3. TTIP'S HARD CORE: TECHNICAL BARRIERS TO TRADE AND STANDARDS

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1. Introduction and structure

The Transatlantic Trade and Investment Partnership (TTIP) is viewed as the single most-important trade deal undertaken by the US and the EU. The two partners have undertaken it in response to the changing geopolitical environment, resulting from, among other things, the stalled Doha Round of multilateral trade negotiations, the rise of Asia and Asian regionalism, and the economic slowdown and sovereign debt crisis. Although the deal is expected to promote jobs and growth and strengthen existing economic ties, the prospect for an ambitious preferential trade agreement is also derived from building on earlier initiatives and experience to promote trade, regulatory and financial cooperation between two economies that are highly interdependent (Hamilton, 2014; Pollack & Shaffer, 2001; Egan, 2005).

The progressive elimination of tariff barriers has shifted attention. The import-weighted tariffs have been reduced over time to less than 4% (with many tariff lines being zero), so the issue in many traditional regional free trade agreements (FTAs) is no longer tariffs, but rather technical barriers to trade (TBTs). These barriers consist of standards, technical regulations and conformity assessment procedures that have emerged in different administrative bodies and standardisation organisations at domestic, regional and international levels, often independently from one another, thereby creating duplicative costs of compliance (see Box 3.1). Standards are usually developed by private standards development organisations (SDOs), to avoid redundant variety (e.g. of components), for compatibility, but also to ensure the health, safety and quality of products, as well as

processes, production methods and other related technical matters. They can define a specific design or performance characteristics, determine performance criteria, or provide guidelines and definitions (NRC, 1995).

Standards are formally voluntary when adopted, but can acquire legal effect when 'referenced' in legislation, or may become dominant in the marketplace through widespread acceptance. Conformity assessment methods and procedures are used to assess whether a particular material, product, or process conforms to a specified standard. Conformity assessment bodies, which can be public or private entities, include testing, certification and inspection organisations. When technical standards are integrated into regulatory requirements, they can create or enhance technical barriers to trade, due to differences in performance, design, testing, and certification measures. Since these requirements are indispensable for entering their respective markets, it can lead to extra costs as the imported product has to be tested and certified acceptable or safe, or, in other words, meet specific safety, health, environment and consumer (SHEC) protection objectives.

TBTs do not concern the level and scope of regulation, i.e. SHEC objectives, but rather reduce the costs of given regulatory differences of instruments that impact market access. Such differences have become a central issue in the ongoing US-EU trade negotiations, so that standards and conformity assessment practices on both sides of the Atlantic remain one of the greatest challenges in TTIP. Removing or reducing the cost of such transatlantic TBTs is likely to result in possibly significant economic gains – which may vary by sector – but this does not mean that regulatory objectives in terms of levels of SHEC protection will diminish, as asserted – without any justification – in social and conventional media as well as stakeholder meetings. At issue are differences in instruments, methods or testing to meet given, specified objectives.

The chapter proceeds in section 2 to establish the significance of TBTs that stem from standards, testing and conformity assessment practices for the costs of international trade and the particular challenges of resolving them. The prior transatlantic efforts to address them are considered in section 3 and the scope of the TTIP TBT approach is addressed in section 4. Section 5 outlines the standards regimes and their respective legal and policy differences in order to illustrate the areas of contention for the ongoing TTIP negotiations. Section 6 shows how these regime distinctions impact bilateral trade

and section 7 focuses on the current state of negotiations in TTIP. The chapter concludes by elucidating the prospects and implications for achieving some form of agreement on TBT issues.

Box 3.1 TBT definitions for understanding TTIP negotiations

A *technical regulation* lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method (Annex 1, TBT Agreement).

A *standard* is a document approved by a recognised 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. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method (Annex 1, TBT Agreement). A technical standard is written by standard bodies and is always voluntary, whether in the US, the EU or elsewhere. This suggests that standards should not normally be regarded as a TBT. Although this is often correct, there are instances where different (voluntary) standards amount to barriers (e.g. no compatibility, requirements for insurance, etc.), that is, they raise the costs of effective market access. Most standards written by standard bodies are purely market-driven, for reasons which market players, including consumers, are expected to appreciate. The principal reasons why standards are advantageous (see Pelkmans & Costello, 1991; Swann, 2010; Blind, 2013) include:

i) well-defined information on measures, weights, or a host of other technical 'codes' which reduce the costs of information for engineers, designers, etc., whilst avoiding confusing differences for technicians;
ii) well-defined codification of certain quality features of goods (including intermediate goods, parts, components) – quality *can* of course include aspects of goods serving safety, health of consumers or workers, environment and/or consumer protection (and often will because markets appreciate it);
iii) agreed specifications needed for interoperability or compatibility of intermediate or final products; and
iv) agreed ways to reduce clear redundancy of variety in order to facilitate economies of scale.

Industry spends resources to write standards, because they want markets to function better and codify new technologies or production solutions, while also allowing variety to ensure competition, innovation and coordination across firms, sectors and supply chains.

An *international standard* (or guide or recommendation, as the World Trade Organization specifies) is widely understood as a standard issued by world bodies such as the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU), except in ICT where other consortia often play a role. The WTO TBT Committee has defined a set of six *principles* for determining whether a standard is 'international': openness, transparency, impartiality and consensus, relevance and effectiveness, coherence and the development dimension (see, e.g. USTR (2014), 2014 Report on TBTs, pp. 25-26).

Conformity assessment procedures are any procedure(s) used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled (Annex 1, TBT Agreement).

2. The meaning of TBTs for trade

Unlike conventional trade restraints, such as voluntary export restraints, quotas or tariffs, technical barriers to trade (TBT) that include conformity assessment procedures are not explicitly designed as trade protection measures to restrict market access and shield domestic markets from competition (Budetta & Piermartini, 2009). Although they are not explicitly discriminatory, as exporters may meet local, national or regional technical standards, regulations and conformity assessment procedures to achieve market access so that the same rules apply to both domestic and foreign products, this tends to impose disproportionate costs on foreign producers that have to conform to different sets of rules and requirements for different markets. Duplicative testing and certification can also constitute a barrier to trade, as this increases costs in meeting the administrative requirements, as well as testing and certification procedures in the importing country, and if different, it places foreign firms at a competitive disadvantage in comparison to domestic firms. Governments and industries may define specific requirements that provide strategic advantages to certain industries or firms.

Germany has recently imposed additional administrative requirements on the sale of pyrotechnic products, as the Federal

Institute for Material Research and Testing (BAM) has required an additional notification fee, and user amendments, beyond that of the EU Pyrotechnics Directive. Since the Directive applies in the automotive sector for safety restraints such as airbags and seatbelts, the issue has become a technical barrier to trade for other car manufacturers, resulting in EU infringement proceedings against Germany. In the US, the slow pace of approval for sunscreen ingredients by the Food and Drug Administration (FDA) has led to applications pending for 12 years, due to the cumbersome regulatory process that has thwarted new European products from accessing the market despite their widespread approval and use in Europe and Asia.[1]

Companies often have to make design or manufacturing changes to sell in both European and American markets, or, especially for SMEs, forego market access due to the costs of adaptation, or perform redundant and duplicative testing to demonstrate compliance with both sets of rules. Differences between toy safety standards, for example, cost $3 billion annually despite the relative convergence of many of the design and testing specifications, which has led both sides together to promote a presumption of equivalence, so that toys compliant with either the US or European standard would be considered 'safe'. This would still allow each jurisdiction to determine the means to establish conformity to lower the costs of two-way market access.[2]

TBTs may take many forms in actual practice and many variations of such forms, often specific to sectors. If differences are slight and procedures light, the costs of TBTs may be small and little might be heard about them. However, the typical TBTs long discussed in transatlantic regulatory fora and exchanges are costly and influence more than marginally the costs of market access. It is exceedingly hard to estimate authoritatively the costs of TBTs (see Berden & Francois, 2015, chapter 4 in this volume), but the TBTs relevant for trade negotiations in bilateral FTAs carry costs equivalent to anywhere from 10% to 80% of the invoice price. This means that, in such sectors, the

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[1] The Sunscreen Approval Act was signed into law in 2014, amending Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.). The Public Access and Sunscreen Coalition (PASS) lobbied hard for the regulatory changes during the FDA review process.

[2] Comments Concerning Proposed Transatlantic Trade and Investment Agreement (Docket number USTR-2013-0019) from Toy Industry Association and Toy Industries of Europe.

full removal of tariffs does little to open up markets because TBTs might entail multiple tariffs and thus render market access quite – or even very – costly, or, for SMEs, simply impossible.

The TTIP negotiations are, however, embedded within a larger context of recent and concurrent trade negotiations involving the US or EU as negotiating partners. Not surprisingly, both sides have exhibited a willingness to advance their trade interests through bilateral FTAs with the larger goal of promoting trade, market access, investment and development. Both sides have separately pushed for stronger market-opening commitments from third countries as bilateral and regional trade agreements have become their preferred trade strategy. To that end, the EU has indicated that it will play a leading role in sharing best practice and developing global rules and standards as well as promoting convergence towards EU or international standards in select policy areas (see European Commission, 1996).

The US has also engaged in a similar strategy to implement WTO TBT commitments, supplemented with technical assistance, and sector specific provisions (see below) (Lesser, 2007). But what adjustment costs are they willing to make when the trade giants are negotiating with each other? Whose standards or, more specifically, regulatory requirements will prevail? Or indeed, should one necessarily prevail, or would 'equivalence' be an option to pursue? Should the US and the EU renew their efforts to improve and extend their 1998 Mutual Recognition Agreement (MRA), which works only for some of the six industrial sectors selected? Their differing regulatory policies in some specific areas have been the constant target of trade disputes, resulting in the US and EU being the most prolific initiators of complaints in the WTO (Young).

3. Prior transatlantic efforts at addressing TBTs

Over the past 20 years, the US and EU have engaged in a variety of efforts to foster transatlantic regulatory cooperation with many pre-existing dialogues, initiatives and commitments (Barker, 2013; Lester & Barbee, 2013). While there are differences between the US and EU that matter for TTIP, collaboration has evolved as the product of prior efforts at promoting trade and investment cooperation. One has to acknowledge that the optimism of the mid-1990s, when it was thought that a relatively simple and 'light' approach such as an MRA in several industrial sectors would be a quick route to lowering the costs of EU/US TBTs, was largely mistaken. An MRA aims to accomplish the acceptance of all relevant aspects of conformity assessment of the

trading partner for the purpose of testing and certifying export goods on the requirements of the importing economy. It works for telecom equipment and EMC (electromagnetic compatibility of equipment) but not for medical devices, GMP in medicines or electrical goods and machinery (a huge sector).

On both sides lessons have been learned about how difficult the creation of a New Transatlantic Marketplace (NTM), deemed in 1995 to be feasible, would be, given the many problems in implementing MRAs in providing effective market access. Moreover, it was also better realised that MRAs are a rather heavy construction for a relatively minor cost advantage: even with a well-functioning MRA, the main reason for TBT costs (regulatory differences and requirements) remains intact. Consequently, regulatory cooperation since 2002, and more so since 2007 in the framework of the Transatlantic Economic Council (TEC), has deepened mutual understanding and also helped to develop practical forms of regulatory cooperation, without formal obligations, linked in cases like medical devices and medicines to global fora of regulators.[3] Moreover, the TEC has emphasised the pre-emption of TBTs in new or emerging product markets or in new technologies (such as electric vehicles). The TTIP TBT chapter is meant to decisively move beyond this status quo and genuinely address the cost of TBTs.[4]

Both sides have struggled to coordinate their administrative approaches, with early warning systems,[5] mutual recognition agreements, exchanges of information, as well as the adoption of broad regulatory principles and guidelines.[6] The two administrative cultures have fundamentally different market and regulatory regimes, which has led to many proposals that, unfortunately, have failed to promote the expected regulatory coherence (Nicolaïdis & Egan, 2001). Nevertheless, in some special instances, there are success stories in transatlantic regulatory cooperation, such as the 2009 EU/US certification of aircraft agreement, the EU/US Veterinary Agreement

[3] For a detailed analysis of MRA implications for TTIP, see Pelkmans & Correia de Brito (2015).

[4] On regulatory cooperation, see Chase & Pelkmans (2015).

[5] http://useu.usmission.gov/062199_report_bonn.html.

[6] http://trade.ec.europa.eu/doclib/docs/2011/july/tradoc_148030.pdf.

(see Josling & Tangermann, chapter 9, in this volume) and the 2012 agreement on organic farming recognition.[7]

The US-EU High Level Working Group on Jobs and Growth (HLWG) laid out its goals regarding transatlantic trade barriers, emphasising the importance of preventing future barriers to trade as well as addressing the current divergences that impede cross-border trade (US-EU High Level Working Group on Jobs and Growth, 2013). The report focused on broad goals in addressing technical barriers with the inclusion of a 'TBT plus' chapter, building on horizontal disciplines in the WTO Agreement on Technical Barriers to Trade, including establishing an ongoing mechanism for improved dialogue and cooperation for addressing bilateral TBT issues, which is not unique to the transatlantic free trade negotiations. The HLWG also promotes greater openness, transparency, and convergence in regulatory approaches and requirements and related standards-development processes; reduces redundant and burdensome testing and certification requirements; promotes confidence in the respective conformity assessment bodies; and enhances cooperation on conformity assessment and standardisation issues globally. The goal is to strengthen horizontal cooperation among regulators through early consultations, impact assessment, upstream cooperation and good manufacturing practices to prevent unnecessary costs and delays, and to enhance cooperation on standards-related issues.

In February 2013, both sides announced they would embark on an FTA together after a decade of competitive liberalisation in which they sought to disseminate new rules in international trade and employ free trade negotiations to establish closer economic links with security partners or use them to isolate economic competitors by excluding them from economic cooperation agreements negotiated with other nations. While many observers felt that TTIP would have an easier time in soliciting agreement than other recent trade agreements, the reality has been more complex. In an FTA, trade negotiations typically seek least trade-restrictive rules and procedures, and not the codification of existing practices. The legal basis of GATT/WTO rules for regional trade agreements (RTAs) (Art. XXIV.5) allows for RTAs as a special exception provided a) duties and other trade regulations of commerce are reduced on or removed from all trade and b) the RTA does not raise the overall protection vis-à-vis other WTO members.

[7] See Chase & Pelkmans (2015) for an annex with all US-EU regulatory cooperation initiatives since the mid-1990s.

While the US and EU have been the main proponents of WTO-plus commitments in RTAs, with both conditional and promotional elements that include incentives, sanction and monitoring, they differ on what should be included as part of a gold standard agreement for TTIP.[8] Though the TBT, SPS (sanitary and phytosanitary) and GATT Agreements provide a source of discipline regarding technical barriers to trade, the multilateral agreement on Technical Barriers to Trade (TBT) seeks to ensure that technical regulations, standards and procedures for assessing conformity do not create unnecessary obstacles to trade. It requires that applicable regulations are transparent, justifiable, non-discriminatory and based on international standards whenever possible. However, in terms of their respective FTA templates, they have varied in terms of their approach. The US follows a standard template focused on fairly light WTO-plus commitments whereas the EU is more varied, although both have included additional issues focusing on governance rather than trade (Baldwin, 2015).

Despite various calls to phase in different elements of the agreement, the US has steadfastly focused on a comprehensive agreement. However, there have been disagreements within the US about the coverage and inclusion of issues in any negotiated agreement, providing a stark reminder of the need to address different domestic constituencies. Congressional demands have focused on opposition to broadening of 'geographical indications', on the maintenance of 'buy American' and 'buy local' provisions, and on the improvement in biotechnology approval, thereby providing a stark reminder of the need to address different domestic constituencies. There is also resistance from some regulatory agencies about their inclusion in the talks. While the US pushed for the exclusion of financial services at the behest of the Treasury and SEC, the FDA has sought to undertake regulatory cooperation with the EU outside of the TTIP negotiations (Inside U.S. Trade, 18 July 2014 – www.insidetrade.com). In the EU, there has been concern over the impact of TTIP on food and safety issues and medicinal products. Therefore, the EU is keen to negotiate

[8] For example, the US did not want the inclusion of competition policy and so instead promoted the idea of the International Competition Network (ICN), which was accepted but differed from the initial EU preference to include competition and binding principles, e.g. most favoured nation (MFN), cartels and other non-binding principles such as vertical restraints.

both a healthcare and SPS chapter as well as addressing regulatory cooperation on medical devices.

4. TBTs in TTIP: What sectors and why?

TBTs addressed in TTIP are not confined solely to the TBT chapter; they are dealt with in four different contexts:

i) the TBT chapter as is traditionally the case in most FTAs;

ii) issues of food safety and animal and plant health (which are dealt with separately in a SPS chapter, based on the WTO SPS Agreement);

iii) the sectoral sub-chapters or annexes (as proposed in TTIP on chemicals, cosmetics, engineering, medical devices, ICT, pharmaceuticals, textiles, and automotive);

iv) a chapter on horizontal regulatory cooperation in TTIP, with a view to future questions in a 'living agreement', which is a continuous process of addressing regulatory barriers to enhance cooperation.

The economic gains from any agreement have received significant attention. The headline figures are of annual GDP gains of €119 billion for the EU and €95 billion for the US derived from two key economic studies on EU/US trade liberalisation commissioned by the European Commission.[9] The economic study by Francois et al. (2013)[10] for the Commission Impact Assessment of TTIP deals with all these segments of TBTs, though measuring the costs of TBTs with some degree of reliability is exceedingly difficult. Francois et al. (2013) is based on ECORYS estimates of 'tariff equivalents' of TBTs, i.e. regarding the TBT costs as equivalent to an import tariff. These costs (in percent of the invoice price, like a tariff) are no less than 21% (EU

[9] See Berden & Francois (2015) for an overview; the U.S. International Trade Commission (ITC) conducted a confidential investigation on the potential economic effects of providing duty-free treatment for US imports from the EU, pursuant to Section 131 of the Trade Act of 1974 (19 U.S.C. 2151) and Section 2104(b)(2) of the Trade Act of 2002 (19 U.S.C. 3804(b)(2)) which it submitted to the USTR in September 2013.

[10] See http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf; see also Pelkmans et al. (2014), for a non-technical explanatory study for the INTA Committee on the Francois (or CEPR) report, underlying model and alternatives estimates.

TBTs for US exports) and 25% (US TBTs for EU exports) on average, with peaks for agro-food (respectively, 57% and 73%), and fairly high TBTs for automotive (25% and 27%), chemicals (14% and 19%), electrical machinery (13% and 15%), other transport equipment (19% and 19%) and metals and metal products (12% and 17%). All these TBT costs are much higher than transatlantic tariffs. By contrast, Fontagné et al. (2013), using a different technique in which the average TBT costs for manufacturing are much higher, with costs amounting to 43% (EU TBTs) and 32% (US TBTs), suggest that the reports result in robust findings on the economic benefits of addressing TBTs.[11]

In addition, strictly regulated sectors such as medicines, automotive, chemicals and cosmetics do not fall under the TBT chapter. In the EU, none of these sectors fall under the New Approach (New Legislative Framework), thus voluntary standards are not used for the simple reason that regulation is highly specific and intrusive while conformity assessment typically relies on pre-market type approval and inspections. However, in engineering (including machinery), there is a preponderant reliance on the 'new legislative framework' that allows compliance with European standards to provide a presumption of conformity in the European internal market.

In the US, Congress appears keen to promote third-party verification, having mandated or authorised its use in recent legislation including the 2011 Food Safety Modernization Act, which strengthened authority to regulate imported food by recognising accreditation bodies to accredit third-party auditors to certify foreign food facilities and imports. In some areas, Congress has directed federal agencies to develop a third-party programme; in others, regulatory agencies have developed programmes under existing statutory authority. In medical devices, there is mandatory pre-market notification (unlike in the EU) and inspection of facilities, whereas cosmetic products do not require preapproval, with some exceptions in terms of colour additives by the FDA. Besides these four sectors with specific annexes, there are of course other sectors and specific goods that may encounter TBTs when trying to access the US or EU market. Thus the TBT chapter attempts to organise a framework to address existing TBTs as well as pre-empt new ones. TTIP also contains a horizontal regulatory cooperation chapter

[11] Berden & Francois (2015) suggest several reasons why Fontagné et al. (2013) might show an upward bias.

aimed at providing greater regulatory coherence and joint governance on issues pertaining to TBTs.[12]

The goal is to promote common principles and good regulatory practices, providing for mutual exchange of information through notice and comment procedures, which can involve stakeholders, and discipline both governments to take account of the trade and investment effects of future regulations. A Regulatory Cooperation Body would be established to identify common priorities, negotiate follow-up draft agreements for discussion and adoption in the respective EU and US legislative and regulatory processes, and implement regulatory provisions of agreement in both goods and services.[13]

5. Understanding US and EU standards and related regulatory regimes

The US and EU have each developed a set of procedures and policies to regulate goods and processes that have resulted in different technical standards and conformity assessment procedures that can be viewed as potentially significant barriers to trade (Pelkmans, 2015). As long as regulation is not linked to standards, the goals are fundamentally similar in that standards reflect market needs and are not simply about techniques or engineering but about improving the functioning of markets (see Box 3.1). However, owing to differences in their origins and development, both sides use private standards in their existing legislation as a means to demonstrate conformity with mandated laws and statutory requirements. In Europe, national governments have established close ties with private standards bodies, often providing public funding for specified 'public' assignments, resulting in a system that recognises a *singular* standards body (per country), which may be autonomous under private law, as a private or non-profit, independent

12 http://trade.ec.europa.eu/doclib/docs/2015/february/tradoc_153120.pdf; see also Chase & Pelkmans (2015).

13 Though not the focus of this chapter, there have been widespread efforts at regulatory coordination, not just across sectors, such as marine safety equipment or consumer products in terms of safety recalls, but also efforts between OMB-OIRA and the Secretariat General of the European Commission to address methodological issues, i.e. related to good regulatory practice, such as impact assessment, stakeholder consultation, etc., in order to improve the understanding of each other's regulatory systems and practices.

or public agency regulated by government statutes (Egan, 2005; Bremer, 2015).[14]

These national standards bodies are then part of a Europe-wide network that creates European standards through CEN, CENELEC and ETSI. In the US, the government took a more informal approach towards collaboration with standards bodies, and the result has been multiple standards development organisations (SDOs), creating a highly decentralised and fragmented system. Though some 200-plus are accredited by the American National Standards Institute (ANSI), an umbrella organisation that brings together standards bodies, conformity assessment bodies, companies and government agencies, there are other SDOs, consortia and fora outside of ANSI, which can also develop their own standards. Although ANSI is a member of ISO/IEC and provides a platform for promulgating standards, there are no officially recognised standards bodies. Standards are developed primarily in the private sector, predominantly by a handful of independent standards bodies that are autonomous and do not receive government funding.

Though ANSI is often viewed as the coordinating umbrella for US professional and trade associations engaged in standard-setting, ANSI does not develop its own standards. ANSI does not determine which standards should be developed but provides a coordination and accreditation function among the various bodies. Thus many prominent standards are developed by a fairly limited number of independent bodies in the US, including ASME, the National Fire Protection Association (NFPA), ASTM and IEEE – perhaps a dozen or at most two dozen in all, which also have a recognised status in many markets in the world. In addition, there are many small or highly specialised sectoral bodies, sometimes even competing on standards. It is estimated that there are 600 standards bodies in the US with more than 100,000 private standards currently in use (Bremer, 2015: 28). The US ITA has defended this system as providing "technological innovation", with proponents arguing that it is "open and accessible" (International Trade Administration, 2009: 2).

Both the US and EU use private technical standards in their regulations to support government mandates. Both have established

[14] Note that the EU countries with public agencies for standardisation are typically former communist countries – the West/North European standardisation tradition is strictly private (industry).

procedures for the public use of private standardisation: the US policy is set out in a statute[15] and executive order,[16] and the EU's is outlined in an annual programme on European standardisation and delineated in a European regulation (No. 1025/2012). What occurs in both the European and American contexts is that standards are incorporated into regulations by reference, so that 'law-making' is not limited to public institutions. Incorporation by reference is the practice of codifying material published elsewhere by referring to it in the text of a regulation (Bremer, 2014). In the US, there is no obligation to have a single standard and any standard may be referenced, if the correct procedure for incorporation by reference is followed. Although this has resulted in more than 360 organisations providing voluntary standards for 26 federal agencies, 10 SDOs provide the majority of standards incorporated into public law (Bremer, 2015; NIST, 2013). In fact, federal, state and local agencies have to justify the development of "government unique standards" when a private consensus-based standard is available (Mendelson, 2013).[17] In terms of the possible misapplication of legal standards, in the US, the antitrust agencies act as enforcement bodies in ways similar to other business review bodies but not as adjudicators of the legality of standards development activity itself.[18] Thus, even if, as has happened, standard-setting provides commercial advantages for participants over competitors, congressional limitations and court decisions have prevailed, allowing private standards to be incorporated into public law (Sagers, 2004; Strauss, 2013).

In Europe, there is an obligation to eliminate all conflicting standards (CEN & CENELEC, 2013). The standards developed by the three European standards bodies are valid in all the EEA countries plus Turkey and Switzerland, and once adopted, member states must withdraw any existing national standard that overlaps or might compete with it. The European Standards Organizations, CEN,

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[15] See National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. No. 104-113, § 12(d), 110 Stat. 775 (1996)

[16] Office of Management and Budget Executive Office of the President, OMB Circular No A- 119.

[17] NIST notes that since the passage of the NCAA Act only 53 government unique standards have been proposed with voluntary consensus standards providing solutions for government legislative mandates.

[18] HR House Report 108-125, Part 1, 108th Congress, Standards Development Organization Advancement Act, 2003.

CENELEC and ETSI provide the standards to meet "essential requirements" (mainly, the technical expressions of SHEC objectives from specific EU directives or regulations) based on a contractual agreement with the European Commission through General Guidelines for Cooperation that provides specific designation to ESOs as monopoly providers. However, the so-called 'mandates' or 'requests' of the European Commission to CEN/CENELEC are full of obligations about verifying all relevant standards in the world, connecting with bodies outside the EU where this would be promising, involving non-EU expertise where relevant, etc. Although the European standards remain voluntary (unless they are US 'referred standards', which become compulsory), once 'harmonised European standards' have been accepted as fulfilling the 'essential requirements' and published by the European Commission, they give a 'presumption of conformity' with the relevant essential SHEC requirements, and thus free movement inside the single market.

In fact, free movement is granted to all goods having a CE mark – a symbol indicating conformity with EU technical laws – whether based on a harmonised standard or not. But the harmonised standard greatly facilitates conformity owing to the full access it allows to 28 countries in the EU single market, which is much appreciated by manufacturers. Note that EU member states do not have regulatory autonomy in areas where EU regulation has been enacted; again, in the US, the states often have regulatory discretion despite federal risk regulation, based on referred standards. It should be understood that such a European harmonised standard remains voluntary and a manufacturer is free to use another standard or present its own (innovative) solution to abide with the 'essential requirements' (basically, SHEC objectives), but in the latter case, the manufacturer has to go through third-party certification by a Notified Body (a recognised conformity assessment body).

This is critical in terms of good regulatory practices because what matters is that the SHEC *objectives* (essential requirements) are met properly, but the instruments or innovative other solutions of doing so are at best secondary, and hence should not be prescribed or restricted unnecessarily.[19] The European Commission has set out broad operating principles that encompass "transparency, openness, consensus,

[19] This system is based on Reg. 2008/765, Decision 768/2008 and Reg. 1025/2012 (the latter on European standardisation). See also the 'Blue book' issued by DG Grow of the European Commission.

independence of vested interests, and efficiency" through national representation. It has pushed the European standards bodies to be as inclusive as possible to ensure wide-ranging participation in technical committees with multiple stakeholders (in particular, SMEs, consumers and labour unions).

Many US government agencies use technical standards created by different American SDOs, and do not give preference to any specific standards bodies, in contrast to their European counterparts that require the adoption of European or internationally agreed standards. Federal law and executive policy have long required agencies to use available voluntary consensus standards instead of creating so-called 'government unique' standards solely to serve regulatory purposes. Currently, there are over 10,000 citations of standards in the Code of Federal Regulations. Over 80% of these references are private sector standards and more than 3,900 are government unique standards that have been replaced by private-sector standards.[20] These standards are rarely the result of government mandates, although this may change as a result of the changes proposed to the OMB Circular A-119, to allow agencies to solicit standards from qualified SDOs. [21]

While the US is deeply committed to private standards development, and although private standards outnumber public standards, the number incorporated into public law is relatively small. However, it was the dissatisfaction with the closed nature of standard-setting in the 1960s and 1970s that led to the expansion of federal consumer and safety protection through the creation of OHSA and CPSC, which pushed the private standards development bodies into reforms towards a voluntary consensus-based process built on the principles of transparency, due process, openness and the promise that standards would be agreed by consensus.[22] These changes allowed the federal government to use such voluntary standards in their federal regulations. Yet this masks the scope of private standards that are not incorporated by reference, and the degree to which statutory requirements allow government agencies ranging from transportation,

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[20] It should be noted that the government unique standards issue hardly plays a role in Europe, except in network industries (which used to be state-owned and not subject to competition, e.g. rail or telecoms infrastructure).

[21] *Source*: Author's interview with former USTR official.

[22] Allied Tube & Conduit Corporation v. Indian Head, Inc., and American Society of Mechanical Engineers v. Hydrolevel Corp.

energy, consumer protection, federal emergency management and homeland security, to participate in private standards development.[23]

Europeans have expressed concern when a designated private standard subsequently becomes part of US law; European suppliers find that few alternative methods or innovative solutions can be used or demonstrated to serve equally well the designated public policy objectives, unless alternative standards are specified in the regulation. Because multiple standards (may) exist, US regulators or federal government agencies choose the most suitable existing standard. This implies that, for an EU company, this system of 'incorporation by reference' risks creating many TBTs for EU exporters, the more so as few US standards are ISO/IEC standards anyway, and more than one referred standard may be encountered at different (US) levels of government. There are also concerns that once a standard has been incorporated by reference in agency rule-making, these can force the private sector to lag behind, as the vast majority of incorporated standards were adopted prior to the new rules outlined in the NTTAA.[24] Recognising that private standards can evolve, and thus that referred standards need updating, the US is trying to avoid continual notice, rule and comment efforts, by updating standards through statutory improvements. Agencies differ in approaches to updating standards referenced in their regulations. While OSHA issues *de minimis* violations to manage updated standards by regulated entities, the Coast Guard allows "equivalence" for an updated standard, and the Environmental Protection Agency updates final rule-making to incorporate changes proposed by SDOs (Bremer, 2013).

The intersection of public law and private standards has generated debates in the US about transparency and copyright issues resulting in tension between the public right to access the law and private intellectual property rights. The Pipeline and Hazardous Materials Safety Administration (PHSMA), asserting their copyright restrictions, refused to allow access to Congress, which then compelled PHSMA by statute to ensure that all its IBR standards were freely available online beginning in 2013. They were then revised, due to

[23] See National Technology Transfer and Advancement Act of 1995 (NTTAA); federal agencies participated in 552 SDOs according to NIST's latest report (2013).

[24] Several authors in criticising the incorporation by reference to standards indicate that many predate 1996 when the NTTAA was signed. This has been difficult to verify.

intense lobbying efforts about the revenue implications for SDOs. Due to the pressure for transparency, changes in administrative procedures have meant that US agencies must ensure the reasonable availability of incorporated materials and also summaries of those materials when standards are incorporated by reference (Strauss, 2013; Bremer, 2013).

6. How the US and EU standards systems impact trade

Europe's standards bodies have worked closely with the international standards bodies, the ISO and the IEC, based on the Vienna and Dresden Agreements which offer a framework for writing new ISO/IEC standards together with European ones, with the same (European) experts, in addition to experts from the rest of the world (including, often, US experts). Over time, this has gradually cumulated in no less than 72% of CENELEC standards being identical to IEC ones, and some 31% of CEN standards being identical to ISO ones. As long as standards – by definition voluntary – are not linked to regulations, European exporters and investors can live with the US landscape in which many standards – at least, from the dozen or so leading prestigious bodies – are well-known and often have a worldwide reputation through use in the marketplace. However, the US rarely adopts either fully or partially ISO or IEC standards, which can create disadvantages in electronic and electrical goods, including machinery, where safety and compatibility issues have been addressed internationally for decades.

However, a longstanding complaint, mainly from US companies but nowadays also from the combined EU and US ICT business sector (see DigitalEurope & (US) ITI, 2015), is that EU member state governments do not (always) recognise global ICT standards in their public procurement. Indeed, until changes were introduced to EU Regulation 1025/2012, governments were obliged to refer only to European standards and – since many global ICT standards are not formally ISO/IEC (or European) standards but developed (rapidly) in consortia or special ICT fora – numerous well-accepted ICT standards could not be listed in public procurement. Furthermore, because the sector is fast-moving, with continual innovation, industry preferred using alternative institutional frameworks rather than the designated European standards bodies.

In the US, the argument has traditionally been that as a technological leader, its standards were often those used in industrial

production. However, the result has been that in the Code of Federal Regulations (CFR), the US government has only referenced a limited number of ISO, IEC and ITU standards. Currently, of the 397 total international standards, the US references 172 from ISO, 156 from IEC, 25 combined ISO/IEC, 37 from ITU and seven from other bodies.[25] Some US standards promulgated by well-known US engineering societies, such as ASTM (which alone has written some 12,000 standards!), are de facto world standards, e.g. for aircraft, computers, power grids, cars, etc., and, in these cases, multinational businesses (including many EU companies) are used to living with two standards.

Usually, two reasons are given for US reluctance to adopt international, i.e. ISO and IEC, standards. The first is that historically, the Europeans have had many votes (when voting together) and the US has only one single vote, creating a permanent fear of being outvoted, especially in the first decades of the ISO. This argument has weakened a great deal because ISO/IEC membership is now worldwide and the EU cannot dominate such an international organisation.[26] In fact, ANSI has whether ISO/IEC standardisation is still subject to block voting by CEN/CENELEC members and found that it is no longer the case. Second, it is asserted that ISO/IEC standards are often too much of a compromise, and US bodies feel they ought to deviate for quality reasons, or promulgate their own. Much more important, it is also difficult and very costly to alter engineering traditions built on familiar standards. The issue of adjustment costs and enormous structural change in designs, production lines, materials, etc., for literally thousands of companies (and not just US multinationals but local ones in numerous countries) would seem to be the root of EU/US friction in the debate over the use of 'international standards'.

The key US standard bodies with an international reputation see their standards used by many companies all over the world. For some of these bodies, their standards are used in local production or in segments of global value chains in more than 100 countries, by thousands of multinationals and SMEs. Even in Europe, there are a large number of 'American' standards in use in markets simply because they are of high quality and usually highly specialised, although they

[25] Two under American National Standards Institute, two under European Standards, two under International Civil Aviation Organization and one under International Maritime Organization.

[26] IEC has 60 members and 23 associate members; ISO has 163 members.

need not always be related to regulation. In the economics of technical standards, this property is called the 'installed base', having (a) enormous 'sunk costs' and (b) formidable 'switching costs', that is, immense adjustment costs when changing to alternative standards (say, IEC/ISO standards).[27] It is first of all crucial that this property and its economic consequences are spelled out far more clearly in the TBT debate in TTIP. Expecting US standards bodies to adjust and radically rewrite their (many) standards, if markets have long embraced them, will be pointless if there is no sense of whether ISO or IEC standards are in fact superior. The degree to which many of these American standards are de facto global standards or, alternatively, compete with similar IEC/ISO standards is not known or analysed authoritatively. To the extent they are truly global, there would be very large adjustment costs for (US and other) companies or value-chains when switching would become the norm. These are exceptionally difficult issues to address.

It is counterproductive for the TTIP negotiators to keep on talking in abstract generalisations about what exactly an 'international standard' is and is not, without publicly recognising fully the economic and market issues underlying the positioning and without seeking a constructive long-term way out of this gigantic 'installed base' issue. Nevertheless, it is and remains true that the very idea of standardisation is to do away with multiple specifications, as long as this can be justified, because a *single* high quality technical standard will, more often than not, be of formidable long-term economic benefit. Following the 'one standard, one test, valid everywhere' which was advocated by the Transatlantic Business Dialogue (TABD) more than 20 years ago, at long last some longer-term and credible forms of accommodation must be found and, if possible, begin to be recognised in TTIP regarding TBTs.

Sometimes standards bodies also act as conformity assessors, mixing up the two functions and risking conflicts of interest. Conformity assessment may present the largest and least understood obstacle to trade. The many NTB notifications in the WTO seems to suggest it, in spite of the TBT Code Agreement encouraging the acceptance of conformity assessment procedures, provided that they conform with equivalent technical regulations or standards equivalent

[27] In the economics of network standards, the examples are typically different, say, a rail infrastructure network or high-voltage transmission system, having very high sunk costs. The economic idea is the same.

to their own procedures. However, there are differences between the US and the EU with respect to conformity assessment, in particular when components or final products have to demonstrate conformance with a prescriptive regulation (often based on 'referred standards').

While the EU uses supplier declaration of conformity (SDoC), the US is more likely to use third-party testing, inspection and market surveillance as a prerequisite for market access, so that mutual recognition is difficult given the different forms of conformity assessment. Of concern in Europe is that conformity with EU essential SHEC requirements are not tested or certified in the US; rather, once a standard is referred to (presumably because it serves one or more SHEC objectives), it is to be followed and no alternative method or solution is accepted (unless already in the regulation). However, accrediting certification bodies is challenging, even more so if the agency is a foreign body, as agencies cannot perform the same kind of oversight that would take place in a domestic context. In the EU, under many directives, alternative solutions can be certified by a Notified Body as long as the relevant SHEC objectives are served.

In the US, much of the US risk regulation is in fact managed by independent federal regulators such as OSHA (protection of workers in the workplace), the Federal Communications Commission (safety and health aspects of telecoms equipment, etc.), the Consumer Protection Safety Agency, the Environmental Protection Agency (many aspects including chemicals), the FDA (medicines and medical devices, as well as food law), the Federal Aviation Administration (aircraft certification), the US Coast Guard (boat and maritime safety), among others.[28] Many firms in the US are reluctant to use third-party inspection. Although inspection might satisfy regulatory requirements in multiple jurisdictions, there has been a low rate of participation in some areas regulated by the FDA, whereas the FCC has found that third-party certification has become the norm.[29]

The practical aspects of conformity assessment depend then on federal agencies, and the degree to which private accreditation bodies

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[28] The FDA established the AP Program, allowing manufacturers of Class II and III (medium- and high-risk) devices to contract with an AP to conduct a third-party inspection, in lieu of an FDA inspection, using the Quality System regulation and other device requirements in the FD&C Act.

[29] www.acus.gov/sites/default/files/documents/Third-Party-Programs-Report_Final.pdf, p. 58. Examples of third-party testing FDA inspection for medical device production facilities, medical devices, and FCC TBC program.

can be recognised directly by federal agencies, either through a designated domestic programme or by an international organisation, such as the IAF (for accreditation of certification bodies) or ILAC (for accreditation of laboratories), can determine the degree to which conformity assessment creates TBTs. There have been longstanding frictions in conformity assessment, with options including mutual recognition agreements, unilateral recognition of another country's conformity results, and acceptance of supplier declaration of conformity. For the EU, problems with OSHA, due to its policy of assigning Nationally Recognised Testing Laboratories (NRTLs) for mandatory third-party certification of electrical goods including machinery, a stronghold of EU exporters, have generated trade frictions.[30]

At first, for all practical purposes, UL was the only NRTL and EU exporters long felt that UL abused its de facto monopoly by higher prices and unjustified complications.[31] Nowadays, a dozen NRTLs have been recognised, but UL does not accept certification of components and parts of other NRTLs (hence, testing is duplicative). Moreover, some 30 US states have enacted provisions singling out UL as the mandatory conformity assessment body, which strengthens UL's dominant position and creates delays and unjustified rigidity. Fortunately, there are reforms emerging in the US with a view to improving such conformity rules and practices. While both Circular A-119 and OSHA's policy with respect to NRTLs are under review, NIST and OMB are revising their guidelines on conformity assessment (Federal Register 19357, 30 March 2012). TTIP is a good opportunity to remove these frictions and costly TBTs, especially for the electrical and machinery sector.

Both the US and EU have accredited conformity assessment bodies on the basis of ISO standards for laboratory accreditation relying on private third-party programmes for conformity assessment (ILAF

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[30] Note that, in the EU, the regime is 'light': conformity assessment is based on SDoC (self-declaration), in turn based on a technical file demonstrating compliance, which must be shown on request of the authorities.

[31] Explained in detail in Orgalime (2011 and 2012). The latter provides a number of details about excessive pricing (compared to other NRTLs, and also due to unnecessarily cumbersome procedural requirements). EU stakeholders hold that the US Department of Justice should have long ago acted against UL on the basis of antitrust law.

and IAF), which results in recognition of results.[32] Moreover, the 1998 MRA between the US and the EU in six sectors (telecoms equipment, EMC, electrical goods, medicines GMP, medical devices and recreational crafts[33]) was expected to focus purely on conformity assessment issues, without ever touching on domestic regulation or standards at all. The results of this MRA were mixed, if not disappointing, but much has been learned from this seemingly modest exercise. While MRAs were widely touted in the late 1990s, they merely accept certification of designated third-party assessment, and hence are much more limited than the TTIP TBT debate. While duplicative testing is expected to be done away with, this will *not* address the underlying differences in rules/standards, which are normally the main costs of TBTs.

7. State of play within TTIP negotiations

While differences in product standards can constitute barriers to trade, they also reflect differences in perceptions of health and safety, environmental requirements and preferences that have mobilised opposition on both sides of the Atlantic, as public opinion and civil society have questioned proposals across many sectors and issues.[34] Though the EU has published a proposal on technical barriers to trade that it made public in January 2015, the US has been less transparent and public in promoting its objectives in the negotiations. The EU proposal on technical barriers focuses on addressing the burdens created by divergent technical regulations, standards and conformity assessment.[35] The EU proposal would also include the WTO Agreement on Technical Barriers to Trade in the agreement. In addition, the proposed TBT chapter focuses on greater regulatory cooperation between both public and private organisations in areas of accreditation, standards and conformity assessment, and promotes global harmonisation within existing international bodies not defined

[32] See, e.g. International Laboratory Accreditation Cooperation, www.ilac.org/; see Pelkmans & Correia de Brito, (2015).

[33] GMP = good manufacturing practices, an OECD standard for factories; EMC = electro-magnetic compatibility, preventing interference between different pieces of electric/electronic equipment.

[34] As an example of this view, see Chemnitz (2014). The U.S. Chamber initially wanted the trade negotiations to focus on tariffs, which in their view would realise significant immediate gains.

[35] http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153025.pdf.

in the text and a single certificate of approval, authorisation or acceptance of conformity to foster mutual equivalence. The TBT chapter as proposed by EU negotiators is much more ambitious than the US template for such FTA-type negotiations, namely, the KORUS.

The US has stated that its trade priorities are to go beyond the existing WTO TBT commitment, increase the transparency and openness of the decision-making process regarding European standards and technical regulations, ensure that US bodies are permitted to test and certify products sold in Europe without the need for duplicative conformity assessment, and promote the recognition in Europe of internationally accepted standards that are used by US exporters and producers. The US also wants to establish an ongoing mechanism to discuss TBT concerns. In May 2015, the US tabled a new proposal on technical barriers to trade, and both sides have worked on an agreement on a 'consolidated text' on horizontal regulatory cooperation. The EU has pushed for a mechanism to promote strategic engagement with each other to prevent future regulatory differences that could create barriers to transatlantic trade. This seems to have much in common with an EU notification system for national draft laws in non-harmonised areas of goods regulation, in which regulations and standards are notified, and may be subject to a 'standstill measure' if the EU wishes to pursue regulatory action.[36] The process is aimed at ex-ante prevention in terms of trade barriers, having achieved significant success by covering both public and private sector activities (Correia de Brito & Pelkmans, 2012).

The US, by contrast, has focused on "good regulatory practices", which in reality is the promotion of their own notice rule and comment procedures that it believes will promote more transparency and reduce regulatory divergences if there are opportunities to comment on early draft proposals. Though pushing the notion in the Administrative Procedures Act (APA) for a public comment period has been a consistent proposal from the US side, the process provides for public feedback after significant inter- and intra-agency reviews of the proposed regulation. However, the US also uses negotiated rule-

[36] In fact, it is tougher: any notification automatically leads to a three-month standstill, which, by committee decision, can be extended to four (routine), six or 12 months (depending on the feared TBTs). All of these merely to iron out the problems with the member state in question. If, however, the possible TBT is so serious and/or might be imitated by EU countries, the standstill becomes 18 months for an EU proposal to be made and adopted by the Council and the European Parliament.

making under the Negotiated Rulemaking Act of 1990, where interested parties are asked to develop a proposal that the agency can then use as a basis for a more widely accepted regulatory proposal, although this approach is not often used. The US process requires a rule-making record so that if legally challenged there is a record of agency deliberations, and hence the US has pushed for a similar means to provide more visible public comments on European rule-making before it becomes adopted into law. Europeans have pushed for transparency in terms of the negotiating texts, having released a significant number on various topics, but without the US positions, the state of the talks is difficult to assess.

American trade officials might argue that their attention has been on securing the so-called 'fast track', i.e. the Trade Promotion Authority (TPA), intended to send a credible signal that any subsequent trade deal will receive a singular vote in Congress without amendments. The passage of the H.R. 1295 Trade Preferences Extension Act, in which the US Administration fought hard to overcome the strident opposition within their own party, will provide significant momentum for trade talks, although the US is also pushing forward with negotiations on the Trans-Pacific Partnership (TPP), the Trade in International Services Agreement (TISA), the Information Technology Agreement (ITA), and the Environmental Goods Agreement (EGA), all in addition to TTIP. As a result, the US focus on concluding TPP has meant that the past six months of transatlantic negotiations have focused on technical issues, in terms of regulatory cooperation across specific sectors, leaving some of the more controversial issues off the table (Inside U.S. Trade, 30 January 2015 – www.insidetrade.com).

Given the paucity of official documents on US proposals, an evaluation of current suggestions from different interest groups may provide some insights into the efforts of addressing TBTs. The Business Coalition for Transatlantic Trade is focusing on regulatory cooperation aimed at providing input on TBTs and developing new regulatory coherence and coherence efforts. This business group also supports the adoption of specific sectoral annexes in any agreement. Equally important, it has emphasised the importance of a common definition of 'international standards' by referencing WTO TBT Committee decisions, as well as referencing equivalence standards that could be applied within the EU 'new approach' directives. It has also requested

more open and direct participation in standard-setting – all goals that reflect US trade objectives.[37]

Yet in other sectors, there is the emergence of transatlantic alliances between industry associations that have voiced common positions in addressing trade barriers. In the case of the automobile, chemical and pharmaceutical sectors, trade associations submitted joint proposals to address regulatory barriers to trade.[38] Part of this is due to integrated supply chains, intra-firm investment and trade patterns that push these associations to seek to reduce trade barriers.[39] While these associations have focused on addressing barriers to trade, they have eschewed harmonisation by pushing for the promotion of mutual equivalence in terms of inspections and the exchange of information for regulatory approvals to avoid making costly adjustments and choosing one standard over another (Egan & Nicola, 2015). There are some associations that have pushed for transatlantic harmonisation, with the pesticides associations wanting agreement on the US standard, and the automotive partners also wanting harmonisation through the UN Economic Commission for Europe Working Group on Global Technical Regulations (GTRs).[40]

However, the opposition to the agreement on both sides has come from different civil society groups, focusing on agriculture and investor disputer settlement, rather than domestic oriented firms, and labour groups such as the AFL-CIO and ETUC (European Trade Unions Confederation). The latter have also coordinated their views in stakeholder meetings in which they have indicated that trade

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[37] http://www.transatlantictrade.org/issues/regulatory-cooperation/.

[38] Active Pharmaceutical Ingredients Committee (APIC) / European Fine Chemicals Group (EFCG) / Society of Chemical Manufacturers and Affiliates (SOCMA); European Automobile Manufacturers' Association (ACEA), the American Automotive Policy Council (AAPC) and the Alliance of Automobile Manufacturers (Auto Alliance); European Chemicals Industry Council (CEFIC) / American Chemistry Council (ACC) and Motor and Equipment Manufacturers Association/ European Association of Automotive Suppliers Pharmaceutical Research and Manufacturers Association (Pharma) / European Federation of Pharmaceutical Industries and Associations (EFPIA). See Young (2015).

[39] Young (2015).

[40] European Automobile Manufacturers' Association (ACEA), the American Automotive Policy Council (AAPC) and the Alliance of Automobile Manufacturers (Auto Alliance).

agreement could be beneficial, provided that it maintains high levels of worker protection that are not constituted as barriers to trade.[41]

The USTR continues to solicit feedback, drawing on expertise in industry and trade associations, standards bodies, professional and academic communities. Some of the debates are not new, as the US pushes its view that transparency does not require a flat obligation to use international standards. The TBT Code provides for notification if international standards are not used. For American trade negotiators, the issue is one of access to European standard-setting. Regional standards are neither international standards nor 'open to all' participants. As such, standard-setting in Europe does not (have to) follow trade principles of non-discrimination and national treatment. The goal is to ensure that there is no preferential treatment given to European standards bodies but fair and equal treatment to American standards bodies, with the option of being recognised in some way.

For Americans, any entity can be recognised as providing standards, whether it is a trade association, consortium, industry-based or local government, and they want to apply the same principle to European standardisation. They view European standards as a tool of industry policy, and want more flexibility, noting that consortia in the ICT sector have evolved and reformed to increase flexibility, which is something that the Europeans have had to belatedly recognise, given their competitive disadvantage in the ICT sector. For Americans, competition within established bodies might create innovation. While recognising that the initial idea of European standardisation has been beneficial in addressing internal barriers to trade, the goal of a unified transatlantic market cannot emerge if the relationship between European standards and New Approach Directives remains exclusive. However, there is no such thing as a TTIP goal of a 'unified transatlantic market' in any of the TTIP official documents.

In terms of concrete efforts, the European standards bodies (SDOs) and the American National Standards Institute (ANSI) have indicated that they plan on building upon their informal contacts to generate a memorandum of understanding (MoU), which is not widely supported by other trade associations and standards bodies in the US that do not want codification of existing practices. However, making progress toward bridging the differences between the US and Europe on what constitutes an international standard based on a set of rules

41 www.aflcio.org/content/download/132421/3553131/AFL-CIO+TTIP+Report_6+%282%29.pdf.

approved in the WTO by the Committee on Technical Barriers to Trade will be challenging. The US has repeatedly indicated that the global relevance of the standard is not which organisation developed the standard, or where it was developed, but its usage in the global marketplace (Froman, 2013). The number of 'international standards' in the formal sense incorporated by reference in the US is 397, primarily from the ISO, IEC and ITU.[42] The US believes that international standards can be developed by any SDO that adheres to WTO TBT principles. For the US, this multiple path approach means that standards can be agreed upon by international organisations such as the ISO and IEC or through direct participation in SDOs such as the IEE and ASTM or through consortia such as the IGRS. This difference in what constitutes an international standard is nothing new according to US participants but does constitute a lingering difficulty in promoting a memorandum of understanding or intent between the two sides that have been in discussions since 2013.

Although increasing cooperation on standards-setting and international accreditation arrangements is the overall goal, the issue is not specific to the transatlantic relationship, as similar discussions have emerged in recently approved negotiations for a non-binding memorandum of intent concerning standards and conformity assessment between the US and Brazil on this same issue, in which Brazil is much closer to the EU position on international standards and also relies on government agencies to conduct conformity assessment. European standards bodies have come under criticism as US officials have argued that the EU promotes its standards as part of trade agreements, aggressively pushing its 'market power', so that its standards are frequently adopted in other markets.

The US has consistently stated in trade talks that there should be openness and transparency in terms of standard-setting. This is an implicit criticism of the structure of European standard-setting in which European SDOs receive formal 'mandates' to adopt European wide standards in turn strengthened by a framework for regulatory cooperation with the ISO and IEC that often leads to the uploading or acceptance of European standards at the international level. With more than 65% of US exports subject to one or more New Approach Directives, US companies are anxious to address the inconsistencies in regulatory approval. The annual trade barrier report noted, "U.S.

[42] Data from Regulatory Standards Incorporated by Reference (R-SIBR) Database.

persons are not able to participate directly and effectively in the development of regulations, standards and conformity assessment procedures in the EU. In particular, some institutional arrangements in the EU appear to either accord exclusive rights to, or effectively favour, EU entities in the development and implementation of such measures. Further, there appears to be no effective mechanisms to ensure accountability to non-EU interests in the adoption and implementation of measures" (USTR, 2014). It is useful to put such remarks in perspective: many experts from US companies do in fact participate in writing European standards at the national level in the EU as well as with the ISO and IEC (sometimes with a US expert even serving as chair!).

Despite a surge in US SME exports to the EU from $67 billion in 2010 to $76 billion in 2011, the US International Trade Commission was asked to survey SMEs across the US as part of its evaluation of the TTIP negotiations.[43] It found significant problems in relation to standards, regulations and conformity assessment, and expressed concern that the lack of national treatment of certification bodies, costly compliance with European standards, and regulatory differences between the US and EU made it disproportionately difficult for SMEs to access the European market.[44] Most of the suggestions focused on harmonisation or mutual recognition, arguing that in a range of sectors from automotive to toy safety, the standards are functionally equivalent, with the same regulatory objectives but different methods to achieve them, e.g. vehicle emissions EPA certification and Euro VI vehicle certification. Many trade associations suggested that the mutual equivalence of conformity assessment to allow domestic testing in the US be accepted in Europe.

This preference begs the question why MRAs in various sectors are not pursued by the US or, alternatively, why the 1998 MRA is not modernised via today's global accreditation quality networks. Some SMEs even suggested that firms should incorporate components that already have the CE symbol to ease compliance problems, or seek government support or financial assistance from public certification or testing facilities.[45] In the TTIP negotiation, a recurrent critique put forward by the US administration is that while European SDOs are centralised, the procedural requirements concerning certification are

[43] www.usitc.gov/publications/332/pub4455.pdf.

[44] Ibid.

[45] www.usitc.gov/publications/332/pub4455.pdf.

highly decentralised, with substantial variation in consistency between and little control over the quality of the accreditation bodies in EU member states, which makes US approval difficult. However, one should distinguish the EU situation after 2008: Reg. 765/2008 and its follow-up, with the new European system of accreditation, much improved the level and consistency of accreditation and the quality of conformity assessment bodies.

A similar study by DG Trade on the impact of TTIP on SMEs found that 28% of the exports to the US were from SMEs, totalling €77 billion.[46] The study found that compliance with food and safety regulations and technical regulations for goods acted as barriers to market access and exports, making TBT and SPS issues the most cited factor in terms of trade barriers.[47] Across sectors, SMEs cited barriers to pharmaceuticals, chemical, and plastic and rubber products, and firms in both the pharmaceutical and medical devices sectors advocated for good manufacturing practice so that they could reduce conformity assessment costs. Their concerns may be warranted regarding pharmaceuticals, as companies are concerned that the FDA review process is almost twice as long as that of its European counterpart, the European Medicines Agency (Holtzman, 2012).[48] For chemical firms, conformity assessment along with the labelling requirements that do not follow UN standards impose higher costs on European exporters.

8. Conclusion

On both sides of the Atlantic, there is a widespread recognition that TBTs arising from different standards, testing and conformity assessment practices can impede trade and raise market entry barriers. Though technical standards are developed by private SDOs through a voluntary consensus process, once they become part of statutory requirements, the result can create trade impediments, as the public law obligations differ. The different procedural requirements have created difficulties in negotiating regulatory cooperation, as 'reference to standards' and 'incorporation by reference' have different market and regulatory effects. In the past, governments on both sides have chosen a variety of tools to reduce or eliminate TBTs, with varying

[46] http://trade.ec.europa.eu/doclib/docs/2015/april/tradoc_153348.pdf.

[47] Ibid., p. 15.

[48] Starting in 2014, with the passing of the Affordable Care Act, a 2.3% medical excise tax was imposed on all sales of devices, regardless of country of origin, which may shift medical device manufacturers to new markets.

success. The goal is to ensure that standards-setting processes are transparent and inclusive, and that the resulting standards do not have anti-competitive effects that impede the prospect of alternative means to meet regulatory requirements for market access.

Conformity assessment (whether in-house labs or third-party testing) must demonstrate its competence to meet specific legal and standards-based requirements. But this will require accreditation of conformity assessment bodies so that their mutual acceptance (or national treatment and non-discrimination) will avoid duplicative testing, certification and other measures. After the long and complex process of a trade negotiation, most governments realise that the task is not complete when a trade agreement has been signed and ratified.

Rather, new challenges must be addressed in order to successfully implement an FTA, which has led to greater emphasis on the institutional framework to address perceived problems as well as future issues in a so-called 'living agreement'. There are previous FTA examples with provisions for regulatory cooperation, technical committees and regulatory councils. However, the according of national treatment to conformity assessment bodies, based on modern global accreditation principles and networks,[49] would build on the strong example set out in the CETA agreement. The TBT Agreement indicates that conformity assessment procedures should not be more trade restrictive than necessary, and should determine merely whether regulatory objectives are similar. It follows that the relevant products should not be subject to additional product approval – this principle should be central to the TTIP, as they often only differ in their origin. In the case of standards, the mandatory versus voluntary status in public law when incorporated into legislation is difficult to change. However, greater transparency, access and non-discrimination in standards (or mutual recognition based on specified SHEC objectives) would facilitate market access.

Finally, TTIP negotiators have to transcend the pointless stand-off over the definition of an 'international standard'; explain in market and economic terms the underlying issues (e.g. widespread use of US standards in numerous markets around the world and in global value chains)); stimulate exploration of the extent of this market-driven 'installed base' problem for thousands of firms all over the world (and

[49] In chapter 27 of the CETA Agreement, an MRA Protocol is elaborated in many sectors, based on accreditation.

not only for the relevant dozen of leading US SDOs); and constructively seek longer-term answers in a 'living agreement'.

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