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**ECONOMIC AND SCIENTIFIC POLICY** **A**

Economic and Monetary Affairs

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**Internal Market and  
Consumer Protection**

# TTIP: Challenges and Opportunities for Consumer Protection

In-depth analysis for the IMCO Committee

DIRECTORATE GENERAL FOR INTERNAL POLICIES  
POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY

# The Transatlantic Trade and Investment Partnership (TTIP): Challenges and Opportunities for Consumer Protection

## IN-DEPTH ANALYSIS

### Abstract

This in-depth analysis examines options for regulatory cooperation in TTIP and assesses its challenges and opportunities for consumer protection. It looks at existing regulatory approaches illustrated by reference to a range of case studies drawn from other briefing papers in the TTIP series for IMCO. Based on established practice and on the Commission's recently published proposal on regulatory cooperation, the briefing eventually discusses the likely approach in the TTIP. Despite desirable opportunities there are also significant challenges of reconciling the different regulatory philosophies ahead. In broad terms it finds that the European Parliament's regulatory powers will not be affected by the Transatlantic Trade and Investment Partnership, but suggests that the EP will need to ensure that the EP's priorities shape the TTIP regulatory cooperation agenda and not the other way around.

This document was requested by the European Parliament's Committee on the Internal Market and Consumer Protection.

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## LIST OF ABBREVIATIONS

AAPC	American Automotive Policy Council
ACEA	European Automobile Manufacturers' Association
APEC	Asia-Pacific Economic Cooperation
CAB	Conformity Assessment Bodies
CBI	Confidential Business Information
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CEPR	Centre for Economic Policy Research
CETA	EU-Canada Comprehensive Economic and Trade Agreement
CLP	Classification, labelling, and packaging
ECHA	European Chemicals Agency
FTA	Free trade area
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GMOs	Genetically modified organisms
ICT	Information and communication technologies
IMCO	Internal Market and Consumer Protection committee
ISDS	Investor-state dispute settlement
ISO	International Organisation for Standardisation
KORUS	US-Korea Free Trade Agreement
ME	Mechanical engineering
MEP	Member of the European Parliament
MFN	Most Favoured Nation
NAFTA	North American Free Trade Agreement
NRTL	Nationally Recognised Testing Laboratory
NTB	Non-tariff barrier
OIRA	Office of Information and Regulatory Affairs (US)
PDBTS	Policy Dialogue on Borders and Transport Security

PP	Precautionary principle
PTAs	Preferential trade agreements
RCB	Regulatory Cooperation Body
REACH	Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals
RIAs	Regulatory Impact Assessments
SDoC	Supplier's Declaration of Conformity
SMEs	Small and medium-sized enterprises
SPS	Sanitary and Phytosanitary (measures, agreement, etc.)
TABD	Transatlantic Business Dialogue
TACD	Transatlantic Consumer Dialogue
TAED	Transatlantic Environment Dialogue
TBT	Technical barriers to trade
TEP	Transatlantic Economic Partnership
TFEU	Treaty on the Functioning of the European Union
TiSA	Trade in Services Agreement
TSCA	Toxic Substances Control Act
TTIP	Transatlantic Trade and Investment Partnership
UNECE	United Nations Economic Commission for Europe
USTR	United States Trade Representative
WTO	World Trade Organization

## EXECUTIVE SUMMARY

Regulatory cooperation is, together with ISDS, one of the most contentious issues in TTIP. The outcome of the negotiations in this area is central to the achievement of TTIP in the sense that most of the welfare gains are seen to be in reducing the (trade) costs of incompatible regulations, standards or conformity assessment measures. The opportunities, in terms of gains for consumers from reduced costs, are important if less visible than the challenges to existing regulatory standards that have been the focus of concerns about a 'race to the bottom'. This briefing paper focuses on the horizontal issues relating to regulatory cooperation, the challenges this poses in terms of the regulatory autonomy of the European Parliament and its various committees. It also discusses the opportunities in terms of welfare gains and better regulation for consumers and reduced costs and better access for EU exporters to the US and wider international markets.

The EU has a clear interest in the success of transatlantic regulatory cooperation. It is the area of the TTIP negotiations that offers most in terms of economic growth and jobs. There is also a positive interest in better access to the US market for EU exporters that would flow from dealing with the additional costs caused by different but equivalent US regulations or standards. For small and medium sized EU exporters such barriers can be prohibitive.

The in-depth analysis argues that regulatory cooperation offers the opportunity of enhancing regulatory standards and that it is by no means axiomatic that regulatory cooperation will lead to lower standards. Transatlantic regulatory cooperation that results in improved regulation and standards can also provide a precedent for wider international standards and thus work against global pressures to reduce standards in order to gain competitive advantages. Existing research also suggests that although there are clear differences in regulatory philosophy across the Atlantic, regulatory cooperation does not mean a stark choice between precaution and science-based approaches.

The in-depth analysis illustrates the major challenges facing regulatory cooperation. These can be found in different institutional processes and approach to legislation and regulation in the EU and US. These together with a lack of continuing commitment to cooperation have frustrated past efforts to enhance transatlantic regulatory cooperation.

With no final text available the in-depth analysis has looked at existing approaches to regulatory cooperation in other EU and US preferential trade and investment agreements as well as the wider international framework of WTO and other commitments of the parties. There is also an indication of the TTIP approach in the shape of the EU's Textual Proposal on regulatory cooperation released in February 2015. This suggests that TTIP will broadly follow the precedents set in previous agreements and will in all likelihood incorporate and seek to build upon existing WTO agreements, that have to date posed no threat to EP regulatory autonomy. Indeed, the limited success with past attempts at transatlantic regulatory cooperation, including decisions on such mechanisms as mutual recognition or equivalence, suggests that the main challenge is how to make more progress in regulatory cooperation whilst ensuring that the EP's regulatory sovereignty is intact.

The EU's approach as set out in the Textual Proposal includes the three core options in dealing with regulatory cooperation; namely intensified exchange of information, equivalence/mutual recognition and harmonisation/'simplification'. The text states that the regulatory cooperation body envisaged will not have rule-making or legal powers. The text also 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. Intensified exchange of information and cooperation in research and regulatory best practice poses no threat to EU regulatory sovereignty in general or the regulatory

sovereignty of the European Parliament in particular. Efforts at harmonisation would have benefits in terms of shaping wider international standards, but also do not challenge regulatory sovereignty. The EP should however, ensure that the regulatory process does not have rule-making powers, is transparent and that priorities of regulatory cooperation reflect broad EU preferences. MEPs should exercise effective scrutiny over the priorities in transatlantic regulatory cooperation. This could be achieved by the EP having a say in the Annual Regulatory Cooperation Programme that is envisaged.

As for many aspects of the TTIP 'living agreement' an assessment of the impact of transatlantic regulatory cooperation can only be made once the process can be observed. Further work will therefore be needed to monitor the procedures established and whether they are successful in making progress on the reducing the costs of different approaches, while ensuring consumer interests are safeguarded.



## 1. INTRODUCTION

The in-depth analysis examines options for regulatory cooperation within the Transatlantic Trade and Investment Partnership and assesses its implication for consumer protection. Its goal is to discuss TTIP's potential opportunities and challenges and to discuss how it might affect the regulatory sovereignty of the European Parliament. 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 standards? Will TTIP influence the regulatory or legislative agendas and, if so, how should the EP ensure that its priorities are properly represented? Who 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?

Chapter 2 sets the scene by providing an overview of the EU's interests in the horizontal chapters of the negotiations as well as an outline of the offensive and defensive interests in specific sectors. Chapter 3 then gives an overview of the EU's past agreements and existing practice in international negotiations and looks specifically at past transatlantic regulatory cooperation initiatives. Based on that, chapter 4 then discusses the opportunities and challenges inherent in the TTIP negotiation in terms of the general approach to regulatory cooperation. This includes a discussion of the approach proposed in the Commission's Textual Proposal of February 2015. Chapter 5 then provides some illustrations of the opportunities and challenges in specific sectors, before chapter 6 provides some conclusions.

## 2. THE EU'S INTERESTS IN TTIP

### 2.1 The Horizontal Chapters

#### Tariffs

It is the nature of tariff negotiations that the EU is offensive in some sectors and defensive in others. Average bound MFN tariffs for goods in the EU and US are relatively low, in the order of 3-4 percent. There are, however, some tariff peaks. For example, the EU has peaks for wine (22%) cigars (38%), live bovine animals (40%) and other prepared meats (39%). The US has somewhat more tariff peaks, despite having generally lower average tariffs for goods, bound tariff, for example fruit and ground nuts 164%, footwear 48%, and prepared fish 35%. But generally these products are not heavily traded. In key sectors of interest to the EU, such as machinery and transport equipment, tariffs are generally low. The impact of tariff cuts depends therefore not just on the level of US MFN tariff but also whether the EU exports the products concerned (see: Customs and trade facilitation briefing, Abbott and Woolcock). The EU has relatively high tariffs in sectors such as motor vehicles and in processed foods (14%). For EU consumers the removal of these and other tariffs is an opportunity. The welfare gains from phasing out all tariffs have been estimated as adding 0.11% to EU GDP and 0.04% to US GDP. The higher figure for the EU is because the welfare gains from reductions in EU tariffs would be greater. Phasing out 98% of tariff lines would reduce this somewhat but provide scope for some protection for sensitive sectors. The challenge of course will be for those sectors that face adjustment costs. Consequently, IMCO should carefully monitor the balance and phasing of tariff reductions to ensure that the benefits for EU consumers are balanced against the adjustment costs for the producers and workers affected.

#### Technical barriers to trade

The EU interest in addressing technical barriers to trade is greater than tackling the remaining tariffs barriers. These TBTs are due to different but equivalent technical regulations, standards or conformity assessment and the means of dealing with them is through regulatory cooperation. The EU interest in promoting economic growth and jobs and getting better access to the US market for EU exports is particularly well served by measures to address TBTs. A large share of the predicted gains from TTIP are in this policy area. The vast majority of TBTs in transatlantic trade result from differences in the EU and US approaches to regulation rather than differences in the desired level of consumer protection. It is therefore in the general EU interest to find ways of dealing with such differences. This will take time and flexibility on both sides. Cooperation must therefore take the form of a 'living agreement' backed by adequate procedural instruments to ensure that there is both sufficient commitment to the process beyond the lives of specific administrations and guarantees that decisions are legitimate and accountable (see: study on technical barriers to trade/standards, Pelkmans).

#### Services

With regard to services, the EU has broad offensive interests, which are discussed in the IMCO in-depth analysis on services (Heydon, 2015). In particular, the estimated trade costs resulting from regulation of financial services in the US appear to be considerably higher than in the EU. The Ecorys study of 2009 suggests a tariff equivalent of more than 30% for finance and nearly 20% for insurance, with the EU equivalent for both around 10%. The fact that the US has so far not agreed to put financial services on the table is therefore of major concern for EU interests. The EU has more defensive interests in business and ICT services. The Ecorys study, the most comprehensive effort to quantify the trade costs of regulatory

measures, put the average tariff equivalent or trade cost at about 7% for all services sectors for both the EU and US.

### Public Procurement

The EU also has offensive interests in government procurement where it is seeking more competitive and transparent procurement markets in the US, especially at the state and city levels. The EU has a comprehensive regime covering procurement at all levels of government across the EU above set thresholds. This EU regime promotes uniform, transparent procurement procedures that facilitate competition. In the US, only federal procurement is governed by a uniform set of rules. The states and municipal procurement, which accounts for 65% of all US procurement, is conducted using a diverse set of procedures (see: in-depth analysis on procurement, Woolcock). The US also has some residual 'Buy America(n)' provisions that the EU is seeking to have removed. More uniform and transparent procurement rules in the US are therefore very much in the interests of EU suppliers. This is especially true for small and medium sized companies that do not have the resources to follow the divergent rules in the US or to access markets through investing in a US affiliate, which is what large companies do to access the procurement markets. The challenge for the EU is how to engage the sub-federal level of government in the negotiations. The coverage of procurement agreements is however, based on reciprocity and to gain greater coverage of procurement rules in the US, the EU will have to make concessions in terms of the coverage of EU utilities and sub-federal level services procurement for US suppliers. From a consumer perspective, greater competition in EU procurement markets should be beneficial, so there are no red-lines as such. Here the EP will wish to ensure that there is broad reciprocity.

### Investment

Investment has been a central feature of the EU debate on TTIP and especially the issue of investor state dispute settlement. It is not possible to summarise all the issues on this here. The investment topic is both a challenge and an opportunity. The challenge is negotiating an outcome that balances the interests of investors with the right to regulate/host state interests. This has indeed, been the challenge that has faced international investment negotiations for at least the last 70 years. In investment, more than any other chapter of TTIP, there is no agreed EU position. This is in no small part due to the fact that EU exclusive competence was only established in the Lisbon Treaty and there is no EU acquis on international investment policy. There is an interest for the EU in having a common EU voice in shaping this ongoing debate. There have been two broad models of investment agreement to date. The first, dating from the 1960s, took the form of bilateral investment agreements negotiated by EU Member States. The second is the NAFTA model, which has of course been largely shaped by the United States. Current negotiations on investment offer an opportunity for the EU to establish investment as exclusive EU competence and to work for a modernisation of international investment agreements that establishes a balance between the interests of the investor and those of other stakeholders as represented largely by the parties to agreements, namely the states. As the two most important actors in international investment policy an agreed policy on investment along these lines will shape policy world wide. Failure to reach an agreement could therefore be a missed opportunity to establish a broad international consensus on investment for the first time. The key objectives in the investment negotiations should be continuing to provide protection for EU investors while securing strong wording on the right to regulate and more accountable and transparent adjudication procedures.

## Customs

Unlike investment, customs and trade facilitation is another area that touches on the direct competences of the IMCO. Here, as indeed in many of the policy issues under negotiation in TTIP, there is already a significant body of international agreements in the shape of GATT and World Customs Organisation agreements and guidelines. The EU interest in TTIP is to drive forward with the implementation of these provisions, such as the application of information technology to reduce the costs of customs procedures and the wider use of trade partnership programmes such as the Authorised Economic Operator scheme (see in-depth analysis on customs and trade facilitation, Abbott and Woolcock). Trade costs due to inefficient border and customs procedures are greatest in developing economies, but they can still be broadly equivalent to tariffs in trade across the Atlantic. Reducing the costs of importing and exporting is in the interests of consumers through lowering prices and exporters, especially for smaller and medium sized companies. The issue to watch here is to ensure that the processing and border controls are made more efficient, whilst at the same time ensuring that unsafe goods do not enter European single market and that trade instruments, such as anti-dumping measures are properly administered.

## Rules of Origin

The EU has an interest in ensuring that the preferences it offers are not circumvented. This means having effective rules of origin. But rules of origin can also be used as protectionist devices. The EU also favours multilateralism so has an interest in using TTIP to drive forward the efforts to simplify and progressively unify preferential rules of origin. Divergent preferential rules of origin are another source of trade costs. Estimates suggest that they add 3-4% or more to the cost of a product. With the growth of global production chains, the costs of proving origin status become more rather than less important. TTIP offers an opportunity to begin to address this problem. Another opportunity in TTIP is the possibility of moving towards diagonal cumulation, which would facilitate global supply chains and the engagement of developing in global supply chains.

## Regulatory cooperation

Last, but by no means least, the EU has an interest in reducing the trade costs of different but equivalent health and safety regulations. The estimates of the potential welfare gains from TTIP has suggested that progress in the removal of unnecessary duplication or recognising regulation or conformity assessment as equivalent would generate significant gains from TTIP. Examples of the estimated trade costs/tariff equivalents of such regulatory 'non-tariff barriers', suggest a 20% average for all sectors, with motor vehicles being a bit higher than this and food and drink being significantly higher. EU consumers on the other hand have a clear interest in ensuring that this is done in a manner that does not reduce consumer safety or the level of protection/safety. The following sections of the in-depth analysis now turn to this topic and in particular address the question of whether TTIP threatens the regulatory autonomy of the EU and of the EP in particular.

## 2.2 Sector Offensive and Defensive Interests

This in-depth analysis is concerned with the horizontal question of regulatory cooperation. In many sectors however, there is a trade off between tariffs and NTBs. For example, in a given sector the EU exporters may favour action to reduce NTBs if they constitute unnecessary barriers but US may exporters favour the rapid phasing out of higher EU tariffs. Producer and consumer interests may converge or show a tendency to diverge. This section therefore

discusses some of the balance of interests with regard to a selection of sectors covered by the in-depth analyses commissioned for IMCO Committee on the TTIP.

### Chemicals

The EU's chemicals sector is a net exporter to the US market. According to research, the tariff equivalent of regulatory/NTBs in chemicals is slightly higher in the US than in the EU (Ecorys, 2009). The EU industry has slightly higher average MFN tariffs than the US, but has for many years sought the elimination of tariffs in transatlantic trade, so does not have strong defensive interests on tariffs. As in other sectors there is an industry interest in improving regulatory cooperation in TTIP.

The main defensive EU interest is in maintaining the existing approach to regulation of chemicals in the form of REACH. This is a key interest of EU consumers and environmental interests. The Commission has stated that REACH is not for negotiation and that neither harmonisation nor mutual recognition/equivalence are feasible approaches to regulatory cooperation in this sector. This means reliance on intensified exchange of information or sharing research on chemicals. For consumer interests therefore it will be important to monitor the negotiations to ensure there is no erosion of the EU levels of protection.

### Automobiles

The EU automobile producers have offensive and defensive interests in TTIP. The automotive sector, along with the machinery sector, is one of the leading EU exporters to the US and maintains a strong export surplus. It has clear offensive interests in regulatory cooperation because it wishes to reduce the costs of different or duplicative regulations that nevertheless seek to achieve equivalent safety or environmental standards. There are also some high tariffs in certain sectors of the US industry. EU tariffs in the auto sector are however, on average higher than those in the US, so the US industry may seek to link regulatory cooperation with EU tariff reductions. In practice, however, most import competition in the EU car industry comes from Japan and Korea and most competition comes in the form of foreign investment in production within the EU (see: study on motor vehicles, Kolev 2015).

The consumer interests in the automotive sector are mostly in maintaining the high EU safety and environmental standards. As the US has equally high standards but just goes about regulation in a different way, the EU consumer interest is in ensuring that regulatory cooperation does indeed reduce the costs of incompatible but equivalent regulatory standards without resulting in any softening of the level of environmental or safety regulation. EU consumers may benefit from the savings achieved in regulatory cooperation if these are passed on through investment in better technology and products. In terms of competition, the EU consumer already benefits from strong competition on the EU market due to suppliers from various countries.

### Engineering

This is another sector in which the EU is internationally competitive and therefore has generally offensive interests. It is, along with the automotive sector, a major exporter to the US and is a sector that is dominated by a large number of medium sized companies that provide the core of much of the EU engineering industry. In this sector regulatory barriers to trade are also the main impediment, so the EU industry has offensive interests in regulatory cooperation. As in the automotive sector, the challenge in TTIP is that the US relies heavily on self-certification of compliance with regulatory standards by producers, whereas the EU approach is based on certification by independent third parties. The challenge is therefore

ensuring that such different approaches do in fact result in the same level of safety. EU tariffs in this sector are generally low so the industry interests are generally offensive.

Consumers stand to benefit indirectly from cost savings in the machinery sector as it is an important input into other sectors. As for the automobile sector it is also a significant employer so in so far as consumers are also workers they will gain.

## ICT

In the ICT sector the EU's offensive interests are less clear cut. There is a common interest in the industry for more uniform e-labelling standards and e-accessibility, which would benefit suppliers and consumers. Consumers are, however, concerned about the US desire to ensure the free flow of data, which may not be compatible with the European consumer interests in data privacy. This is something that would need to be carefully monitored.

## Textiles and Clothing

While this sector accounts for a relatively small share of transatlantic trade, the absolute level of trade is still important for some EU producers. EU exporters face high US tariffs in some sectors, so they have an offensive interest in removing these. The US offensive interest is in ensuring that their relatively stringent regulation on product labelling prevails. This could mean adjustment costs for some EU suppliers. The US has also used rules of origin to defend its textiles and clothing sector. From a consumer point of view lower tariffs and more stringent labelling requirements provided they are suitable for the EU market would be positive (see textiles in-depth analysis, Villafranca et al).

### 3. PAST AGREEMENTS AND EXISTING PRACTICE

Regulatory cooperation in TTIP builds on a number of existing international agreements, such as the 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.

#### 3.1 Shaping Multilateral Rules

The EU has led the way in raising awareness of the impact of divergent regulation 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 (ISO, CEN, CENELEC). These EU-shaped international agreements are incorporated in virtually all PTAs and can be expected to be reaffirmed in TTIP.

The existing international rules take the form of the 1994 TBT Agreement, contain a binding commitment to national treatment (non-discrimination) in the application of regulation and conformity assessment, best endeavours wording on mutual recognition and include a Code of Good Practice for standards making bodies. But as experience within the EU has shown, national treatment does not remove regulatory barriers/trade costs resulting from divergent regulations or standards. The GATT Sanitary and Phytosanitary Agreement (SPS) – 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 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 been seldom used.

#### 3.2 Past Transatlantic Regulatory Cooperation Initiatives

In addition to being the main actors shaping existing multilateral rules, the EU and 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 New Transatlantic Agenda Task Force, which had among other things, the aim of promoting regulatory cooperation. This resulted in mutual recognition agreements on electrical safety, pharmaceutical and medical devices and pleasure craft that were implemented with some considerable delay due to the slow legislative adoption process in US. It is also worth recalling that stakeholder dialogues (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 common understandings on regulation and regulatory policy aims. The Transatlantic Legislators Dialogue was also established to strengthen EP–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, 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 reconciling the different regulatory philosophies discussed above, a lack of consistent political support for detailed regulatory work and reluctance on the part of legislators to cede any regulatory autonomy, particularly in the US. Regulatory standards in the US and EU result from the respective market structures and consumer preferences and might 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 TTIP (Gerstetter, 2014; pp. 5). Surmounting the “transatlantic deadlock” (Alemanno, 2009; pp. 27), will be the main challenge for negotiators and regulators on both sides.

### 3.3 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 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 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 sector 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 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. So as for TBT the agreement really seeks only to implement more fully the existing SPS commitments.

With regard to services, the EU–Korea agreements builds on the GATS by encouraging the professional bodies responsible to 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.

### 3.4 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 (over arching) Trade Committee. In CETA the parties also agree to apply the (voluntary) Code of Good Practice for Standards Making Bodies.

CETA includes separate protocol on conformity assessment in Annex I. This strengthens the case for mutual recognition of the results of conformity assessment by stating that Canada will recognize 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. not self-certification by producers). 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.

### 3.5 US – The General Approach to Recent PTAs

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 similar to the EU–Korea FTA in that it 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. There is a reference to the APEC Mutual Recognition Arrangement for Conformity Assessment in Telecommunications, which is no doubt specific to Korea. 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 sector committee

on automobile standards, which is to work towards joint implementation of UNECE standards. 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.

## 4. OPPORTUNITIES AND CHALLENGES

### 4.1 Opportunities

#### 4.1.1 Reduced costs and more competitive markets

For the EU, industrial transatlantic regulatory cooperation offers the opportunity of reducing the waste of complying with competing but equivalent regulatory standards. 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 standards. Sectors such as financial services, public transport equipment and construction also stand to benefit from improvements in services regulation and procurement. All sectors as well as EU traders and wholesales stand to benefit from a reduction in trade costs due to border controls and improved trade facilitation. TTIP therefore offers an opportunity to strengthen EU international competitiveness and to create more wealth and jobs in the EU. The scale of the welfare and trade gains has been the subject of much debate (CEPS, 2015) but gains from reduced costs due to different but equivalent regulation represent the most important economic gains from TTIP.

#### 4.1.2 Shaping international trade rules and standards

In addition to improving economic growth, TTIP has been justified on the grounds that it will enable the EU and 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 standards in this respect.

It should, however, be remembered that the EU and 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 TiSA (see the in-depth analysis on services, Heydon) or in the negotiations on government procurement in the 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 long promoted international standards through the ISO and other bodies, but the industry-market- led approach of the US 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, which has only been touched upon in the briefing papers prepared for IMCO, is that of rules of origin. Here the EU and 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.

#### 4.1.3 Increase consumer welfare

Increased competition due to progress in regulatory cooperation offers the prospect of lower prices for and an increased variety of goods and services for consumers (Diels and 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 standards of health and safety regulations. Rather than fearing that the EU might trade away the principle of precaution, 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 precautionary principle.

An intensified exchange of information offers an opportunity to further 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 EU's proposals on regulatory cooperation. Moreover, it is acknowledged by the negotiating parties that existing barriers to a free flow of data should be reduced and no new ones created (European Commission, 2015 (b)). Where 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. 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 and Thorun 2014; pp. 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.

#### 4.1.4 Momentum for continued EU reform

In order to keep pace with international competition the EU must maintain the momentum for domestic reform. External pressure in the shape of international competition or negotiations with key trading partners has always played an 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 in the form of providing the additional external driver that may be needed to break domestic deadlocks on policy reforms due to entrenched vested interests that will be beneficial for EU consumers as a whole.

## 4.2 Challenges

### 4.2.1 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 EU, whilst ensuring there is no diminution of consumer safety and protection or environmental policy objectives. It is 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 make progress.

#### 4.2.2 Dealing with differences in regulatory philosophies and practice

Beyond the technical difficulties that are involved with regulatory cooperation, one of the largest challenges facing TTIP will be reconciling the different regulatory philosophies such as the difference between the EU's use of precautionary principle (PP) and the US's 'science-based risk assessment, cost-benefit analysis and cost-effectiveness analysis' ('science-based approach') (Bergkamp and 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). The precautionary principle is anchored in Article 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 Commission from engaging into an agreement that could potentially nullify some of its effects (Bergkamp and Kogan, 2013).

The US scientific approach to regulation is supported by the central role of the White House's Office of Information and Regulatory Affairs (OIRA) and the "Regulatory Impact Assessments" (RIAs) that agencies are required to produce. Both are based on science-based cost-benefit analysis. (Alemanno and Parker, 2014). 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 and Kogan, 2013). In multiple cases the US Supreme Court has ruled that the US's Office of Safety and Health Administration must have demonstrated "significant risk" prior to regulation (Wiener and Rogers, 2002; pp.318).

There may be some signs that the US could be inching towards a greater use of precaution. For example, President Obama's most recent reference to precaution in his statement on deep seabed mining policy, and the US House of Representatives' decision to highlight 'scientific inadequacy' in its regulatory decision on endangered species (Bergkamp and Kogan, 2013; pp.500). However, it would be relatively naïve to believe that the US's regulatory philosophy will significantly alter any time soon.

Differences in regulatory principles in the EU and US have led many to be concerned that any attempt of regulatory convergence in TTIP may imply deregulation of European consumer protection. The greatest concern is that the science-based approach to risk assessment in the USA differs from the use of the precautionary principle in EU risk assessment. Science-based risk assessment has not always been sufficient, as the case of BSE showed. 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. In the field of chemicals the previous science-based risk assessment arguably failed to identify the long term impact of certain chemical substances on consumers, hence the introduction of REACH in the EU (Karlsson, 2015). For a detailed discussion of the consumer concerns see Diels and Thorun 2014 and Alemanno 2014. However, several studies have demonstrated that, with some possible exceptions, the high standards required by both the EU and US will ensure a high level of consumer, health and environmental protection (Bergkamp L. and Kogan, K., 2013, pp. 507). A further study by Fabry and Garbasso (2014; pp.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.

### 4.2.3 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 proved difficult or, at best very, time consuming. For consumer protection, the issue is whether the common standards 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 standards in some states have led to a levelling up: the so-called Californian effect (Vogel, 1997).

#### Mutual recognition

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 the cooperation is geared to satisfy consumer interests and not unduly focused on the removal of regulatory barriers to trade or increased trade costs. This is of course the basis for the 'new approach' to regulatory cooperation within the EU that formed the basis of 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.

In practice, the way regulations and standards have been dealt with in trade agreements is a little more complicated. Here it is helpful to differentiate between a number of 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 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; the International Standards Organisation (ISO), CENELEC (for electrical equipment) and 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 standards, but only where these are appropriate, thus allowing significant scope not to apply the standards. 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 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 discussed above.

The options discussed above have different implications for regulatory sovereignty and thus the scrutiny function of the EP and its committees. Taking these each 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 also involvement of the private sector. Agreed international standards are adopted by voting on in the international bodies in which the European standards making bodies have a very strong presence.

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 US Congress to make legislative changes has been a significant impediment. The European Commission has stated that regulatory cooperation provisions in TTIP will not have rule-making powers. At this level therefore there would seem to be no threat to the EU's regulatory autonomy. The European Parliament would therefore have to exercise effective scrutiny as provided in the EU procedures.

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.

#### 4.2.4 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 regulatory standards 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 regulatory standards that would be detrimental to consumer/environmental interests. The briefing paper 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 standards 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 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.

#### 4.2.5 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 effort. Again this is a lesson that has been learned in the EU's efforts to reduce such barriers to competition within the European Single Market. A key challenge in TTIP is therefore getting the process right. This means ensuring the framework established to carry the work forward is appropriate. In the context of TTIP this means ensuring that the mechanisms, such as the proposed Regulatory Cooperation Body (RCB), are effective and transparent.

#### 4.2.6 Safeguarding EU's, and in particular the EP's, regulatory sovereignty

A question of interest to MEPs is whether the proposed process poses a challenge for EU regulatory sovereignty. This in-depth analysis argues that the European Parliament's regulatory sovereignty in terms of legislative rule-making 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 TTIP has been set out in the initial EU's Textual Proposal made public on the 9<sup>th</sup> February. It should be understood that this is only an indication of what might be in 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 9<sup>th</sup> round of negotiations in New York in the week of the 20<sup>th</sup> 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 standards of consumer protection or any other standards, neither to lower such standards (Fabry and 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 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 consider how the regulation relates to:



- (a) relevant international instruments;
- (b) take account of the regulatory approaches of the other party; and
- (c) 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). Impact assessments are used by the US and the EU but it will be important to assess how this meshes with EU regulatory and legislative processes. Impact assessments are widely used in the pre-legislative phase in the EU, but rarely for delegated or implementing measures (Alemanno and Parker, 2014; pg.7). Regulatory cooperation in 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 rulemaking 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 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 IMCO Committee 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.

## 5. CASE STUDIES

### 5.1 Chemicals

The area of chemicals entails considerable divergence between US and EU legislation and thus marked interest in greater regulatory consistency. The EU's central piece of legislation is the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)<sup>1</sup>, 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<sup>2</sup>. 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 certain information on the properties of the chemicals to ECHA; a chemical safety assessment must be conducted by registrants. Certain chemicals, included in Annex XIV of the Regulation, are subject to pre-marketing authorization; criteria for including substances into the list are defined (Gerstetter, 2014; pp. 30).

In May 2014, the 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 legislations 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 Commission proposes to assess possibilities for enhanced cooperation with the US via 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 Commission would formulate a proposal and the relevant Committee, composed of Member States 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 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 standards.

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<sup>1</sup> Regulation No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

<sup>2</sup> Regulation No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures.

## 5.2 Automotive sector

Automotive sector is another industry that could benefit greatly from regulatory convergence. The EU's automotive industry is after China, the second largest manufacturer of motor vehicles worldwide, and 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, testing methods, classifications and product labelling. The EU and 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, 2014; pp. 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 government approval in the EU. The European vehicle regulations include both EU directives, which must be implemented by the member states, and standards promulgated through UNECE<sup>3</sup> 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 standards 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 standards between the US and EU concerning fuel economy and emissions standards (Canis/Lattanzio, 2014; p.5).

The 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 standards 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 UNECE 1998 Agreement should lead to the adoption of Global Technical Regulations in the near future. Strengthening the EU-US cooperation is considered essential regarding the role of the EU and US as potential standard 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, 2014; pp. 26).

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3 United Nations Economic Commission for Europe.

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 fundamental standards 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.

### 5.3 Engineering

In 2013, 42.6% of the total EU goods exports volume to the US consisted of goods from the EU machinery/engineering sector (European Commission, 2014a). Other sectors known as large economically, such as chemicals and automotive products, do not come even close to this share. Although the EU has a trade surplus in these goods, it should be realised that EU imports of engineering products from the US are also large. This immediately clarifies the great economic importance of the sector in a TTIP context. The inclusion of an engineering chapter within TTIP might enable more effective and less costly access to the US market, a clear offensive interest of the Union (Pelkmans, 2015; pp. 9).

With an ambitious Atlantic Partnership in trade and investment, the long-standing and costly TBTs in this sector should receive the attention it deserves, in order for Europe's highly competitive engineering sector can enjoy far better market access, boost existing exports and undertake new initiatives. Mechanical engineering (ME) is dominated by relatively small companies and over time this sector has become increasingly important as an enabling industry. Innovation in ME often serves as a building block for key technologies and equipment used in other sectors (Pelkmans, 2015; pp. 11). This characteristic is also reflected in the complex European network of specialised industrial clusters.

Orgalime, the European Engineering Industries Association <sup>4</sup>, has published three position papers on TTIP <sup>5</sup> so far. The Association is clearly in favour of TTIP, mainly because the Trans-Atlantic economic relationship has unexploited potential. Orgalime's principal concerns are in the area of TBTs, often highly specific issues, and in the related regulatory cooperation whether in the TBT chapter or horizontally.

Orgalime aims for a high-quality regulatory dialogue, to help approximate legal requirements based on common regulatory objectives in their sector. Its positioning is entirely about two long-standing and deep frictions with the US: one on different technical standards and one on very costly conformity assessment procedures for (mostly) electrical goods. The sector emphasises that addressing these TBTs by means of mutual recognition would disadvantage the European side, as US electrical goods and machinery only need SDoCs (self-certification, declared via a Supplier's Declaration of Conformity) to get to the EU market, whereas EU goods undergo costly and rather special third party certification under rigid OSHA rules and problematic certification procedures by its designated CABs

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<sup>4</sup> Speaking for 37 trade federations. See [www.orgalime.org](http://www.orgalime.org)

<sup>5</sup> Position Papers of 5 Oct 2012, Orgalime priorities for the upcoming EU-US trade and economic negotiations; of 29 May 2013, Orgalime position paper on the negotiations of the comprehensive TTIP; of 8 May 2014, The TTIP negotiations – a way forward.

(called NRTLs)<sup>6</sup>. In terms of horizontal regulatory cooperation, it suggest three elements to mitigate (and partly pre-empt future) regulatory divergences and ‘incoherence’: (a) early consultations between the US and the EU on the trade impact of new regulation or major reviews, (b) setting up of regulator-to-regulator cooperation and careful procedures for it, and (c) enhance transparency In the broad sense of open and predictable procedural requirements, facilitating regulatory comparisons and solid impact assessments.

The European Commission is in favour of an engineering chapter for the simple reason that TBTs have played and still play a major role in effective market access to the US market.

The European Commission proposes a range of initiatives, including

- a. Promoting regulatory convergence and international disciplines. The main vehicle consists of regulator-to-regulator cooperation, with mechanisms like exchange of information on regulatory plans (and the opportunity to provide comments and get feedback), a commitment to closely cooperate in the development of international disciplines and, where feasible, joint initiatives in international organisations. Additionally, it consists of cooperation for ‘the review of conformity assessment procedures’ with a view to ensuring proportionality to the risk they intend to address. The suggestions made above, in section 6, fit perfectly in this proposal and could be used right away.
- b. Cooperation between standard setting organisations, both on new and existing technologies. This should include collaboration in international standardisation organisations. Of course, a strong encouragement is all that can be accomplished as standard bodies are private organisations, be it with a link to regulation in selected cases
- c. Cooperation in market surveillance and enforcement. In the electronic sector an informal cooperation between the US, Canada and the EU is now under way, and the EU would like it to become formalised, as well as other new initiatives.
- d. There are transparency and fragmentation issues in the US market which the EU would like to be addressed. The industry – especially SMEs, since they are numerous in the sector – regards the lack of transparency and difficulty in finding out various (and often distinct) rules at the state level as a serious barrier of access to the US market.

Finally, industry is encouraged to come up with specific proposals to be taken up in TTIP. The VDMA (German member of Orgalime)<sup>7</sup> contributed a large number of specific proposals for such regulatory cooperation. They include targeted suggestions on mechanical safety, electrical safety, pressure equipment, explosion protection, food contact machinery and public procurement, all areas where TBTs play a significant role. If supported at a high level and through TTIP clauses, concrete results might be harvested.

## 5.4 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

<sup>6</sup> Nationally Recognised Testing Laboratories

<sup>7</sup> VDMA (2013), VDMA on TTIP, [www.vdma.org](http://www.vdma.org)



consumer protection – data privacy measures – may make it particularly challenging for negotiators to bridge the regulatory transatlantic divide.

With the regards to the European Commission's offensive interests in the ICT sector (European Commission, 2015), regulatory cooperation does not seem to be a significant challenge. For instance, efforts in establishing e-labelling standards 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 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 – 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.<sup>8</sup> 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, organizations 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, 2014b).

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

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<sup>8</sup> Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) (COM/2012/011 final) reforming this system is currently subject to legislative trilogues between the European Parliament and the Council.

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 standards of relevant international organization they are a part of, in TTIP. 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 TTIP.



## 6. CONCLUSION

Focussing on the area of consumer protection, this briefing argues that the EP's regulatory sovereignty – in terms of the legislative, rule-making ability – is unlikely to be affected by the TTIP. The discussion of the 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 EP's 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 European Parliament 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 normal EU policy making procedures that include the European Parliament. The EP 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 by the European Parliament to ensure that they reflect the broader EU and consumer priorities.

An assessment of the impact of transatlantic regulatory cooperation can only be made once the process can be observed. Further work will therefore be needed to monitor the procedures established and 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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