

7. TTIP AND CONSUMER PROTECTION

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1. Introduction

This chapter examines options for regulatory cooperation within the Transatlantic Trade and Investment Partnership (TTIP) and assesses its implications for consumer protection. Its goal is to discuss the TTIP's potential opportunities and challenges and to discuss how it might affect the regulatory sovereignty of the respective legislatures. While the analysis focuses on the impact on EU regulatory sovereignty, the findings will also be relevant for the US. Will it contribute to a lowering of 'standards' and consumer protection rules? What will be the impact of the use of methods such as equivalence on regulatory requirements? Will the TTIP influence the regulatory or legislative agendas and if so, how should the European Parliament ensure that its priorities are properly represented? From the European perspective, which will be the 'competent body' representing the EU in any regulatory cooperation body and how can it be ensured that this body reflects balanced EU preferences?

The second section sets the scene by providing a short overview of the EU's past agreements and existing practices in international negotiations, and it also looks specifically at past initiatives in transatlantic regulatory cooperation. Against that background, section 3 then discusses the opportunities and challenges inherent in the TTIP negotiations in terms of the general approach to regulatory cooperation. This includes a discussion of the approach proposed in the European Commission's Textual Proposal of February 2015. Section 4 then provides some illustrations of the opportunities and challenges in specific sectors, before the final section offers some conclusions.

2. Past agreements and existing practice

Regulatory cooperation in the TTIP builds on several existing international agreements, such as the Technical Barriers to Trade (TBT) Agreement in the WTO, numerous past transatlantic attempts to promote regulatory cooperation and, more recently, initiatives in preferential agreements negotiated by the EU and, to a lesser extent, the US. This section sets the scene for the current debate by summarising the experience with other relevant agreements.

2.1 Shaping multilateral rules

The EU has led the way in raising awareness of the impact of divergent regulations as a barrier to trade. The EU's so-called 'new approach' to such barriers in the 1980s had a significant impact on international agreements in the WTO and the work of the international standards-making bodies, e.g. ISO, CEN and CENELEC. These EU-shaped international agreements are incorporated in virtually all PTAs (preferential trading arrangements) and it is expected to be reaffirmed in the TTIP.

The existing international rules take the form of the 1994 TBT Agreement, which contains a binding commitment to national treatment (non-discrimination) in the application of regulation and conformity assessment, 'best endeavours' wording on mutual recognition and a Code of Good Practice for standard-making bodies. As experience within the EU has shown, however, national treatment does not remove regulatory barriers/trade costs resulting from divergent regulations or standards. The GATT Agreement on the Application of Sanitary and Phytosanitary Measures, also known as the SPS Agreement – covering human, animal and plant life and health – seeks to prevent the use of SPS measures that unnecessarily distort trade. The SPS Agreement is largely 'science-based' but also provides for the use of precaution (Art. 5(2) SPS). But the SPS Agreement has not prevented transatlantic disputes on GMOs (genetically modified organisms) or hormones in beef, etc. Finally, the General Agreement on Trade in Services (GATS) provides a framework for commitments on national treatment and mutual recognition, but the option of mutual recognition has seldom been used.

2.2 Past transatlantic regulatory cooperation initiatives

In addition to being the main actors shaping existing multilateral rules, the EU and the US have engaged in numerous bilateral attempts to

promote regulatory cooperation. These have taken place within the framework of bilateral cooperation established by the Transatlantic Declaration of 1990, a largely politically motivated effort to redouble transatlantic cooperation at the end of the cold war. In 1995, a renewed effort to deepen transatlantic economic relations resulted in a Joint Action Plan and the New Transatlantic Agenda Task Force, which had, among other things, the aim of promoting regulatory cooperation. This resulted in mutual recognition agreements on telecommunications equipment, electrical safety, pharmaceutical and medical devices and recreational crafts being implemented with varying degrees of difficulty (Pelkmans & Correia de Brito, 2015). It is also worth recalling that stakeholder dialogues, e.g. the Transatlantic Business Dialogue (TABD), the Transatlantic Consumer Dialogue (TACD) and the Transatlantic Environment Dialogue (TAED) were established at this time with a view to promoting a common understanding of regulation and regulatory policy aims. The Transatlantic Legislators Dialogue was also set up to strengthen European Parliament-US Congress contacts.

The limited success of the New Transatlantic Agenda led to a redoubling of efforts in the form of the 1998 Transatlantic Economic Partnership (TEP), which also had an Action Plan, including regulatory cooperation. This led to the adoption of a Veterinary Equivalence Agreement and the introduction of an 'early warning system' to help identify and head-off potential conflicts over regulation. These efforts were disappointing, especially the lack of progress on mutual recognition, and were not able to head-off trade disputes (European Commission, 2000). In an attempt to reframe the transatlantic trade agenda in a positive light following a number of high-profile disputes – stemming in no small measure from differences in regulation – the Positive Economic Agenda was launched in 2002. At this time a number of new regulatory dialogues were established, such as the Financial Market Regulatory Dialogue between DG Market and the US Treasury and Securities and Exchange Commission in 2002 and the Policy Dialogue on Borders and Transport Security (PDBTS) to address security concerns following 9/11.

Without dwelling on the past (see Chase & Pelkmans, 2015, for an exhaustive list of US-EU regulatory cooperation since 1995), it is therefore worth recalling previous efforts at regulatory cooperation and learning from them. The broad conclusion is one of rather disappointing results due to the difficulty in reconciling the different regulatory philosophies, a lack of consistent political support for detailed regulatory work and reluctance on the part of legislators to

cede any regulatory autonomy. Regulatory requirements in the US and the EU result from the respective market structures and well-established consumer preferences that make regulatory cooperation inherently difficult. Where regulatory differences result from diverging policy choices, it is fair to assume that the reasons that have prevented a closer alignment of regulation in the past will not suddenly disappear with the TTIP (Gerstetter, 2014, p. 5). Surmounting the 'transatlantic deadlock' (Alemanno, 2009, p. 27) will be the main challenge for negotiators and regulators on both sides.

2.3 The EU-Korea FTA

The EU-Korea agreement reaffirms the parties' obligations under the TBT Agreement and sets out a general aim of joint cooperation in order to avoid unnecessary divergence in regulatory approaches (Art 4.3, EU-Korea FTA). It encourages cooperation between public and private standards and conformity assessment bodies.

The approach to technical regulations is based on intensified cooperation. The parties agreed to ensure the notification of the other party when a regulatory change is envisaged, allowing the other party time to respond and to participate in any formal public consultation. This is little more than a requirement to ensure that the TBT commitments are effectively implemented, which is not always the case. On voluntary standards, the EU-Korea agreement is also not TBT-plus. On conformity assessment, it simply offers a series of alternatives in the form of a) the mutual acceptance of the test results of the other party, b) the recognition of the conformity assessment of the other party or c) acceptance of suppliers' declaration of conformity. In two respects the EU-Korea agreement is new. It introduces a series of sectoral working groups covering, for example, automobiles and parts, machinery, chemicals, etc. These working groups report to the Trade Committee (on which the EU is represented by the European Commission). Secondly, it introduces TBT Coordinators in each party, who have the job of finding speedy remedies in cases of unnecessary barriers to trade, something that is seen as helping small- and medium-sized firms in particular.

With regard to the SPS chapter in the EU-Korea agreement, it reaffirms the existing obligations of the parties under the WTO SPS Agreement. In line with the practice established first in the EU-Chile FTA, it includes detailed procedures on how principles set out in the SPS Agreement can be implemented, for example, equivalence or the designation of disease- or pest-free regions. Thus, as for TBTs, the

agreement really seeks only to implement more fully the existing SPS commitments.

With regard to services, the EU-Korea agreement builds on the GATS by encouraging the professional bodies responsible for determining qualifications to make recommendations to the Trade Committee on mutual recognition. The Trade Committee is then to decide on whether to negotiate a mutual recognition agreement that would be negotiated by 'the competent authorities'. A Working Group on Mutual Recognition is also established to monitor this aspect of the agreement.

2.4 The EU-Canada Comprehensive Economic and Trade Agreement (CETA)

The approach employed in CETA is broadly in line with that in the EU-Korea agreement, but with a number of innovations.

On technical regulations (Chapter 6), CETA also reaffirms commitments under the TBT agreement, but appears to go further by adding a provision according to which a party may request recognition of equivalence with the existing regulation of the other party (Art. 4 (4) CETA). In other words, the EU can request Canada to accept EU regulations as equivalent to Canadian requirements or vice versa. This request would be considered by the Committee on Trade in Goods, which will make recommendations to the (overarching) Trade Committee. In CETA, the parties also agree to apply the (voluntary) Code of Good Practice for Standards Making Bodies.

CETA includes separate protocol (as chapter 27 of the draft treaty) on conformity assessment, with an Annex. This strengthens the case for mutual recognition of the results of conformity assessment by stating that Canada will recognise conformity assessment bodies established in the EU if accredited by Canadian authorities or designated by an EU member state. The EU in turn agrees to recognise third-party conformity assessment in Canada (i.e. in cases where self-certification by producers is not allowed). The protocol also identifies priority sectors. Included is the safeguard that 'nothing shall be interpreted as requiring recognition' of conformity assessment.

On SPS, the CETA follows the same approach as the EU-Korea FTA by reaffirming obligations under the existing SPS agreement and then adding detail provisions on how the SPS agreement should be applied.

Likewise in services, CETA adopts the approach of encouraging professional bodies to initiate the process of negotiating mutual recognition agreements by making recommendations to the Committee on Trade in Services, which will then make a recommendation to the Trade Committee.

Finally, CETA includes the establishment of a Regulatory Cooperation Forum that will have the role of promoting cooperation across all sectors. This is perhaps the model for the Regulatory Cooperation Body (RCB) proposed by the European Commission for TTIP (see discussion below).

2.5 The general approach to recent PTAs in the US

This section draws primarily on the KORUS agreement between the US and Korea, which is an indication of US preferences in this policy area.

The US also reaffirms commitments under the TBT agreement in Chapter 9 of KORUS. There is an article on joint cooperation (9.4), which encourages general mutual understanding and provides for sectoral initiatives. On conformity assessments, KORUS is less ambitious than the EU-Korea FTA in that the former merely lists a range of six mechanisms, including mutual and autonomous recognition of conformity assessment, accreditation and supplier declarations. If recognition is requested but not granted, the reasons for not granting recognition must be given (see Pelkmans & Correia de Brito (2015) for a detailed comparison of the TBT chapter in KORUS with that of the EU-Korea FTA). There is a reference to the APEC Mutual Recognition Arrangement for Conformity Assessment in Telecommunications, of which Korea is a member. KORUS broadly follows the TBT approach on transparency and urges the use of electronic forms of communication. But here, as in the general provisions on technical regulations, there is only ‘best endeavour’ wording for the ‘level directly below that of central government’. In other words, state level government in the US is not bound. Analogous to the EU-Korea agreement, there is a sectoral committee on regulatory requirements for automobiles, which is to work towards joint implementation of the regulatory requirements set out by UNECE (United Nations Economic Commission for Europe). Additionally, the TBT provisions are to be monitored by a Committee on Technical Barriers to Trade on which USTR represents the US.

The KORUS provisions on SPS are even briefer than those on TBTs. Chapter 8 reaffirms the SPS Agreement and establishes an SPS

Committee that should ensure that SPS measures rely on ‘science and risk-based assessments.’ (Chapter 8(3)).

In services, KORUS provides some further ‘best endeavours’ wording on transparency and the provision of information. Article 12(9) provides for the recognition of qualifications either mutually or autonomously, but stresses that there is no requirement to recognise.

3. Opportunities and challenges

3.1 Opportunities

3.1.1 Reduced costs and more competitive markets

For the Parties, industrial transatlantic regulatory cooperation offers the opportunity of reducing the waste of complying with competing – but equivalent – regulatory requirements. Better regulatory cooperation can also enhance market access for EU exporters, especially small- and medium-sized companies. This is particularly of interest for the leading EU exporters to the US in sectors such as automotive, machinery and chemicals in terms of regulatory requirements and to US exporters in food and health products and machinery. Strong sectors in the EU such as financial services, public transport equipment and construction also stand to benefit from increased cooperation in services regulation and procurement. All sectors, as well as traders and wholesalers, stand to benefit from a reduction in trade costs due to border controls and improved trade facilitation. The TTIP therefore offers an opportunity to strengthen international competitiveness and to create more wealth and jobs in the EU and the US. The scale of the welfare and trade gains has been the subject of much debate (Pelkmans et al., 2014) but gains from reduced costs due to different but equivalent regulation represent the most important economic gains from the TTIP.

3.1.2 Shaping international trade rules and consumer protection levels

In addition to improving economic growth, the TTIP has been justified on the grounds that it will enable the EU and the US to share leadership of the international trading system and shape the trade rules ‘democratically’. Transatlantic trade does account for a significant share of world trade. The EU and US are also the most active and advanced actors when it comes to addressing regulatory issues in trade and investment. On this view, agreeing to common approaches

through regulatory cooperation offers the opportunity of setting international norms and high levels of consumer protection in this respect.

It should, however, be remembered that the EU and the US have been doing this for some time, whether in the form of shaping the approach to rules on trade in services in the OECD, WTO and now in the TiSA (Trade in Services Agreement) or in the negotiations on government procurement in the (GPA) Government Procurement Agreement of the WTO. In these fora, the agendas and outcomes have been largely shaped by the transatlantic dialogue. In the area of technical standards and regulation, this has been much less the case. The EU has simultaneously promoted international standards through the markets and bodies such as the ISO and IEC. But the success of some leading American standards-making bodies selling their technical standards internationally has meant that it has eschewed binding commitments on standards. Progress on regulatory cooperation in this area could therefore have a real impact on shaping international norms.

Another area is that of rules of origin. Here the EU and the US are the main actors in shaping preferential rules of origin, with the PanEuro and NAFTA models being the two dominant but different models. Regulatory cooperation that could bring about a convergence and ideally a simplification of these two models would have significant benefits for the rest of the trading system.

Lastly, the existing system of investor-state dispute settlement (ISDS) is subject to reform within the TTIP, hence implying the shaping of international trade rules 'democratically'. In response to the EP's recent resolution, EU Trade Commissioner Cecilia Malmström emphasised that the old system of ISDS should not and cannot be reproduced in TTIP, and that the Parliament's call for a "new system" must be heard, and it will be (European Commission, 2015c).

3.1.3 Increase consumer welfare and levels of safety

Increased competition, due to progress in regulatory cooperation, offers the prospect of lower prices and an increased variety of goods and services for consumers (Diels & Thoran, 2014). Regulatory cooperation could also bring about improved consumer protection and safety. The assumption that the level of consumer protection is basically higher or more sophisticated in the EU is not sustainable. In place of the EU's precautionary principle, the US has a stringent civil liability system that acts as a means of ensuring high levels of health and safety,

via liability insurance requirements or induced regulations. For instance, the strong and high level of consumer protection regulations on toys and infant and toddler products in the US could greatly increase consumer protection and welfare for Europeans in this sector (CFA, 2014). Rather than fearing that the EU might trade away their precautionary principle approach to regulation, it could be seen as an opportunity to learn from each other's experience, to strengthen regulatory collaboration and to provide more transparency on the use of the PP.

An intensified exchange of information offers an opportunity to advance consumer policy interests. Intensified exchange of information is in line with the existing practice in dealing with regulatory divergence and barriers to trade and forms a central element in the proposals on regulatory cooperation. Where the TTIP leads to shared approaches, those are more likely to be followed around the world, meaning a regulatory race to the top rather than a race to the bottom.

The TTIP negotiations carry the potential to promote the interests of consumers. For example, negotiators could expand opportunities for consumers and micro-businesses by removing duties for personal imports, eliminating excessive pricing of telecommunications (i.e. roaming fees) and broaden access by consumers to the digital market, for instance, by preventing online geographical price discrimination (European Consumer Organisation/BEUC/Bilate, 2015; Renda & Yoo, 2015). However, this potential will only be fully tapped if the narrow focus of negotiations is extended to a modern and broad comprehension of consumer welfare (Diels & Thorun, 2014, p. 48).

Making regulations more compatible does not mean going for the lowest common denominator, but rather seeing where divergence is unnecessary and where coordination is beneficial for both economic interests and consumer welfare. Therefore, impact assessments for the purpose of transatlantic regulatory cooperation must not be limited to the impact on trade, but also consider consumers' interests, such as safety, information and sustainable consumption as is the case with the holistic approach to impact assessment. The use of impact assessment on both sides of the Atlantic also provides scope for the engagement of a variety of stakeholders, for example in the common definition of concrete tools to measure the impact on consumer safety.

3.1.4 *Momentum for continued EU reform*

In order to keep pace with international competition, the EU should maintain the momentum needed for further domestic reforms as a means of boosting its own competitiveness. External pressure in the shape of international competition or negotiations with key trading partners has always played a role in the development of EU commercial policy and the creation of the Single Market. Negotiating TTIP or any agreement with a major developed market economy poses more of a challenge for the EU than PTAs with smaller, less-developed economies or arguably negotiations in the WTO (with the possible exception of agriculture). But such negotiations also offer an opportunity to provide the additional external driver that may be needed to break domestic deadlocks on policy reforms due to entrenched vested interests, resulting in breakthroughs that will be beneficial for EU consumers and firms as a whole.

3.2 Challenges

3.2.1 *Making regulatory cooperation a success*

The essential challenge is to make transatlantic regulatory cooperation a success and thus tackle the additional (trade) costs resulting from different but equivalent regulation, standards or conformity assessment in the US and the EU, whilst ensuring there is no diminution of consumer safety and protection or environmental policy objectives. Inevitably, some sectors will prove to be difficult or near impossible for substantial regulatory cooperation to take place due to grave and irreconcilable concerns that the public may have. Consequently, the EU has been explicit in stating the issues that will be exempt from negotiations, such as GMOs and beef-with hormones (see Josling & Tangermann, 2014 for more information on agriculture and the TTIP) food and data-privacy laws. However, relevant consumer protection associations, such as BEUC (European Consumer Organisation, 2015) and the TACD (2015), have expressed major concerns that this is not enshrined in the European Commission's Textual Proposal document. Furthermore, in order to ensure that regulatory cooperation is a success, citizens and consumer advocacy groups need increased transparency and involvement, which means that the US should follow the EU's lead in publicising their negotiation proposals and increase the public's involvement (CFA, 2014a; TACD, 2015; and European Consumer Organisation/BEUC, 2015).

It is also worth recalling that there have been various previous attempts to promote transatlantic regulatory cooperation that have at best been only partially successful. With the main economic gains from TTIP projected to come from addressing regulatory barriers, the main challenge is to tackle them effectively.

3.2.2 *Dealing with differences in regulatory philosophies and practice*

Beyond the technical difficulties that are involved with regulatory cooperation, one of the greatest challenges facing TTIP will be reconciling the different regulatory philosophies, such as the difference between the EU's use of the precautionary principle (PP) and the US reliance on science-based risk assessment, cost-benefit analysis and cost-effectiveness analysis ('science-based approach') (Bergkamp & Kogan, 2013, pp. 495-497). The following section will provide a brief overview of both philosophies.

The precautionary principle enables the EU to invoke more stringent levels of regulation or standards in cases when a potential adverse impact on human health or the environment can take place and/or there is scientific uncertainty, such as scientific controversy, disagreements or a lack of scientific knowledge (von Schomberg, 2006). Prior to drafting legislation, the EU normally drafts Impact Assessments as a means of understanding a piece of legislation's far-reaching impact (Alemanno, 2014). Even with the European Commission's Delegated and Implementing Acts, Impact Assessments are normally conducted when significant economic, environmental or social impacts are expected as a result of the act (Alemanno, 2014). It is worth noting that part of the EU's precautionary principle is anchored in Art. 191(2) TFEU, which states that environmental policy should be based on the precautionary principle. So it cannot be 'negotiated away'. That said, this does not prevent the European Commission from entering into an agreement that could potentially nullify some of its effects (Bergkamp & Kogan, 2013).

The US scientific approach to regulation is supported by the central role of the White House Office of Information and Regulatory Affairs (OIRA) and the Regulatory Impact Assessments (RIAs) that agencies are required to produce. Both are simply based on a science-based cost-benefit analysis (Alemanno & Parker, 2014), which stands in contrast to the EU's more precautionary and holistic examination of the potential societal and environmental impacts that a piece of legislation may have. In place of the precautionary principle, the US has a stringent

civil liability system that acts as a means of ensuring that health and safety regulations and product standards are not lax (Bergkamp & Kogan, 2013). In multiple cases, the US Supreme Court has ruled that the US Office of Safety and Health Administration must have demonstrated “significant risk” prior to regulation (Wiener & Rogers, 2002, p. 318).

There may be some signs that the US is inching towards a greater use of precaution in their regulatory approaches. For instance, President Obama made reference to precaution in his statement on a deep seabed mining policy and the US House of Representatives decided to highlight “scientific inadequacy” in its regulatory decision on endangered species (Bergkamp & Kogan, 2013, p. 500). However, it would be relatively naïve to believe that the US will significantly alter its regulatory philosophy any time soon.

Differences in regulatory principles in the EU and US have led many to be concerned that any attempt at regulatory convergence in the TTIP may imply deregulation of European consumer protection. The greatest concern is that the science-based approach to risk assessment in the US differs from the use of the precautionary principle in EU risk assessment. Science-based risk assessment has not always been sufficient, as shown in the case of the mad-cow disease epidemic. This was an example of science-based risk assessment getting it wrong. This and other episodes have influenced thinking in the EU towards more scope for the use of precaution, such as in the field of chemicals with the introduction of REACH in the EU (Karlsson, 2015). (For a detailed discussion of consumer concerns, see Diels & Thorun, 2014 and Alemanno, 2014.) However, several studies have demonstrated that, with some possible exceptions, the high standards required by both the EU and the US will ensure a high level of consumer, health and environmental protection (Bergkamp & Kogan, 2013, p. 507). A further study by Fabry & Garbasso (2014, p. 4) suggests that differences between precaution and science-based risk assessment have been overplayed and that differences are more due to a selective application of precaution to different risks in different places and times.

3.2.3 *Selecting the best options for regulatory cooperation*

The recent literature on approaches to regulatory cooperation from a consumer protection standpoint has identified harmonisation, mutual recognition or equivalence and intensified exchange of information as options in addressing regulatory divergence.

Harmonisation

Harmonisation has been used for voluntary standards but has proven difficult or, at best, very time consuming. For consumer protection, the issue is whether the common levels of consumer protection represent a levelling up or down. The work on this suggests that contrary to fears of a 'race to the bottom', there is some evidence of a levelling upwards, as has been the case within the US where higher levels of consumer protection in some states have led to a levelling up in the quality of consumer protection in a variety of states: the so-called 'California effect' (Vogel, 1997).

Mutual recognition or equivalence

Mutual recognition in its various forms or equivalence can be appropriate when the policy goals are the same but the approach used to meet these goals differs. This approach offers the prospect of being more effective in reducing the costs of incompatible provisions. It poses no threat to consumer protection, provided the goals are indeed equivalent. From a consumer perspective, the interest here is to ensure that regulatory cooperation is geared towards satisfying consumer interests and not unduly focusing on the removal of regulatory barriers to trade or increased trade costs. This is, of course, the basis for the 'new approach' to technical harmonisation and standards within the EU that led to the success of the Single Market programme in the 1980s and 1990s. But in the EU case, it was based on a harmonisation of minimum essential requirements as well as a broad approximation of regulatory aims.

Intensified exchange of information

Considerable opportunities lie in an intensified exchange of information and research between European and US regulators. Informational coordination on issues of common interest promises not only greater but also increased consumer protection through mutual learning. However, this free flow of information that benefits consumers should never be confused with the flow of commercially valuable personal information regulated under data protection and privacy frameworks on both sides of the Atlantic. Moreover, a free flow of information is also not necessarily the same as an increased level of transparency.

In practice, the way in which regulations and standards have been dealt with in trade agreements is a little more complicated. Here it is helpful to differentiate between several elements.

Transparency constitutes a fundamental basis of trade agreements. In this context, it involves the publication of all regulations and testing procedures as the first essential step to the removal of barriers to market access. This can be facilitated by the requirement to use modern electronic communications and by ensuring there is a central focal point to answer any enquiries concerning regulations.

Technical regulations are defined in the WTO as measures that are obligatory and laid down in national or EU legislation. The TBT agreement requires national treatment, but this does not, of course, deal with the trade costs resulting from differing regulations. The alternative approach is mutual recognition of regulations, but there are only 'best endeavours' wording on mutual recognition in the WTO TBT Agreement and most other trade agreements. Standards are defined as voluntary measures that may or may not provide a means of showing compliance with regulatory requirements. International standards-making bodies cover goods, e.g. the International Standards Organisation (ISO), CENELEC (for electrical equipment) and for minimum requirements underlying SPS measures, the Codex Alimentarius.

Both the TBT and SPS agreements make reference to international standards. In the former, there are 'best endeavours' wording only on the use of international standards and a voluntary Code of Good Practice on Standards Making. The SPS agreement urges the use of Codex regulatory requirements, but only where these are appropriate (e.g. too low), thus allowing significant scope to waive the requirements. Conformity assessment relates to the process or procedure by which compliance with agreed standards or regulations are tested. Most trade agreements, including the TBT agreement, require national treatment for conformity assessment, so that imported products must be tested in the same way as nationally produced products. As for technical regulations, this does not address the additional costs of complying with unnecessarily complex or different conformity assessment measures. So again there is the option of mutual recognition or equivalence of conformity assessment.

Institutional provisions are included in agreements. These usually take the form of committees to monitor and promote the application of regulatory cooperation. There may also be specific

committees, such as in the case of the recent EU–Korea FTA or KORUS discussed above.

The options discussed above have different implications for regulatory sovereignty and thus the scrutiny function of the EP and its committees. Taking each of these in turn, harmonisation of voluntary standards is carried out by standards making bodies, the representation in these is through the national standards making bodies and on detailed technical work there is strong involvement of private sector experts. Agreed international standards are adopted by voting in the international bodies in which the European standards-making bodies have a very strong presence, which is often still seen in the US as skewing the balance against the ‘more industry-led’ approach to standards used in the US.

Mutual recognition can take a number of forms. In the past mutual recognition agreements have been based on legislation. If this is the case, legislatures on both sides of the Atlantic will retain regulatory sovereignty. But, as noted above, the reluctance of the regulators and legislators to make changes has been a significant impediment in the past. The European Commission and the USTR have stated that regulatory cooperation provisions in the TTIP will not imply rule-making powers. At this level therefore there would seem to be no threat to the regulatory autonomy. The respective legislatures would however, have to exercise effective scrutiny.

The third alternative of intensified exchange of information raises few issues for regulatory scrutiny. This option seeks to influence the preparatory phase of regulation. Through exchanges of research and thinking on the form and stringency of regulation, incompatibilities should be reduced from the outset. The proposed legislation would then be compatible or more compatible, but the EP and US Congress would still retain legislative sovereignty.

3.2.4 *Identifying suitable priorities*

In order to make progress, it has been recognised by negotiators on both sides that what is needed is to identify those areas where levels of consumer protection are equivalent but the means of achieving them differ. In these areas it should be possible to reconcile the procedural differences through mutual recognition or acceptance of equivalence, subject of course to effective scrutiny to ensure that this does not lead to a reduction in consumer protection that would be detrimental to consumer/environmental interests. This chapter suggests that this

should be possible in sectors such as engineering and automobiles and perhaps in aspects of trade facilitation such as supply chain security.

It will equally be necessary to recognise, as the negotiators appear to have done, that there will be some areas in which levels of consumer protection diverge so that the more ambitious forms of regulatory cooperation such as mutual recognition in its various forms are inappropriate. Such sectors appear to be in REACH in the chemical sector (see Elliot & Pelkmans, 2015) and probably significant areas of food safety. In these areas it will be necessary to recognise that regulatory cooperation will have to take the form of less ambitious instruments, such as intensified exchange of information or joint research on future standards as a means of limiting future divergent standards.

3.2.5 *Getting the process right*

The nature of these challenges suggests that regulatory cooperation will have to be a continuous process. As has long been recognised in the debate on TBTs, the conclusion of an agreement is only the beginning. Real progress in removing regulatory barriers requires more or less continuous efforts. Again, this is a lesson that has been learned in the EU's attempts to reduce such barriers to the cross-border intra-EU movement of goods, services and factors of production. A key challenge in the TTIP is therefore getting the process right. This means ensuring that the framework established to carry the work forward is appropriate. In the context of the TTIP this means ensuring that the mechanisms, such as the proposed Regulatory Cooperation Body (RCB), are effective and transparent. Calls from the TACD (2015) have proposed that as a way to boost the effectiveness and transparency of the RCB, consumer groups and citizens should be integral to its design and that the good practices of meaningful, public and transparent consultations should be enshrined in the TTIP.

Another key challenge in getting the process right is ensuring that future attempts to implement new regulations do not become overly burdensome – more specifically, costly and time-consuming. It is important to note that this may have greater implications for the US compared to the EU due to a difference in regulatory systems and legislative functions (TACD, 2015; VZBV, 2015).

In the European Commission's textual proposal document, it states that impact assessments and meaningful consultations are required to take place on planned regulatory acts at the central level.

Furthermore, each Party is required to inform the other Party about proposed regulatory acts (at the central level) that will likely have a “significant impact” on “international trade or investment...between the parties” (European Commission, 2015a).

The European Commission’s proposed IA (impact assessment) and consultation process may slow down future attempts of implementing new regulations and make it more costly for legislators complying with regulatory requirements for three reasons. First, the European Commission’s proposal for an increased usage of IAs will most likely result in a greater administrative workload when regulations are being proposed. This is especially true for the US where IAs are not as frequently employed as it is in the EU (TACD, 2015). This proposal may prove difficult for the administrative departments or agencies that are responsible for drafting IA if they are overstretched or under-resourced.

Second, since IAs are not clearly defined in the European Commission’s textual proposal, these IAs may be more extensive than the IAs that the US normally conducts. More specifically, beyond a cost-effectiveness analysis (which the US IAs primarily focus on), European IAs are more ‘holistic’ in that they will also analyse, for instance, social and environmental impacts (Alemanno & Parker, 2014). However, US consumer advocacy organisations, such as the CFA, are in favour of IAs with a more holistic analysis (CFA, 2014b).

Third, the European Commission’s interest in binding the US’s sub-federal units to the TTIP (i.e. US states) may also magnify the potentially burdensome impacts of IAs and consultation (TACD, 2015).

While some groups, such as the TACD (2015), BEUC (2015) and the VZBV (2015), believe that this may cause a “significant slowdown and chill on regulatory processes”, these concerns may be over-exaggerated in that the European Commission’s latest textual proposal document outlines that each Party will be charged to determine whether a regulatory act will have a “significant impact” (European Commission, 2015a). Furthermore, US federal agencies proposing “significant” new regulation, already conduct stringent regulatory IAs and normally opt for a more consultative process as a means of averting potential judicial reviews (Alemanno & Parker, 2014). As for the EU, the European Commission conducts at least broad consultations with parties impacted by new proposals for delegated acts and publicises the consultation process of an implementing act’s proposal (Alemanno & Parker, 2014). The European Commission’s May 2015 proposal for “Better Regulation(s)” will result in a more frequent use of Impact

Assessments in the Commission's delegating measures (European Commission, 2015d).

In addition to ensuring that regulatory cooperation is a continuous process once the TTIP is concluded, negotiators need to ensure that future attempts of implementing new regulations are not overly burdensome.

3.2.6 *Safeguarding regulatory sovereignty: The case of the EU*

A question of interest to MEPs is whether the proposed process poses a challenge for the EU's regulatory sovereignty. The present analysis argues that the European Parliament's regulatory sovereignty, in terms of legislative rule-making authority, is unlikely to be affected by the TTIP. In the discussion so far it has become clear that the RCB will have no rule-making powers.

The EU's proposed approach to the TTIP has been set out in the initial European Commission's Textual Proposal made public on the 9th February 2015. It should be understood that this is only an indication of what might be in the TTIP. The outcome of the negotiations is of course unknown at this stage. No US textual proposal has been made available for discussion even though regulatory cooperation was the subject of discussion in the 9th round of negotiations in New York in the week of the 20th April. The EU text sets out the general aim of 'reinforcing regulatory cooperation' (Art 1) without restricting the right to regulate in pursuit of legitimate public policy objectives, such as 'a high level of protection of inter alia: the environment; consumers; working conditions; human, animal and plant life, health and safety; personal data; cyber security; cultural diversity; or preserving financial stability.' Both the EU and US negotiators have repeatedly emphasised that there is no intention to restrict the right to regulate levels of consumer protection or any other regulations, neither to lower such standards (Fabry & Garbossa, 2014). As the US supports this position there is no reason to believe that the final outcome will diverge from this position.

One area of contention is coverage. The EU's proposed text refers to cooperation at the level of central government (Art. 3), although there is a note that the scope will be reviewed at a later stage of the negotiation. At issue here is whether the US will accept an extension to the sub-federal, i.e. state level regulation. In a number of regulatory policy areas, the states play an important role. In other trade agreements, the US has offered no more than best endeavours for the

coverage of sub-federal regulation, so including state level regulation in the process will be a challenge for the EU.

According to the EU proposal, transparency provisions would require the parties to provide a list of planned regulations 'at least once a year'. The EU's proposed approach under regulatory policy instruments is that the parties 'affirm their intention' to carry out impact assessments of planned regulatory acts at the central level (this would mean the EU level and the US federal level). In carrying out such impact assessments, the parties shall i) consider how the regulation relates to relevant international instruments and ii) take account of the regulatory approaches of the other party and the impact on international trade or investment (including investors) (Art 7).

In the course of such impact assessment, the parties would be required to exchange information and promote the exchange of experience. Stakeholders would also have to be given a 'reasonable opportunity' to provide input through public consultations (Art 6). The US and the EU currently use impact assessments, but it will be important to assess how this meshes with the EU's regulatory and legislative processes. Impact assessments are widely used in the pre-legislative phase in the EU and normally take place for delegated or implementing measures (Alemanno & Parker, 2014; Alemanno, 2014). Regulatory cooperation in the TTIP could therefore result in a greater use of impact assessments.

An Annual Regulatory Cooperation Programme would be established to set priorities for regulatory cooperation. This is similar to previous transatlantic approaches to regulatory cooperation, but an annual programme suggests greater intensity. Since such an approach would effectively shape the priorities for the RCB, it would be important for the European Parliament to have an input into and provide scrutiny of the programme.

Articles 9 and 10 of the EU textual proposal deal with information and regulatory exchanges. These are in line with the well-established approach used in long-standing trade agreements, such as the provisions on TBT or SPS in WTO or preferential agreement already concluded by the EU. The EU proposal does, however, include specific reference to an obligation to inform the other party of proposed regulatory acts that 'do not originate from the executive branch'. This appears to be designed to ensure that rule-making emanating from US regulatory agencies is also included, and is necessary given the nature of the US system. The regulatory exchanges will take place between regulators and competent authorities.

In Article 11, the proposal includes the central element of promoting regulatory compatibility. This shall apply to areas where ‘mutual benefits can be realised without compromising the achievement of legitimate public policy objectives’ as set out in Art 1. The text includes a number of options, namely:

- ‘mutual recognition of equivalence of regulatory acts, in full or in part’ ... based on equivalent outcomes as regards the fulfilment of the public policy goals pursued by both parties;
- harmonisation of regulatory acts, or their essential elements through the application of existing ‘international instruments’ (e.g. international standards);
- the approximation of rules and procedures on a bilateral basis; or
- simplification of regulatory acts in line with shared principles and guidelines.

This approach seems balanced and would not undermine the EP’s regulatory sovereignty provided the RCB has no rule-making powers.

The RCB would be composed of ‘regulators and competent authorities’. The expectation must be that the competent body on the part of the EU would be the European Commission’s Directorate General responsible for the regulatory policy concerned. If this is the case, then there can be some assurance that regulatory policy objectives, such as consumer interests, would not be less likely to be compromised in the interests of ‘trade’ or market access. But this is something the European Parliament should monitor.

The RCB would have the power to create sectoral working groups. This seems to be in line with the typical powers granted to similar committees in other preferential trade agreements (PTAs). This is necessary due to the technical nature of regulation and regulatory barriers to competition in markets. The RCB would hold a meeting open to the participation of stakeholder ‘at least once a year’, prepared with the involvement of the co-chairs of the Civil Society Contact Groups. Therefore, formal consultations with civil society are envisaged.

In summary, the EU’s proposals are based on intensified exchange of information with a view to reinforcing regulatory cooperation. The options offered are fairly simple and include equivalence/mutual recognition, harmonisation or ‘simplification’. The text includes a safeguard in the sense that it expressly reserves the

right to regulate in pursuit of high levels of protection for consumers and other legitimate public policy objectives. MEPs will wish to ensure that this is the case in the final text and that they have an input in the priorities in regulatory cooperation, such as through scrutiny of the Annual Regulatory Cooperation Programme.

The research for this chapter has focused on the case of the EU. When it comes to the US, regulators and the US Congress have a solid record of defending their regulatory sovereignty. As noted above, there is as yet no (published) US textual proposal on the approach to regulatory cooperation. If the (unofficial) text for regulatory cohesion in the TPP is a model, however, the US approach would appear to pose no threat at all to regulatory sovereignty as the emphasis would be on promoting coherence within the US (and the EU if this approach were used in the TTIP). The role of any joint body to set agendas for regulatory cooperation across the Atlantic would therefore be less, so there could be no danger that such a body might somehow undermine regulatory sovereignty.

4. Case studies

4.1 Chemicals

The area of chemicals entails considerable divergence between US and EU legislation and thus marked interest in greater regulatory consistency (for more on chemicals, see Elliot & Pelkmans, “Great TTIP ambition in chemicals: Why and how”.) The EU’s central piece of legislation is the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), which entered into force in June 2007, and streamlines the legislative framework on chemicals of the EU. Classification and labelling of substances is governed by the so-called CLP (classification, labelling, and packaging) Regulation. Basically, under REACH, producers or importers must register chemicals to be put on the market in quantities exceeding a certain threshold with the European Chemicals Agency (ECHA). As part of the registration, they must provide specific information on the properties of the chemicals to ECHA. Registrants must also conduct a chemical safety assessment. Certain chemicals, included in Annex XIV of the Regulation, are subject to pre-marketing authorisation; criteria for including substances into the list are defined (Gerstetter, 2014, p. 30).

In May 2014, the European Commission published a position paper for the TTIP negotiations on chemicals, stating that “neither full harmonisation nor mutual recognition seems feasible on the basis of the

existing framework legislation in the US (Toxic Substances Control Act, TSCA) and EU (REACH)” and that proposals for greater consistency have to be within the existing legislative framework of the EU. Although current EU and US regulations on chemicals differ, there are areas where the two systems allow for joint work. The position paper outlines four areas for which the European Commission proposes to assess possibilities for enhanced cooperation with the US via the TTIP:

1. Prioritisation of chemicals for assessment and assessment methodologies;
2. Promoting alignment in classification and labelling of chemicals;
3. New and emerging issues (e.g. endocrine disruptors, nanomaterials); and
4. Enhanced information sharing among regulators while protecting Confidential Business Information (CBI) (e.g. on test data to reduce animal testing).

This suggests an intensified exchange of information approach, which means in practice that US and EU regulators might agree to work together during their assessment through evaluating the same substances at the same time and exchanging respective information. This bears cost-saving potential for both the companies and the regulators, but it would not change the level of protection offered by EU law. The EU decision-making process might be concerned by decisions emanating from an US-EU regulatory cooperation, for instance on the inclusion of substances in any of the Annexes. In such a case, the European Commission would formulate a proposal and the relevant Committee, composed of member state representatives, would be involved. In other decisions under REACH, ECHA itself or the competent authorities of member states are involved. Thus, TTIP will not change the fundamental decision-making structure of the EU.

The example of chemicals regulation shows that the scope for autonomous decision-making by the European Commission is limited, as in major implementing acts a number of actors are involved. The goal is to seek opportunities for cooperation between the relevant regulators in order to better coordinate certain practices and therefore increase efficiencies and reduce costs for authorities and economic units, but without lowering any existing consumer protection levels.

4.2 Automotive sector

The automotive sector is another industry that could benefit greatly from regulatory convergence. (For more on the automotive sector, see

chapter 15 in this volume by Freund & Oliver). The EU's automotive industry is, after China, the second-largest manufacturer of motor vehicles worldwide and it generates millions of jobs – directly and indirectly – EU-wide. The US represents by far the largest market for EU automobile exporters (followed by China, Russia and Turkey).

A significant stimulus for transatlantic trade of motor vehicles and parts can be created by addressing trade related costs which arise from NTBs, such as different product standards or regulations, testing methods, classifications and product labelling. The EU and the US have different regulations in relation to lights, door-locks, seat belts, steering and electric windows. As these regulations assure a similar level of safety across the Atlantic, there is a wide range of regulations where mutual recognition seems possible (Kolev & Matthes, 2014, p. 8). Nevertheless, the processes by which the US and EU establish product regulations in the automotive industry have very different paths. Contrary to the US system of self-certification, the safety of motor vehicles is attested via pre-market government approval in the EU. The European vehicle regulations include both EU directives, which must be implemented by the member states, and regulations promulgated through UNECE with optional implementation by the national governments of the member states. Signatories to the UNECE Agreement commit to mutual recognition of approvals for vehicle components. However, the US did not join the agreement, as it was not ready to recognise regulations generated outside the US. What this means for manufacturers is that they have to run tests twice in order to get cars approved in both markets. Besides safety, there exist main differences of regulatory requirements between the US and EU concerning fuel economy and emissions requirements (Canis & Lattanzio, 2014, p. 5).

The European Commission's May 2014 proposal for regulatory cooperation on motor vehicles outlines a possible approach to promote regulatory compatibility while achieving the levels of health, safety and environmental protection that each side deems appropriate. The ultimate goal pursued in the TTIP negotiations concerning the automobile manufacturers is according to the EU's position twofold:

- “Firstly, the recognition of motor vehicles (and their parts and components, including tyres) manufactured in compliance with the technical requirements of one party as complying with the technical requirements of the other. [...]

- Secondly, a significant strengthening of EU-US cooperation also in the framework of UNECE 1998 Agreement, especially on new technologies.”

The first step in the process of mutual recognition of technical requirements is the development of a methodological approach enabling regulators to assess whether the regulations of one side are equivalent (in terms of, for example, safety levels and environmental protection). In areas where equivalence of regulatory outcome can be confirmed, “the relevant regulations of the other TTIP partner would have the same legal effect as compliance with domestic regulations”. Regarding the second point, the hope is that the EU-US cooperation in the framework of the UNECE 1998 Agreement should lead to the adoption of Global Technical Regulations in the near future. Strengthening EU-US cooperation is considered essential regarding the role of the EU and US as potential regulatory requirement-setters in the global automotive industry. The reinforcement of EU-US cooperation is already a central element in the field of new technologies such as hydrogen and electric vehicles, test-cycle on emissions and advanced safety technologies (Kolev & Matthes, 2014, p. 26).

In the context of future regulatory cooperation, it is important to clearly define which measures concern TBTs and redundant administrative burdens and which measures are linked to desired levels of consumer protection and regulations and should not be altered. The EP’s democratic scrutiny over EU regulatory processes will be crucial when creating the framework for future cooperation. At the same time, it has to be vigilant about a balanced involvement of stakeholders such as the European Automobile Manufacturers’ Association (ACEA) and the American Automotive Policy Council (AAPC) within the stakeholder consultations included in the development of a regulatory proposal.

In summary, it is of particular interest for the EU to achieve an ambitious TTIP incorporating the commitment of the parties to promote regulatory convergence without sacrificing vehicle safety or environmental performance.

4.3 ICT

The Information and Communications Technology (ICT) industry – which is a “combination of manufacturing and services industries that capture, transmit and display data and information electronically” (OECD, 2012) – is one that can greatly benefit through increased

regulatory convergence between the US and the EU. However, a sensitive area to consumer protection – data privacy measures – may make it particularly challenging for negotiators to bridge the regulatory transatlantic divide (for more on the ICT sector, see Renda & Yoo, 2015).

With the regards to the European Commission's offensive interests in the ICT sector (European Commission, 2015b), regulatory cooperation does not seem to be a significant challenge on ICT goods (Renda & Yoo, 2015) For instance, efforts in establishing e-labelling requirements are expected to have little difficulty in regulatory cooperation since the US's E-LABEL Act was enacted in November 2014. This measure will especially help SMEs in reducing manufacturing costs of digital devices since it gives them the ability to not place labels, stickers and etches of regulatory compliance on their (electronic) devices by providing the regulatory compliance information digitally in the device's screen and/or software. Additionally, issues of e-accessibility – making ICT easier to use by people with disabilities – and interoperability – allowing users to exchange data between different products easier – do not seem to be highly contentious. The same could also be said about the European Commission's objectives in establishing better enforcement regulations and common principles for certifying ICT products, especially in the realm of cryptography.

In spite of the EU's offensive ICT interests, where consumers and firms alike will reap large benefits from increased regulatory cooperation, a more uncertain aspect of TTIP's regulatory cooperation lies in one of the European Commission's primary defensive interests – ICT services issues relating to the free flow of data – which has large implications for consumer protection.

Recent concerns with data privacy has prompted the EU to adopt increasingly stricter data protection measures, resulting in some countries adopting data localization efforts – legal requirements that an organization containing critical data of EU citizens must be physically stored in data servers in their respective country (Lakatos, 2014). Stringent data requirements, such as the EU's 1998 Directive on Data Protection, make it challenging for businesses abroad to do provide digital goods and services to the EU. In order to streamline digital trade between the EU and US and to ensure that the data of EU citizens were highly protected, the US-EU Safe Harbour Agreement was created in 2000. Consequently, organisations in the US that register to the US-EU Safe Harbour programme must provide certain protections, rights and assurances to EU citizens that their data is well-protected.

However, increased concerns surrounding data privacy in 2013 prompted the European Commission to review the US-EU Safe Harbour Agreement as they proposed a series of reforms to improve the security of personal data. While substantial progress has been made in negotiating a reformed Safe Harbour agreement, the EU and US have also been negotiating a Data Protection Umbrella Agreement to protect the personal data transferred between the two countries for law enforcement purposes since 2011 (European Commission, 2014).

Despite the European Commission making it clear that it does not want to negotiate on the topic of data privacy in TTIP (European Commission, 2013), the US has been keen on including some commentary on this in TTIP's e-commerce chapter as they have tabled a proposal to prohibit data localization measures (Lakatos, 2014; Järvinen, 2014). The US Trade Representative (USTR) increasingly faces pressure from lawmakers that have made multiple attempts in Congress to pass legislation that would give the USTR a stronger mandate against data localisation efforts in trade agreements (Bendrath, 2014). For instance, the "Law Enforcement Access to Data Stored Abroad Act", introduced in February 2015, states, "the (USTR) should pursue open data flow policies with foreign nations." However, there is a challenge within the EU as different countries are now exceeding the EU's requirements on data protection by having data localization efforts, which may make regulatory convergence all the more difficult on this issue.

In conclusion, it would be of interest to the EU if they could negotiate provisions similar to those in CETA, where Parties are required to respect the international requirements of relevant international organisations they are a part of, in TTIP. This would be of great interest to consumer advocacy groups, such as the TACD, that demand issues surrounding data flows to not be negotiated with (TACD, 2013). In addition to this, it would ideal if such provisions could reference the US-EU Safe Harbour agreement and the currently negotiated Data Protection Umbrella Agreement. If such provisions could be negotiated to protect the personal data of consumers, the EU stands to benefit from regulatory cooperation in the ICT sector in the TTIP.

5. Conclusion

Focusing on the area of consumer protection, this chapter argues that regulatory sovereignty of American and European legislators - in terms of the legislative, rule-making ability - is unlikely to be affected by the

TTIP. The discussion of the European Commission's recently published paper on regulatory cooperation has shown that the provisions are procedural and intended to promote, guide, monitor and help facilitate regulatory cooperation. There is, of course, as yet no final agreement. The EU's approach to TTIP as set out in the Textual Proposal and the existing EU and US approaches to regulatory cooperation in other PTAs does not suggest much of a challenge to the present regulatory sovereignty. The three options for addressing regulatory divergence – harmonisation, mutual recognition and intensified exchange of information – have different implications for the scrutiny function of the legislators and its committees. Transatlantic regulatory cooperation, such as through the proposed Regulatory Cooperation Body, will have to identify which areas of regulation are suitable for harmonisation, which for mutual recognition/equivalence and which for intensified exchange of information. Decisions on this will be taken in the RCB, but any action requiring legislative change will be dealt with under existing policy-making procedures. The American and European legislators should, along with other institutions, ensure that the work of the RCB is transparent. The priorities in regulatory cooperation that will be set by the Annual Regulatory Cooperation Programme should be scrutinised to ensure that they reflect the broader consumer priorities.

A final assessment of the impact of transatlantic regulatory cooperation on consumer protection can only be made once the process can be observed. Further work will therefore be needed to monitor the procedures established and assess whether they are successful in making progress on the reducing the costs of different approaches, while ensuring that consumer interests are safeguarded.

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