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TTIP: Opportunities and Challenges Technical Barriers to Trade, including Standards

Study for the IMCO Committee

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TTIP: Opportunities and Challenges in the area of Technical Barriers to Trade, including Standards

STUDY

Abstract

The study explores the possibilities for reducing the costs of technical barriers to trade (TBTs) between the US and the EU, found in standardisation, technical regulations and/or conformity assessment procedures and acceptance of their results. This is important for many industrial sectors but also horizontally as TBTs generally. The EU proposal is ambitious, but without a US text, feasibility is hard to assess, given that the two systems differ considerably. A preliminary attempt to construct the US demands and some partial solutions for TTIP are discussed. The 'living agreement' is critical for an effective TBT chapter and needs to be given time, as long as it is driven by an agreed ambitious objective of reducing TBTs as much as possible.

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LIST OF ABBREVIATIONS

APEC	Asia-Pacific Economic Cooperation
CA	Conformity Assessment
CAP	Conformity Assessment Procedures
CAB	Conformity Assessment Bodies
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CETA	Comprehensive Economic and Trade Agreement
EC	European Communities
EEA	European Economic Area
EMC	Electromagnetic Compatibility
ETSI	European Telecommunications Standards Institute
E85	Gasoline containing 85% ethanol
FDI	Foreign Direct Investment
FTA	Free Trade Agreement
GHTF	Global Harmonization Task Force
GMP	Good Manufacturing Practices
ICH	International Conference on Harmonization
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
KORUS	US-Korea Free Trade Agreement
MRA	Mutual Recognition Agreement
NRTL	Nationally Recognized Testing Laboratory
NTB	Non-tariff Barrier to trade
NTM	Non-tariff Measures
OMB	Office of Management and Budget (US)
OSHA	Occupational Safety and Health Administration (US)
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme

SDoC	Supplier's Declaration of Conformity
SEA	Single European Act
SHEC	Safety, Health, Environment, and Consumer Protection
SINGEU	Singapore-EU Free Trade Agreement
SITC	Standard International Trade Classification
SME	Small and Medium Enterprises
TBT	Technical Barriers to Trade
TEC	Trans-Atlantic Economic Council
TTIP	Transatlantic Trade and Investment Partnership
UN GTR	United Nations General Technical Regulation
UNECE	United Nations Economic Comission for Europe
WTO	World Trade Organization

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EXECUTIVE SUMMARY

Background

For more than 20 years, the EU and US are trying to reduce Technical Barriers to Trade (TBTs) bilaterally, and more so than implied by the WTO TBT Agreement. TBTs exist due to differences in standards, technical regulations and conformity assessment, or, indeed a combination of two or all three of them. Two routes have been travelled thus far: MRAs (Mutual Recognition Agreements) on conformity assessment in seven sectors and ad-hoc Atlantic regulatory cooperation, both horizontally and occasional sectorial or highly specific agreements. Both routes have only been selectively successful. TTIP offers a great opportunity to transcend these scattered approaches and address TBTs in earnest and systematically. Economic studies show that this is the area par excellence where considerable economic gains can be had without in any way questioning existing Safety, Health, Environmental or Consumer protection objectives – further referred to as SHEC objectives - on both sides. The study focuses on the TBT chapter in TTIP, already a major challenge for both Parties, and leaves out SPS issues, the nine sectorial annexes (from automotive or chemicals to ICT hardware and textiles and clothing) and horizontal cooperation. This area is somewhat technical and requires a lot of knowledge, in order to understand the problems or positioning, as well as the nature of possible solutions. Thus, it is inevitable to incorporate some careful explanation before offering possible solutions or proposals.

Aim

- Setting out the basics of Trans-Atlantic TBT issues as an indispensable foundation before TTIP TBT solutions can be proposed and assessed. Done in Part I, it explains why misunderstandings about TTIP may arise, how the US and EU systems of risk regulation (including all three aspects of TBTs) differ (but also how these differences are at times exaggerated for strategic reasons) and what the EU and US demands are, as far as these are public. This is also helpful to appreciate the offensive and defensive interests of the EU and the US. The most prominent offensive interest of the EU is to find ways, over time, for the US to begin adopting more systematically IEC and ISO standards. In numerous instances, this is in the enlighted self-interest of the US in the longer run given globalisation and its companies' participation or even leadership of global value chain. The gap between the EU and the US in this respect is enormous and adaptation, though crucial, can only be very gradual.
- Identifying the scope and possible approaches for reducing TBTs in TTIP.
- This is done in steps. First, the focus is on FTAs, recently concluded by the EU, that is, on their TBT chapters. Given that the American demands probably rely on the US – Korea FTA [KORUS] as a template, a detailed textual exegesis is presented comparing the TBT chapter of KORUS with the published TBT proposal by the EU, which brings out the expected 'gaps' in the two positions. In addition, a shorter comparison with the TBT chapters of the EU/Singapore FTA and that of CETA is offered as well, for a better appreciation of the scope and options.
- Subsequently, a range of options is explored for TTIP, such as harmonisation, mutual recognition of conformity assessment, the 'equivalence' approach and the notion of mutual recognition of standards. The options can be linked directly with offensive and defensive interests of the EU. It is attempted to clarify the scope for using or not using them, or, even offer TTIP proposals for negotiators.

- Finally, the experience of the MRAs with the US (and some interesting developments after 2003) is summarised and some conclusions and lessons for TTIP are drawn.

Table 1: Main results

1. Broad offensive interests of the EU in TBT matters
• The offensive interests of the EU in TTIP TBT matters are best served by an ambitious approach as proposed by EU negotiators in January 2015 and based on a mobilising objective to reduce TBTs as much as possible, given the economic gains to be reaped. An ambitious approach would have to cover the adoption of ever more true world standards by both partners, selected attempts to come to harmonisation or acceptance of equivalence of SHEC objectives (or the 'level of SHEC protection') and the minimisation of the costs of responsible conformity assessment, also by selective mutual recognition.
• The 'living agreement' is bound to be of cardinal significance for the TBT area, because of the intricate and highly technical nature of a solid low-cost TBT regime, as well as the links with horizontal cooperation and the nine sectorial chapters. Ambitious arrangements, based on a powerful objective of addressing TBTs, will take time and the 'living agreement' should comprise a rolling programme governed by regulators, but not be pressed by tight deadlines.
2. On the EU interests in the TBT chapter of a basic TTIP agreement
• Given that the US/Korea FTA [KORUS] is the template TBT-plus example of US trade policy so far, and in the absence of a publicly known US proposal on TBT, one cannot but have the strong impression that there are major 'gaps' on the negotiation table between the EU text proposal and the US template based on KORUS. These gaps concern both offensive and defensive interests of the EU.
• The more important gaps include substantive provisions on standardisation, technical regulation and marking & labelling, all quite well specified in the EU text proposal but absent in KORUS. These are crucial for the EU in its attempt to obtain appreciable economic gains from TTIP. However, US companies are likely to benefit from these provisions when accessing the EU market.
• There are promising elements, too. The US and the EU are likely to find agreement on ambitious transparency provisions and the 'joint regulatory cooperation' provisions. The latter can be elaborated with a view to the 'living agreement' stage, following the conclusion of a basic TTIP agreement, in conjunction with the separate horizontal regulatory cooperation chapter.
3. Opportunities and challenges: specific TBT issues and some proposals for TTIP
• Harmonisation of technical regulations is proposed by the EU, where appropriate, at world level, which is bound to be rare. More important might be the EU proposal to promote 'harmonised or compatible technical regulations' in case a regulation is prepared of 'equivalent scope', that is, either a new one or a major revision. A special mechanism to make this possible has not been suggested yet, perhaps via the TTIP Regulatory Body in the horizontal chapter. Clearly, this would be quite ambitious. It

would also have to be rooted in the domestic legislative processes of both sides, which would make it slow and heavy. Critical for its success is a focus on the equivalence of SHEC objectives (no lowering of "standards", here objectives) as the criterion for compatibility. But one should note that harmonisation has happened before, for instance in automotive and ICT equipment (in UN-ECE) and in ATEX equipment (idem) as well as marine equipment (in IMO). In these areas, it has proven to be very helpful, although not always followed up by the US.

- Harmonisation of standards is possible via an encouragement to develop or adhere to ISO/IEC standards or bilaterally between standardisation bodies. Both will not happen immediately with full force, given past investment in standards (in particular, for some prominent internationalised US standard bodies with status in world markets) and in how producers design manuals and products. Here, it is crucial that the standardisation bodies of both sides are encouraged to cooperate much more on a structural basis, e.g. by setting up programmes for such purposes. The offensive interest for the EU (but also in the long-run interest of the US) is to persuade US standardisation bodies to align, as a rule, with ISO and IEC standards, given globalisation of sales and global value chains. Obviously, this will take time and has to be pursued with due respect to past investments and traditions.
- Mutual recognition of regulations (in fact, their SHEC objectives above all) is not normally possible in TTIP – the EU regime shows how demanding that is.
- The EU has a defensive interest in clarifying why the suggestion of 'Mutual recognition (MR) of standards', apparently pushed by the US, entails systemic costs for the EU single market in the longer run and would eventually also work against the US in that the inevitable US move towards truly international standards of IEC/ISO, so critical in value chains, would be slowed down and discouraged. The systemic EU costs of MR of standards consist in the serious long-run risk of unravelling of the single market with a single standard, a critical and highly advantageous accomplishment of the 'new approach'. The unravelling is to be expected, once US standards can be used via MR for compliance with EU risk regulation, and national standard bodies in CEN/CENELEC would still expected to withdraw their own standards. Surely, sooner or later, national standards will not always be given, and a process of unravelling begins. Once begun, it will be hard to stop it. Moreover, this is bound to be followed by various other trading partners having or desiring FTAs with the EU. It is everybody's guess where this unravelling will end and it will be nearly impossible to reverse it later. Therefore, if presented as a wholesale drive to promote across-the-board MR of standards, it makes no sense at all, and must be rejected firmly. The only exception would be where equivalence of SHEC objectives would first be agreed by the US and the EU (as attempted in TTIP for automotive). In addition, whilst there may be short-run advantages to US business to MR, there are no gains whatsoever for EU exporters in improving market access to the US for European standards to be used for compliance with US risk regulation. US regulators usually choose a single standard as compulsory, so another European standard, even when equivalent, would not be accepted, unless major reforms in the US would be adopted. However, there is a window of opportunity with the ongoing review of these practices (governed by OMB Circular A-119) by US regulators: the review of Circular A-119 ought to be linked to TTIP commitments in order to enable a (new) 'standardisation request procedure' to allow equivalent European standards, based on technical merit.
- Given the lessons of the 1998 MRA and the recent Protocol concluded in CETA, arrangements can be agreed that come some way to overcome long-standing

objections about the costs of conformity assessment regimes of some US regulators. The ongoing review of CABs designated by OSHA may accommodate EU demands that there should be a genuine free choice between designated CABs, that anti-competitive practices by UL are terminated and that sub-federal regulators align their requirements with those of federal regulators.

- The 'joint cooperation' provision in the EU text proposal is also crucial because the aftermath of the MRA has shown that 'soft' (non-treaty-based) regulatory cooperation can be more effective than a MRA. Thus, the accomplishments in e.g. medical devices and medicines in international fora should be incorporated in TTIP.
- Following CETA, it should be considered whether TTIP could incorporate MRA-like provisions for a larger set of sectors than previously, as has been successfully done in CETA. This would also satisfy the US demand that US bodies are permitted to test and certify products sold in Europe. It may require a toughening of the EU compliance regime for SDoCs (e.g. market surveillance and sanctions) because US regulators under the legal duty to be re-assured by empirical evidence. This toughening is also in the EU interest, and, in fact, has been discussed frequently – the main problem remains the inadequate resources for market surveillance by Member States (despite the rules requiring it) and weak sanctions.

1. INTRODUCTION: PURPOSE AND CONTEXT

KEY FINDINGS

Although between the US and the EU the levels of Safety, Health, Environmental objectives and Consumer protection [=SHEC] are frequently found to be similar, in all those areas /sectors where this seems to be the case, the two partners can only show a rather selective and overall poor harvest of reducing or removing TBTs. Where SHEC objectives and the related regulation are truly different, this is another matter, and such areas are either excluded in TTIP or expectations are very low indeed. The challenge is first to appreciate better why (often) regulation and enforcement, driven by similar SHEC objectives, nevertheless lead to costly TBTs that have proven hard to address seriously. This will be done by first explaining in some detail what reducing TBTs means and does not mean, by carefully distinguishing three perspectives on TBTs (wider, narrow and horizontal), by setting out how the US and EU systems of risk regulation differ and finally what both partners demand in the negotiations (offensive and defensive interests). Given this foundation, it becomes possible to explore a range of options and suggest some proposals for TTIP in TBTs.

For more than 20 years the EU and US are trying to reduce Technical Barriers to Trade (TBTs) bilaterally, and more so than implied by the WTO TBT Agreement. TBTs exist due to differences in standards, technical regulations and conformity assessment, or, indeed a combination of two or all three of them. Two routes have been travelled thus far: MRAs (Mutual Recognition Agreements) on conformity assessment in seven sectors and ad-hoc Atlantic regulatory cooperation, both horizontally and occasional sectorial or highly specific agreements. Both routes have only been selectively successful.

The 1998 US/EU MRA includes six sectors: telecoms equipment, EMC (electro-magnetic compatibility; against interference between different electrical / electronic devices), electro-technical goods, medical devices, GMP in medicines[1] and leisure boats. A seventh MRA was concluded in 2004 on marine equipment. The results of the MRAs are mixed and far below original expectations[2]. Ad-hoc Atlantic regulatory cooperation began in 2002, if not earlier [see Quick (2008) for an overview] and intensified after the TEC (Transatlantic Economic Council) was established in 2007. Apart from some common principles and other declarations, as well as some useful work on new technologies (e.g. electric vehicles), only a few narrow agreements were concluded such as the 2009 one on mutual recognition of aircraft certification, a 2006 wine agreement (with so far only phase 1 activated), a 2011 Mutual Recognition agreement for organics and e.g. the 2007 common approval procedure between the US FDA and the EU EMA for orphan drugs (see Chase & Pelkmans, forthcoming for more detail). Whilst FTAs were concluded by both partners with other WTO countries, incorporating WTO TBT-plus arrangements, no systematic approach with respect to TBTs was envisaged between the USA and the EU. Empirical economic studies were made trying to estimate how costly TBTs were for (mutual) market access. Doing this is notoriously difficult but the thrust of these studies (even when not fully comparable and problematic in some respects[3]) is that, when expressed as a percentage of the invoice price (as if it were

[1] Good Manufacturing Practices (an OECD/WHO standard) ; mutual recognition of inspections of GMP in factories would prevent factories to be checked twice (on exactly the same standard) which is costly.
[2] Discussed in section 3.4.
[3] See the study for the Commission's Impact Assessment of TTIP by Francois et al (2013) and the explanatory companion report by Pelkmans et al (2014) for the EP INTA Ctee.

a tariff on imports – called 'tariff equivalent'), the TBT costs for industrial goods can range from around 15 % up to as much as around 70 %. This is a multiple, and for some cases, a large multiple of tariffs. In principle, therefore, a powerful case to tackle TBTs in earnest, can be made, especially because there are many indications that TBTs incorporate a lot of 'waste' of resources due to duplication or a lack of trust or understanding. It should be feasible to reduce them significantly and reap economic gains on both sides.

TTIP offers a great opportunity to transcend the scattered approaches of the recent past and address TBTs in earnest and systematically. The study focuses on the TBT chapter in TTIP, already a major challenge for both Parties, and leaves out both the nine sectorial annexes (from automotive, medical devices or chemicals to ICT hardware and textiles and clothing) and horizontal cooperation. TBT is a demanding subject, is also somewhat technical and requires quite a lot of knowledge, before it is possible to understand the variety of intricate problems or the firm – at times, overly firm – positioning of both sides and/or their stakeholders, as well as the nature and precise articulation of possible solutions. Thus, it is inevitable to incorporate some careful explanation and demystifying some strong positioning, before offering possible solutions or proposals.

In Part I, an attempt is made to offer a foundation for a search for constructive approaches and solutions or proposals. Section 2.1 clarifies what reducing TBTs implies and does not imply, because there are misunderstandings on (or, mistrust about?) the nature and strict functioning of risk regulation in the EU and US. Section 2.2 clarifies the differences between the wider, narrow and horizontal perspectives on TBT reduction. Although there is no doubt that these three are connected in various ways, the study focuses on the TBT chapter in TTIP, the narrow perspective. However, one should not be mistaken in assuming that the 'narrow' perspective implies zooming in on a small policy area of limited economic interest. Not at all, TBT reduction is the core of TTIP right from the beginning and the economic gains, hoped for, leave no doubt about it. The idea is: what the EU (or, the US) can do with (say) Singapore or Korea or Canada in TBTs is surely much more worthwhile when doing it with the US (resp. the EU). Section 2.3 explains the differences in standards and risk regulation between the US and the EU. A good deal of these differences have their roots in systemic divergences. It is indispensable to appreciate these differences before considering solutions. It is emphasized that, without belittling the differences, the divergence tends to be exaggerated on both sides, presumably for defensive reasons or to caution negotiators. Sections 2.4 and 2.5 set out what we know about the demands of the EU, respectively the US, for the negotiations on TBT reduction. This is easier for the EU as it has been unusually transparent. However, transparency is of little use if it is not reciprocated by the US. The US has hardly given any detailed information on its positioning in TTIP[4] and there have been no leaks that might have helped outside observers. Nevertheless, there are several indirect ways to make reasonable guesses about the US position, not least because its FTA strategy has been based on a given template. There are also insights from the recent history of regulatory cooperation of and frictions between the US and the EU.

In Part II, the scope and options for the TBT chapter are explored. In addition, some proposals for solutions are presented as well. The scope and possible ambitions are derived from what we know from recent FTAs as well as from the EU text proposal on the TBT chapter published in January 2015. In section 3.1 a detailed comparative analysis and annotations are presented of the Korea /US FTA [KORUS], as a proxy of what the US might want, and the EU text proposal on TBTs. The gap is large, with the ambition of the EU being far greater than that of the US (at least, in KORUS). In section 3.2 two other examples are inspected, the Singapore /EU TBT chapter and CETA's TBT chapter. The former is interesting as it is close to the EU ambition whereas CETA is not so interesting with respect

[4] Neither has it done so for TPP, the Asia-Pacific variant of TTIP.

to TBTs in general (the ambition is modest) but it does greatly advance the MRA approach, improving drastically on the existing and only partially functioning MRA between Canada and the EU. Section 3.3 explores the often heard options for TBTs. The problem is that only rarely these options are spelled out carefully, causing the TTIP debate to remain somewhat superficial. Four options are spelled out: harmonisation, mutual recognition of regulations and of conformity assessment, 'equivalence' (as meant in the WTO TBT agreement) and the tricky notion of 'mutual recognition of standards'. A modest attempt is made which might help somewhat in relaxing the 'stalemate' of tactical /strategic positioning on both sides, without in any way affecting negatively the two systems. Section 3.4 analyses the experience of the 1998 MRA, and subsequent developments and draws conclusions as well as a few lessons for TTIP. Section 4 discusses opportunities and challenges.

2. BASIC TRANS-ATLANTIC ISSUES AND INTERESTS IN STANDARDS AND RISK REGULATION

KEY FINDINGS

Reducing TBTs has nothing to do with the level and ambition of regulation. Addressing TBTs is not about altering SHEC objectives and it should not be. The focus on the TBT chapter in TTIP is necessarily 'narrow', though still extremely broad and full of numerous specificities. The wider view should not be lost out of sight; it includes the nine sectorial annexes or chapters as well as horizontal regulatory cooperation.

For all three types of TBTs, there are differences between the US and the EU. For standards, standardisation traditions are different and so is the use of standards for regulatory purposes. The latter risks creating stubborn TBTs for many types of goods exported from the EU, and mutatis mutandis for US exporters. Moreover, there is often no US federal regulatory regime (unlike the EU single market): states are free to adopt the use of a different approach for regulation, causing costly fragmentation of the US internal market for US and EU suppliers. The US has one manifest weakness, especially in times of globalisation: it has adopted very few ISO /IEC standards (despite active collaboration in Geneva) whereas the EU/EEA/Switzerland/Turkey enjoy a 72 % identity of CENELEC standards with IEC standards and a 31 % identity of CEN standards with ISO standards. Although conformity assessment principles are the same in the US and the EU (based on world standards), the requirement of third party certification can be problematic in some sectors (e.g. electrical goods and machinery).

The EU wants a comprehensive and ambitious TTIP approach to cutting TBT costs. A comparison with KORUS shows that the US has so far used a more modest so-called TBT-plus template. The US is keen to develop transparency – often meant to enable extensive two-way consultation – and 'openness', e.g. of CEN/CENELEC when writing standards for regulation, and insists on science-based risk assessment as the basis for risk regulation and the related standards. It also insists on 'EU recognition of international standards used to support global trade by US exporters and producers', but this phrase implies EU recognition of (a subset of) US standards, even though only some of those are truly 'international' and rarely ISO/IEC ones.

2.1 What addressing TBTs implies and does not imply

The most important barriers in North Atlantic goods trade are due to regulation, or, more precisely, to differences in regulation, and its enforcement. Abiding by regulation in the EU is often insufficient for entering the US market: it leads to extra costs, as one has to abide by other regulatory requirements or the product has to be tested and certified that the imported product is acceptable as 'safe' (or meets other objectives such as public health, environment and consumer protection). And the other way around for US products exported to the EU market. Most of these 'regulatory barriers' are in fact 'technical barriers to trade' (TBTs). In the WTO, TBTs are disciplined by the TBT Agreement but far from being removed or from reduced very much (there are some encouragements to do so in various ways). In the light of some soundings in the media and/or 'stakeholder meetings', and in order to avoid any misunderstanding, it should be stressed that TBTs is a neutral term which has nothing to do with the level and ambition of regulation. Sector x might be strictly regulated in the US, but if it is also strictly regulated in the EU, in a similar fashion, (costs of) TBTs may well be very low. Sector y in the EU may be regulated fairly 'lightly' because risks are low, and yet it might happen that the US maintains a stricter position or a costly

testing & certification approach, causing the costs of TBTs to be relatively high. For the same reason, removing or reducing the costs of North Atlantic TBTs is likely to create economic gains – in some sectors, even large ones – but that has nothing to do with reducing the ambition of regulation itself, or with deregulation. It is merely and only about reducing the costs of given regulatory differences, insofar as they are relevant for market access.

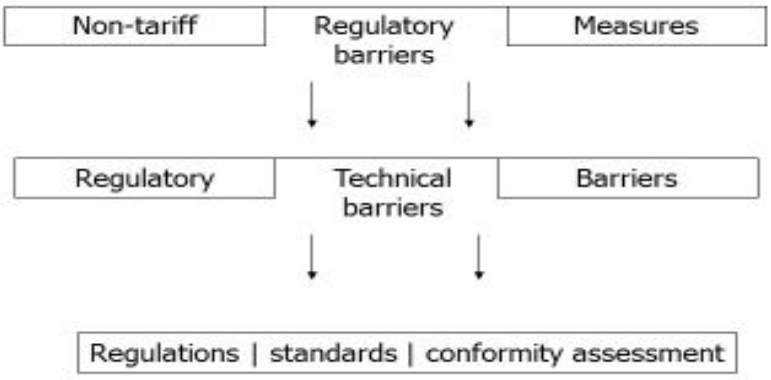
Sometimes, one comes across the following reasoning: there are instances where the US and the EU have divergent objectives and that removing or reducing TBTs would 'therefore' mean convergence of the objectives: the partner with the more ambitious objective would see their objective(s) compromised. Theoretically, this might be imagined but this idea is at the very least far-fetched, if not false : it is most unlikely if not practically impossible, certainly for the US and the EU. Why? Both the Union and the US have built up extensive regulatory systems which have become more ambitious over time, especially in terms of objectives of SHEC (Safety, Health, Environment & Consumer Protection). This so-called 'risk regulation' is a response to market failures in these four areas. The fundamental driver behind risk regulation is rising per capita income levels, or, ever greater affluence. Once people have some disposable income beyond the satisfaction of basic needs, they will insist that society addresses risks in SHEC. Risk regulation can be costly but more easily affordable once per capita incomes are high enough. Every country chooses a cost / benefit combination by reducing risks to lower levels (the benefits of regulation) in its own way ; this combination tends to adjust towards higher costs for greater benefits over time when incomes allow. In gradually raising ambition in US and EU risk regulation, and hence enjoying lower SHEC risks, there are numerous possibilities that the two partners do this in ways so different that the costs of TBTs rise as well. The fundamental drive of having low SHEC risks (i.e. ambitious objectives) is not at issue in TTIP. Neither is the firm presumption at issue that the level of SHEC objectives are not and cannot be object of TTIP negotiations. The latter are about instruments, methods or testing for given objectives. It is explicit in the mandates, in published proposals so far, http://www.scoopnest.com/user/Gottemoeller/517034063719575552 and in endlessly repeated statements by the negotiators. Anyway, there are many guardians in the two systems such as laws (occasionally even constitutional rights or, for the EU, the treaty requirement of 'high level of protection' of what amounts to SHEC) ; short of disregarding what Member States have been doing for many years and what they have mandated the Commission to follow in the negotiations, one can safely assume that Member States and/or the European Parliament will insist on such high levels of protection, too ; a similar requirement about 'high levels of protection' exists in the US, especially for US independent regulators who are also liable if they would deviate; finally, the so-called civil society and the media play a role as well.

Thus, addressing TBTs is not about the level of SHEC objectives and it should not be. It is not part of TTIP, nor – as far as the author knows – of any other regional trading agreement anywhere on the globe. This is not what the TBT Agreement in the WTO is about.

2.2 TBTs in TTIP: wider, narrow and horizontal focus

TTIP is mainly about regulatory issues affecting trade and investment. But this must mean that TBTs cannot be confined to the TBT chapter in the TTIP negotiations. Although the present study is focusing solely on the TBT chapter – if only for reasons of time available and brevity of the study - it is crucial to understand the broader context of regulatory, including technical, barriers. In Figure 1, the first layer employs the term non-tariff measures (NTMs) which comprise any hindrance of trade other than tariffs, whether at the border or domestic; one major part of these are 'regulatory barriers' caused by

Figure 1: What are technical barriers?



differences in regulation. The second layer identifies TBTs as a major segment of regulatory barriers, for all those numerous instances where laws and decrees, as well as decisions of regulators relate to technical properties of goods for reasons of serving SHEC objectives. The third layer shows that there are three types of TBTs: differences in standards, differences in technical regulations and differences in, or unnecessary duplication of conformity assessment. In this general sense, TBTs are dealt with in

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

(ii) issues of food safety and animal & plant health [but they are always dealt with separately in a SPS chapter, based on the WTO SPS Agreement, also in TTIP] ;

(iii) the sectorial 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, also with a view to future questions in a 'living agreement'.

This wider conceptual view on TBTs shows how ambitious TTIP really is. The economic study by Francois et al (2013) [5] for the Commission Impact Assessment of TTIP implicitly deals with all these segments of TBTs, be it inevitably in a very crude way. Measuring the costs of TBTs with some degree of reliability is exceedingly difficult. The Francois et al. study is based on ECORYS estimates of 'tariff equivalents' of TBTs, i.e. regarding the TBT costs "as if" they were an import tariff. These costs (in % of the invoice price like a tariff) are no less than 21 % (EU TBTs for US exports) and 25 % (US TBTs for EU exports) on average, with peaks for agro-food (resp. 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 Atlantic tariffs. However, how reliable the estimates are is very uncertain. Two examples: (a) in Fontagne et al (2013) a different technique is employed and the average TBT costs for manufacturing are much higher than in Francois et al: rather than 21 % (EU TBTs) and 25 % (US TBTs), the authors found 43 % (EU TBTs) and 32 % (US TBTs); (b) in other empirical studies of (intended) EU FTAs with e.g. Japan and Canada, Pelkmans et al (2014) find a range of disparate TBT costs with various methodological problems. Nevertheless, it seems a rather robust result

[5] See http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf ; See also the non-technical explanatory study for the INTA Ctee on the Francois (or CEPR) report, underlying model and alternatives estimates, by Pelkmans, Lejour, Schefler, Mustilli & Timini (2014): www.europarl.europa.eu/RegData/etudes/etudes/join/2014/528798/IPOL-JOIN_ET%282014%29528798_EN.pdf

that TBTs in manufacturing are high and addressing them is surely economically worthwhile, much more than tariffs.

A narrow view of TBTs in TTIP implies a focus on the TBT chapter. Strictly regulated sectors like medicines, automotive products, chemicals and cosmetics do not fall under this TBT chapter. In the EU, none of these sectors fall under the New Approach, nowadays the NLF (New Legislative Framework). In these sectors, voluntary standards are not used for the simple reason that regulation is highly specific and intrusive whilst conformity assessment typically relies on stricter forms than mere private certification, such as (pre-market) type approval and inspection. For the remaining sectors, engineering is the most prominent beneficiary of the NLF with a preponderant reliance on many thousands of European standards, indeed, often 'harmonised standards' giving a 'presumption of conformity' in the EU internal market, hence free movement. This is also true for medical devices, be it that the regime has been tightened somewhat over time in response to shortcomings. In textiles & clothing, the EU relies on the General Product Safety directive (under review) which says that producers can only bring on the market products which are 'safe'. Of course, they are also liable in case of defective products creating a safety risk. But the EU has no flammability regulation 'on top of that' (although there are CEN testing standards) whereas the US requires third party certification about non-flammability for children clothing, based on different testing standards. In addition, there are labelling questions. In fact, all these issues are very similar indeed to NLF approaches (as the review of the GPS directive acknowledges). Finally, the ICT sector is largely working on global standards and the TTIP issues comprise aspects such as e-labelling, e-accessibility (for the disabled), interoperability (where not yet addressed) and e.g. common principles for certification of encryption of ICT products. A longstanding complaint, mainly from US companies but nowadays also from EU and US ICT business together [6], is that EU Member States' governments do not (always) recognise global ICT standards in their public procurement. Indeed, until Reg,. 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. Some accommodation has been included in the new regulation, but business desires an automatic acceptance, as long as typical WTO TBT (annex) criteria have been adhered to, because the sector is a fast-moving one with permanent innovation.

Besides these four sectors with specific annexes, there are of course other sectors and specific goods which may encounter TBTs when trying to access the US (and EU) market. Thus, the TBT chapter attempts to organise a framework, more ambitious (at least, from the point of view of the EU) than ever before in any FTA[7], to address more structurally existing TBTs while trying to pre-empt new ones. This is discussed in sections 3.1 and 3.2.

TTIP also contains a horizontal regulatory cooperation chapter[8]. It constitutes an effort to build a TTIP 'governance' of market regulation based on common principles about designing and assessing regulations, with ample opportunities for mutual interaction (e.g. notice & comments) between the US and the EU, also with stakeholders. The chapter matters for the 'living agreement'. It would establish a Regulatory Cooperation Body. Regulatory coherence and joint governance matter for the TBT chapter because these horizontal

[6] See DigitalEurope and (US) ITI (2015), ICT industry recommendations for regulatory cooperation in the TTIP, Brussels and Washington DC, Febr. 2, 2015

[7] With two exceptions : the EEA (which is formally a FTA) which essentially applies internal market rules, plus Switzerland (coming quite far into this direction); and the Trans-Tasman MRA between New Zealand and Australia which functions in the context of the wider CER (economic integration) between the two countries. An assessment of the TTMRA is provided in annex C of Pelkmans & Correia de Brito (2015a).

[8] On 10 February 2015, the Commission has published a text proposal, submitted to the 8th Round. See http://trade.ec.europ.eu/doclib/2015/february/tradoc_153120.pdf and Chase & Pelkmans (forthcoming).

approaches / principles are likely to help reducing TBTs and disciplining future actions of the two governments. However, to keep this study within its limits, the focus will be on the TBT chapter.

2.3 Standards and risk regulation: how the US and EU systems differ

For all three types of TBTs, there are differences between the US and the EU. Whilst these differences have to be highlighted for this study and whilst they matter for TTIP, one should never forget that there are many similarities, too. Also, the TBT Agreement is firmly adhered to by both. But one has to acknowledge that the optimism of the mid-1990s when it was thought that a relatively simple and 'light' approach such as a MRA in several industrial sectors, would be a quick road to lower the costs of EU/US TBTs, was largely mistaken. On both sides lessons have been learned (see e.g. section 3.4) and regulatory cooperation ever since 2002, and especially 2007 in the framework of the Trans-Atlantic Economic Council (TEC), has deepened mutual understanding and also helped to develop practical forms of regulatory cooperation, without formal obligations. The TTIP TBT chapter is meant to decisively move beyond this status-quo and genuinely address the cost of TBTs.

For standards, there are two systemic differences with the US: one is the overall standardisation tradition in the US, the other is the link between regulation and the use of standards for such regulation. Standards (see also BOX 2) are by their very nature arrangements on technical specifications which markets value and which, as such, have nothing to do with regulation. Bed sizes such as King-size and other ones are asked by the market, if only because beds can then be made in large series and matresses as well, knowing for sure that the matresses will fit. It also helps consumers understand the offerings in an easy way. But this compatibility standard does not mean that individual suppliers or special brands cannot make other bedsizes, in smaller series or on demand. Technical standards are therefore not really about techniques or engineering, though obviously that is indispensable, but about economics. Markets function better with standards. Here, one finds one of the several caricatures still alive in some circles: the standardisation tradition in the US is often presented there as an ideal approach ('market based'), even though European standards are just as much 'market based'. As long as regulation is not linked with such standards, it is fundamentally similar : standards reflect market needs - a standard developed without articulated demands from market players is doomed not to be adopted, hence, not to be sold, hence, no income for standard bodies : it is pointless. But there is one important difference for such standards : in the US, a single country, there is of course no history of a deeply fragmented (like once the European) market, therefore, no 'national standard bodies' joined into a common overarching 'nation-wide' standardisation organ like CEN/CENELEC. This allowed a tradition to flourish of a liberal climate to initiate a standard body. Figures vary [9] but there are several hunderds in very many subsectors or cross-cutting domains. Some 200-plus are members of ANSI, the American National Standardisation Institute, a member of ISO/IEC, but in fact more a platform and itself not promulgating standards[10]. ANSI discourages competing standards (although it has no say over non-members) but it takes a very liberal view on non-competing or complementary standards from many different specialisations. European SMEs complain that it is difficult to find out who does what and where EU SMEs may become members or simply obtain (the right) standards they need. There is something to this outcry but it is exaggerated because the large majority of standards for use in US regulations is developed by only 9 bodies, all very well-known and some of them with

[9] From some 300 bodies (ANSI), to 400 (as the European Commission notes) to some 700 (as CEN/CENELEC suspects).

[10] In ANSI one finds standardisation bodies, conformity assessment bodies, companies, government agencies as members.

worldwide reputation (e.g. ASTM with some 25 % of these standards alone, IEEE, ASME, SAE, etc.)[11]. Another drawback may be that, in some instances, standards serve as a 'business model' for a trade association of specific products, which creates a risk of a too-close-for-comfort connection between standards and the vested interests of that association. Sometimes, standard bodies also act as conformity assessors, mixing up two separate functions and risking conflicts of interest. In Europe, European standards are always CEN/CENELEC/ETSI ones – so, no wide and intransparent spectrum of standard bodies, many of which act entirely on their own. The advantages of the European approach are (a) a clear uniform procedure of how the standard is written (e.g. with open inquiry, stakeholders, etc.)[12], (b) valid for all of EEA plus Turkey/ Switzerland, (c) no competing standards, by means of an obligation, based on the central adoption by CEN (etc.), to withdraw any existing (national) standard. As long as standards – by definition voluntary anyway – are not linked to regulations, EU exporters and investors can live with the US standards landscape despite some drawbacks. Except for one widespread shortcoming which is problematic, however: the US bodies rarely adopt (fully or even partially) ISO and IEC standards. This is most disadvantageous in electrical and electronic goods, including machinery, where safety and compatibility issues have been addressed internationally for far over 100 years, and where CENELEC has ensured that no less than some 72 % of European standards are identical to IEC standards. For non-electrical goods (by CEN and ISO), this is closer to 31 %, still several thousand[13]. Apparently, in the US the total of identical ones for both is not even 200, far less than one percent of US standards. Although historically one can understand some degree of 'insulation' of the US, before globalisation' began, and when – after World War II - it was a technological leader, it is no longer easy to appreciate this predicament today. Usually, two reasons are given : (i) historically, the Europeans have many votes (together) and the US only one single vote in Geneva, creating a permanent feeling of being outvoted, certainly in the first decades of ISO ; this argument has weakened a great deal because ISO/IEC membership is now worldwide and the EU cannot dominate [14]; (ii) 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 [15]; this argument seems self-serving, especially for IEC standards, because it is unlikely to be correct as a rule (imagine that it would mean that the bulk of thousands of European standards would be second-rate), but, in any event, there are no reports with systematic empirical evidence substantiating the assertion so generally ; the suspicion that vested interests play a decisive role, is difficult to disregard ; another rationale is that it is also difficult and costly to alter engineering traditions built on familiar standards. Nevertheless, it is and remains true that the very idea of standardisation is to do away with multiple specifications, where possible and functional, and writing mere performance standards. US practices are also inconsistent with the 20 years old credo of the TABD [16]: 'one standard, one test, valid everywhere'. The importance

[11] Also, there are many European companies active in ASTM and selectively also in some of these other prominent US standard bodies. ASTM is a not-for-profit organisation and European SMEs can become full voting members for some € 50 per year, and this includes free acces to ASTM standards they are interested in.

[12] But this does NOT imply a 'top-down' approach (that is, no longer market-based) to standards, as some Americans misread this. The uniform procedure is purely a protection of stakeholders and other safeguards (open inquiry) ; the initiative is always bottom-up and market based and its contents is determined in technical committees by experts. The root of this misunderstanding is that Americans often use the term 'standard' in its colloquial way, whereas what they often mean is a technical regulation.

[13] Note that in the Dresden and Vienna arrangements, CEN/CENELEC tries to ensure that new standards are written for both IEC/ISO and CEN/CENELEC at the same time (with the same European experts).

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

[15] As noted, the share of CENELEC standards overlapping fully with IEC standards (72 %) is far higher than the overlap of CEN standards with ISO ones (31 %). This has two reasons, one being the greater incentive in electrical goods to achieve compatibility, but the other one is undoubtedly that ISO standards are more often compromises or have remained too general (in order to be adopted). Interviews confirm that, in the US, this plays a role just as in Europe.

[16] Trans-Atlantic Business Dialogue (CEOs of EU and US multinationals)

of adhering to international standards hardly needs to be stressed in times of globalisation and global value-chains. Of course, US multinationals do de-facto export US standards willingly or unwillingly, and this perpetuates the hope or 'strategy' to export one's own standards which might bring extra advantages for US industry. Some US standards promulgated by well-known US engineering societies such as ASTM and some others are de facto world standards (e.g. for aircraft, computers, power grids, cars, etc.) and, in these cases, multinational business (and including many EU companies) are used to living with two standards (e.g. they have an ASTM stamp). Nevertheless, the extremely low rate of adopting ISO/IEC standards cannot be justified or made respectable by these prominent examples.

Box 1: Technical standards: what and why?

A technical standard [for definition, see BOX 2] is promulgated 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, unfortunately, there are instances that different (voluntary) standards do amount to barriers, 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 [17] include:

a. 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;

b. 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);

c. agreed specifications needed for interoperability or compatibility of intermediate or final products ;

d. agreed ways to reduce clear redundancy of variety in order to facilitate economies of scale.

Typically, industry invests profoundly in standard writing (for over 100 years) [18] because they want markets to function better, without losing sensible variety (as a precious tool of competition and a way to satisfy a range of preferences in demand) ; industry will also see a need to codify new technologies or product solutions where one of the four reasons (above) applies, or where new materials are playing a role.

None of this implies, let alone, requires, regulation. The overwhelming share of standards written in the US and in the EU [19] belongs to this category of voluntary standards purely and only to serve expected or articulated demand characteristics or reduce redundancy [20] in B2C or B2B exchanges.

When voluntary standards are used in support of (US) regulation, however, the differences between the US and EU systems are amplified. In the EU, this is mainly done in the NLF

[17] See for instance, Pelkmans & Costello (1991), Swann (2010) and Blind (2013).

[18] It is estimated that European industry invests nearly € 1 billion a year on standards writing, more than 95 % of all costs of European standardisation.

[19] Some 20 000-plus European standards have nothing to do with regulation at all and this total increases with a 1000 or so standards every year.

[20] An example : does one need, in the B2B market, 55 or 155 types of steel quality and functionality? Redundancy means that participants in the steel market and value-chains using steel agree that a number of these variations are simply not necessary and it would be advantageous for all to (say) reduce it to 55 well-specified and agreed standards.

based on 'essential requirements' of SHEC, formulated by the EU legislator and translated into a Commission mandate to write standards for CEN/CENELEC/ETSI in support of EU regulation. Such standards are so-called harmonised European standards, that is, they give a 'presumption of conformity' with these essential SHEC requirements, hence, free movement, but for the rest they retain ordinary standards features that reflect market needs. In fact, free movement is granted to all goods having a CE mark, whether based on a harmonised standard or not, but the harmonised standard greatly facilitates because the presumption of conformity is much appreciated by manufacturers. Critical is that such a harmonised standard remains voluntary and a manufacturer is free to use another standard or present its own (innovative) solution abiding with the essential requirements, but in that case, has to go through third party certification by a Notified Body. This is critical in terms of good regulatory practices because what matters is that the SHEC objectives (essential requirements) are served properly, but the instruments or innovative other solutions of doing so are at best secondary, hence should not be prescribed or restricted unnecessarily[21]. The US system[22], in contrast, is based on 'incorporation by reference' and that referred standard then automatically transforms into an obligation itself: it becomes part of law, whether federal, state, municipal or even county level. No alternative methods or innovative solutions can be used or demonstrated to serve equally well the SHEC objectives at stake, unless such alternative standards are specified in the regulation. This is one problem. A second problem consists in the lack of any guarantee, indeed no coordination whatsoever, that different government levels choose the same standard: Departments of Transport or Energy or US regulators manage their own requirements.

Box 2: TBT definitions and why they matter for TTIP

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 labeling requirements as they apply to a product, process, or a 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 labeling requirments as they apply to a product, process or production method. (Annex 1, TBT Agreement) It should be noted that the colloquial use of the word 'standard' is often different. It may mean a SHEC objective (say, in « not lowering the 'standard' «) or an authoritative example ('TTIP should become the gold standard for regulatory convergence'). Thus, the term standards should be used carefully in TBT matters, following the TBT agreement and ISO practices.

An international standard (or guide or recommendation, as the WTO specifies) is widely understood as a standard promulgated by world bodies like the ISO, IEC and the ITU, except in ICT where often other consortia play a role. There is no disagreement on this, also not with the US : ISO and IEC standards are international standards. However, the US has a longstanding position going beyond this, in a rather artificial legalistic reasoning. The US argues that the WTO TBT Agreement does not designate ISO and IEC or any

[21] 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.

[22] Described in OMB Circular A-119 and further explained in detail in the 2009 Report on the Use of Voluntary Standards in support of Regulation in the US, for the US-EU High Level Regulatory Cooperation Forum, see http://gsi.nist.gov/global/docs/Voluntary_Standards_USRegs.pdf . See also the US report on TBTs, 2014, from the USTR.

other 'body' as international ; instead, the TBT Ctee 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. 25/6). This has prompted the US to maintain a strategy of incorporating this artificial approach in its several FTAs. Thus, in its FTA with Korea [KORUS], art. 9.3 stipulates this. Strictly, there is nothing against repeating a decision of the TBT Ctee in a FTA. However, this is a strategy to acquire greater credibility for this artificiality. Behind it, one can surmise that, what used to be 'domestic' US standards, can now be exported as 'international standards' if the principles are met and a few foreign companies or experts are involved in writing these standards in the US ! In some cases like ASTM (a truly internationalised US standard body, with e.g. many EU companies involved) one might be able to understand such a position – even when one disagrees because it undermines 'one standard, one test, accepted everywhere'. But as a general rule it is strongly resisted in the EU, as it artificially hides an attempt to delay or refuse US moves to employ more global standards from ISO/IEC. It is also problematic for the US FTA partners : Korea has KORUS with this provision and KOREU without it. The overwhelming majority in the world prefers ISO/IEC standards as international standards but countries are sometimes pressed by the US to subscribe to the Ctee Decision (which, of course, is textually innocent). At the same time, especially ISO will have to earn its credibility in a larger number of cases, otherwise the US and some other countries, but also the EU (which does not follow ISO in two-third of standards) will continue to live with a multi-standard reality in global trade. The EU is unlikely to accept the 'KORUS' provision in TTIP and a clever way out will have to be found. A wholesale switch of the US to ISO/IEC standards cannot be realistically expected, as it would be disruptive for industry's technical (standards) infrastructure, including in-factory manuals, technical training, etc. In this respect, the Commission 'Factsheet' on TBTs shows some understanding:'Governments and firms on both sides…have invested a lot in running and developing their systems. We need to take this into account'. But a gradual acceptance of much more IEC standards by the US should be possible and not disruptive.

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

Neither is there a requirement or any coordination that (say) referred standards at lower levels of governments have to be withdrawn once the federal level has incorporated standard x. The upshot is frequently that the US internal market becomes fragmented when risk regulation is enforced. Because multiple standards (may) exist, government chooses the most suitable existing standard[23], implying that joining a standard body and investing efforts to help write or vet standards is no guarantee that this investment pays off for public procurement or, more importantly, the supply of numerous goods under SHEC regulation. Clearly, this system of 'incorporation by reference' risks to create 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 levels of government. It is also rigid (given that a standard is turned into part of a regulation, usually without any scope for alternatives) and rarely updated. However, in US Presidential Executive Order no. 12866, it is explicitly mentioned that performance standards should be preferred, and this should be considered with flexibility.

[23] But does not necessarily pay attention to the governance of how the standard was written (e.g. stakeholders).

There are also 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'). First, conformity with the SHEC objectives (in the EU, essential requirements) themselves is 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). Second, much of the US risk regulation is in fact managed by independent federal regulators like OSHA (protection of workers in the workplace), FCC (safety and health aspects of telecoms equipment, etc.), the CPSA (Consumer Protection Safety Agency), the EPA (Environment Protection Agency (many aspects including chemicals), the FDA (medicines and medical devices, as well as food law), the FAA (aircraft certification), the US Coast Guard (boat and maritime safety) among others. Although the US Dept of Defence is not a Federal Agency, of course, it is committed to the adoption and use of voluntary standards in much the same way. This implies that the practical aspects of the conformance policy of the Federal agency is often decisive for whether conformity assessment (CA) turns into a TBT. For example, the EU has a long-standing friction with OSHA, due to its policy of assigning NRTLs (Nationally Recognised Testing Laboratories) for mandatory third party certification of electrical goods, a stronghold of EU exporters[24]. 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[25]. Nowadays, a dozen NRTLs have been recognized, but UL does not accept certification of components and parts of other NRTLs (hence, testing is duplicative) with the excuse of liability. Moreover, some 30 US states have enacted provisions singling out UL as the mandatory C. A. 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 C.A. rules and practices, now that both Circular A-119 and OSHA's policy with respect to NRTLs are under review. TTIP is a good opportunity to remove these frictions and costly TBTs (here, for the electrical goods and machinery sector) via a consensual and targeted TBT chapter.

Note that C.A. principles are not very different in the US and in the EU since C.A. bodies tend to be accredited on the basis of ISO standards for laboratory accreditation. Also, reliance on the international private quality networks for C.A. and accreditation (ILAF and IAF, see Pelkmans & Correia de Brito, 2015a) is (selectively) encouraged in the US, which implies that the European C.A. bodies in these networks are often recognised in the US for C.A. and its results. 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[26]] was expected to focus purely on C.A. issues, without ever touching 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 (see section 3.4). The modesty of a MRA, compared to today's TTIP TBT debate, is quickly understood once one realises that all a MRA does is to accept certification from a designated C.A. body in A on the rules and standards in B, and the other way around. So, it is expected to do away with duplicative testing but not with the underlying differences in rules/standards, which are normally the lion's share of the costs of TBTs.

[24] 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, that must be shown on request of the authorities.

[25] Explained in detail in Orgalime (2011), Position Paper of 24 Oct., EU manufacturers suffer from malfunctioning of the US certification market : potential abuse of dominant position ; and Orgalime (2012), Position Paper of 5 Oct., Orgalime priorities for the upcoming EU-US trade and investment negotiations, which provides a number of details about excessive pricing (compared to other NRTLs, and also due to unnecessarily cumbersome procedural requirements).

[26] GMP = Good Manufacturing Practices, an OECD standard for factories ; EMC = electro-magnetic compatibility, preventing interference between different pieces of electric/onic equipment

2.4 What the EU wants in the TBT chapter

The official EU mandate[27] first instructs that it is going to be a TBT-plus agreement as well as establishing 'a mechanism for improved dialogue and cooperation for addressing bilateral TBT issues'. The following citation captures what the EU wants, be it in trade diplomatic language in order to provide negotiation space to the Commission: 'The objectives of these provisions would be to yield greater openness, transparency and convergence in regulatory approaches and related standards-development processes, also with a view to adopting relevant international standards, as well as, inter alia, to reduce redundant and burdensome testing and certification requirements, promote confidence in our respective conformity assessment bodies, and enhance cooperation on conformity assessment and standardisation issues globally. Consideration should also be given to provisions on labelling and means of avoiding misleading information for consumers. This text is very close to that of the US/EU High Level Group Report of February 2013. Therefore, it does not clearly distinguish between preferences that the EU wants and the US does not want, or that the US does not articulate. The EU text proposal (see section 3.1 below) is foreshadowed in an important and fairly detailed Commission document: 'TTIP, the regulatory Part'[28]. Since the EU text proposal has now been published, a lengthy analysis of the former valuable document seems superfluous in a short study like this. It is instructive to read the five 'guiding principles' the EU inists on : (i) removal of unnecessary barriers to trade arising from differences in ….technical regulations, standards and CAPs – the word 'removal' tends to be stronger than what the US would normally use ; (ii) although 'compatibility is important', …'the systems of the two regions are different… And it is not possible for one side to impose its system on the other…' ; (iii) 'aim for methods … not more trade-restrictive than necessary' [but still] '… give preference to internationally harmonised methods' ; (iv) no new hindrances for the rest of the world ; (v) do not compromise existing Atlantic cooperation related to TBT matters. For the rest, the structure of the later text proposal is already used but sections 3.1 and 3.2 will show that this structure is not followed by the US (e.g. in KORUS) or in other recent FTAs the EU has concluded.

2.5 What the US wants in the TBT chapter

The knowledge in the public domain about the US preferences in the TBT negotiations in TTIP is scant if one refers to textual proposals. The USTR has published a TTIP Factsheet [29] in rather general language. A summary of four central issues is as follows:

- 'seek to eliminate or reduce non-tariff barriers that decrease opportunities for US exports, such as unjustified TBTs'
- 'while maintaining the level of health, safety and environmental protection… we seek greater compatibility of US and EU regulations and related standards development processes inter alia by promoting transparency in the development and implementation of regulations and good regulatory practices, establishing mechanisms for future progress and pursuing regulatory cooperation initiatives where appropriate'
- should be TBT-plus ('build on key principles of the WTO TBT Agreement', etc.)
- seek 'commitments to base SPS measures on science and international standards or scientific risk assessments'; although this applies to SPS, there can be little doubt

[27] Made public on 9 Oct 2014 by the Council : Directives for the negotiation on the TTIP between the EU and the USA, originally dated 17 June 2013, doc.11103/13, p. 12
[28] September 2013, DG Trade website
[29] USTR (2014), US objectives, US benefits in the TTIP : a detailed view, March ; www.ustr.gov/about-us/press-office/press-releases/2014/March/US-Objctives

that this principle should also be applied to TBTs and may play a role for the US (in most cases, the EU would probably agree on the principle for TBTs, as is customary inside the EU, too).

In the text accompanying these four items, one finds some interesting elaborations. One is 'a path to increase transparency and openness in the developments of standards and technical regulations'. The US complains already for years that European standards writing is a closed process: not open for companies or experts from countries where the national standards body is not a member of CEN/CENELEC/ETSI. Strictly, this is true and it contrasts with the US where such 'openness' is practiced. First, it is crucial to appreciate why this 'closed' system was once introduced. The principal reason is: the national bodies have to withdraw any competing existing or emerging standard, once the three European bodies have formally approved a standard. That is not the case in the US, as discussed above. However, here is clearly room for some opening up: for instance, one could create positions for experts in technical working groups under technical committees if there are convincing market reasons (e.g. an alternative standard) or leading expertise. After all, standards ought to be written on 'merit' and state-of-the-art trends. The voting is another matter due to the withdrawal obligation (e.g. SMEs or labour /consumer unions also have no vote, even though they are involved). But the US argument is not very powerful, for the following reasons : (i) US companies are involved routinely via national standard bodies, and, for some leading ones, directly in ETSI ; (ii) CEN/CENELEC have very many ISO and IEC standards which are identical to their own, and frequently written in a single process with the same experts (and US experts participate in writing these standards, and occasionally chair technical committees) ; (iii) in the open /public inquiry period, of course, US companies and standards bodies can comment and suggest alternatives or even common standards. As to the last point, perhaps there are greater possibilities to justify or explain why outside suggestions are or are not taken into account - this could be a subject of deeper cooperation between ANSI and CEN/CENELEC as a parallel achievement of TTIP.

A second one is to 'ensure that US bodies are permitted to test and certify products sold in Europe'. This refers to the fact that EU law says that Notified Bodies have to be suggested by Member States and accredited via the EA (European system of Accrediatation) based on ISO standards for such accreditation. Moreover, national accreditation bodies are not to be market-oriented but purely service oriented; hence, only one such body per Member State. One way reconciling these provisions with greater openness is to conclude MRAs about conformity assessment. This was done in 1998 (section 3.4) but it turned out that the US itself exhibits several rigidities (especially via regulators). However, there are upcoming US reforms in this highly technical area, for example, OSHA is reviewing its system of NRTLs (like Notified Bodies in the EU) and the famous Circular A-119 (on how standards ought to be used for US regulation) is equally under review, partly due to political commitments by the US prior to TTIP. With sensible and well-informed diplomacy, there is surely space for pro-trade solutions, without in any way disrupting one another's systems.

A third one is to 'promote EU recognition of international standards used to support global trade by US exporters and producers'. To appreciate the full meaning of this sentence, which – seemingly – is in line with the EU view to render international standards even more prominent, the reader is referred back to BOX 2. The term 'international standard' is not what the EU insists on, in particular because the sentence connects it with 'support global trade by US exporters'. Why? The reason is that the US has insisted for many years on the notion that the TBT Agreement in annex 1 (and subsequent TBT Ctee decisions) does not designate ISO and IEC as the (only) writers of international standards; ISO/IEC are producing international standards because they adhere to the six principles mentioned in BOX 2. But also a number of US standard bodies adhere to these principles and, when they have even the slightest international involvement (say, a few foreign experts or

companies), they would, in this legalistic (but highly strategic) concept, therefore produce international standards. In other words, the sentence in the USTR document implies that the EU should support US standards – very rarely identical to ISO/IEC standards - as international standards. For profound economic (in times of globalisation) and systemic reasons, this position is unacceptable for the EU, and, one may argue, not in the global interest either. However, the standardisation scene in the US is quite uneven. In BOX 2 it was already mentioned that, amongst hundreds of bodies in the US, 9 of them are prominent and often truly international as well. Hence, there are many instances where standards from them have acquired well-accepted status in world markets, together with 'domestic' bodies without any status in markets outside the US and trying to stay away conveniently from ISO /IEC standards. Perhaps a thorough study of the actual market situation with respect to US standards (and European non-ISO ones) might be useful to move the TTIP negotiation out of the stalemate on this crucial point.

It is also instructive to read the 2014 TBT report of the USTR[30] on the EU. Most of the examples, set out in careful detail also with respective to the EU initiatives and 'notice and comments' or impact assesment, clarify why the US is so keen on 'good regulatory practices' and principles like scientific underpinning of risk regulation. Examples such as the reduction or elimination of F gases in equipment and semi-conductors show that these procedures have not been properly executed in the EU (as is also an intra-EU concern) and that extremely tight deadlines for change-over can be unnecessarly damaging for trade. The problem is even more serious in the case of EDs (endocrine disruptors) where DG Environment employed a hazard-based approach (without clear criteria) for classification and work programme. The US (but also inside the EU, even a group of authoritative toxicologists!) protested sharply. The economics and long traditions of the practice of risk regulation (e.g. OECD, WHO, etc.) reject such approaches. One has to dispose of overwhelming arguments and alarming empirical indications before one can switch to hazard-based approaches, and even then risk assessment (to the extent possible, if there is a lack of knowledge) ought to be practiced carefully and impartially. In EDs there is no reason for this as insisted by the scientists. Yet, eventually, such an approach is likely to result in a series of TBTs, without solid justification (not to speak of whether this is in the European public interest in the first place) in plant products and chemicals. These examples selected in the TBT report of the US show that 'better regulation' is not only in the interest of the EU itself, but also tends to pre-empt unjustified TBTs. At the same time, it is of course possible, too, that the US occasionally suffers from the same weakness and, in doing so, throws up new TBTs. This underscores that sound regulatory procedures and practices are good for both trading partners.

[30] Especially pp. 66 – 78. See www.ustr.gov/sites/default/files/2014%20TBT%20Report.pdf

3. ACHIEVEMENTS IN RECENT FTA AGREEMENTS AND OPTIONS FOR THE TTIP TBT NEGOTIATIONS CHAPTER

KEY FINDINGS

Comparing the EU text proposal on TBTs with KORUS, one can appreciate the 'gaps' on the TTIP negotiation table. There is a large overlap in the transparency provision and some in regulatory cooperation, but KORUS has no articles on standardisation, technical regulations or marking & labelling, and, most important of all, it lacks the mobilising idea ('objective') that TBTs ought to be effectively reduced and, where possible, eliminated. KORUS includes a reference to what the US calls 'international standards', which is seen by the EU as an artificial legalistic construct to allow many US standards to be called 'international standards', precisely when very few US standards are identical with ISO/IEC standards in the first place. Whereas the Singapore/EU TBT chapter is close to that of the EU proposal in TTIP, also reinforcing the emphasis on going for (genuine) international standards, the CETA TBT chapter is more modest. However, the great merit of CETA is the Protocol on mutual acceptance of conformity assessment results, greatly improving the old MRA and significantly widening its sectorial scope.

Chances for harmonisation of regulations are very low in TTIP, except for special cases. Mutual recognition as known inside the EU is out of the question. As with CETA, the MRA could be enhanced and widened sectorially but this will be far less easy than with Canada, due to rigidities of regulators (but new US reforms might help). A theme for the 'living agreement'-- seeking 'equivalence' agreements is demanding but perhaps possible.

The old MRA showed mixed results, although subsequent cooperation 'outside' the MRA context has brought remarkable successes in medicines and medical devices. It shows that not the treaty base is decisive but, rather, that domestic regulators must be satisfied during and after the negotiations that their pursuit of SHEC objectives is not watered down. Therefore, regulators must (also) be in charge of regulatory trade policy.

3.1 Comparing KORUS and the EU TTIP negotiation text on TBTs

It is highly instructive to go through an elaborate comparison exercise of the KORUS TBT chapter and the EU TTIP text. It helps one to understand in fairly great detail the similarities and differences, indeed in some respects the 'gaps', between the US and the EU on the negotiation table. In Table 2, below, this exercise is done. Table 2 compares KORUS and the EU text proposal published in January 2015 provision by provision. The last column makes annotations and some further explanation or interpretation will be provided following the Table.

Table 2: Concordance between KORUS and the EU TTIP TBT text proposal

No.	Substance	KORUS	EU Text proposal	Annotations JP
1.	Link to TBT Agreement	Affirmation of TBT Agreement (art. 9.1)	Incorporated (art. 2)	EU speaks of 'made part of TTIP'
2.	Scope and coverage	broad scope (standards, regulation, conformity assessment), except for public procurement, and for assigning SPS to a separate chapter	Almost identical for 'scope and coverage' in art. 1.1, 1.3 and 1.4, but the EU begins with a clear objective	There is no overall, leading objective in KORUS TBT chapter 9; the EU objective in art. 1.1 is 'to promote convergence in regulatory approaches' [which is quite ambitious and fairly general], 'by reducing or eliminating conflicting technical requirements as well as redundant and burdensome C.A. requirements'
3.	'International standards'	A detailed/precise reference, on when an 'international standard' exists, to the Decision of the WTO TBT Ctee of 1995 , in art 9.3 of KORUS	(see above, art. 2 incorporates the TBT Agreement, and the terms used, with it)	Art. 9.3 of KORUS reflects a long-standing insistence by the US that an 'international standard' is determined by reliance on the principles of the Code of Conduct [including 'openness'] and not by what body promulgates the standard ; the US means that ISO & IEC should not have a monopoly on what 'international standards' are ; this allows the US to maintain that some of its national standard bodies promulgate 'international standards' – the status of some leading US bodies in markets is surely international, in many other cases this is incorrect (see the discussion in section 2.3 and 2.5) ; for many in the world, 'international standards' are ISO/IEC standards, except in ICT (see also the explanation following this table)
4.	'Joint cooperation'	Strengthen 'cooperation … facilitating access to their respective markets'; e.g. transparency, good regulatory practices, alignment with international standards and use of accreditation for C.A. bodies (art. 9.4)	Similar cooperation art. 3, but with a wider scope, e.g. also market surveillance as well as monitoring & enforcement activities ; moreover, EU proposes explicit reference to chapter on horizontal cooperation ; encouragement that accreditation & C.A. bodies participate in 'cooperation arrangements' promoting the 'acceptance of C.A. results'	EU proposal for cooperation suggest 'deeper' and wider cooperation ; probably due to overall objective (see item 2, above)
5.	Technical regulation	No provision	Objective-driven (see item 2, above) cooperation 'to ensure	The lack of any provision (except for automotive) in

		[except a short article 9.7 on automotive regulations (and cooperation in UN-ECE WP 29); a special annex 9B is devoted to automotive ; note that in the EU proposal, automotive is in a separate chapter]	[as far as possible] that their technical regulations are compatible with one another' such that TBT costs are minimal (art. 4.1); in art. 4.2, ambitious provisions are meant to promote 'harmonised or compatible technical regulations' in case a technical regulation of equivalent scope is being prepared by the other party; two provisions on compatibility : in art. 4.3 cooperation 'towards global harmonisation' ; in art. 4.4 an endeavour to ensure 'that products originating in the other party are subject to only one single authorisation, certificate or approval in the entire market'	KORUS on regulations, let alone equivalence, compatibility, a harmonised regulation and global harmonisation, makes it a modest WTO-plus FTA with respect to TBTs ; The EU clearly follows its stated objective - it wants to reduce/eliminate TBTs as much as possible - hence, this quite ambitious art. 4 ; whether, how and to what extent the US in TTIP is willing to match the EU ambition is unknown, but - so far - there is no public sign of such preparedness
6.	Transparency	KORUS, art. 9.6, is extensive and fairly detailed ; persons of the other party are allowed to participate 'in the development of standards, technical regulations and C.A. procedures' ; provisions on a 'notice and comments' procedure in case of proposed new regulations and C.A. procedures, with dissemination and explanation requirements ; specific publication requirements also for lower levels of government; clarify links with international standards; publication in a single official journal, single internet site, while also using an agreed Inquiry Point bilaterally ; when the regulation is final, an explanation of objective(s), rationale and responses to significant comments is compulsory (even 'alternative approaches considered' can be requested)	In art. 5, EU proposes similar provisions (although, not on participation) ; goes beyond when not just publishing responses on 'comments' but (on request) discuss the comments, also with the regulatory authority of the other party ; there is greater ambition in information of new and [later] existing regulations and standards at lower levels of government (complete registry) ; an extra provision is that when an imported good is detained at the port of entry, the importer has a right of appeal	The EU and the US agree that an ambitious approach to 'transparency' [while not affecting the right to regulate] can render the WTO TBT Agreement far more effective, without any harmonisation, mutual recognition or 'equivalence' ; in this area, much should be accomplished
7.	Standardisation	KORUS has no provisions on cooperation of standards bodies [but art. 9.6 on transparency speaks about allowance of persons from the other party to participate in standardisation]	An ambitious art. 6 promoting a 'closer cooperation between the standardisation bodies' about mutual information, harmonisation, developing common standards, also in 'new' areas ; art. 6.2 seeks (best endeavours) to achieve that planning of standardisation becomes known to the other party (including time tables) and that comments on drafts can be	Again, art. 6 of the EU text proposal reflects the objective [art. 1.1] as well as some of the frustrations about the selection of standards by (US) regulators, the absence of an obligation to update (in EU, every 5 years) and the rigidity of US regulators in disallowing other standards serving the regulatory

			made ; in addition, there are three provisions on standards used for reference in technical regulations: (a) transparent criteria, published before, for selection, and explicit consideration of international standards and standards developed by bodies of the other party ; (b) updating of such standards ; (c) 'endeavour' to ensure that a standard used for regulation does not become a 'regulation' itself by making it compulsory, but instead remains voluntary (as in the New Approach) and other standards used can imply conformance, provided that this is proved with technical documentation	(SHEC) objective just as well ; if this article were agreeable to the US, it would be a significant advance and help to pre-empt (and remove, here and there) TBTs EU exports to the US suffer from
8.	Conformity assessment [=CA] procedures	KORUS [art. 9.5] encourages the facilitation of the acceptance of C.A. results (from C.A. bodies of the other party) in fairly soft ways ; the list of six options in its art. 9.5.1 is simply adopted from a report in 2000 of the WTO TBT Ctee [for detail, see Pelkmans & Correia de Brito, 2015a, for extensive analysis] ; in other words, all these options can be followed already without KORUS ; other provisions require that decisions about non-acceptance of C.A. results be explained, also for (refusal to) recognise or accredit C.A. bodies of the other party ; criteria for licensing or accrediting C.A. bodies must be published before ; finally, Korea and the US will implement phase II of the APEC MRA for telecoms equipment (phase I is about mutual acceptance of test data ; phase II implies mutual acceptance of equipment approvals)	In art. 7.2 the EU proposes to reduce C.A. procedures' "unnecessary burdens" [towards the least burdensome] in electrical safety, EMC, machinery and telecoms equipment [3 out of 4 sectors are in the US/EU MRA of 1998] ; a soft art. 7.4 on third party C.A. speaks of the parties to 'undertake to give consideration to mechanisms to facilitate the mutual acceptance' of C.A. results of bodies of the other party ; two problems restricting or distorting (sometimes) third party C.A. in the US are addressed in art. 7.5 (a and b) – it calls for a separation of C.A. and standardisation functions of bodies writing a standard chosen by a US regulator [conflict of interest] and it imposes an obligation on the other party not to limit the choice of (recognised) CABs for producers ; two additional provisions about 'unnecessary' burdens or undesirable aspects are about the re-certification of already certified parts/ components once the entire final product (say, a machine) is under C.A. , and the prevention of any CAB establishing or abusing a dominant position; finally, a provision on administrative simplification in case of registration	The C.A. provisions proposed by the EU are far more ambitious than those in KORUS ; they are also quite specific and can be explained by the experience of the 1998 MRA (in six sectors), other experiences of EU exporters, and as a result of many years of exchange in the High Level US/EU Regulatory Forum ; the KORUS provision on the APEC MRA would probably not present a problem for the EU (as in this sector the MRA with the US works)
9.	Marking and labelling	KORUS contains no provisions	A specification of the TBT obligation that labels and marking should not create unnecessary burdens to trade ; in art. 8 it is explicit that	

			marking about compliance is to be limited to 'what is essential' ; followed by a 'living agreement' provision to identify sectors where divergences could be reduced ; a provision on taking measures against falsely purporting to indicate origin (in the territory of the other party)	
10.	Ctee on TBTs definitions	Lengthy art. 9.8 of KORUS, but provisions mostly are what one would expect a Ctee to do; In KORUS, art. 9.10; definitions are those of the TBT Agreement ; uniquely, the article provides a detailed summary of [8] 'good regulatory practices'	Art. 9 of EU proposal not yet spelled out The EU has not yet filled in the art. on definitions (but WTO definitions apply in any case, see item 1)	The 8 GRPs, specified in KORUS do not seem to present a problem for the EU ; indeed, 'better regulation' principles overlap and have a wider scope

Note: C.A. = conformity assessment; CAB = conformity assessment body

On the whole, KORUS is WTO-plus but not very much. Compared to the EU TTIP TBT text proposal, KORUS does not go far at all. There are overlaps such as 'scope and coverage' but in the coverage, several critical areas are not worked out in separate articles such as standardisation and technical regulations; there is also overlap in 'cooperation,' though the EU text goes further; the overlap in 'transparency' is probably the greatest which would suggest that progress can be made quickly there. Put differently, KORUS and the EU text display important gaps: KORUS has no articles on standardisation, technical regulations, marking and labelling. All of these are important for the EU, and, other than regulations, represent offensive interests. Moreover, in comparing KORUS and the EU text, one discerns simmering tensions or outright conflicting views, such as on defining 'international standards', the lack of a KORUS provision on technical regulations, the lack of a standardisation provision and divergence, if not a major gap, in issues of conformity assessment. The most fundamental question concerns the lack of a leading objective of the TBT chapter in KORUS as against a fairly ambitious objective in the EU text proposal driving a good deal of the remainder of the TBT chapter. There is some difference between an approach adding to and refining the TBT Agreement (WTO-plus), and then the mobilising idea that TBTs ought to be effectively reduced and, where possible, eliminated. This is inspired by the idea of economic gains of fewer and lower TBTs, underpinning the objective in art. 1.1 of the EU text. In the Francois et al (2013) study for the Commission's Impact Assessment of TTIP - and reviewed and explained on request of the INTA Ctee in Pelkmans et al (2014) - the economic gains from TTIP are derived for nearly 60 % from the reduction of TBTs. There can be no doubt that, given the somewhat disappointing experience of the 1998 MRAs and the systemic 'gap' between the US and EU on how regulation, related standards and other instruments can facilitate market access without any effect on SHEC objectives, this critical TTIP chapter needs to be driven by an overarching and ambitious objective. Of course, KORUS need not be congruent with the text proposal the US has tabled (which remains secret). If TTIP negotiators would succeed in agreeing on a fairly ambitious objective for the TBT chapter in straightforward language, perhaps some combination of greater ambition than KORUS in some respects and a 'living agreement' on other aspects which inevitably will take time (and trust!), might be feasible. For the European Union, this would be important and would eventually yield significant economic gains.

ICT standards is a somewhat special case, and it is surely an important issue for the US. The intention is to have a special ICT (goods) chapter or annex in TTIP.

3.2 Would EU/Singapore and CETA TBT chapters be of help for TTIP?

The TBT issues with the US are in some respects not unique and occur with other trade partners as well; in other instances, they are idiosyncratic for the US. However, all countries have their peculiarities, including Singapore and Canada. Taking these peculiarities into account, what can the TBT chapters in these FTAs – signed but not ratified – tell us for a better articulation of the needs in a TTIP TBT chapter?

3.2.1 The TBT chapter in the EU / Singapore FTA

The Singapore /EU FTA [SINGEU] text deals with TBTs in two ways. One part is a set of, in total, three sectorial annexes on four types of industrial goods: motor vehicles (and parts), medicines, medical devices and electronics. The annex on motor vehicles and the one on pharma and medical devices are attached to ch. 2 on National Treatment and Market Access; the annex on electronics is attached to the TBT chapter. The automotive annex is quite powerful in promoting regulatory convergence as it recognises the UN-ECE WP 29 as "the relevant international standard-setting body" (art. 2.1). If Singapore (not having an automobiles industry) decides to introduce a type-approval system, it will consider

becoming a signatory of the 1958 UN-ECE Agreement. Note that the US is only part of the 1998 Agreement which is more limited. Moreover, in art. 3.1, parties refrain at any time "from introducing any new domestic technical regulation diverging from UN-ECE Regulations" (so-called GTRs), an exceptionally strong convergence commitment. Annex 2C on pharmaceutical products and medical devices confirms 'enhancing cooperation' in the frameworks of various international organisations and fora such as the WHO and the OECD, but also the dedicated global ones such as the ICH and PIC/S for medicines and GHTF for medical devices. Art. 2 stipulates that the "Parties shall use international standards, practices and guidelines" from all these fora and organisations. In the transparency art. 3, even the procedures for listing, pricing and/or reimbursement of medicines have to be explained. These two annexes to the market access chapter of the FTA go relatively far into the direction of regulatory convergence (with 'living agreement' characteristics, too) and are demanding in terms of transparency. This sets an interesting example for TTIP, first because Singapore already has a FTA with the US, and second because it shows that more ambitious regulatory convergence provisions are appreciated by trading partners.

Annex 4A on electronics is merely about EMC, electro-magnetic compatibility of electrical and electronic equipment. The crux of the Annex is that it offers a framework within which Singapore can undertake careful reforms permitting a switch from mandatory third party certification to self-certification (SDoCs). Technically, this is done by reducing the positive list of specified products for which third party certification will be retained, now and again in 5 years. This is done in three sub-annexes. Where third party certification is retained, the Annex functions as a kind of MRA outlining procedures for designation of competent and recognised testing laboratories (based on ISO/IEC 17025).

The TBT chapter (4) in SINGEU is fairly close to the EU TTIP TBT text proposal as summarised in Table 1. In other words, it goes much further than the TBT chapter in KORUS. Since Singapore also has a FTA with the US (but older than KORUS), one can read a recognition in the Singapore / EU text that the EU approach is appreciated. Without going into a provision-by-provision exegesis, it is noteworthy that SINGEU (a) starts with a clear objective driving the substance of the TBT chapter [unlike KORUS], (b) does have explicit articles on both standardisation and technical regulation [lacking in KORUS], (c) contains a specific provision going beyond the TBT Agreement, which does encourage the use of international standards, by stipulating "to use, to the maximum extent possible, relevant international standards" (art. 4.6.b.; emphasis added), a provision which would be helpful in TTIP [31]; (d) comprises an elaborate article on marking & labelling (including 're-labelling', crucial for Singapore, in authorised premises).

The conclusion is that SINGEU can be utilised as one alternative template to persuade the US to agree to the TTIP TBT text proposal as much as possible.

3.2.2 The TBT chapter in CETA

CETA is quite distinct from both KORUS and SINGEU. There are several reasons for this. First, on the way of addressing TBTs: no annexes on sectorial TBTs are attached to the Market Access chapter and only one annex to the TBT chapter [32] is included: on automotive products. Second, a most interesting breakthrough in CETA is the inclusion of a Protocol on the Mutual Acceptance of the results of Conformity Assessment, which, in fact, is to replace the 1998 MRA with Canada, which is similar to the US/EU MRA. It is foreseen to broaden the coverage of the Protocol later ('living agreement'). Third, although the TBT chapter – together with the protocol in ch. 27 of the published CETA text - is therefore an advance, it

[31] Note that, in KORUS, there is an explicit reference to the 1995 TBT Technical Ctee decision on 'international standards', which the US interprets somewhat artificially as also applying to some of its national standard bodies. But SINGEU does not incorporate such a clause (see art. 4.3).

[32] Formally, the place of the annex is still to be decided.

does not contain an article on standardisation. However, in art. 3, the general encouragement of 'cooperation' also refers to standardisation bodies, without any further detail ; moreover, in the transparency article (6/2), closer cooperation between standardisation bodies is promoted, i.e. with a view to harmonisation of standards. Fourth, and unlike SINGEU, but similar to KORUS, the TBT chapter has no overall mobilising objective like the EU TBT text proposal for TTIP. Thus, apart from the Protocol on the Mutual Acceptance of the results of Conformity Assessment, the TBT chapter as such is not so ambitious[33].

Art. 4 on compatibility of technical regulations is little more than a cooperation provision. If A has developed a regulation of 'compatible objective and product scope', it can request B to recognise it as 'equivalent'. But B is not obliged to do so, be it that this has to be explained (not necessarily 'justified') ; there is no common basis for such equivalence anywhere in the text. The transparency provisions are mainly about 'notice and comments' and are not going far. Moreover, the EU TTIP proposal for TBT also specifies that discussion with regulators of the other party about comments be allowed. Art. 6.6 on publication of technical regulations and conformity assessment procedures merely mentions 'official websites' whereas KORUS mentions a 'single website'. The publication requirements in the EU TBT proposal for TTIP speak about a 'complete registry', also for lower levels of governments, through a single information point – in CETA TBT art. 6.7 there is no reference to the provinces for example. When goods are detained in a port of entry, art 6.8 merely speaks about notifying the importer, but no right of appeal is foreseen (as the EU proposes in TTIP). Art. 7 amounts to a short provision on marking & labelling which is very close to the relevant provision of the TBT Agreement, hence barely WTO-plus. Altogether, CETA signifies modest progress in the TBT chapter, but in conformity assessment the Protocol forms a welcome improvement.

Th Protocol can be regarded as a kind of MRA-plus with greater sector coverage and a 'living agreement' provision with an annex of product categories that might, after three years, be included in the list under the Protocol for which mutual acceptance of C.A. results of designated CABs is agreed. Art. 12 includes a series of provisions on recognition of accreditation bodies, also comprising explicit references to ILAC and IAF with their ISO standard based rigorous peer reviews, etc. The list of sectors is much larger than in the existing MRA with Canada, adding sectors such as toys, machinery, measuring instruments, hot water boilers and (possibly) ATEX equipment (used in explosive atmospheres) as well as (possibly) outdoor noise equipment. In addition, in electrical safety, the MRA was not operational[34] and this (competitive) sector will now enjoy easier access to Canada (for Canadian firms, nothing changes as the EU uses SDoCs). In annex 2, the candidates for later inclusion are six, e.g. marine equipment (where IMO has worldwide harmonisation anyway), medical devices (where the 1998 MRA is not operational, given that the Canadian regulator wants control over approval of CABs, despite the text of the MRA), pressure equipment, rail systems and related equipment. The Protocol should be expected to lower the costs of C.A. for EU exports of industrial goods to Canada. The question is whether this success can be imitated in TTIP and the short answer is : unlikely, at least not in the short run, as C.A. and its acceptance by US regulators is often organised differently. It might serve as a shining example, however, and may thus have an effect in a 'living agreement' approach.

[33] In fact, in art.s 1 and 2, somewhat restrictive definitions and a limitation of what articles of the WTO TBT Agreement apply or not in CETA, seem to confirm a prudent attitude.

[34] European Commission, 2012, MRA Newsletter no. 6, April, p. 6

3.3 Are harmonisation, mutual recognition and 'equivalence' realistic options?

3.3.1 For regulations and conformity assessment

Harmonisation of regulations or at least equivalence of their objectives is demanding, when done outside a common regime like the one of the single market. It would probably imply separate Protocols and the subsequent domestic ratification procedures. It is not impossible as shown in e.g. marine equipment where a multilateral harmonisation of technical regulations has taken place (in IMO), but it is bound to remain exceptional. The EU text proposal insists on 'harmonised or compatible technical regulations' (in case rules of 'equivalent scope' are prepared). This means it would apply to new regulations or major revisions. One suspects that special mechanisms have to be designed to make this possible and it is too early and indeed unclear whether this will be acceptable to the US. One can harmonise standards when used for regulation purposes. There are essentially two ways of doing this. One is the 'royal' route of ISO/IEC standards – TTIP should include an encouragement in any event for new standards where needed, coupled to a strong commitment. For existing standards, the case has to be strong and cannot be entirely one-sided. One can also do it bilaterally. Some examples have been suggested by VDMA[35]. Harmonisation of conformity assessment procedures is probably not a productive idea, but the mutual acceptance of results is key. That is the area of MRAs.

The idea of mutual recognition is appealing, until one zooms in on the arrangements to make it work smoothly and ensure that SHEC objectives are not affected negatively. Mutual Recognition [MR] is the single most successful regulatory export example of the EU for policy makers all over the world, yet, it turns out that very few countries or FTAs actually apply it at all or only under restrictive conditions. One can apply MR to SHEC objectives of risk regulation or to (results of) conformity assessment[36]. Although the latter is far more modest (in lowering the costs of TBTs), both require a carefully constructed regime that must be trusted by regulators and the wider public of users/consumers. The EU enjoys, as a very deep form of economic integration, 'free movement' as a cardinal principle of the internal market [TTIP will of course never have that] and the CJEU to protect it against intra-EU TBTs, unless these are 'justified' and not (yet) subject to EU regulation. The case law is strict. Again, TTIP will never have a Court. But it is in this context and under this regime that MR of SHEC objectives can work. However, even in the very careful and judicially protected EU regime of MR, it turned out to be necessary to make sure that companies can effectively benefit from MR in the single market, by means of a special MR regulation 764/2008, comprising procedural safeguards for companies and stipulating the residual rights of Member States. MR inside the EU does not lower SHEC objectives because it presupposes that SHEC objectives are 'equivalent' ; if not, there is a justification for either national TBTs or harmonisation, light or heavy dependent on the case.

Therefore, MR of SHEC objectives can not easily be organised in TTIP or its 'living agreement', with the possible exception of far-reaching harmonisation between the US and the EU (e.g. certification of aircraft safety) or on a world level (like e.g. rules for marine equipment, in the IMO). But upon reflection, what does MR mean once most technical details are already harmonised? The idea of MR is precisely that one needs no harmonisation of the instruments or technical standards but 'only' equivalent SHEC objectives! Behind that is the crucial notion that the market failures one regulates have to do with objectives (is it safe?), whereas the instruments of pursuing this equivalent objective may well be different but in any case they are secondary. Were one still to pursue MR of objectives in TTIP, it would require an elaborate regulatory regime, and solutions for

[35] See VDMA (2013), VDMA on TTIP, August, www.vdma.org
[36] The following is based on Pelkmans (2007) and (2012) as well as on Pelkmans & Correia de Brito (2015a).

effective enforcement without a Court. It seems not worth it. Occasional harmonisation gives more certainty, and enforcement can be dealt with more 'easily'.

MR of CAPs and their results is radically different. In this form of MR, the SHEC objectives of each party are fully retained, irrespective of whether they are different or not. Indeed, also the technical standards used for regulation or other specifications, as well as the CAPs themselves can all differ (and often do). This is the area of Mutual Recognition Agreements (MRAs). MRAs are attractive precisely because the domestic regulatory regime stays fully intact, and all what MRAs do is to ensure that designated CABs in party A can conduct C.A. in A on the rules and specifications of party B, for products to be exported to B ; and the other way around. As the 1998 EU/US MRAs and many other ones since[37] have clearly shown, MRAs can be made to work but only in some sectors and their effective functioning is costly and far from easy. CETA, with its Protocol (see section 3.2), is now the most ambitious MRA in the world (outside the EU/Switzerland arrangements) and it has a wide coverage of sectors as well as a 'living agreement' approach. Given the way conformity assessment by US regulators is organised, it will be far more difficult and time-consuming to achieve anything somewhat similar under the TTIP 'living agreement'.

This leaves 'equivalence'. The notion of equivalence has been applied in e.g the US/EU Veterinary Equivalence Agreement (1998) with some but limited success. Equivalence in the TBT and SPS Agreements[38] is used with degrees, until 'full' equivalence is agreed; once that has been agreed, such products can enter the other market without any further control or new tests. Equivalence looks similar to MR but it is not. First, 'equivalence' is decided by the importing country, that is, it refers to a product conforming with the rules of the importing country, whereas MR refers to a product conforming to the rules of the exporting country (as these rules are under MR). Second, it is usually product-specific and progress on equivalence is typically case-by-case, whereas MR is driven by (equivalent) SHEC objectives, hence, by nature wider or indeed very wide over many sectors. In typical trade language, MR is based on a negative list approach, and to get a product or subsector on the list is very difficult (e.g. justified that the SHEC objective is not met or the underlying science is doubtful); equivalence comes with a positive list approach, that is, the problem is to get the product on a full equivalence list by convincing the other party that 'full' equivalence is accomplished. Third, the (more narrow, specific) objectives of a regulation for a product have to be the same. Fourth, the effectiveness of a regulation has to be the same. Fifth, trust is the overriding element, backed up by verifiable efforts of enforcement and prevention in both parties (e.g. for agro-foods and animal products, typically, trust that the other party carries out inspections and verfications with equal diligence). The EU/US Veterinary Agreement took six years for this process and ever since only a few products were added to the equivalence list. One could consider adding sector-specific 'equivalence agreements' as annexes to TTIP or in a 'living agreement' approach. However, one should expect some of the difficulties that the 1998 MRA ran into, therefore, a carefully prepared framework seems a conditio-sine-qua-non. The author has not come across detailed proposals on equivalence so far.

3.3.2 Can and should standards be mutually recognised?

Although the US position on TBT has not been published (but see section 2.5), there have been repeated soundings that the US would suggest the 'mutual recognition of standards'. CEN/CENELEC is fiercely against this idea, stronger, it considers that this suggestion would disrupt or undermine the carefully built-up European system underpinning the single goods market with single standards. Because no official proposal from the US has been made or at least made public, there is hardly or no debate in public, presumably as CEN/CENELEC

[37] See section 3.4, and Pelkmans & Correia de Brito (2015a and 2015b).
[38] See also Josling & Tangermann (2014)

does not want to treat the suggestion as respectable[39]. However, among experts and some negotiators, the suggestion is known and one is aware of the firm objections from the European standardisation bodies. There are two reasons to discuss this question in greater detail: (i) decision-makers in Europe but also in the US need to appreciate what exactly such a suggestion might mean and not mean (the wording is far too general and vague, and it will be sharpened below); (ii) there are in fact two levels of debate on this issue, one general and seen as threatening, and one far more technical and specific where, in the view of the present author, some modest possibilities of lowering the costs of selected TBTs, both ways, should and could be seized in TTIP.

First, what does it really mean to 'mutually recognise standards' between the US and EU? What is meant here are solely standards used for regulation, not standards for pure market purposes. Thus, in the US they are 'referred standards' (as discussed above) and in the EU they are 'harmonised European standards' as published in the Official Journal of the EU, ensuring the manufacturer (and others down the value-chain) that, in using this standard properly, there is a 'presumption of conformity' (with the objectives, called 'essential requirements', of the relevant EU regulation), hence, free movement in the single market. Both systems have a degree of rigidity. The US is seen as rigid by EU business and standardisers in that a referred standard becomes mandatory and no alternative solution (whether via a standard or otherwise) is open. It is held by Europeans that the EU model is better: one should be able to offer an alternative solution (maybe, a European standard or an innovative other solution) as long as it fulfils the SHEC objective of the US regulation, as verified by conformity assessment. In other words, not the technical standard but the SHEC objective should be the core criterion whether or not a (European) product is approved by a US regulator. In this sense, a recognition of a European standard for US regulation might be possible. Since, more often than not, SHEC objectives in the EU and the US are equivalent, this would lower the costs of market access for European business significantly.

The US, on the other hand, apparently would like the EU/EEA to open up for US standards, if the underlying SHEC objectives for EU and US regulation are regarded as similar. In their view, that is next to impossible due to what is called the 'top down' model of determining the European [harmonised] standard. The EU does that via a 'mandate', recently re-baptised as a 'Commission request', to the three European standard bodies. The mandate is derived from the often somewhat generally formulated SHEC objectives [essential requirements, a term originating from EU case law]. The mandate transforms these objectives into a more precise technical request to write European standards which should satisfy the attainment of these objectives, hence, enjoy a 'presumption of conformity'. US business and standardisers hold that this essentially prevents them to participate in the writing of such a European standard, because they are not 'in' CEN/CENELEC, even when they have already standardisation experience in the area or ready solutions[40]. Mutual recognition, here the recognition of a suitable US standard serving the relevant objective(s) of EU regulation, would significantly lower the cost of EU market access for their business. CEN/CENELEC fears that such a general recognition (under conditions of serving the objectives, of course) would undermine the EU system of sticking to one single standard for the entire EEA market, a great achievement compared to the hopelessly fragmented 'uncommon market' in the now distant past. First, it would introduce a second standard, causing confusion. Second, it might set into motion a process of unravelling because there are bound to be national standard bodies in the EEA arguing that the withdrawal of national standards makes no sense if, at the same time, US bodies get their standard recognised besides the single European one - thus, EEA standardisation bodies would become

[39] In CEN/CENELEC (2013), Position paper on EU-US TTIP-TBT – initial position paper, September, see www.cencenelec.eu the MR of standards is not even mentioned.

[40] In such a general formulation, this objection is exaggerated, see section 2.5.

unwilling to accept withdrawal and this might sooner or later lead to more standards. Third, it is also likely to induce other countries in the world to demand mutual recognition via FTAs or otherwise, hence, possibly getting their standards accepted as well, further diminishing the clarity and simplicity – if not destroying the idea - of having one single standard for 31 EEA countries (plus Switzerland and Turkey). In this sense, it would undermine the achievements of the single goods market, so carefully built up via the new approach.

I shall argue why both positions are somewhat overblown and suggest possible options for the TTIP negotiations that could 'build bridges' (as the 2011 EU/US declaration on standard systems is entitled in this field[41]). The options are, in fact, already available in the technical details of the rules (on both sides) but can be designed and elaborated in ways that (a) do not in the least undermine or disrupt the systems, (b) facilitate market access in practical ways.

An understandable objection of EU business is that US regulators choose from whatever standards are available anywhere in the world and pick one, without the EU standard being given a serious chance via consultation or an assessment. However, there are cases where US regulators have chosen European standards [though few]. More interesting is that US regulators can also identify several equivalent standards, all serving the SHEC objective[42]. Perhaps a 'standardisation request procedure', derived from a TTIP commitment, might be established where a European standard is shown by European stakeholders to be a proper option. This would have to be allowed if justified, based on technical merit and the satisfaction of the relevant SHEC objective in the US regulation. Allowing several equivalent standards would boil down to 'recognition'. The task of TTIP negotiators, now or in the 'living agreement', would be to lay down the basics for a domestic obligation to carefully and explicitly deal with a substantiated request from a European stakeholder. The current review of OMB Circular A-119 offers the opportunity to do so on a routine basis.

For this to become 'mutual' recognition, the following has to be considered. European harmonised standards, written on the basis of a Commission mandate, serve SHEC objectives [43] and, when companies use them, give a 'presumption of conformity', hence free movement. But these standards remain voluntary, i.e. do not become the compulsory solution. Therefore, alternatives always remain possible; indeed, EU stakeholders (rightly) underline this degree of flexibility in the NLF. Thus, a product not following the European harmonised standard, can still be brought onto the market but only after a Notified Body has certified that product, assessing whether the SHEC objective(s) in the regulation are served. This gives room for innovative approaches and/or for new materials or other solutions, e.g. based on (say) US standards. So, the question is why US companies do not routinely use this clear and often propagated route to get their products into the EU market without much or any change (if serving SHEC objectives), thereby lowering their costs of market access? The complaint that SHEC objectives are too vague is not credible because that applies with equal force to the EU process itself. Mandates are public and the resulting European standard also offers some clarity about the operationalisation of objectives. Interviews and informal discussions suggest, however, that, on the one hand, EEA Notified

[41] See http://trade.ec.europa.eu/doclib/docs/2011/december/tradoc_148393.pdf

[42] Examples include : i. the US Dept of Energy when regulating commercial 'walk-in freezers', provides a choice of test procedures referencing EN DIN, ASTM and ASHRAE ; ii. The US Federal Emergency Management Agency (FEMA) runs a voluntary private sector 'preparedness' accreditation and certification programme – three standards were put up for Notice and Comments, and the final outcome is that standards from ASIS International, British Standards Institute and the US National Fire Protection Association will be treated as functionally equivalent and suitable ; iii. The US Environmental Protection Agency, acting on 'residential wood heaters' under the Clean Air Act, has recognised EN3030-05 as producing the same results as EPA and ASTM methods (allowing some 100 distinct European models of hydronic heaters to enter the US market).

[43] And are otherwise no different from normal standards.

Bodies show some hesitation in giving a certificate of conformity based on (say) a US standard serving EU SHEC objectives, and, on the other hand, there is a degree of mistrust about some procedures in getting recognition of US standards long-used even in the European market. The problem for the present author is that there seems to be no systematic published literature or hard data available to underpin these complaints. The dissatisfaction amongst US standard bodies and/or some US companies boils down to the disillusion that there is a right in EU law to rely on Notified Bodies, but a throttling of its validity in actual practice. If this degree of dissatisfaction is not publicly addressed, it will linger and undermine exactly the spirit TTIP will need in order to be successful. At the same time, a quick check of selected mandates to CEN/CENELEC shows that the Commission often requests a first scrutiny of existing standards (when no ISO/IEC ones exist, of course) and, moreover, cooperation with standard bodies e.g. to 'ensure coherence' ; thus, for example, for child safety cooperation with CPSC (US regulator) and ASTM has been explicitly requested. As far as the author knows, there is no systematic reporting about the actual outcomes in many of those cases, and it would take a painstaking and elaborate study before one can draw reliable conclusions.

Another proposal is about 'new work items'. Interviews suggest that ASTM, IEEE, ASME and other prominent US standardisation bodies have been advised informally many times to travel the route of a European standard in CEN/CENELEC for 'new work items'. The author has not been informed about the reasons for not doing so, but discussions suggest two reasons: the US bodies are unwilling to withstand the scrutiny of European stakeholders and there might be sensitivities about the copyrights of their standards. Moreover, an agreement between relevant US bodies and CEN/CENELEC would of course be necessary, too. It should be noted that 'mutual recognition' of standards for purposes of EU regulation cannot of course be decided by the standard bodies but by the Commission (quite apart from the drawbacks or effects, as noted above). Moreover, one should not ignore that only CEN, CENELEC and ETSI have been accredited by the EU for the purpose of standardisation providing compliance [or, more precisely, a 'presumption of conformity'] with EU risk regulation. The upshot is that the EU does offer an alternative route to satisfy SHEC objectives in the NLF and CEN/CENELEC are open to 'new work items' brought in by US bodies, but, in actual practice, not much use has been made of these options. If this analysis is correct, but it is exceedingly hard to be fully sure about it, one has to conclude that US companies or standard bodies cannot have it both ways: the route on 'new work items' is far more attractive to get better access to the EU market than the options for the EEA standard bodies to suggest 'new work items' in the US (indeed, where can a decisive and single solution for the US market be agreed?) ; and US companies can go to Notified Bodies with products incorporating US standards which should be approved if similar SHEC objectives are served correctly [44].

One additional solution to facilitate market access is found in the Vademecum on European Standardisation (a Commission handbook for various procedures related to Reg. 1025/2012, including the formulation of mandates and the verification of harmonised standards before publication in the Official Journal of the EU). Also here, a revision is actually ongoing, hence, an opportunity to improve the options for US companies and standardisers, without in the least transforming the NLF. Two critical provisions in the Vademecum can be regarded as directly helpful. The first is the 'clear and precise indication of the relationships between the normative clauses of a requested European standard and the legal requirements' (art. 3.6) which'… enables market surveillance authorities (including Notified Bodies) to identify to what extent they should accept a priori presumption of

[44] One source has confirmed to the author that an Italian company recently obtained a certificate from a Notified Body on the basis of the essential requirements of the Pressure Equipment directive, while applying in full an ASME standard. A clear proof that it can be done.

conformity'; 'this will avoid …legal uncertainties afterwards'. This clause would seem to make it reasonably predictable whether or not a US standard be accepted by a Notified Body[45]. If somehow this is not working satisfactorily, TTIP should have mechanisms to discuss this in earnest, based on empirical reporting. The second provision is – in the views of the author – reflecting the TTIP spirit (although the Vademecum predates TTIP) in art. 3.9, stating 'Where based on standards or technical specifications originally developed and published by other bodies, a mandate can make reference to such standards… and to the need for cooperation between the ESOs and these other bodies. Meeting SHEC objectives with alternative, but functionally equivalent standards is not uncommon elsewhere in the world or in the EU itself[46]. The point is not that this is likely to happen frequently, but rather to offer openings precisely to those US standards that are already internationally used, yet not in the way of ISO/IEC standards, and without harming the single market with single standards as a system. However, the key words here are 'trust', 'time' and an 'overriding and forceful objective' to lower costs of market access. Only a 'living agreement' can provide the desirable mechanism to be successful [47]

These proposals for mutual recognition are carefully circumscribed and cannot be 'framed' as a general undermining of the EU or US systems of using standards for regulation. On the contrary, they enhance current features in each of the systems, with a view to allow functionally equivalent standards under strict and limiting conditions, rather than sticking automatically always to a single solution to serve SHEC objectives. They are proposed in the spirit of TTIP where the broad overall sentiment is that, very often, EU and US SHEC levels required by law are providing equivalent protection to workers and consumers.

3.4 Nexus of conformity assessment in TTIP: lessons from the EU/US MRA

3.4.1 Why did the MRA hardly work?[48]

It is striking that, in the TTIP debate so far, there is little or no mention of the US/EU Mutual Recognition Agreement (MRA) concluded in 1998. At the time, expectations of the gains from the MRA were high in business and in trade policy circles. Both business in the TABD and government negotiators (e.g. in the EU /US summits and at ministerial /Commissioners level) were committed to the process at the highest levels. MRAs are a tractable example of reducing TBT costs because they are based on a treaty, relatively modest in ambition and well-focused on sectors and technical competences. One should expect the MRA to be instructive for TTIP and entail some lessons to be learned for today's attempt to lower TBTs across the North Atlantic.

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[45] Incidentally, it also 'enables the ESOs [European Standardisation Organisations] to offer to the Commission European standards originally developed by other bodies..' (art. 3.6.1.).

[46] One example is in toy standards (EN 71 series). Canada used to refer three [EN 71, F963 (an ASTM one) and ISO 8124] but recently has decided to go only for the ASTM one. Singapore (with which the EU has a FTA now, with a good TBT chapter) allows all three. In building products (Reg. 305/2011), innovative products can be specially assessed (so-called ETA) and, in the absence of European test methods, ASTM and other methods are permitted.

[47] To give a telling example how difficult this might be and how important it is to always see two sides of the TBT intricacies, consider complaints of US steel, stainless steel and alloys producers to get access to the EU market, when it concerns pressure equipment (dir. 97/23 and 2009/105). They complain that it is (very) difficult to obtain EAM status (European Approval of Material) from Notified Bodies and that Member States (via a Standing Ctee) may politically influence the assessment (in a non-binding way). Materials based on ASTM standards have rarely, if ever, been accepted. However, in an informative report by VDMA (2013), it is underlined that the US system for pressure equipment is based on a radically different philosophy and on the 'highly dominant role' of ASME. The ASTM standards for materials are a foundation for the ASME code. That code is not in all aspects compliant with EU legislation. If EU companies want to enter the US market they will need to apply the ASME code (which is very different in technical aspects such as welding and materials, etc.). VDMA recalls that talks between ASTM and EU representatives were opened a few years ago but broken off rather quickly. They advocate to restart these talks in earnest. This is exactly the kind of initiatives which fit the living agreement.

[48] The section 3.4 draws freely from Pelkmans & Correia de Brito (2015b).

It is good to realise that the MRA experience revealed clearly how difficult it is to accomplish the acceptance of all relevant aspects of conformity assessment of the trading partner for the mere purpose of testing and certifying export goods on the requirements of the importing economy. This modest purpose is what a MRA is supposed to achieve: a MRA neither questions the domestic regulatory regimes, or their objectives, nor the technical requirements or conformity procedures. There is no harmonisation whatsoever. Yet, this regulatory cooperation has succeeded only in a few sectors. The ambition in TTIP with respect to TBTs is said to go much further. It is therefore important for all those involved or interested in TTIP to learn the lessons of this early exercise in lowering TBT costs.

In the MRA, the 'Framework' (umbrella) specifies the 'conditions by which each party will accept or recognise results of CAPs, produced by the other party's CABs or authorities, in assessing conformity to the importing party's requirements' (art. 2). This is the purpose of the MRA. Art. 2 clarifies that the objective of such mutual recognition is to provide 'effective market access'. Apart from the pre-able, 11 main provisions are listed. Much of it is procedural, e.g. about what designation precisely is, designation procedures, recognition conditions, transition periods for 'confidence building', rules for suspension and withdrawals (of CABs), some administrative provisions and a general proviso on the preservation of US and EU regulatory authority.

This is followed by six sectorial annexes covering 1) Telecoms equipment; 2) Electro-Magnetic Compatibility (EMC); 3) Electrical safety for appliances (and indeed also for telecoms equipment); 4) medical devices; 5) Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) for pharmaceutical products; and 6) recreational craft (basically, boats for leisure).

Art. 3 of the treaty says that the US (EU) 'shall accept or recognise results of specified procedures used in assessing conformity to […] provisions of the US (EU), produced by the other party's CABs and/or authorities'. Once the transition periods have been successfully completed, such CAPs for this purpose assure conformity 'equivalent to the assurance offered by the receiving party's own procedures'. Art. 4 lists all of the detailed provisions which follow, and adds that the MRA shall not be construed to entail mutual recognition of standards or technical regulations. There is also – besides transition periods, suspension of listed CABs, withdrawal of listed CABs, monitoring of CABs, and suspension of recognition obligations – a termination clause.

The sectorial obligations are far more detailed, with specifications of laws and requirements, the enumeration of CAPs and authorities and transition periods. Clauses may sometimes have a meaning that is not easily understood from legal texts. Thus, the subcontracting provision in telecoms in fact reflected a tradition of US producers to let US CABs subcontract certification to Notified Bodies in the EU. In this way they built up durable trusted relationships. Moreover, the costs of duplicative testing (which the MRA was meant to reduce or eliminate) were already reduced via private alternatives. The same is true for leisure boats. It is true that EMC, electrical safety, and recreational craft have no appendices, and telecoms equipment has a minor one. The pharma GMP one has 5 appendices (with the many criteria for equivalence in appendix 4) and the one on medical devices 2 appendices, but in addition a 21 page-long table specifying hundreds of medical device types under US legislation. The likely reason for this is that, in the EU, medical devices of lower risk classes are under the New Approach with SDoC, whereas in the US the FDA certifies them all; also, the risk classification of such devices differed somewhat between the US and the EU.

The sectorial obligations and the details seem relatively 'light' in the cases of telecoms, EMC and recreational craft, heavier for electrical safety (with OSHA lab assessment

procedures) and most heavy for pharma GMP and medical devices. The latter also has a post-vigilance process with reporting, presumably a kind of market surveillance.

Dependent on the sector, implementation of the sectorial MRAs has either been relatively smooth, difficult, or a stumbling block. Three sectors proved to be relatively easy - telecoms equipment, EMC and recreational craft – although only two Annexes (Telecoms and EMC) are in operation today. The first two had been central aspects of the MRA right from the beginning, and especially telecoms was rapidly turning into a truly global equipment market, based more and more on international standards. In telecoms by June 2001,[49] the US had designated 23 CABs, and 43 for EMC. The EU had designated a similar number of CABs for EMC. In 1998 the EU relaxed its rather strict 1992 telecoms equipment directive towards one where SDoCs would be allowed. This self-certification provision meant that the designation of US CABs for telecoms equipment to be sold in the EU had become much less important. Recreational craft has a simple annex on safety aspects and a short transition period. The need for a MRA in this sector arose from the EU's requirement of certification by a Notified Body; with the US Coast Guard and the relevant US authority already being permitted to self-certify recreational craft. However, US exporters did not exercise much demand for US CABs able to obtain certification (on EU requirements); they preferred to continue using pre-existing subcontracting arrangements with EU CABs (probably, Notified Bodies) as they had built up long-run relations.[50] The recreational craft annex has not been in operation since 2006 – as a consequence of a revision of the EU directive in this area, adding emissions and noise requirements, and thereby moving beyond 'safety' issues, the focus in the annex, as well as in US legislation and in their conformity assessment.

Matters turned out to be a good deal more difficult in electrical safety. The EU saw the electrical safety annex as an imbalanced set-up because US exporters had relatively easy access – in terms of compliance costs and time-to-market – to the EU market given the Low Voltage Directive (with SDoCs), whereas EU exporters faced regulatory reviews and approvals by OSHA. But OSHA was unsatisfied and required third party certification under its direct control. The gap here could not be bridged and the MRA in electrical goods never worked[51].

On medical devices, the story is little different, only more complicated. Regulatory culture, views on risks and sensitivities about the balance of costs and benefits of (how far) bringing risks down for patients all differed between the EU and the US. The FDA was stricter in its risk classification of some medical devices and it systematically practiced (centralised) pre-market approval via designated CABs as well as factory inspections, also abroad. Largely in contrast, the EU approach to medical devices was mainly based on the New Approach with self-certification, except for high-risk devices (such as pace makers) for which third party certification by Notified Bodies was required. But none of this required pre-market approval. The MRA failed also here.

In pharmaceuticals the problems were probably even greater. Although the agreement is on GMP, the definitions of GMP of the US and the EU are not even harmonised in the annex: in Art. 1.3, both definitions have been included, with a clause stating that the parties have agreed to 'revisit' these concepts. The core of the annex is the recognition of the 'equivalence of the regulatory systems of the parties' (Art. 2, called – in the wording of this article itself – the 'cornerstone of this annex'). The three years transition 'aimed' to

[49] See Shaffer, op. cit., p. 14

[50] Shaffer, op. cit., p. 17 notes, only UL applied to be a US CAB under this annex but must have lost interest since the Commission Newsletter on MRAs of April 2012 states that no US CABs are designated. See trade.ec.europa.eu/doclib/docs/2012/may/tradoc_149385.pdf

[51] For more detail, see the in-depth analysis for the EP IMCO Committee on the Engineering sector in TTIP to be published.

arrive at this recognition which seems more like an 'endeavour' than a fully-fledged MRA. The FDA felt that not only did it have to review multiple EU directives and related EU documents but also each Member State's implementing legislation, regulatory structures and practices. Before recognising an EU country's 'equivalence', the FDA required EU countries to engage their officials in joint training and joint inspections.[52] All this suggests that the underlying idea of mutual recognition of assuming that other countries also care about the health and safety of their citizens and patients, as a starting point to set up a MRA, was lacking. In addition, in both the cases of medical devices and pharmaceuticals, the agreed confidence building activities were not completed – and were not able to resolve key technical challenges to implementation of the annexes. At the same time, one has to recognise that the EU internal market for medicines was still seriously incomplete. Also here the MRA failed.

One can draw two conclusions. The first conclusion is that the MRA of 1998 had failed for one half and was (is) successful for the other half; however, in trade flow terms, the MRA coverage was around 20% of the 1995 total for five sectors (without the recreational craft one), with the EU experiencing a negative trade balance.[53] On the whole, a disappointing outcome and a far cry from the expectations of business and top decision makers in 1998. Second, the EU's attempt to 'balance' the MRA package in the negotiations – so typical for trade negotiators - did not work out. The concern of EU trade negotiators emerged from the narrowing down of 12 sectors, when the MRA talks began in earnest in 1994, to telecoms equipment and EMC only one year later. Sectors such as electrical goods, medical devices and medicines showed EU trade surpluses for many years and their inclusion in the MRA package would restore 'balance'. The US showed little enthusiasm for this balancing approach but eventually gave in. But precisely in the sectors brought in by the EU in 1995, problems – in particular by what the EU saw as a lack of flexibility on the part of the relevant independent US regulators - eventually led to a failure due to regulatory diversity in implementation. It confirms that 'regulatory trade policy' cannot be successfully conducted like classic trade diplomacy: domestic regulators must be satisfied during and after the negotiations that their pursuit of SHEC objectives will not be watered down in any way. Regulators should therefore (also) be in charge of regulatory trade policy, in TTIP and in other such negotiations. "

3.4.2 Did TTIP partners move to cooperation beyond the MRA?

If one were to draw the conclusion that the MRA has failed and therefore market access to the US had barely improved except for some sectors (telecoms, EMC and leisure boats), it would be mistaken for two sectors: medical devices and pharmaceuticals. In electrical goods, a decade later, an attempt was undertaken to get recognition of SDoCs from OSHA but this was rejected after a two-year investigation culminating in a kind of impact assessment (including, here, attention for risks as well)[54]. However, OSHA has begun reviewing its policy with respect to the designated CABs it uses, and this might give openings for TTIP.

In medical devices and in medicines, essentially two developments took place. First, regulation and conformity assessment (or inspection) were tightened and made more uniform in the single market. Some of these weaknesses had probably played a role when

[52] Shaffer, op. cit., p. 20, quotes a FDA official that the FDA has 'refused to compromise its mission of protecting health for balance of trade purposes' whilst, at the same time, claiming that the FDA received insufficient resources for the additional and costly burden of implementing the MRA. In fairness, the FDA faced, to some extent, a similar problem across 50 US states and Puerto Rico.

[53] In Devereaux et. al, op. cit., p. 314, 1995 trade flows are provided. On the EU side telecoms equipment exports to the US amounted to around 12 % of the total flows for the 5 sectors; on the US side, its telecoms exports amount to 23 % of total flows.

[54] The full details are set out in Pelkmans & Correia de Brito (2015b)

the FDA became ever more hesitant in the late 1990s. It can be shown that nowadays it should be easier to make the MRAs work, on an improved basis for trust, or, find other effective ways to cooperate so as to improve effective market access. Second, both sectors turned away from the MRA approach, as a dead-end street, and began exploring international regulatory cooperation with non-EU-US partners. After a number of years, this yielded impressive results, even though these accomplishments are not based on hard treaty obligations. Still, one should call them by the name: they are exercises in 'regulatory alignment' very much driven and specified by regulators themselves. Thus, in medicines, the EU and the US now have comparable rules and standards of inspection via the so-called PIC/S [55] - remember, that, precisely in inspection, the MRA failed hopelessly. Moreover, in ICH, the US, EU, and partners (e.g. Japan) have agreed on some 50 Guidance documents greatly reducing regulatory diversity. For example, with the CTD (Common Technical Document), one single file for the approval process is required with all required data, and this is accepted in the US, the EU and Japan. In medical devices, the GHTF has now been overtaken de facto by the new International Medical Devices Regulators Forum, focused on global standards (such as ISO 13485), a pursuit of Unique Device Identifier (of each medical device produced) and a harmonised format for product registration submissions. This demonstrates the crucial finding in OECD (2013) that there is a whole spectrum of international regulatory cooperation alternatives, on which MRAs are merely one of many options. And, perhaps surprising to many, the treaty approach may not necessarily be superior to the 'soft' (law) approach. What seems more decisive is to let regulators drive and manage the process, incentivised but at a distance from international business.

[55] See www.picscheme.org for the organisation arranging this.

4. OPPORTUNITIES AND CHALLENGES

TTIP represents a major opportunity, in particular because the 'hard core' of TTIP consists of addressing systematically costly TBTs in goods, causing significant hindrances to mutual market access between the US and the EU. The costs of TBTs are a multiple, and often a large multiple, of EU and US tariffs. The opportunity is therefore to benefit economically from a reduction of TBTs, and these benefits will likely be greater – possibly much greater - than those arising from tariff elimination in TTIP. Tackling TBTs has nothing to do with the existing or future level of protection; it is solely about arriving at less costly methods or instruments to verify compliance or to serve given SHEC objectives.

In order to reap these economic gains, TTIP comprises four approaches : the TBT chapter, the SPS chapter (on animal and plant safety), sectorial chapters (from Engineering or automotive, to textiles/clothing) and horizontal regulatory cooperation. The present EP study focuses on the TBT chapter 'only', even though all the four approaches are – in different degrees – interrelated. But the TBT chapter surely forms a significant opportunity on its own. It is appropriate for the EU to assume an ambitious approach to the TBT chapter and this is done in the January 2015 publication of a negotiation text by the European Commission. However, one has to add immediately that no US text is publicly available, hence, it is difficult to assess whether such an ambitious approach is actually feasible with the US. However, informal suggestions and the US tradition to negotiate FTAs based on 'templates' lend credence to the conviction that the US is negotiating on the basis of a text close to the TBT chapter of the US / Korea FTA [KORUS]. This KORUS text is compared with the EU proposal, provision by provision, in section 3.1. and found wanting.

The most important challenge, therefore, is to get the US to move beyond its KORUS, and all too modest template, and to work towards an ambitious TBT chapter which would serve both parties well. It might be that the US is more willing to address specific sectorial issues in great detail (as e.g. in automotive) than moving ambitiously in generic TBT issues, as the latter may touch upon 'systemic' questions such as different standardisation systems, the de facto far lower status of ISO and IEC in the current stock of US standards than is the case in the EU, and the contrast between how US regulators and the EU link standards to compliance with risk regulation as well as the organisation of conformity assessment in some crucial sectors. In addition, although both the US and the EU are 'federal' systems when it comes to the regulation and freedoms in their domestic internal markets, the EU would seem to be more rigorous than the US in disallowing local or national (for the US, inter-state) TBTs.

It is thus important to develop in TTIP an attractive and workable 'living agreement', following up on the basic TTIP treaty, with a firm commitment to address TBTs in earnest but letting regulators from both sides take the lead, building 'trust' and allowing time to develop robust solutions satisfying regulators whilst helping market players to access the two markets at lower costs.

An important challenge for the EU, but arguably one that is also in the long-run US interest given globalisation, is to persuade the US to begin aligning more systematically over time with ISO and especially IEC standards. It is realistic, but also sensible, to distinguish a small set of prominent and already internationalised US standard bodies, having promulgated many standards which have status with business in substantial parts of the world market, from several hundred other US ones which are domestic if not inward looking. Ways have to be found to carefully offer openings for productive cooperation with the first group and this is bound to be complicated given the highly valuable stock of standards which serve SHEC objectives in the US and often other countries, and/or have been used by European companies as well. Stronger, in some of these bodies European

companies (may) play a prominent role, too. If this is done in a cooperative spirit rather than in adversarial terms – as has happened more than once in the past – and presumably in the realm of the 'living agreement', building trust and seeking cooperation on what binds the US and the EU (e.g. SHEC objectives and related issues), much can be achieved. In any event, operational mechanisms for new work items for standardisation need to be designed with a view to arrive at common, preferably IEC/ISO, standards as a rule. Moreover, the tradition of US regulators (governed by OMB Circular A-119) to select just one standard (turned into a compulsory one) as providing compliance with US risk regulation should be addressed. A modest proposal is made for allowing a 'standardisation request procedure', to be incorporated in the Circular, in case a European standard can be proven to give an 'equivalent' level of protection', based on technical merit. If successful, the US regulator should allow the standard to have the same status as the chosen one.

Various modes can be pursued such as harmonisation of SHEC objectives – probably quite rare but not impossible given some recent examples, harmonisation of standards (as noted above) and 'equivalence' in some special cases. Mutual recognition of rules (as exists in the EU single market) should not be pursued as the entire mutual recognition regime cannot possibly be credibly constructed under TTIP. Also, the US suggestion of 'mutual recognition of standards' is not welcome. It is crucial for the EU to clarify in detail why this would almost certainly lead to a very costly and pointless unravelling of the single goods market with a single standard, a great and beneficial achievement, in particular by the 'new approach'. Moreover, for EU exporters this form of mutual recognition would not bring any improvement in market access for products under US risk regulation, unless a drastic reform of how US regulators would deal with European standards would be introduced (which is not to be expected). Nevertheless, there are modest but potentially useful instances where some (carefully restricted) forms of flexibility in the EU system, accommodating US standards, can be exploited without, however, affecting the EU system as such. The Vademecum on European Standardisation already provides some options for e.g. US standards (if serving EU SHEC objectives) and the question in TTIP is to make these options work better than before, if indeed complaints by US stakeholders are justified (which is hard to verify).

For the EU there are also concrete opportunities in improvement US conformity assessment. The lessons from the 1998 US/EU MRA should be used for constructing a better and more flexible US regime fitting TTIP. Ongoing reforms in the US (both on Circular A-119 and with respect to CABs designated by OSHA [so called NRTLs]) may well be helpful in laying the basis for lowering the costs of these specific TBTs for European exporters. These reforms ought to be linked to TTIP. The FTAs that the EU concluded with Korea, Singapore, and Canada show convincingly that, in some sectors, it is only the US that has idiosyncratic problems in this area. Especially the Protocol in CETA (ch. 27), essentially a deepened and widened MRA over a range of sectors, demonstrates that much can be done here. It is wise to accept that the US and their regulators have to be given time, e.g. in a 'living agreement', and it might also be possible that the EU would have to tighten the supervision of and actual compliance with provisions of its SDoC regime (which is in its own interest anyway), as US regulators are under a duty to be re-assured by empirical evidence.

5. CONCLUSIONS

KEY FINDINGS

The last section provides some concluding remarks and proposals but no assessment of the expected effects of TTIP on the reduction of TBTs between the US and the EU, as this is at present plainly impossible. There are substantial 'gaps' between the US and EU approaches of reducing TBTs via the TBT chapter, except perhaps in 'transparency' and broader regulatory cooperation provisions. An assessment is offered of key provisions in the TBT chapter likely to play a major role in the negotiations. A series of specific issues is discussed, including some constructive though admittedly modest solutions for TBT matters in TTIP, without negatively affecting the US and EU regulatory systems or, for that matter, the integrity and single-standard-tradition of the single market.

The offensive interests of the EU in TTIP TBT matters are best served by an ambitious approach as proposed by EU negotiators in January 2015 and based on a mobilising objective to reduce TBTs as much as possible, given the economic gains to be reaped. Going by what KORUS stands for as the US template of FTAs, the EU should insist on ambitious provisions on technical regulations, standardisation and marking & labelling (all lacking in KORUS). Above all, a clear objective on TBT reduction and removal is essential (also lacking in KORUS), not least if the partners want the 'living agreement' to be successful. The 'living agreement' is bound to be of cardinal significance for the TBT area, because of the intricate and highly technical nature of a solid TBT regime, as well as the links with horizontal cooperation and the nine sectorial chapters. Ambitious arrangements in the area will take time (and the US/EU MRA experience has shown that this time needs to be given, if only to build trust) and the 'living agreement' should not be pressed by tight deadlines. However, the counterpart to that is a consensus on an ambitious objective to bring down TBTs as much as possible. There are also areas where the partners should be able to find common ground, such as ambitious provisions about transparency.

Harmonisation of technical regulations is proposed (by the EU), where appropriate, at world level, which is bound to be rare. More important might be the (EU) proposal to promote 'harmonised or compatible technical regulations' in case a regulation is prepared of 'equivalent scope', that is, either a new one or a major revision. A special mechanism to make this possible has not been suggested yet, perhaps via the TTIP Regulatory Body in the horizontal chapter. Clearly, this would be quite ambitious. It would also have to be rooted in the domestic legislative processes of both sides, which would make it slow and heavy. Critical for its success is a focus on the equivalence of SHEC objectives (no lowering of "standards", here objectives) as the criterion for compatibility.

Harmonisation of standards is possible via an encouragement to develop or adhere to ISO/IEC standards or bilaterally. Both will not occur all that frequently, given past investment in standards (especially by a small set of prominent and internationalised US standard bodies) and in how producers design manuals and products. Here, it is crucial that the standardisation bodies of both sides are encouraged to cooperate much more on a structural basis, e.g. by setting up programmes for such purposes. The EU has proposed an encouragement for standards bodies to cooperate on a systematic basis, despite their historically distinct approaches.

Mutual recognition (MR) of standards used for regulations has been framed as a threat, especially in Europe. Indeed, if presented as a wholesale drive to promote across-the-board

MR of standards, it makes no sense at all, on both sides. However, it is possible, as shown in section 3.3.2, to allow strictly conditional flexibility in both systems for the use of standards for regulation, without in the least affecting the system as such. In the US, the incipient reforms under OMB Circular A-119 provide opportunities for TTIP to commit to a 'standardisation request procedure' for European companies to allow 'equivalent' and suitable standards, with justification and consultation elements. Doing this more systematically and based on a TTIP commitment would create greater possibilities for European companies to sell products without expensive retooling or adjustments. In the EU NLF, US companies already have the option of obtaining certificates of conformity based on US standards, if these standards properly serve the EU SHEC objectives in EU regulation. It remains unclear why US companies do not pursue this route more often, even when European companies have occasionally done it successfully based on standards from prominent US standardisation bodies! Another proposal is about bringing in 'new work items' in CEN/CENELEC by US standard bodies. To do this efficiently and effectively, one would need a cooperation agreement between the three European standardisation bodies and US counterparts, either ANSI or – perhaps more practically - a subgroup of (one would presume) the nine or so prominent and already truly internationalised US standard bodies. Given such a cooperation agreement, TTIP might include the optional clause of including such US bodies in Annex I of Reg. 1025/2012 for specific purposes, of course with the obligations that come with this listing in the Annex.

One can go one step further in what probably are exceptional cases. In the current ongoing revision of the Vademecum on European Standardisation, it could be facilitated or encouraged that the European standardisation bodies can propose more than one single standard for compliance with EU regulation, just as US regulators are asked to do via the suggested 'standardisation request procedure'. This could only be done when four conditions are fulfilled. First, no ISO/IEC standard exists for this purpose. Second, an agreement with the relevant US standard bodies be concluded organising this option properly. Third, the relevant standard bodies are included in Annex I of Reg. 1025/2012 (that is, next to CEN, CENELEC and ETSI), of course with the obligations that this implies. Fourth, the US standard should already have a proven status of acceptance in substantial parts of the world market, ensuring that not just any standard can be expected to be accepted.

More problematic is the occasional fragmentation of the US internal market as a result of uncoordinated multi-level differentiations of regulatory requirements down to state, city or even county level. Would the US Council of States (voluntarily) accept to align rules with what federal regulators have specified because TTIP asks for an endeavour? Or, could US-wide (so-called) 'compacts' be agreed between US states stipulating the alignment with what federal regulators require?

When it comes to conformity assessment, the lessons from the US/EU MRA experience and the recent conclusion of the CETA Protocol (enlarging and improving drastically the former MRA) strongly suggest that – with some care and building trust – arrangements can be agreed in TTIP which would travel some way to overcome long-standing objections about the costs of conformity assessment regimes of some US regulators. The ongoing review of the NRTLs (CABs designated by OSHA) may accommodate EU demands that there should be a genuine free choice between NRTLs and that the (organised) dominance, if not its abuse, of UL via special requirements must be terminated. There is nothing unreasonable about these requests at all. The main lesson of the MRA is that regulators, not trade negotiators, should be left to arrange this with all the care for their regulatory duties serving SHEC objectives. The aftermath of the MRA has also shown that 'soft' regulatory cooperation e.g. in medical devices and GMP for medicines, can be superior in effectiveness to a formal MRA. Therefore, the 'joint cooperation' provision in the EU text proposal is

crucial and should not be watered down. The results of the international cooperation – without a treaty base – in medical devices and (GMP) medicines should be incorporated in TTIP. Following CETA, it is to be considered if TTIP could incorporate MRA-like provisions for a larger set of sectors than previously. This would also satisfy the US demand that US bodies are permitted to test and certify products sold in Europe.

It is far too early to make statements about the possible economic effects of a TTIP chapter on TBTs. Not only is this far more complex than e.g. a sectorial analysis (say) of automotive products, it is often next to impossible to acquire reliable information about the possible responses of companies to the potential provisions in TBT. Clearly, the TBT chapter is more important for a sector like engineering (see the EP in-depth analysis on the Engineering sector for IMCO and INTA) than for some other ones but little more can be said today. Probably, the way to go about collecting serious qualitative information on the effects of an ambitious TBT chapter is to organise sectorial and even more specialised studies, and to evaluate the results later. It is worth noting that the present study shows that even the ambitious proposals by EU negotiators on the TBT chapter are not detailed enough for any such economic assessment to be made.

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