mandatory) technical regulations. The National Technology Transfer and Advancement Act (United States, 1995), for example, requires US federal regulatory agencies to use private sector standards to define public regulatory requirements whenever possible. In the EU, manufacturers are not required to use the standards developed by the (non-governmental) European standards development agencies. However, products that are based on these standards are "presumed" to meet the essential requirements of the CE marking system for regulating product safety (Directorate General Enterprise, 1999). There is no other way to gain the benefit of this presumption.

3. The Agreement on Technical Barriers to Trade

The Agreement on Technical Barriers to Trade (TBT) is the major international convention that is intended to reduce the impact of international differences in product standards and regulation on international trade.

The TBT was negotiated during the 1994 Uruguay Round of the GATT talks (World Trade Organization, 2006) to reduce the impact of national differences in standards and technical requirements on international trade. It strengthened the provisions of the original TBT which was adopted in 1979 at the end of the Tokyo Round.

The TBT establishes the international expectations for developing and enforcing technical requirements. There is a strong emphasis on minimizing the potential impact of technical requirements on international trade. Technical requirements should not be any more trade restrictive than necessary to fulfill legitimate objectives. Requirements must be based on available scientific information and technology (World Trade Organization, 2007, Technical Barriers to Trade Agreement, article 2.2). Technical requirements should be discontinued when they are no longer needed (World Trade Organization, 2007, Technical Barriers to Trade Agreement, article 2.3). International standards should be used as the basis for developing technical requirements where feasible (World Trade Organization, 2007, Technical Barriers to Trade Agreement, article 2.4).

The TBT also covers relations among countries in the development and enforcement of technical requirements. Signatories are pledged under the TBT to give public notice when they are developing a technical requirement that could have an impact on international trade. Other member states should be given the time and information needed to comment intelligently on the draft (World Trade Organization, 2007, Technical Barriers to Trade Agreement, articles 2.9 and 11). The notification requirement can be overridden in response to the emergence of urgent problems of safety, health, environmental protection or national security (World Trade Organization, 2007, Technical Barriers to Trade Agreement, article 2.10).

Technical requirements should be enforced in a non-discriminatory manner (World Trade Organization, 2007, Technical Barriers to Trade Agreement, articles 2.1, 5.1, 5.2 and 8). Where relevant, member countries should consider adopting international and regional systems of conformity assessment (World Trade Organization, 2007, Technical Barriers to Trade Agreement, article 9). Signatories should also consider accepting products that have been developed on the basis of foreign technical requirements, even if they are different from national requirements, as long as they adequately fulfill the objectives of the national regulations (World Trade Organization, 2007, Technical Barriers to Trade Agreement, article 2.7).

Since standards are developed by the private sector, the provisions of the TBT that apply to technical requirements do not necessarily apply. Article 4 of the TBT states that signatory governments should "take such reasonable measures as may be

available to them" to ensure that relevant local government and non-government standards development bodies comply with the TBT Code of Good Practice for the Preparation, Adoption and Application of Standards (World Trade Organization, 2007, Technical Barriers to Trade Agreement, article 4.1).

The TBT Code of Good Practice (World Trade Organization, 2007, Technical Barriers to Trade Agreement, Annex 3) is based on the ISO/IEC Code of Good Practices (International Standards Organization, 2004). The Code includes the same general provisions on national treatment and non-discrimination that govern the application of technical requirements. The process of developing new standards is to include the publication of a draft, an open comment period, and a requirement that the written responses be developed for all substantive comments. The process is to be publicized through ISONET (TBT, Annex 3). ISONET is a service managed by ISO that provides a forum for affiliated standards development organizations to publicly share information on the process of standards development (ISO, 2007) Signatory countries are also pledged to participate in the processes of developing international standards within the limits of their resources (World Trade Organization, 2007, Technical Barriers to Trade Agreement, article 2.6).

4. Trade, technical requirements and the TBT

Does the TBT help liberalize international trade? Does it help mitigate the trade impact of national differences in international technical requirements and standards? We can begin to answer these questions by comparing the sorts of issues covered in the processes developed through the TBT with the real world problems created by national differences in technical requirements standards and conformity assessment procedures.

The international notification process developed through the TBT is a tremendous step forward in the harmonization of future standards. It can provide companies in foreign countries with notice of pending regulatory initiatives before they have been adopted as a new standard or technical requirement. The US notification office, the National Center for Standards and Certification Information, makes notifications available to interested companies over the internet (National Institute for Standards and Technology, 2007). This is a common practice in many other countries.

However, notifications may mitigate future problems, but are not likely to have much impact on existing standards and certification requirements. The impact of large inventories equipment and products built and certified according to legacy standards severely complicates the search for international convergence.

National differences in metrology pose particularly difficult problems for the international harmonization of compatibility standards. The USA and Liberia still use

the English system of measurement. Every other country is on the metric system. The compatibility difficulties are substantial. Metric bolts will not fit on English screws. Precise conversions from English to metric units can involve many decimal places and be difficult to implement. Until the US adopts the metric system, national convergence around international standards is unlikely to occur. Given the magnitude of the US legacy infrastructure that has been built to English units, a full switch to the metric system is unlikely to occur.

Another example, international differences in conformity assessment procedures can pose problems for the exporting manufacturer. In the US, conformity assessments are generally carried out by accredited third parties that compete in the marketplace for recognition. The National Institute for Standards and Technology has listed over three hundred US certification marks. The Underwriter's Laboratory UL logo is probably the best known US certification mark for assuring electrical safety. ASME, The American Society for Mechanical Engineering, is the leading source of safety certification for boilers and pressure vessels. In most cases, the certifying agency takes broad control of the product review process in the US.

In the EU, product safety standards are generally enforced through the CE marking system. The manufacturer has the primary responsibility for assuring that the design, manufacture, performance and documentation of a product complies with the standards used to implement the CE Marking requirements. Manufacturers dealing with higher risk products must hire certified groups, called "notified bodies", to review their work.

Both the certification agencies in the US and the notified bodies in the EU derive a substantial portion of their revenues from serving the existing system of conformity assessment. Their clients have made significant investments in conformity assessment on the basis of their national systems. Both groups are likely to resist pressures to adopt the system used in the other country.

The task of modifying established standards to reduce international differences is likely to be difficult, especially if the differences go to basic issues of design strategy or product classification. For example, the ASME Boiler and Pressure Vessel Code assures the safety of pressure vessels through a strategy of thick walls, thick welds, low stresses and relatively limited quality controls. This approach reflected the technology available when boilers used on river packets were first being regulated in the US. In contrast, the European standards implementing the Pressure Equipment Directive were developed on the basis of modern systems for quality control and testing. These standards are based on a strategy of thin walls, thin welds, high stresses and more rigid quality control measures, including radiographic testing for weld integrity. Both systems lead to safe products. However, compliance with one system does not assure compliance with the other system.

Another example; both the US and the EU set the stringency of manufacturing reviews and conformity assessment procedures for medical devices according to

the intrinsic levels of risk they present. Both systems impose far more rigid quality controls on companies manufacturing cardiac pacemakers than on companies manufacturing tongue depressors (United States Food and Drug Administration, 2007, Directorate General Enterprise, 1993). The EU classifies products into four categories of intrinsic risk. The US has three categories plus an "unregulated" category for safe products. Unfortunately, the two systems use different procedures for classifying products by intrinsic risk. In the EU, Medical Device Directive (Directorate General Enterprise, 1993) sets forth seventeen rules for product classification. The manufacturer is responsible for determining the appropriate category for her product. In the US, the classification of new products is carried out by the FDA staff.

There are no guarantees that a classification in one system will carry over into the other system. Any changes made in the system used in either region to harmonize it with the system used in the other region will inevitably lead to the reclassification of existing products. The manufacturers of the affected products would have to change their systems of manufacturing controls and conformity assessment procedures. This is likely to be an expensive and difficult process. Although medical device manufacturers generally support global harmonization, most would resist changes that lead to uncertainties, delays and added costs.

Standards are often used to summarize component characteristics and to ensure product compatibility and interoperability. Businesses that rely on a particular set of compatibility standards are likely to build up a large inventory of equipment built to those standards. This legacy infrastructure can complicate efforts to integrate national standards into international models in accordance with the TBT. For example, a company that manufactures TV equipment to US video standards is likely to resist a shift to EU TV standards.

The picture is not totally dark. This impact of national differences in standards on trade is, in general, less serious in high technology areas where product life cycles are short, new standards are always under development and manufacturers expect to sell in the global marketplace. Industry experts participating in the technical committees are likely to insist that the draft standards they develop are consistent with their companies' marketing goals. Even companies using new technologies are likely to have an interest in expanding their potential customer base by encouraging widespread acceptance of their proprietary standards. This will usually involve a strong interest in international compatibility, if not outright convergence.

The US and the EU, as anchors for the largest bilateral trade flows in the world, have gone beyond the requirements of the TBT to promote regulatory harmonization. The 1008 US-EU Summit led to the development of a new "Transatlantic Economic Partnership (European Commission, Directorate General Trade, 2007), According to the Office of the President (United States, 2005), the goal is: to build

effective mechanisms to promote better quality regulations and to minimize unnecessary regulatory divergences to facilitate transatlantic trade and investment and increase consumer confidence in the transatlantic market.

The overall framework for the partnership is set forth in the Guidelines for Increased Regulatory Cooperation and Transparency (United States Trade Representative, 2002). The US-EU High-level Regulatory Cooperation Forum was organized under the framework provided by the Guidelines (Office of the President 2007; European Commission, 2007) to implement regulatory convergence.

The Regulatory Forum is focusing on three areas for enhancing regulatory cooperation, medicinal products, transportation safety and consumer protection (US Department of State 2003). The Forum is also carrying a review of the regulatory processes under the "how we regulate" program. The US Director of the Office of Management and Budget represents the US and the European Commission represents the European Union in these discussions (United States Trade Representative, 2005).

The Regulatory Forum is charged in part with reviewing administrative basic procedures on both sides of the Atlantic and then identifying the best practices that should be adopted by both regions. The gaps though are relatively large. Administrative practices in the US emphasize procedural commitments through statutes such as the Administrative Practices Act. The emphasis in the EU is on policy strategies. Their formal commitment to the "precautionary principle" is one example.

The US-EU Regulatory Forum is also charged with promoting regulatory harmonization at the agency level. A formal exchange of experts is one tool for promoting this goal. For example, European experts are assigned to work in the FDA, for example, and American experts may work in DG Health and Sanitation.

In some cases, industry groups are actively lobbying different government to promote international convergence. The Transatlantic Business Dialog is a coalition of European and US business representatives who work to bring a business perspective to the work of the regulatory Forum (Transatlantic Business Dialog 2006) A parallel organization, the Trans-Atlantic Consumers Dialog, brings a more critical perspective to the work of the Forum (Transatlantic Consumer Dialog, 2007).

Business groups are also promoting international regulatory convergence independently of the US-EU framework. The Global Harmonization Task Force for example, is an international effort led by trade associations in the US and EU to promote international convergence in the technical requirements governing medical devices (Global Harmonization Task Force, 2000) Although these initiatives are very useful, they will not overcome the barriers created in national differences in units of measure, material specifications and in areas such as basic pressure vessel and electrical safety requirements.

Overall though, the provisions of the TBT that encourage international convergence are not likely to have much impact on legacy standards and conformity assessment procedures. Standards in both the US and EU are generally going to be developed on the basis of these legacy systems. Joint efforts, such as the Transatlantic Regulatory Forum and the TABD, are excellent efforts, but they these initiatives are a long way from addressing the problems of harmonizing existing standards and conformity assessment arrangements. These initiatives are also outside of the TBT framework and do not represent general commitments from the international community.

In short, any hope for general convergence in the short term is likely to be fruitless. If international convergence in national standards, technical requirements and conformity assessment procedures is unlikely to occur, then has the TBT been an exercise in futility?

5. A modest proposal

Other provisions of the TBT are likely to provide a stronger basis for trade liberalization. Under the terms of articles 2.7 and 6.1, signatory countries are pledged to recognize the equivalencies of foreign standards, technical requirements and conformity assessment procedures, if it is feasible to do so. (World Trade Organization, 2007, Technical Barriers to Trade Agreement).

An emphasis on equivalencies would bypass the problems associated with efforts to harmonize standards, technical requirements and conformity assessment requirements. National standards development associations and regulatory agencies on both sides of the Atlantic could continue with business as it has always been done. However, trade would not longer be affected by these differences. For example, the US would accept CE marking as an acceptable alternative to UL certification and the EU would accept UL certification as an alternative to CE marking .

An administrative structure would have to be developed to allow for the identification and recognition of equivalencies. The parties managing the various conformity assessment processes would have to state what types of issues are addressed by their mark. In the US, certification marks might address product performance, safety, environmental impact, quality, and equipment compatibility. A UL mark assuring electrical safety on a heart-lung machine would mean little if the machine did not otherwise perform properly.

The managers of the conformity assessment marks (including the CE mark) might also have to specify the basis on which the certification was carried out. Some of the alternatives might be manufacturer's self-assessment, a third party design review or a full testing of the product.

Finally, the presumption that certification marks from different countries provide equivalent levels of product assurances would have to be rebuttable. There would have to be some forum and process for determining whether assertion of equivalency was, in fact, accurate. The presumption of equivalency could only be set aside on the basis of positive evidence that the systems being compared, in fact, did not offer the same general levels of protection. Addressing the task of proving (or disproving) the equivalencies of various conformity assessments and certification processes could provide very useful information about the relative effectiveness of different regulatory strategies. This obligation of proof would have to apply to governments as well as individuals. No country could reject an assertion of equivalency without some show of relevant evidence.

For this system to work, an agency such as ISO would have to develop the standards that would define these terms, specify the minimum acceptable procedures and provide some assurances that the definitions and requirements were being used in similar ways in different countries. The work being done by the US-EU Regulatory Forum on best practices in administrative regulation could be very useful here.

An emphasis on establishing equivalencies rather than encouraging convergence would not work in all circumstances. In some cases, governments issue technical requirements as a means for forcing new the development of new technologies. In the US, for example, the corporate average fuel economy standards were intended to encourage auto makers to develop more fuel efficient cars. In the EU, the RoHS requirements were also been intended to force the development of new products that did not include the banned substances. Unless different countries were to adopt similar goals for technology forcing, equivalencies in these areas may be hard to find.

This approach may also be less effective when comparing national regulations of pharmaceuticals and medical devices. For most manufactured products, the goal is to assure product safety. The issue of whether the product actually works or not is largely irrelevant to everyone but the purchaser. In the medical area though, the regulators have to balance the medical benefits against the risks in using the device. They also have to assess the potential costs and benefits of the device against the costs and benefits of what is currently on the market. As the task of weighing risks and benefits becomes more complex, the prospects for accepting the equivalence of regulatory alternatives become more remote. This is especially likely if the medical device regulatory agencies in the different countries strike the balance between risk and effectiveness in different ways. In the US, for example, the FDA is notoriously risk adverse which the regulatory authorities in the EU tend to be more client friendly.

Overall though, we believe that a greater emphasis on establishing the equivalencies of different systems is more likely to liberalize trade than the present emphasis on promoting regulatory convergence.

References

Atkins R. (2007), *China Exports to the EU More than the US for the First Time*, Financial Times, March 23, p. 4.

Bonay B. (1983), *Protectionism: Challenge of the Eighties*, Union Bank of Switzerland, Zurich.

Bounds A. (2007), *US and EU to Set Dates for Transatlantic Trade Zone*, Financial Times, February 20, p. 2.

Chen M., Otsuki T., Wilson J. (2006), *Do Standards Matter for Export Success?* World Bank Policy Research Working Paper WPS 3809.

Egan M. (2001), *Constructing a European Market*, Oxford University Press, Oxford.

European Union, Directorate General Enterprise (1993), Directive 93/42of the European Parliament and of the Council on Medical Devices.

European Union, Directorate General Enterprise (1999), Guide to the Implementation of Directives Based on the New Approach and the Global Approach to Regulation (Brussels, European Commission).

European Union, Directorate General Environment (2002), Directive 2002/95/EU on the Restrictions of the Use of Hazardous Substances in Electrical and Electronic Equipment.

European Union, Directorate General for Trade (2007), United States Barriers to Trade and Investment: Report for 2006, Brussels.

Global Harmonization Task Force (2000), GHTF Guiding Principles, GHTF/AHPG/NIR7: 2000.

Hanson D. (2005), *CE Marking, Product Standards and World Trade*, Edward Elgar, Cheltenham.

Hanson D., Manchego G. (2006), *A Global Perspective of Regulation and Standardization*, Standards Engineering vol. 45(6), p. 3.

ISO (2004), ISO/IEC Code of Good Practices in the Preparation, Adoption and Application of Standards, ISO, Geneva.

ISO (2007), ISONET Directory: About ISONET, at wssn.net/WSSN/RefDocs/issndir/introduction, html.

United States, National Institute for Standards and Technology (2007), NIST Technology Services: National Center for Standards and Certification Information, at ts.nist.gov/Standards/Conformity/ncsci.cfm.

United States, Office of the President (2005), The United States and the European Union Initiative to Enhance Transatlantic Economic Integration and Growth, The White House, Washington DC.

United States Congress, Office of Technology Assessment (1992), Global Standards: Building Blocks for the Future TCT-512, US Government Printing Office, Washington DC.

Organization for Economic Cooperation and Development (2000), An Assessment of the Costs for International Trade in Meeting Regulatory Requirements, TD/TC/WP (99)8/Final.

Organization for Economic Cooperation and Development (n.d.), Consumers, Product Safety Standards and International Trade, OECD , Paris.

Transatlantic Business Dialog (2006), Towards a Barrier-free Transatlantic Market: Report and Recommendations to the 2006 EU-US Summit Leaders, Washington DC.

Transatlantic Consumer Dialog (2007), Position Paper and Resolution on Horizontal Regulatory Initiatives in EU-US Regulatory Cooperation, Washington DC.
United States Department of State (2003), US-EU Cooperation on Regulatory Affairs: Charles P. Reis Testimony before the Senate Foreign Relations Committee, Subcommittee on European Affairs, Washington DC.
United States Food and Drug Administration (2007), Search Classification Database, at accessdata.fda.gov/scripts/cdrh/cfdpdc/ classification.cfm.
United States Government (1995), National Technology Transfer and Advancement Act, P.L. 104-113 of March 7, 1995.
United States Trade Representative (2002), United States and European Commission Agreement on Guidelines for Increased Regulatory Cooperation and Transparency. Washington D.C.
United States Trade Representative (2005), Roadmap for EU-US Regulatory Cooperation and Transparency, Washington, DC.
World Trade Organization (2006), Agreement on Technical Barriers to Trade.