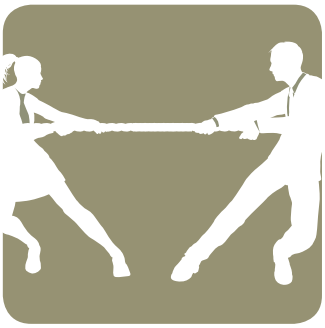
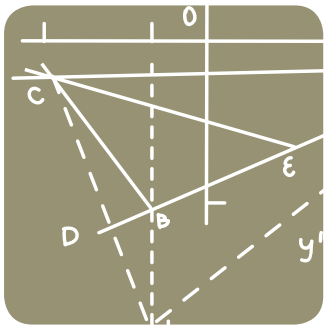
Kommerskollegium 2015:9

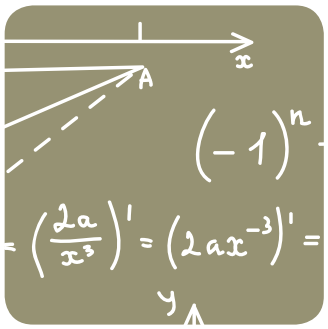
From Competition to Convergence

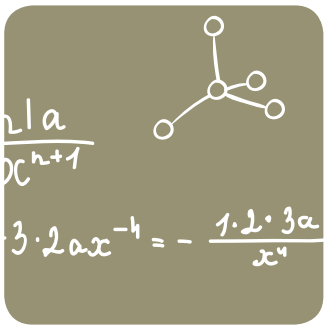
TTIP and the Evolution of Global Standards

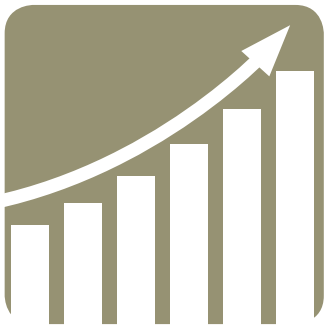


TTIP









Kommerskollegium
National Board of Trade

The National Board of Trade is a Swedish government agency responsible for issues relating to foreign trade, the EU Internal Market and to trade policy. Our mission is to promote open and free trade with transparent rules. The basis for this task, given to us by the Government, is that a smoothly functioning international trade and a further liberalised trade policy are in the interest of Sweden. To this end we strive for an efficient Internal Market, a liberalised common trade policy in the EU and an open and strong multilateral trading system, especially within the World Trade Organization (WTO).

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Foreword

A key part in the ongoing TTIP negotiations is about regulatory cooperation and improved regulatory practices between the EU and the US. Technical barriers to trade constitute a major obstacle for many EU and US companies aiming to trade with their big neighbor on the other side of the Atlantic. The need to adapt products to either EU or US regulatory regimes affects also companies from other parts of the world. Incompatible standards between the two largest markets have negative repercussions across product sectors and supply chains globally. But standards can also foster trade, create confidence and offer brilliant solutions when applied in the right way. Standards and good regulatory solutions play a vital role in solving some of today's global challenges. However, dealing with regulatory differences requires refined ways of cooperation and dialogue.

With this report, we hope to shed light on the different characteristics of the European and American standardization systems, and how they relate to international level standardization. Particularly, we underline the need to find a link between transatlantic regulatory solutions on the one hand and a cohesive and predictable international regulatory environment on the other. This report elaborates on ways forward in TTIP based on a value-added approach utilizing the best features of the European and American way of making high-quality standards.

The report is written by Emanuel Badehi Kullander. I wish to give our special thanks to external reviewers Jan E. Frydman, Sylvana Ricciarini, Peter Unger and Erik Wijkström.

Stockholm, October 2015

Anna Stellinger
Director General
National Board of Trade

Executive Summary

The European Union and the United States have built their product regulatory systems in different ways, yet they often achieve equivalent regulatory outcomes. These differences result in unnecessary divergence in technical regulation, standards and conformity assessment procedures. Besides hampering trade, EU-US regulatory divergence also affects global rule-making and holds back global regulatory solutions. This becomes clearer as world trade takes new forms and creates mutual interdependencies through for example global value chains, digitization and shared international standards.

International standards have had an increased significance in providing global solutions that better incorporate the business realities of increasingly integrated markets, while ensuring safe and qualitative products. The WTO TBT Agreement has pledged an important role in binding states to accept international standards. The number of international standards has grown substantially since the beginning of the seventies.

Today's regulatory dynamic, the context in which TTIP is being negotiated, is characterized by various stakeholders' interests in influencing international standards. In being among the most advanced regulators, the EU and the US have offered equivalent, but also different, regulatory solutions to be conveyed at international level rule-making. This has tended to put the EU and US in a competitive relationship with each other, as their regulations and standards are reflections of their own, distinctive, regulatory models.

The EU and US product regulatory systems are built in different ways and abide by distinct principles. Their distinct features relate to the essential objectives of their internal markets and the role public policy objectives and implementation have in terms of actively facilitating regulatory integration and trade. The EU standardization system has a few SDOs that harmonize standards across Europe, while the US system is decentralized and consists of many SDOs[1] that develop standards in competition with each other. These differences affect how the EU and the US have integrated their product regulatory systems at international level within three arenas: international standardization, free trade agreements and areas not directly covered by international cooperation.

In the arena of international standardization, it is evident that the EU has systematically integrated its standards with ISO and IEC standards. By comparison, it is hard to get an overview of US implementation of equivalent international standards. Available figures suggest a substantially weaker relationship between US standards and ISO and IEC standards. Similar tendencies are also found with regard to intergovernmental standardization, where the EU often strives towards achieving regulatory integration through the empowerment of international institutions and expanded policy scopes, whereas the US is more vigilant in allowing domestic policy choices to be extensively overtaken by international ones. These differences have impacted on EU and US positions over time, particularly the definition of international standards itself.

Both the EU and the US are currently in the process of negotiating new FTAs with many of their trading partners. Measures to address NTBs, such as sector provisions, product standards and regulatory cooperation, have grown in importance in new generation FTAs. In this regard, the EU and the US tend to emphasize different approaches in terms of achieving regulatory convergence with third countries. EU FTAs appear to promote the dispersal of international regulatory solutions which are also applied in the EU. In comparison, the US promotes consultation and transparency procedures within third countries rule-making procedures and their emphasized definition of international standards.

Outside areas covered by international regulatory cooperation, large internal markets and strong regulatory capacity tend to influence foreign businesses and agencies to comply with the strictest requirements applied in the largest markets. In this regard, the EU has dispersed its regulations and standards in areas where it is perceived as the strictest regulator. When EU and US regulatory solutions are mutually incompatible they might negatively affect the other on a global scale. This is particularly true if one side's standards attain worldwide dispersal, but the other's do not. Regulatory distinctions, which essentially are unnecessary, can therefore cause regulatory competition between the EU and US, which creates unnecessary barriers to trade and hampers the dispersal of good regulatory solutions.

In the area of standards, global efforts to unify various product regulatory systems have so far focused on either placing a specific status on the *body* that develop standards, or defining the *procedures* for how standards are to be developed. There is a need to consider another approach when looking at the peculiarities and differences of the EU and US product regulatory systems, an approach that can utilize the best features of the two systems, offer flexibility where they are different and reinforce the components that they have in common. A *Transatlantic Standards Approval Scheme* (TSAS) can lay the foundation for this.

Policy conclusions

- In the arena of international standardization, diverging EU and US approaches split international rule-making in two and negatively affect the formation of viable global solutions. From a macro perspective, interpretational differences affect the status of international standards and create uncertainties about what significance international standards may have. A common standpoint on international standardization between the EU and the US would increase the predictability and reliance of the international standardization system and counteract the emergence of new trade barriers due to non-compatible standards.
- In the arena of FTAs, both the EU and the US endorse approaches that fit with their regulatory practices – approaches which in some cases are mutually non-compatible. There is therefore an increased need to reach a common ground in important regulatory areas and product sectors when new and more comprehensive FTAs are negotiated. This is particularly important with regard to so-called mega FTAs like TPP which, alongside TTIP, may bring a large part of global GDP output under FTA regulatory regimes.
- In areas not directly covered by regulatory cooperation, increased regulatory convergence between the EU and the US could help facilitate the development of future international standards. It is important that TTIP enable regulatory dialogue in the various stages of regulatory development. Converging regulations will support the development of converging standards. Eliminating unnecessary EU-US regulatory differences may have global ripple effects and support widespread regulatory improvements. Access to the combined EU-US market through shared standards could trigger global benchmarks in areas such as health and environmental protection.
- A Transatlantic Standards Approval Scheme (TSAS) is a new measure aiming to achieve long-term regulatory convergence in the area of standardization between the EU and the US. If implemented in TTIP, such a mechanism would allow for the EU and the US to take gradual steps towards reaching agreement in areas where no uniform international standard exist. In areas where domestic standards diverge and there is a lack of international standards, TSAS provides an intermediate level of cooperation where standards can converge before a certain regulatory area becomes subject to international standardization.

Acronyms and Abbreviations

ACCA	Agreements on conformity assessment and acceptance of industrial products
ANS	American national standards
ANSI	American National Standards Institute
APEC	Asia-Pacific Economic Cooperation
ASME	American Society for Mechanical Engineers
ASTM	American Society for Testing and Materials
BSI	British Standards Institutions
CAFTA-DR	Dominican Republic-Central America Free Trade Agreement
CAP	Conformity assessment procedure
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CSR	Corporate social responsibility
DIN	German Institute for Standardization
DVD	Digital versatile disc
EEA	European Economic Area
EFTA	European Free Trade Association
EMC	Electromagnetic compatibility
ETS	EU Emissions Trading Scheme
ETSI	European Telecommunications Standards Institute
FTA	Free trade agreement
FTAA	Free Trade Agreement of the Americas
GRP	Good regulatory practice
GSM	Global system for mobile communications
IBR	Incorporation by reference
ICAO	International Civil Aviation Organization
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSMS	The Information and Communication System for Market Surveillance
IEC	International Electrotechnical Commission
IEEE	Institute for Electrical and Electronics Engineers
IMO	International Maritime Organization
ISO	International Organization of Standardization
SIS	Swedish Standards Institute
MFN	Most favoured nation
MRA	Mutual Recognition Agreement
NAFTA	North American Free Trade Agreement
NANDO	New Approach Notified and Designated Organisations Information System
NBT	National Board of Trade
NIST	National Institute of Standards and Technology
NTB	Non-tariff barrier to trade
NTTAA	National Technology Transfer and Advancement Act
PINS	Project Initiation Notification System
PSA	Partial Scope Agreements
PSDO	Partnership standards developing organization agreements
RAPEX	Rapid exchange of information on dangers arising from the use of products
RCB	Regulatory Cooperation Body
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
RoHS	European Restriction of Hazardous Substances Directive
RIA	Regulatory impact assessment
SDO	Standards developing organization
SDoC	Supplier's declaration of conformity
SME	Small and medium sized enterprise
SOLAS	International Convention for Safety of Life at Sea
SPS	Sanitary and phytosanitary measures
SWEDAC	Swedish Board for Accreditation and Conformity Assessment
TBT	Technical barrier to trade
TEC	Transatlantic Economic Council
TPP	Trans-Pacific Partnership
TSAS	Transatlantic Standards Approval Scheme
TTIP	Transatlantic Trade and Investment Partnership
UNECE	United Nations Economic Commission for Europe
WHO	World Health Organization
WTO	World Trade Organization

Contents

1. Introduction

When the EU and the US are negotiating the Transatlantic Trade and Investment Partnership, TTIP, they do it with the aim of reducing non-tariff barriers, bringing the EU's and the US's regulatory systems closer to each other and creating better conditions for the EU and the US to improve global regulatory practices. This report focuses on the last aim, and highlights how the EU and the US have converged their regulatory models globally. In particular, this report focuses on how the different characteristics of their product regulatory systems have generated a delicate line between EU-US cooperation and competition in the context of international rule-making.

The EU and US internal markets are, with the exclusion of China, by far the largest markets in the world and their economies are the most integrated in terms of private investment. The EU and the US also share regulatory and institutional approaches in many areas. Both have extensive and well-developed regulatory systems that support public and corporate demands, and both have systems with mechanisms that safeguard legitimate policy interests such as human health, consumer safety and environmental protection. In comparison with many other countries in the world, the regulatory models of the EU and the US have perhaps been depicted as more different than they really are.

While the EU and the US, have many regulatory components in common, in terms of the potential for ensuring equivalent regulatory outcomes, it is equally clear that both have built their regulatory systems in different ways. Completely separate lines of production are sometimes necessary in order to produce products viable for both markets, leading to costly product adaptations, duplicative approval procedures and negative effects on technology transfer and incorporation of innovations. Many differences can be explained by the fact that the EU and the US have product regulatory systems – technical regulations, standards and conformity assessment procedures – that over time have evolved in parallel and picked bits and pieces from each other.

Seen in a global context, systemic regulatory differences have led the EU and the US to provide alternative, and sometimes competing, regulatory solutions to other parts of the world. Naturally, both have promoted an outcome in different fora which best suits the integrity and outreach of its own regulatory system and overall purposes. As globalization progresses and new trade realities appear, such as global value chains, digitization and increased industrial ambitions of emerging economies, the importance of regulations and standards for global trade have increased considerably. The effective implementation of ambitious trade enhancing measures will ultimately be dependent on the interoperability of regulations and standards in various countries. A large part of TTIP's potential therefore lies not only in connecting the EU and US product regulatory systems with each other, but also in creating a platform for enhanced regulatory cooperation which could propel deep and substantial regulatory integration globally and support the multilateral cause of the World Trade Organization (WTO).

The purpose of this report is to look at *how* the EU and the US have converged their product regulatory systems with the rest of the world and what regulatory solutions this might bring to TTIP. The report is based on valuable insights from previous reports from the National Board of Trade. Particularly, the report *Regulatory Co-operation and Technical Barriers to Trade within TTIP* (2015). The main focus of this report concerns technical barriers to trade (TBT). However, other regulatory areas, like sanitary and phytosanitary measures (SPS) and services, are touched upon indirectly.

This report is divided into four parts; the first is an introduction to product regulatory systems and technical barriers to trade (chapter 2), the second highlights the differences between the EU and US product regulatory systems (chapter 3), the third, the bulk of this report, highlights EU and US global regulatory convergence (chapter 4) and the last part discusses potential solutions within TTIP (chapter 5). Readers that are acquainted with trade policy and regulatory issues can start reading from chapter 3.

2. Product Regulatory Systems

A first step in describing how the EU and US regulatory systems relate to the international context, is to generally explain what product regulatory systems are, how they may vary between countries and how the global regulatory system has evolved over the last decades.

Most of the products that are put on the market today are subject to regulations and product standards. These technical requirements are virtually everywhere, and can range from consumer products like foodstuffs, home electronics and textiles to industrial products like trains, gas appliances, electricity grids and power plants. They can cover anything from the smallest screw, its dimensions and characteristics, to a complete car that consists of over two thousand parts. In this way, regulations and standards affect single products and categories of combined and assembled products.

Each regulatory system, like the ones in the EU, the US or China, may have its own means of regulating products and defining product characteristics in accordance with the overall demands and requests of its constituency and business sector. The substantial product requirements or general requirement levels, the methods of ensuring conformity with the applicable requirements, as well as the manifestation of conformity approval, can consequently differ between various regulatory systems. As examples, the EU uses the CE as a mark of product compliance, the US has the FCC mark for electro technical products, and China has the CCC mark for imported products.

2.1 Technical Regulations, Standards and Conformity Assessment Procedures

Most national product regulatory systems can be differentiated based on how each system's technical regulations, standards and conformity assessment procedures (CAPs) relate to each other – for example, how technical requirements are governed among the regulatory agencies and the industry, the institutional order for issuing them, and the legal status that technical specifications may have. Each national product regulatory system may also separately define applicable requirement levels within relevant areas and the means of implementing them in the marketplace. The effective correlation between technical regulations, standards and CAPs is very important for the purpose of improving productivity, quality assurance and technological progress. When these mechanisms are properly implemented they strengthen industrial competitiveness and enable consumer trust to grow.

Facts

Technical regulations

Lay down mandatory product characteristics or their related processes and production methods. Technical regulations are governmental measures that encompass substantial product requirements that, for example, define the required level or the necessary means to safeguard public interests such as safety, health and environmental protection.

Facts

Standards

Consist of voluntary documents which have been approved by a recognized body responsible for establishing rules, guidelines, or characteristics for products or related processes and production methods.[2] The main distinction between technical regulations and standards is that compliance with standards is voluntary and standards are developed by industry stakeholders as prerequisites for efficient industrial production and technology facilitation. Standards often also support public and governmental objectives in facilitating ways to ensure expected product quality and functionality.

Facts

Conformity assessment procedures

Are used to determine that relevant requirements in technical regulations or standards are fulfilled. Conformity assessment may include a multitude of measures, such as sampling, testing and inspection, evaluation, verification, assurance of conformity and registration, accreditation and approval.[3]

A balanced use of various product requirements can consequently be an effective way to develop the economy. Moreover, these mechanisms can also have substantial effects on trade. Complying with divergent national regulations and standards is crucial for companies who want to enter foreign markets. This became particularly clear after the GATT reduction of world tariffs for manufactured goods and a period of increased integration of world product markets, which put a focus on non-tariff barriers to trade (NTBs) and technical regulations and standards that were not uniform across countries. At the time, technical regulations and standards were increasingly adopted to address more prominent domestic concerns for different policy interests, such as health, safety and environmental protection. However, product standards did also become more common for purely protectionist purposes. By making country-unique standards mandatory, domestic industries could effectively be relieved from global competition through high entrance costs for foreign businesses.[4]

These developments spurred a global effort, through the WTO, to eliminate what would be referred to as technical barriers to trade (TBTs). One of the solutions was to promote the internationalization of product regulatory systems and strengthen various international rule-making processes.

2.2 Internationalization of Product Regulatory Systems

The WTO Agreement on Technical Barriers to Trade was established as a result of the Uruguay Round negotiations in 1995. The TBT Agreement sought to strike a balance between domestic concerns in connection with fulfilling legitimate regulatory objectives and the general functioning of the global trading system.

One of the ways of striking that balance was to promote the use of *international standards*. The TBT Agreement states that "Where technical regulations are required and relevant international standards exist (…) members shall use them, as a basis for their technical regulations".[5] Additionally, it states that "Whenever a technical regulation is (…) in accordance with relevant international standards, it shall be rebuttably presumed not to create an unnecessary obstacle to international trade".[6] The wording of the TBT Agreement thus establishes international standards and the harmonization of technical regulations as one of the primary means of facilitating global trade in goods.[7]

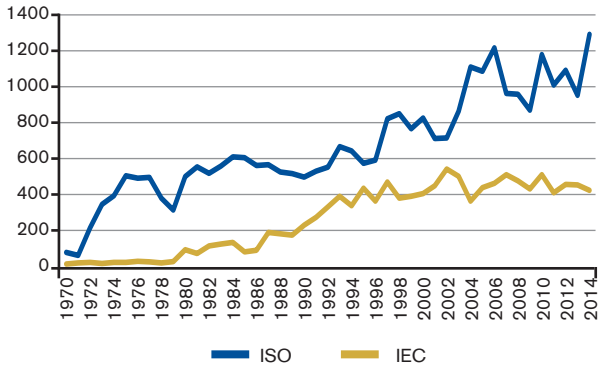
The bodies that develop international standards, the international standards developing organizations (SDOs), were given special status, which accelerated the importance of international product standardization in world trade. Complying with international standards offered improved trade prospects for manufacturing companies and the TBT Agreement provided the legal means of obliging states to accept international standards. These developments meant that national regulatory systems, regulatory agencies and SDOs became increasingly intertwined in an international regulatory context.

The increased significance of international standardization put a focus on many international organizations that developed various types of technical specifications and product standards. The TBT Agreement does not, in contrast to the SPS Agreement[8], define international standards, but merely

describes an international body or system as a body "open to the relevant bodies of at least all members".[9] The implementation of the TBT Agreement did however coincide with an increased significance of standards emanating from the *International Organization of Standardization* (ISO) and the *International Electrotechnical Commission* (IEC), as can be seen in Figure 1.

Both ISO and IEC are non-governmental and centrally coordinated organizations that develop technical standards for worldwide use. Roughly 85% of all international product standards are estimated to be developed by ISO and IEC.[10]

Figure 1. Development of the total amount of ISO and IEC standards 1970 – 2014



Source: ISO and IEC secretariats

Many countries incorporated ISO and IEC standards as a basis of their national legislation and technical regulations. This included not only industrialized countries, but also many emerging economies, such as China, Brazil and India.[11] For emerging and developing economies, adapting to international standards offered opportunities for improved manufacturing quality assurance and made it easier to restrict dysfunctional products in their national markets.[12] For all those countries that were prone to benefit from international standards, ISO and IEC provided the example showing that international standards could support economic integration with foreign markets – specifically markets that were also inclined to conform to those standards.

The use of international standards thus made it possible for national product regulatory systems to better accommodate the business realities of increasingly integrated markets and remove trade barriers that were a result of unnecessary cross-national regulatory differences. These measures supported the exports and imports of trading businesses, increased global scale competition and made it possible for consumers to buy new products at lower prices. In particular, it made it possible for businesses to avoid costly certification induced product adaptations and to find simplified entrances to foreign markets.

At the same time, internationalizing predominantly nationally governed bodies, such as regulatory agencies and standardization organizations, did increase the complexity of rule-making. National regulators suddenly found themselves in an environment where standards set at the international level became the benchmark for their own regulations. Something which was previously national became global.

2.3 Today's Global Regulatory Dynamic – the Context of TTIP

Today, as globalization progresses, internationally developed regulations and standards are spread globally, and affect countless businesses and consumers all over the world. They contribute to raising general product quality requirements and facilitating global implementation of improved technologies. Numerous very different stakeholders are broadly affected by all sorts of standards that may at first be perceived as rather technical and remote.

Facts

How businesses are affected by changing regulatory frameworks

For many companies, adapting to new international standards brings great possibilities for having their products accepted elsewhere – but also involves costs. International standardization may have a profound impact on the business reality of many businesses. Products manufactured according to a standard that were once competitive in important markets may not be competitive anymore. In order to comply with international standards and reach wider markets, businesses may have to redesign their products and reshape their production methods. For those who adapt to international standards, lowering switching costs is of great importance for staying competitive. For those who do not switch, reduced demand may lead to restructuring or shutdown.

Facts

How consumers are affected by changing regulatory frameworks

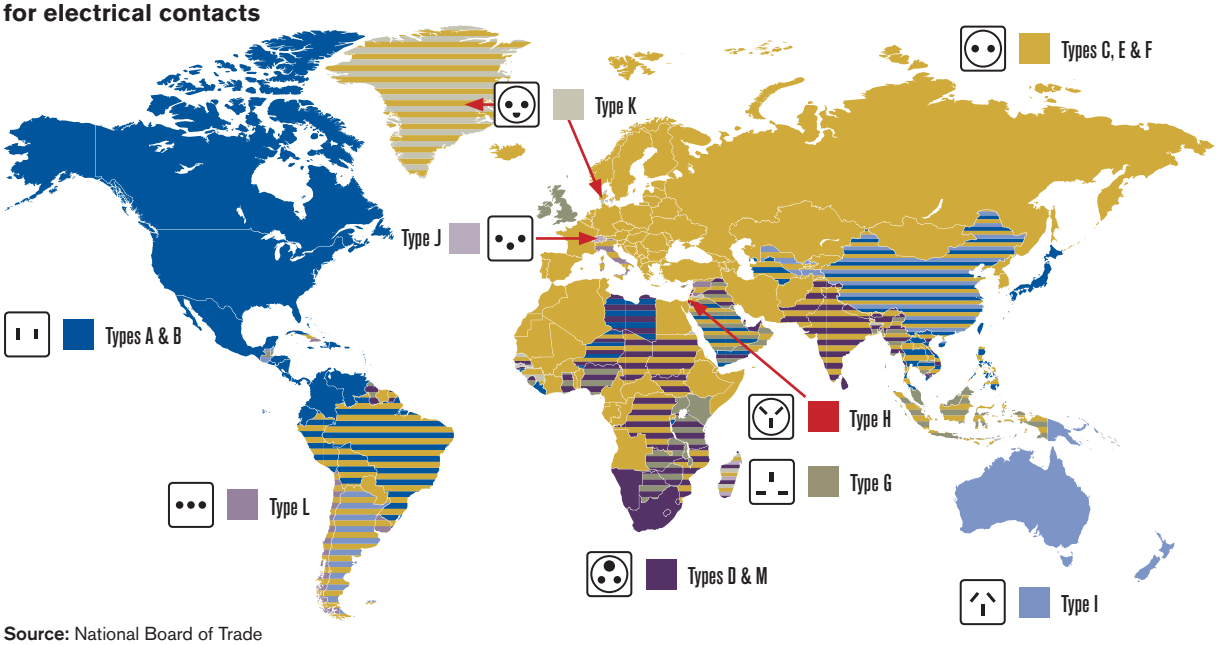
As regulations and standards are effective means of ensuring product quality and performance, they also affect consumers in various ways. For example, standards ensure that the water you drink is safe, that your computer can communicate with other electrical devices and that the car that you drive has reduced CO2 emissions. Consumers play a vital role in driving up demand for the type of solutions that serve various public needs. International cooperation and standardization enable consumer demand to be amplified and expressed at the global level. A rise in global consumer protection may particularly assist emerging and developing countries in improving product quality for the benefit of their consumers. It also entails questions about how progressive and national-specific consumer interests may be taken into account globally.

Facts

How governments are affected by changing regulatory frameworks

State-governments are increasingly affected by decisions made by international bodies. As many international regulations and standards are incorporated into national legislation by national regulatory agencies, international standards may impact greatly on the procedures and norms of state administrations. This requires governments to be able to channel the needs of their national stakeholders and effectively convey them at international level. International decision-making also impacts on the effective adoption of public policy objectives. At the same time, globalization brings opportunities for inspiring others, sharing values and spreading good regulatory practices to other countries. In particular, this involves measures that address problems which are of cross-national concern, for example environmental protection and data protection.

Figure 2. How regulatory differences may affect products: an example with different standards for electrical contacts



Source: National Board of Trade

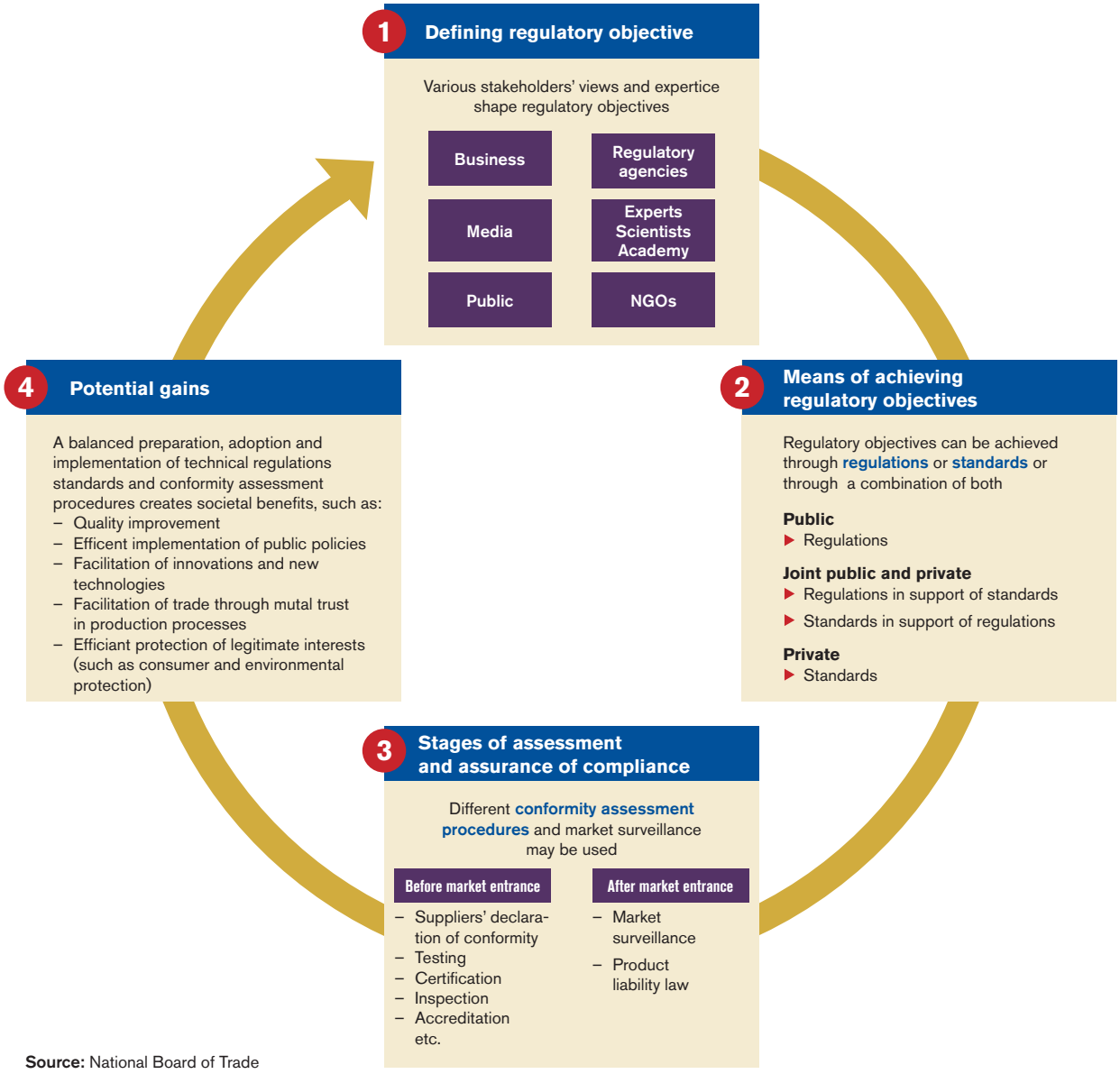
The global regulatory dynamic is complex and is becoming increasingly sophisticated. Many different stakeholders are affected by the regulations and standards that are developed internationally – ranging from regional trading blocs, governments, standards developing organizations (SDOs), multinational corporations and small and medium sized enterprises (SMEs), to consumers and citizens who ultimately are the ones affected by the products introduced on the market. To develop a standard that can become *the* global standard is therefore something which is of great interest to a very large number of stakeholders.

There is thus a strong interest in influencing what might become an international standard. For example, companies may avoid switching costs and enjoy increased competitiveness if the standard they apply becomes an international standard. Public officials and consumer representatives may more effectively accomplish public policy objectives if a particular interest of theirs is incorporated in an international standard. Concerns of a universal character may be better addressed while integrated with practices that enhance trade and nourish mutual reliance and trust between regulators. Overall, these combined interests may create an upward demand for regulatory solutions that are qualitative and efficient, as well as governance structures that allow these solutions to be conveyed globally.

The most advanced regulators, including European and American regulatory agencies, SDOs and businesses, have so far had an important role in developing and inspiring effective global regulatory solutions. The dynamics of international standardization often consist of an interplay between domestic regulatory experiences and the mutual acceptance of recognizing them internationally. In being among the most advanced regulators, the EU and the US have at times offered equivalent, but also different, solutions to be mirrored at international level. These differences are foremost a result of diverging engineering solutions and preferences based on national judicial systems, rather than objectively superior solutions. Technical regulations and standards are often a reflection of history, culture and traditions. However, at international level, harmonization mostly pursues a single regulatory solution that can be dispersed globally. This development has tended to put the EU and the US and their associated stakeholders in a competitive relationship with each other, which is reflected in the overall global acceptance of their respective regulatory systems and the products produced in accordance with those systems.[13]

As global trade and regulatory integration increase, elements of *regulatory competition*, translated into what might be a preferred regulatory solution for other countries or businesses, is becoming more evident. The more a regulatory

Figure 3. An overview of how technical regulations, standards and conformity assessment procedures relate to each other



Source: National Board of Trade

solution is used and accepted by others, the more likely it is that it will receive the status of an international standard one day. Such a development can be pursued through various forms of international cooperation, regional and bilateral free trade agreements and private partnerships, where for example a set of standards is pitched from one party to another.[14] This is a context that TTIP will have to relate to. That is why it is important to assess how the product regulatory systems of the EU and the US relate to the international level. Because if TTIP achieves longstanding regulatory convergence between the EU and US, the probability of reaching shared and global regulatory outcomes will increase.

A first step in analysing EU and US regulatory integration at international level is to look at the differences and similarities that exist between the EU's and the US's product regulatory systems. The following part therefore highlights and compares some of the main features of the EU and US product regulatory systems.

3. EU and US Product Regulatory Systems

When comparing the regulatory systems of the EU and the US it is common that they have a high degree of equivalence in what they achieve. In many areas both systems generally reach similar outcomes in terms of product requirements and level of protection.[15] Nevertheless, the product regulatory systems of the EU and the US differ in terms of *how* they reach regulatory outcomes.

3.1 General internal market objectives

An important starting point for comparing the EU and US product regulatory systems, is to understand the driving mechanisms of their internal markets. For the EU, the internal market lies at the epicentre of creating a political and economic unity in Europe. One of the means of doing this has been to remove trade barriers by harmonizing product sectors and applying the principle of mutual recognition outside harmonized areas. The member states of the EU have transferred parts of their regulatory power to EU institutions, which in turn have adopted harmonized regulatory frameworks to be implemented among the member states. The quest for integrating sovereign states into a common market governed by common rules has required a strong systematic approach that enables different and diverse states to fit in and accept new regulatory regimes. Regulatory mechanisms that allow for coordination and cohesion have therefore been applied to integrate national markets and balance the various priorities that the different member states may have.

In the US, the situation is different. The US is a federal country, and as such does not actively strive towards creating an internal market through the use of systematic and centralized regulatory models. On the contrary, the US Constitution establishes a dividing line between federal and non-federal regulatory power and fosters a more constant order in which the states can regulate outside the realm of federal power, and the economy can grow freely based on the terms of an open marketplace. The US also has a strong tendency towards industry self-regulation and best practices developed outside the governmental sphere. In comparison with the EU, the US regulatory system does not explicitly aim at integrating different foreign markets as part of a public objective, but focuses instead on sustaining conditions for a competitive business environment within the US. The regulatory nature of the EU targets the effective incorporation of various countries into a structured and trade-enhancing regulatory framework that can be applied by different countries, including those outside the EU.

3.2 The basic structure for standardization

The EU standardization system is a central part of the EU product regulatory system. It facilitates harmonization in the internal market and coherently connects SDOs to a cohesive and organized system. The system has two branches; one regional and one national. The regional branch consists of the European SDOs, the *European Committee for Standardization* (CEN), the *European Committee for Electrotechnical Standardization* (CENELEC) and the *European Telecommunications Standards Institute* (ETSI). The national branch is composed of each member state's own standardization body, like the *British Standards Institutions* (BSI), the *German Institute for Standardization* (DIN) and *The Swedish Standards Institute* (SIS). The European national SDOs are deeply integrated into European standardization at regional level. As the members of CEN and CENELEC are the national SDOs, national SDOs have representatives on the regional level standards committees. The national SDOs then use "mirror committees" at national level that keep interested stakeholders informed and enable national SDOs to agree on common national positions to be expressed at the regional level. When a regional European standard is approved, each national standardization body adopts the standard as a national standard and withdraws any conflicting standards.

Standards are also an integral part of the US regulatory system. The standardization system consists of several large SDOs, for example the *American Society for Testing and Materials* (ASTM), the *American Society for Mechanical Engineers* (ASME) and the *Institute for Electrical and Electronics Engineers* (IEEE), which produce standards for a broad range of products, and several hundred smaller SDOs that produce specific and highly specialized standards. US standardization is coordinated by two bodies: the *American National Standards Institute* (ANSI) and




the *National Institute of Standards and Technology* (NIST). ANSI is a private body that oversees and accredits US standardization. As ANSI does not develop standards itself, it is not an SDO. On the governmental side NIST, a measurement agency and science laboratory, supports standardization through product testing and coordination. Both ANSI and NIST have supportive roles in relation to the development of standards. Standardization, however, is led by the privately empowered SDOs.

The US standardization system is very diverse and decentralized.[16] It does not seek to harmonize product regulations as in the EU. Instead, most US SDOs offer multiple standards for various industrial and public policy needs. While many US SDOs are non profit, many SDOs are financed through the sale of their own propriety standards and through membership fees. Standardization is primarily driven by commercial incentives. This implies that different SDOs are free to produce conflicting standards in competition with each other. A large part of US standards are also produced by regulatory agencies, particularly the US Department of Defence.[17] Standardization in the EU and the US is consequently very different in terms of how they function and what purposes they serve. This becomes even clearer when comparing how standards in the EU and the US are connected to legislation.

3.3 The relationship between technical regulations and standards

A significant feature in the EU product regulatory system is that European SDOs can be directed by the legislator to develop standards in support of legislation. The *New Approach* doctrine implies that the European Commission issues standardization mandates to European SDOs. Products developed according to these standards, known as harmonized standards[18], are presumed to be in conformity with general objectives set out in pre-drafted legal acts.[19] In this way the legislator can connect the public authority of the regulators with the industrial competence and technological resources of the privately empowered European SDOs. This principle does however not apply within non-harmonized areas. In these areas, national SDOs and member states' regulatory agencies can develop their own national standards and incorporate them into national legislation provided that they are in compliance with EU law.

In the US, standards are commonly *incorporated by reference* (IBR) into legislation. IBR implies that certain laws make reference to standards and requires that those standards be followed.[20] Regulatory agencies can reference standards whenever it is found necessary. In this way, many voluntary consensus standards become mandatory when referenced or adopted by public authorities. Federal legislation encourages agencies and departments, as a means of carrying out policy objectives or activities, such as approval procedures and procurement, to use technical standards that are developed or adopted by voluntary consensus standards bodies. Authorities are also generally encouraged to avoid developing their own agency-unique standards.[21] However, in comparison with the EU, the incorporation does not follow a pre-defined procedure where SDOs are requested to develop standards that relate to specific legislation. Agencies can instead choose and reference the specific standard they find suitable for the given regulatory

purpose.[22] This means that US SDOs are not obliged to develop standards for public policy needs defined by a regulatory agency, but rather they develop and distribute standards according to the predicted needs of the market, wherein public policy objectives may be expressed in parallel with other interests.

3.4 Coordination and representation

The European standardization system is built upon structures which support coordination among regional and national branches. An example of this is the strongly embedded principle of removing conflicting standards through regional harmonization – standards issued by CEN, CENELEC and ETSI. In this way, the regional layer introduces a hierarchical element to European standardization. Since European standardization revolves around a *few* standardization bodies, there is a strong demand for participation within European SDOs. The EU standardization system therefore includes broad stakeholder groups. Public representation and partial public funding in EU standardization also implies that the standardization process must take into account public principles such as transparency and stakeholder involvement. The merging of different interest groups and positions has required sophisticated forms of cooperation that enable consensus-building, but which can also be time-consuming and delay standardization.[23]

In comparison, the US standardization system does not have any hierarchal structures. Instead, the US system allows for stakeholder involvement through *numerous* specialized SDOs instead of a few. In this regard, the pluralistic US standardization system has likely promoted the effective production of many innovative standards. At the same time, the fragmentation may bring additional costs through duplications and restricted interoperability between conflicting standards. ANSI, the private sector coordinating and administrative body for US SDOs, has attempted to reduce duplication and overlap. In 2013 ANSI launched a notification procedure named Project Initiation Notification System (PINS).[24] Many business models of US SDOs are however not easily combined with centralization. Information sharing between the SDOs and ANSI is for example limited in terms of the extent to which sharing information can be translated into commercial value.[25] This makes US standardization difficult to oversee and coordinate.

Facts

Key elements in European standardization

- Hierarchy
- Coordination
- Public driven cohesion
- Regional and national

Facts

Key elements in American standardization

- Decentralization
- Competition
- Private sector integrity
- National

3.5 Market access

Conformity with EU harmonized standards enables direct access to the EU internal market. Other standards may also meet the technical requirements of EU legislation, but they do not have presumption of conformity with essential product requirements specified in EU regulations and directives. This structure steers businesses to comply with harmonized standards when trading with the

EU. The concept of one standard per product reduces the thresholds for entering the EU internal market. At the same time, it also means that businesses are compelled to comply with harmonized standards instead of others.

In the US, a variety of standards can be applicable to one product. As standards may compete with each other, the standards necessary for market access is determined by the demand of the marketplace. This provides a flexibility for the trading businesses to decide which standard they want to apply. However, it may also have the effect of creating uncertainty about which standard should be used for effectively entering the market, as well as creating a demand for compliance with local-specific standards, particularly in the area of conformity assessment.

3.6 Conformity assessment

Conformity assessment plays an important role in the EU product regulatory system. In harmonized new approach areas, there is a linkage between general legislative product requirements, technical standards, and the method of showing conformity to the applicable requirements. The CE marking is affixed to the products that are compliant. The type of conformity assessment depends on the risk and characteristics of the product category, the relevant *product module*.[26] Regulations and directives that cover low risk products often allow supplier's declaration of conformity (SDoC) as a means of conformity assessment. High risk products are instead covered by other types of conformity assessment, mainly third party conformity assessment conducted by notified bodies. Notified bodies are privately or publicly run laboratories and testing facilities that verify product compliance with applicable EU requirements. Notified bodies must be accredited by an accreditation body. The accreditation bodies are appointed by public authorities and there can only be one accreditation body per member state. Conformity assessment is further supplemented with market surveillance conducted by all member states and their national authorities.[27]

The US conformity assessment system is, in contrast to the EU system, mainly market driven, decentralized and not coordinated by the government. As in the EU, different forms of conformity assessment may be used in the US, including for example first, second and third party certification. Regulatory agencies may indicate the desired level of conformity assessment in regulations. The actual testing and verification is primarily conducted by privately operated bodies in competition in an open market. In areas where the method of conformity assessment is not specified in regulations, the level of verified conformance to standards is defined by the marketplace demand. There is no generally organized post-market control.[28] Instead, the US has an extensive product liability law that functions as a deterrent to various forms of market abuse.

3.7 Concluding remarks

These differences reflect the distinct ways in which EU and US product regulatory systems function. While both systems aim at providing the best conditions for innovation, industrial competitiveness and ensuring that the products sold on the market are safe, the main difference is the extent of government involvement at different stages of the standardization process. In the EU, the harmonisation of standards is perceived as a driving force for sustaining an internal market based on the integration of different countries with different regulatory traditions.[29] In the US, standards are more profoundly defined by marketplace demand and the rewards it may bring to the development of qualitative standards. The US system favours efficient development of standards needed by industry and public agencies. While the EU system also pursues the development of qualitative standards, it has fewer standard developing organizations (SDOs) than the US, where SDOs are specialized in certain areas. EU SDOs therefore have to include broadly defined needs that they ought to serve, not least market integration and trade enhancement. The merging of different stakeholders' interests brings in an element of competition at the initial stages standardization, whereas in the US, competition is expressed between finalized standards developed by different SDOs. These differences are particularly reflected in terms of coordination of standardization, plurality or singularity of standard's and the standards relationship to the international level.

These distinct features will be taken into account in the next section, an analysis of how the EU and US product regulatory systems relate to the international level rule-making and standardization.

4. Regulatory Integration within Three Main Arenas

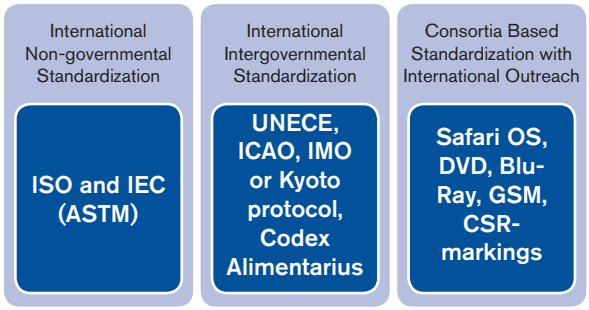
The report has so far described the nature and characteristics of the EU and US product regulatory systems. With that perspective in mind, this chapter looks at how the EU and US regulatory systems are integrated and how they converge at the international level. In order to get a clearer picture of the different ways in which global regulatory practices are developed, the following analysis focuses on three *arenas*:

- International standardization
- Free trade agreements
- Areas not directly covered by regulatory cooperation

4.1 International standardization

International standardization encompasses a variety of organizations and constellations that develop technical specifications and product standards in different ways for worldwide dispersal. The figure below maps out the various bodies that formally or informally develop standards which may be dispersed globally. As the exact definition of an international standard is contested, the below figure only exemplifies institutional structures that support the outreach of various standards.

Figure 4: Institutional structure of international standardization[30]



Source: National Board of Trade

Non-governmental standardization (1) and intergovernmental standardization (2) are further described and elaborated upon in the following sections with regard to EU and US involvement. The last category, consortia based standardization (3), relates to specifications developed by private undertakings. These are not formal standards, but represent various innovations and solutions that have achieved a de facto worldwide standard status. As consortia standards do not necessarily correspond to the recognized concept of standards (see the above definition 2.1) in terms of how they satisfy the requirements of stakeholder involvement and transparency when developed, this category is not further elaborated upon in this text.

4.1.1 Non-governmental standardization

The majority of all international standards are produced through non-governmental international standard developing organizations (SDOs). Prominent organizations include the *International Organization for Standardization* (ISO) and the *International Electrotechnical Commission* (IEC). ISO issues standards in many different areas, such as, health, water, food, cars and energy. Well known examples of ISO standards include the common specifications and dimensions of shipping containers, the metric A4 paper standard (though not adopted in the US) and the colour palette specifying varying paint shades.

IEC, on the other hand, publishes standards and conformity assessment procedures for electric and electronic products, commonly known as electrotechnology. This includes smart grids, functional safety, smart energy, electromagnetic compatibility (EMC), and renewable energies. Size codes for bat-

Facts

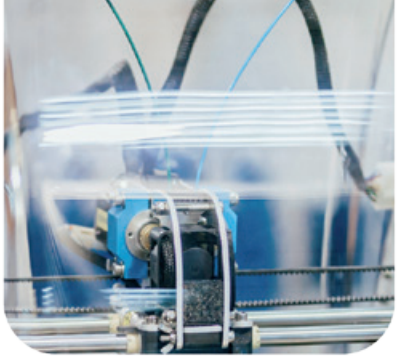
ISO facts Figures 2012[31]

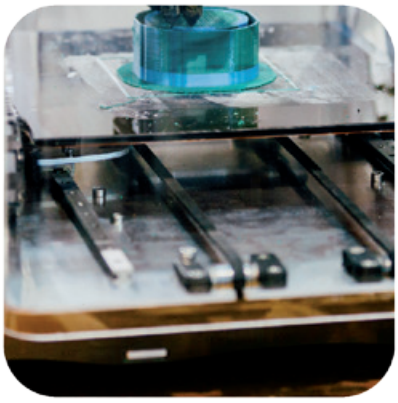
National member bodies	111
Countries represented	164
Staff	154
Technical committees	224
Subcommittees	513
Individual participants ca[32]	50.000
Published standards	19.573

Facts

IEC facts Figures 2012

National member bodies	59
Countries represented	162
Staff	30
Technical committees	94
Subcommittees	80
Individual participants ca	10.000
Published standards	5.520



teries, specifications for safe and effective radiation levels in x-rays and methods for measuring electrotechnical interference between different electrical devices, are examples of IEC standards. ISO and IEC together also develop joint international standards in some areas. An example of this is credit and bank card dimensions.

Facts

The process of developing an international standard at ISO and IEC

The standardization processes of ISO and IEC are very similar. The process often starts with informal discussions between the member bodies about developing an international standard. The member bodies are national SDOs that represent their country at international level. While it is possible for several national SDOs to be members of ISO and IEC, only one body per country has the right to vote. The right to vote is consequently distributed country-wise. This is important when a national SDO proposes a new "work item" for a technical committee or subcommittee, since the approval is dependent on the outcome of a majority voting. If accepted, a working group of experts develop a draft standard and circulates the document at committee level. The committee then elaborates on the draft further until consensus is reached. The final draft is circulated among the member bodies for comments and preliminary voting. The voting requires sixty-six percent of the votes of the relevant technical committee and seventy-five percent of all member bodies that choose to vote.[33]

EU and US SDOs's cooperation agreements with ISO and IEC

European standardization is closely bound to ISO and IEC. The regional European SDOs, CEN and CENELEC, have ambitious partnership agreements with ISO and IEC – the *ISO-CEN 1991 Vienna Agreement* and the *IEC-CENELEC 1996 Dresden Agreement*. The Vienna Agreement features mechanisms aimed at countering conflicting standards and duplications between European and international standardization. In this regard, the agreement specifies ISO-voting as the means of deciding whether a standard is to be developed by ISO or CEN. If a standard is developed by ISO, CEN adopts the international standard at EU regional level through parallel voting. The agreements consequently allow for European SDOs at regional level to effectively cooperate and integrate with SDOs at international level. This order enables coordination, quick information sharing and early initiative at the first stages of the standardization process. In particular, it counteracts duplication and overlap between the EU and the international level through the harmonization of standards.

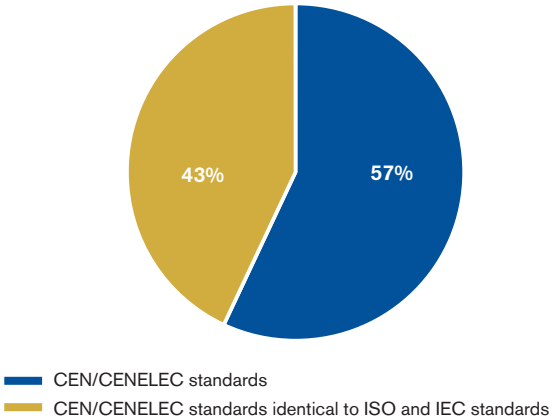
US SDOs also have agreements that connect US standardization to ISO and IEC. Several large US SDOs have entered into partnership agreements, so-called *partnership standards developing organization agreements* (PSDO). ASTM has, for example, signed an agreement with ISO concerning development cooperation of international standards for additive manufacturing. IEEE has signed an agreement with ISO on the subjects of information technology, intelligent transport systems and health informatics.[34] The cooperation between US SDOs and ISO and IEC may be specific in areas covered by PSDOs, but it is not as comprehensive, in terms of who ini-

tiates a standardization process as well as broadly binding SDOs to ISO and IEC standards, as the European SDOs agreements with ISO and IEC are. The adoption of ISO and IEC standards within the EU is therefore more systematic in nature and follows an international, regional and national logic which is not seen in the US. The way in which ISO and IEC standards are adopted in the US is more commonly based on the commercial preferences of each and every SDO reflected in their PSDO. Besides differences in how EU and US SDOs have concluded cooperation agreements with ISO and IEC, there is also a difference in the level of identity between EU and US standards and standards developed by ISO and IEC.

Identicalness to ISO and IEC standards

When measuring the proportion of identical EU and US standards to ISO and IEC standards, it is evident that the EU standardization system has kept track of its relationship to ISO and IEC standards. European SDOs have systematically implemented the principles of the Vienna and Dresden Agreements; EU standards are closely monitored and bound to correlating international standards. Exact figures concerning the implementation of ISO and IEC standards in the EU are therefore very accessible.

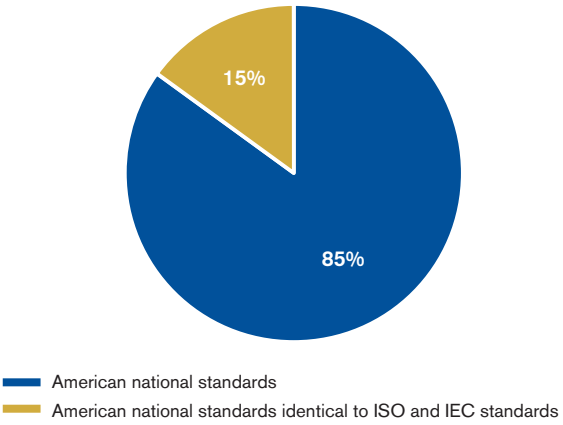
Figure 5. Integration between European and International Standards



Source: CEN and CENELEC as of mid-2015

For the US, it is much more difficult to overview of the proportion of US standards that are identical to international standards. The number of US standards is hard to track, as the US standardization system is decentralized and standards are developed by a plurality of SDOs. However ANSI, the US standardization coordinating body, has measured the number of ISO and IEC standards that are adopted as American national standards (ANS).[35] Only SDOs which have had their procedures accredited by ANSI can develop ANS. When measuring US standards in total, ANS are therefore only a part of a larger total number of US standards that includes standards developed by SDOs not accredited by ANSI.

Figure 6. Integration between American and international standards



Source: ANSI as of mid-2015

These figures show that the correlation between EU standards and ISO and IEC standards is substantially stronger than that between ANS standards and ISO and IEC standards.

Interpretational differences

The contrasting figures presented above indicate that there are differences in how the EU and US standardization systems relate to ISO and IEC. The figures can also give an indication of how harmonization of standards and the cohesive prevention of overlapping standards is perceived in the EU and in the US in relation to the international level. By looking at the "status" that the EU and the US attach to ISO and IEC, it is clear that there are some substantial interpretational differences.

For example, the EU recognizes ISO and IEC along with a number of intergovernmental organizations, as international SDOs in accordance with the TBT Agreement. The US on the other hand recognizes ISO and IEC, but also adds domestic SDOs as potentially international SDOs. The US draws the distinction based on whether participation is

open to all, including other foreign SDOs, and whether the standards produced are used in more than one country. A standard developing organization can consequently, according to the US, be both domestic and international at the same time.

The basis for the US interpretation is the so-called *six principles* established by the TBT Committee.[36]

Facts

Background to the six principles

In 2000, at the Second Triennial Review of the Agreement, the Committee noted that in order for international standards to make a maximum contribution to the achievement of the trade facilitating objectives of the Agreement, it was important that all Members had the opportunity to participate in the elaboration and adoption of international standards. In order to improve the quality of international standards and to ensure the effective application of the Agreement, the Committee agreed that there was a need to develop principles concerning:

- *transparency,*
- *openness,*
- *impartiality and consensus,*
- *relevance and effectiveness,*
- *coherence,*
- *developing country interests*

that would clarify and strengthen the concept of international standards under the Agreement and contribute to the advancement of its objectives.[37]

The US interpretation of the TBT Agreement does connect several of its largest SDOs, like ASTM, to the international standardization system in this way, through the production of their own "international" standards. The production of international standards would thereby not necessarily require participation in the committees of ISO and IEC or other recognized international SDOs.

An important factor in these interpretational differences is that the internal structure of ISO and IEC largely resembles the structure of European standardization. Both ISO and IEC abide by principles familiar to European SDOs – they coherently coordinate standardization, each country has its national SDOs represented as a voting member and conflicting standards are counteracted. Where international standards exist, privilege is given for the purpose of harmonization. The setup is similar to the structure that exists between national and regional SDOs in the EU.[38] In comparison, a system that allow for competing and potentially conflicting standards, like in the US, does not as easily connect with a system that is based on a hierarchical structure, like ISO and IEC, where the concept of *one* standard instead of many prevails. A more suitable solution for US SDOs is therefore to side-step hierarchical structures and engage in horizontal cooperation with ISO and IEC in the development of international standards. However, horizontal cooperation among a few US SDOs raises questions about how effectively an overall integration with ISO and IEC is achieved in the US – concluded PSDOs cover only a minimal part of total ISO and IEC standardization.

Another aspect concerns the voting conditions at ISO and IEC. Though consensus based decision-making plays an important part in the technical parts of the standardization process, voting has a central role at the first and final stages of standardization (as explained above). The EU is represented at ISO and IEC through all of its twenty-eight national SDOs. The US is, in comparison, solely represented by ANSI. Although the US, in terms of voting, is disadvantaged in comparison to the EU, there is no support for the case that the EU systematically would vote in unity or that US SDOs would be deprived of adequate means to influence and take part in the development of standards at ISO and IEC. Perceived disadvantages cannot, however, be disregarded as a factor that could have influenced US SDOs approach and involvement in ISO and IEC.

In sum, it is likely that the differences between the EU and US standardization systems have resulted in different starting points in communicating and converging their own standardization initiatives with their international ISO or IEC counterparts, as well as implementing the standards developed by ISO and IEC in their internal markets. Similar tendencies can also be seen in the context of intergovernmental standardization.

4.1.2 Intergovernmental standardization

Many intergovernmental organizations are actively involved in developing and adopting technical specifications that are distributed globally. These organizations commonly consist of member states that

become part of the organizations through the ratification of associated conventions. The member states are then represented through their governments. These organizations are often governed by a voting assembly that consists of member states. Other functions, like a secretariat, committees and subcommittees that conduct technical tasks, may also be part of many intergovernmental organizations.

Several of these organizations are agencies of the United Nations, like the *International Civil Aviation Organization* (ICAO), the *International Maritime Organization* (IMO) and the *World Health Organization* (WHO). There are also organizations where technical requirements are developed through collaborations between regulatory authorities and industry. An example of such an organization is the *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use* (ICH). Besides organizations, development of technical requirements can also occur through the drafting and adoption of ad hoc international agreements. Examples of such agreements are the Kyoto Protocol that regulates greenhouse gas emissions and the *International Convention for Safety of Life at Sea* (SOLAS) covering safety and construction standards at sea.

Intergovernmental organizations are often the means of achieving a global harmonization or convergence between varying domestic regulations and standards within a certain regulatory area. Governments desire to exert influence may, in parallel, trigger queries in terms of which regulatory orientation the organization should pursue and how it reflects a country's national regulatory system and overall domestic considerations. As with non-governmental standardization, voting conditions cannot be disregarded as a substantial factor in this regard. Another factor lies in whether the regulatory orientation of the intergovernmental organization is significantly similar to or different from the national one. This may affect a government's decision to join, participate partly or stay outside.

EU and US engagement

Considering the EU and the US in this context, both fundamentally share the idea of a rule-based international cooperation.[39] Nevertheless, different starting points have had an impact on their participation in these organizations.

One aspect of this can be exemplified through the *United Nations Economic Commission for Europe* (UNECE). UNECE is an intergovernmental organization that facilitates regulatory cooperation through its working parties, covering for example telecom standards and common motor vehicle regulations. Although initially being foremost a European regulatory integrator in the wake of post-World War II, its regulatory cooperative model has widened to include countries outside Europe. The World Forum for Harmonization of Vehicle Regulations[40] and the 1958 Vehicle Agreement[41] includes for example Australia, New Zealand, South Korea, Thailand, Malaysia and South Africa. While many countries generally recognize the technical content of UN'58 vehicle regulations, market access enhancing measures like type approval and certifications, the US do not.[42] Instead, the US applies its domestic federal motor vehicles safety standards, and stays outside the most substantial vehicle-related regulatory cooperation at the UNECE. In the motor - vehicle sector, this has led to the formation of two separate, and mutually incompatible, regulatory regimes that are based on either globally endorsed UNECE regulations or domestic standards.

This and other examples, indicate that the EU has been generally striving towards achieving regulatory integration through the empowerment of international institutions and expanded policy scopes. This can be seen in the context of its own experience and means of developing increasingly shared regulations between countries. Besides the regulatory cooperation that occurs within the EU itself, environmental protection and the ratification of the Kyoto Protocol is an example of such a commitment.[43] The US has in this regard also been pushing for the establishment of international regulatory institutions, and as such shares many traits with the EU, but there are also factors that suggest that it has been more vigilant in allowing domestic policy choices to be extensively overtaken by international ones.[44]

These different EU and US approaches to international regulatory cooperation are also reflected in how the EU and the US define their obligations towards international regulatory organizations. This became clear when the EU and the US exchanged views at the WTO concerning a US TBT notification for air transported lithium batteries.[45] When notifying their draft regulations, the US was accused of setting more restrictive transportation packaging requirements for lithium batteries that went beyond those laid out in international standards set by the *International Civil Aviation Organization* (ICAO).

However, the US did not contest that the requirements went beyond ICAO requirements; instead, they argued that the requirements set by ICAO did not achieve sufficient protection against the risk of the batteries catching fire while being transported by air. But more importantly, the US also argued that ICAO did not fulfil the criteria for setting international standards according to the decision and recommendations of the TBT Committee. The US argued that standards developed though voting, which is the common procedure for most UN intergovernmental organizations, could not satisfy the consensus requirement of the six principles mentioned above. Without consensus, the ICAO standard could not – according to the US – be regarded as an international standard, and domestic US standards could be applied. The EU, on the other hand, argued that consensus was a vital requirement, but not a necessary one. The outcome of the EC-Sardines case supported the EU interpretation.

Facts

Extract from the Appellate Body in the EC-Sardines case regarding the *consensus requirement*

"(…) the logical conclusion, in our view, is that the omission of a *consensus requirement* in the definition of a "standard" in Annex 1.2 of the TBT Agreement was a deliberate choice on the part of the drafters of the TBT Agreement (…). Had the negotiators considered consensus to be necessary to satisfy the definition of "standard", we believe they would have said so explicitly in the definition itself (…). Therefore, we uphold the Panel's conclusion, that the definition of a standard in the TBT Agreement does not require approval by consensus for standards adopted by a *recognized body* of the international standardization community."[46]

The EU and US interpretations of what constitutes an *international standard* thus divide their perceived obligations towards organizations that develop standards in various international fora. In the context of non-governmental standardization, explained above in 4.1.1., the EU argues that national SDOs cannot develop international standards, whereas the US argues that international standards can be developed by SDOs that conform to the six principles. In intergovernmental standardization, explained in this section, the EU argues that consensus is not a necessary requirement for an international organization to develop international standards. The US argues that consensus is required for a standard to be international.

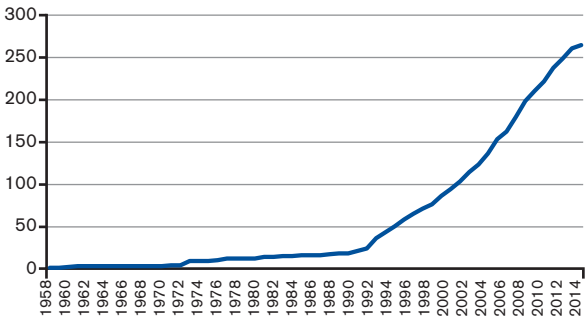
These interpretational differences reflect the EU and US approaches to international standardization and how the EU and the US engage in various international organizations. Although both the EU and the US generally abide by the concept of international standards, disagreement over its definition may hold back regulatory integration and increase regulatory division in important areas, as uneven engagement at international level may negatively affect the formation of viable global solutions. As the next part will show, EU and US perspectives and priorities in this regard have also had an impact on the free trade agreements that they have concluded with other countries.

4.2 Free Trade Agreements

Different types of bilateral and regional free trade arrangements have steadily increased in number since the beginning of the nineties. Free trade agreements (FTAs) have become an important trade instrument for many countries. Almost two hundred and sixty FTAs are in force today. Together, these FTAs form a web of agreements that specify own terms of trade between the signatories. FTAs enable countries to deepen their regulatory partnerships with each other and converge their regulatory regimes.[47]

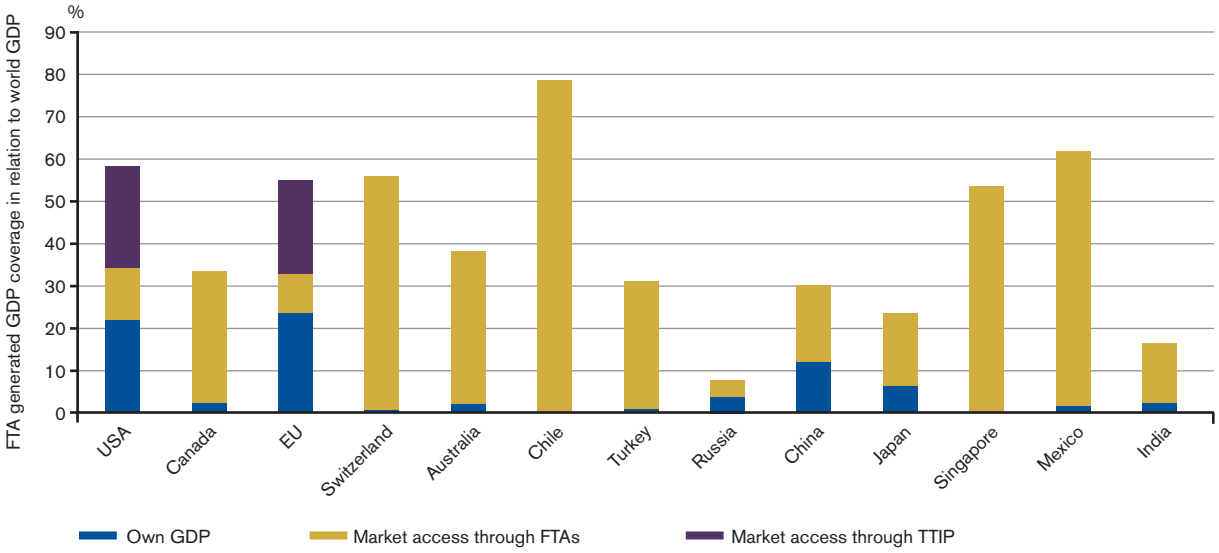
The EU and the US are among those who have signed the highest number of FTAs with other countries. However, in terms how much preferen-

Figure 7. Number of Free Trade Agreements in force 1958 - 2014



Source: WTO (Mid-2015)[48]

Figure 8. Market access generated by FTAs measured in GDP coverage



Source: World Bank nominal GDP figures (2013)[50]

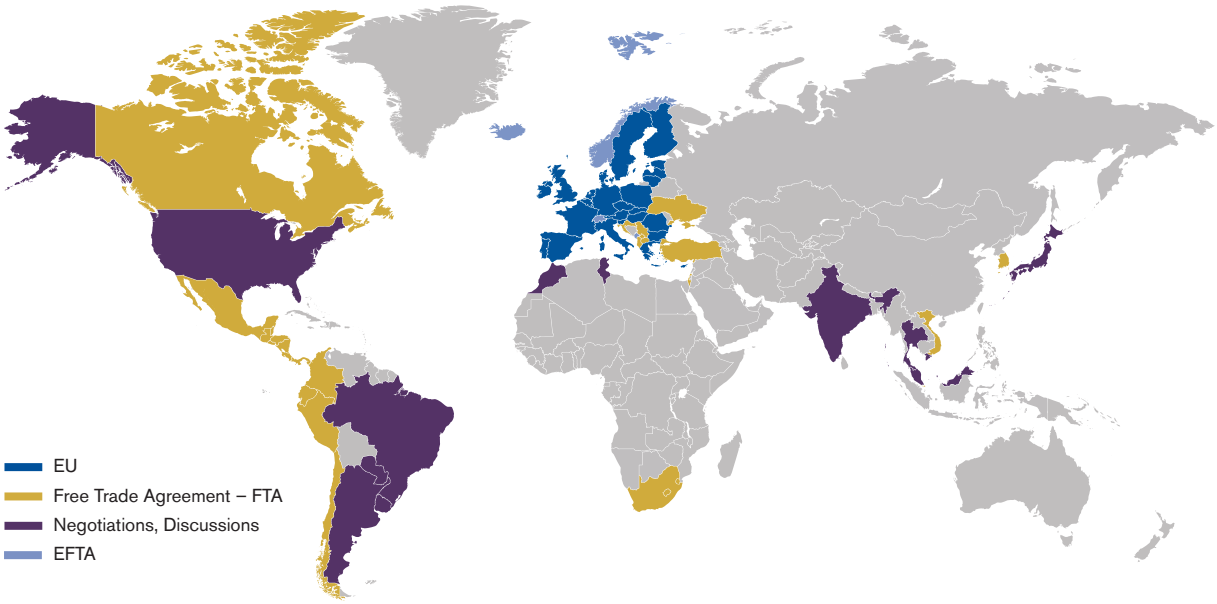
tial market access they create, EU and US FTAs remain moderate (figure 8).[49] With regard to the combined market size of the EU and the US, TTIP would bring substantial parts of the global economy under a new "mega" FTA. The same applies to the *Trans-Pacific Partnership* (TPP), which is being negotiated among a group of Pacific countries including the US, Japan, Australia, Mexico and Canada. Together, TTIP and TPP can have a profound impact on the FTA landscape and affect the premises of future regulatory cooperation.

4.2.1 Regulatory cooperation and convergence through FTAs

With the general tendency shift towards the removal of non-tariff barriers instead of already reduced tariff barriers, the significance of including technical regulatory cooperation, standardization and TBT components in FTAs has increased. This is particularly the case with respect to the most modern FTAs, the so-called new generation FTAs, which are substantially deeper and contain more comprehensive regulatory chapters and sector annexes than their predecessors. In this regard, FTAs enable signatory countries to deepen the type of TBT commitments that are provided for in the TBT Agreement, through for example enhanced regulatory transparency and information sharing, or go beyond the TBT Agreement and apply its regulatory principles in new, non-settled or disputed areas, such as non-product related processes and production methods. Besides horizontally defined areas, FTAs can also provide the means for countries to align their regulations and product standards in specific sectors, like electrical products, vehicles and chemicals. Through the adherence to common technical specifications, standards and the acceptance of conformity assessment results, FTAs may provide prospects for improved regulatory compatibility and trading conditions between the signatory countries.

Meanwhile, the type of regulatory convergence that FTAs may generate between signatory countries can also offer specific opportunities for countries to exert regulatory influence over others. This can for example be the case when, in the context of agreeing on FTA provisions, two sets of regulatory frameworks are incompatible with each other, when one system is superior to the other or where one party lacks a comparable set of regulations. In these cases, FTAs can facilitate regulatory dispersal through a mutually beneficial trade-off between, on the one hand, making regulatory adjustments and, on the other, attaining preferential terms of trade. Regulatory dispersal through FTAs is generally more likely to occur when there are different economic starting points between the signatories, for example when the internal market of one signatory exceeds the size of the corresponding market.

Figure 9. EU Free Trade Agreements



Source: National Board of Trade

Bringing the EU and the US into this context, it is clear that both have extremely large markets. This implies, with regard to the above, that many third countries would be inclined to accept the regulations and standards of the EU and US. By comparing the content and outreach of EU and US FTAs, it is possible to understand how they have converged and dispersed their regulatory practices to various partner FTA countries.

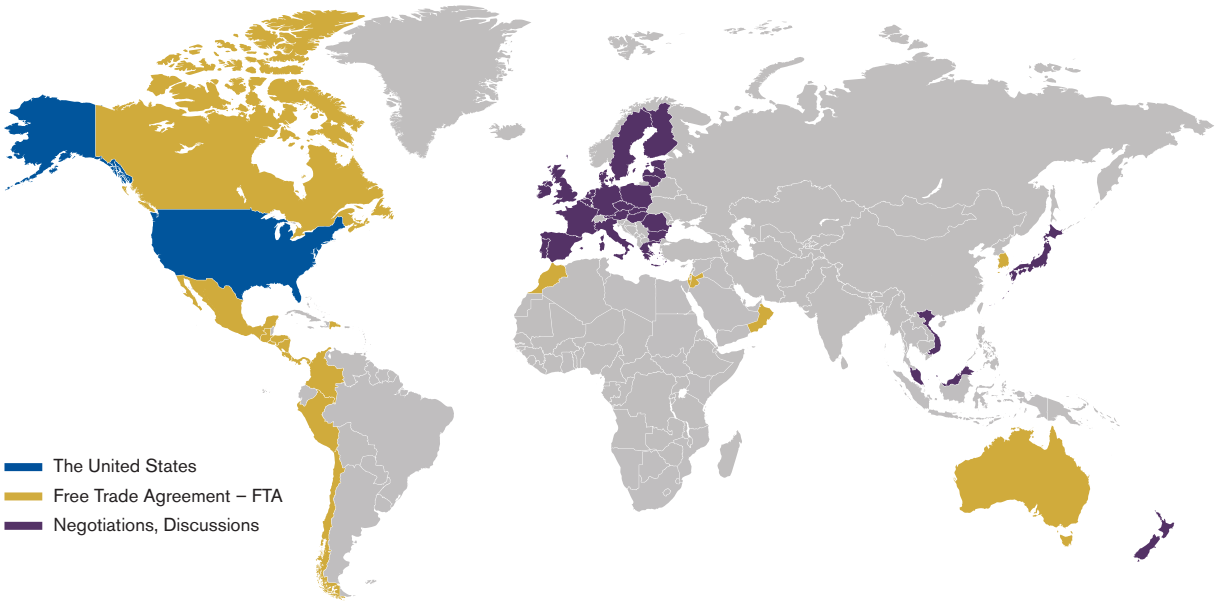
EU FTAs

EU FTAs can largely be divided into three groups: FTAs signed with countries in European proximity, new generation FTAs and older FTAs. In terms of regulatory integration, these agreements reflect different levels of ambition.

Many of the FTAs that the EU has with neighbouring countries are based on the aspiration of a deep and substantial integration with the EU internal market or, in some cases, future accession to the EU itself. The *European Economic Area* (EEA) which includes the EU and the *European Free Trade Association* (EFTA)[51], the integration agreements between the EU and Switzerland and the customs union between the EU and Turkey[52] do all include undertakings that support extensive technical alignment with the EU. Several countries in the Euro-Mediterranean area, Eastern Europe and the Balkans have signed or are negotiating FTAs with the EU.[53] The language used in these agreements often refers to the promotion of EU technical regulations and standards for industrial and agri-food products and certification procedures.[54] Furthermore, many of these agreements are combined with *Agreements on conformity assessment and acceptance of industrial products* (so-called ACAAs). ACAAs are specific types of mutual recognition agreement based on the alignment of the product regulatory system of the country concerned with those of the EU. Algeria, Egypt, Jordan, Lebanon, Morocco, Palestinian Authority, Tunisia, Ukraine and several countries in the Balkans are under consideration to enter ACAAs with the EU. An ACAA with Israel covering pharmaceutical products entered into force in 2013.[55] FTAs with neighbouring and candidate countries can thus be differentiated, in terms of the ambition of regulatory alignment, from FTAs that the EU has with countries distant from Europe.[56]

Since 2006, the EU has started – under the "Global Europe" strategy – to negotiate and conclude new free trade agreements with key partners beyond EU proximity. Many of these so-called new generation FTAs go further in terms of regulatory cooperation than traditional FTAs. South Korea, Canada, Singapore and Ukraine are some of the countries that have concluded new generation FTAs with the EU.

Figure 10. US Free Trade Agreements



Source: National Board of Trade

Newer FTAs, and in particular, FTAs of the new generation, are more explicit in terms of defining a preferred regulatory model within specific sectors. For example, *supplier's declaration of conformity* (SDoC), acceptance of certificates and equivalence of EU standards, as well as UNECE vehicle standards, are promoted in several FTAs. These are systems which are applied in the EU.

In comparison, older FTAs, like those with Chile and Mexico, generally tend to reinforce existing mechanisms for regulatory cooperation and do not go as far as newer agreements. These FTAs often refer to the principles of the TBT Agreement, international standards and bilateral regulatory cooperation with mutual regard to each other's systems.

Facts

EU mutual recognition agreements (MRA)

Besides FTAs, the EU also has MRAs with a number of countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland and the US MRAs specify terms under which a signatory country will accept conformity assessment results conducted by a conformity assessment body in another country. MRAs therefore enable companies to trade without having to do additional product testing. These agreements do not however lead to one system supplanting the other, but in principle allow for two models of CAPs to run in parallel.[57]

US FTAs

The US has concluded a number of FTAs since the middle of the eighties. The attention of US FTA negotiations was at first, with the exception of the FTA with Israel, centred on countries of the Americas. The FTA with Canada was concluded in 1989 and later formed, together with the accession of Mexico, the *North American Free Trade Agreement* (NAFTA) in 1993. NAFTA affirms existing WTO principles, such as national treatment and most favoured nation (MFN) for goods and services, and encompasses chapters on both TBT- and SPS-related measures. NAFTA also contains a trilateral framework for regulatory cooperation that encourages regulatory harmonization or mutual recognition where possible. The parties to NAFTA are, for example, to the "greatest extent practicable", obliged to make their respective standards-related measures compatible.[58]

Besides NAFTA, the US has gradually concluded FTAs with Central American countries and the Dominican Republic (commonly known as CAFTA-

DR). An all-inclusive, *Free Trade Area of the Americas* (FTAA) was negotiated for some time.[59] However, the FTAA negotiations failed in 2005. An FTA with Chile was concluded shortly thereafter. Other FTAs with American countries have been concluded with Peru, Panama and Colombia. The US has also concluded a number of FTAs with countries outside the Americas, such as Singapore, Australia, Jordan, Morocco and South Korea. In parallel with FTAs, the US is a party to the *Asia-Pacific Economic Cooperation* (APEC). APEC is a regional economic forum of twenty-one countries which promotes free trade in the Asia-Pacific region. Within APEC there is a framework for technical and regulatory cooperation. The cooperation aims, for example, at promoting convergence of national standards, alignment to international standards and transparency in standards and conformance requirements.[60]

Common to many US FTAs is that they reaffirm the principles established by the TBT Agreement, such as transparency, notice and comment, as well as consultation on specific trade concerns. In terms of more substantive obligations, many US FTAs require FTA partners to accredit or otherwise recognize US testing and certification bodies under terms that are no less favourable than those that FTA partners afford their own testing and certification bodies. Several FTAs also contain provisions that encourage the acceptance of each other's regulations as equivalent to their own. With regard to the interpretation of what constitutes an *international standard*, a number of US FTAs reinforce the application of the *six principles* (mentioned above under 4.1.1.) by referring to the *principles of the 2000 TBT Committee decision.*[61]

Facts

US mutual recognition agreements (MRA)

The US has an MRA on conformity assessment of telecommunications equipment (APEC TEL MRA) with countries in the APEC region. The APEC TEL MRA covers testing and type approval, electromagnetically compatibility (EMC) and electrical safety. The US also has operational MRAs with the EU on telecommunications equipment and EMC. Other MRAs have been concluded with Japan, Israel and several EEA/EFTA states.[62]

Numerous US FTAs tend to focus on providing the means for regulatory influence within FTA partners' rule-making processes, standards and conformance processes. This may enable systemic scrutiny of other countries' and US's regulatory systems, and the elimination of potential barriers to trade before they arise. Open consultation procedures also make it possible for different stakeholders, public as well as private, to influence regulations before they enter into force. Some FTAs, like NAFTA, contain committee-based cooperation within specific areas. The latest agreement, the US South Korea FTA, has also an extensive vehicle annex which ensures compliance with South Korean safety standards if they meet US federal safety standards.

4.2.2 General comparisons and possible future developments

Both the EU and the US have gradually expanded their FTAs into a network of agreements that stretch to various parts of the globe. However, EU and US FTAs differ in terms of how they converge or disperse their regulatory preferences with FTA partners.

EU FTAs tend to disperse regulations and standards that have been developed by international SDOs, and which the EU also abides by. The EU thus reinforces FTA partners' commitments and aligns them to systems which the EU, and its FTA partners, define as international. US FTAs do not tend to suggest particular regulatory systems in a

Facts

EU-South Korea FTA impact on trade

FTAs of the new generation are yet to be analysed in terms of how they impact on trade. However, initial estimates of the effect of the EU-South Korea FTA, an agreement of the next generation concluded 2011, generally indicate increased trade flows for sectors subject to regulatory annexes. While trade has generally increased between the parties, EU exports have increased into a trade surplus. Though it remains to be seen if the effects are attributable to the FTA, it cannot be excluded that regulatory cooperation and adaptations based on FTAs may impact on trade flows.[64]

similar way, but rather emphasize a model of open and transparent consultation procedures within FTA partners' rule-making processes. This approach of US FTAs may on the surface re-direct governmental ownership in fostering regulatory convergence towards other non-governmental stakeholders. Another general aspect is that EU FTAs are wider and more all-encompassing, whereas US FTAs tend to have a more legally enforceable language in a chosen set of areas, such as intellectual property protection.[63] Overall, this analysis suggests that the EU and the US reflect their regulatory preferences in concluded FTAs, especially taking into account their different interpretations of international standards.

With the trend of negotiating mega FTAs, like TTIP and TPP, there is a great opportunity to achieve regulatory convergence between many countries, particularly taking into account that many of these countries are parties to previously concluded FTAs. TTIP and TPP may facilitate the development of convergent technical regulations and product standards, and connect concluded agreements to mutually shared FTA frameworks. Alongside opportunities, there are also risks. As described above, EU and US FTAs often reflect their respective regulatory preferences. It is important in this regard that expanded FTA networks do not entrench positions in ways that fragment international regulatory practices. Solutions in TTIP and TPP should therefore correlate with each other where possible so that the prospects of finding common ground are improved.

4.3 Market Size and Regulatory Capacity

The sections 4.1 and 4.2 above have explained the macro tendencies that exist in the various constellations of regulatory cooperation in the context of the international standardization system and free trade agreements, and how the EU and the US relate to these settings. The following section analyses how regulatory regimes in different countries tend to interact and converge outside areas covered by regulatory cooperation and joint regulatory solutions, and how this affects the EU and the US.

How, for example, do different national or regional regulations and standards interrelate in the increasingly significant context of globalization? Important factors – such as increased commercial transnational interdependencies, global value chains, digitization and other mechanisms that define global challenges such as climate change and data protection – impact on industries' and regulatory agencies' regulatory preferences.

These aspects seem to generate a self-standing dispersal of regulatory solutions which is derived from a combination of global market realities and the regulatory capacity of the regulators that set the rules. Companies may adapt their production to a certain regulatory regime for the purpose of gaining global market advantages and increasing their competitiveness. For example, many motor vehicle manufacturers choose to comply with globally recognized Euro 5 or 6 vehicle emission standards instead of complying with a country-specific standard. They benefit from complying with a standard that is accepted elsewhere. Regulatory dispersal can also be derived from a certain regulatory model or solution that efficiently achieves its regulatory objectives, and hence inspires regulators in other countries to implement similar policies. An example of this is the Australian tobacco plain-packaging regime. It has inspired several European countries to propose similar plain-packaging reforms.

With regard to the regulatory cooperation sought for in TTIP and its potentially global impact, it is also necessary to reflect on the general dispersal of regulatory solutions that occurs outside the context of applied policy mechanisms and coordinated regulatory integration.

4.3.1 Market size and regulatory capacity of the EU and the US

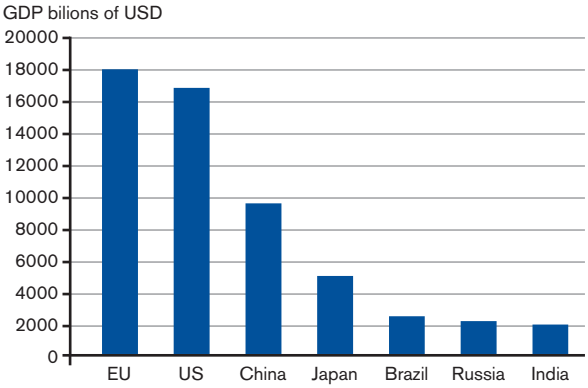
Few economies in the world have a regulatory capacity comparable to the EU and the US. Both the EU and US internal markets are each under a jurisdictional umbrella that makes them, with the exclusion of China, by far the two largest internal markets in the world (see Figure 11). The EU and US markets consist of about 500 and 320 million consumers each, and they are the first and second largest importers of goods and services. Many third country businesses base their production and business models on exporting consumer products to the EU and US consumer markets. Reaching out to either the EU or US internal markets can be vital when purchasing power in the domestic market or alternative third country markets is low, particularly when facing international competition.

However, access to the EU and US markets requires compliance with comparatively high levels of requirement expressed in regulations and standards. Both the EU and the US are among the strictest regulators in the world and they have sophisticated regulatory systems that cover most, if not all, products available to their consumers. Compliance with the applicable safety levels is ensured by regulatory agencies and governmental institutions, but also by industry self-regulatory regimes, company specific standards and civil society. If a foreign company wants to successfully export its products to the EU and the US it must comply with the regulatory regimes applied there. As a consequence, the combination of large internal markets and a strong regulatory capacity tends to translate into a regulatory adjustment and progression within third country production. Though it initially may create market access thresholds for less developed third countries, these dispersal effects can contribute towards raising product quality infrastructure in foreign markets, as well as improving the prospects of selling third country output elsewhere and in new markets.[65]

Accordingly, both the EU and the US share the market characteristics and regulatory structures that create dispersal effects of regulatory norms and standards to other parts of the world, but also between themselves. For example, during the seventies and eighties US regulations often influenced European regulatory practices. Swedish vehicle emission standards were modelled on those applied in the US, and US ozone protection standards and lead restrictions in fuel were copied in the EU.[66] Today, an increasing number of EU regulations and standards are externalized and dispersed outside the EU internal market, including to the US. This is particularly the case for regulatory areas where EU regulations are perceived as relatively strict and where company opportunity costs make it difficult for companies to sidestep the EU internal market. Regulatory dispersal tends to appear when compliance with EU norms leads to direct access, not only to the EU internal market, but also to most third country markets, as they may have less strict legislation in comparison to the EU.[67]

Emerging examples of EU regulatory dispersal appear in a number of sectors and product markets. The European chemicals legislation – *Registration, Evaluation, Authorization and Restriction of Chemicals* (REACH) – affects large groups of companies all

Figure 11. World's largest markets



Source: World Bank nominal GDP figures (2013)

over the world which voluntarily adjust their production to REACH-compliant standards. As chemicals are widely used in products, chemical regulation generally impacts on large quantities of different products, production processes and value chains worldwide. South Korea has implemented an analogous legislation to REACH (known as K-REACH) and the US States of Massachusetts, Maine and California have adopted stricter legislation than the federal chemicals legislation.[68] Canada, China, Japan and Russia have also adopted stricter legislation since the implementation of REACH in the EU.[69] The *European Restriction of Hazardous Substances Directive* (RoHS) is another EU regulation that is conformed to outside the EU. RoHS has had a significant global impact on the manufacture of electronic products as well as on the restriction of electronic waste, and has inspired legislators to implement similar types of regulations, including in China, Japan, South Korea, and California (the latter is known as Cal RoHS). Similar tendencies can be seen in other regulatory areas such as food safety, antitrust, vehicle standards and environmental protection areas such as the EU Emissions Trading Scheme (ETS).

4.3.2 Company-driven regulatory convergence

Dispersal of a set of regulations and standards from one country to another is, to a large extent, driven by businesses engaged in international trade. Private sector adjustment to stringent domestic regulatory regimes lies at the core of this development. In the search for new and more effective production processes in global markets, some global companies tend to avoid multi-regulatory environ-

ments and adapt to a single regulatory regime that generates access to the most beneficial markets. Complying with a single standard that is accepted elsewhere reduces the burden caused by market-specific product adaptations and may enable international companies to sustain a more efficient production chain. By converting their production to the most stringent standard, companies generally come closer to the type of predictable regulatory environment often striven for – a stringent standard is typically accepted within less stringent markets, but not vice versa.[70] As a result, regulatory adaptations among businesses do not only seem to trigger harmonization, they can also stimulate a *race to the top scenario* in areas where compliance with the strictest standards is necessary for entering the most lucrative markets.[71]

When exporting businesses choose to convert their production processes with the purpose of effectively reaching out to new markets, the regulatory environment present in its domestic market may become sensitive to upwards regulatory adaptations. Domestic regulatory leniency might cause uneven competition between national companies that have adapted to global standards and foreign competitors that have not. Governments and regulatory agencies are therefore, with the purpose of balancing competition, inclined to implement similar regulations to those applied in export markets. K-REACH in South Korea is, for example, an adaptation of the European original.[72]

Seen in this context, regulatory convergence and removal of regulatory incompatibilities between the EU and the US, would substantially increase the attractiveness of EU and US regulatory norms. TTIP therefore has the potential, in areas where there are no international standards, to support the dispersal of efficient regulatory practices and high quality standards to other parts of the world, as conformance to these standards would provide access to the combined markets of the EU and the US.

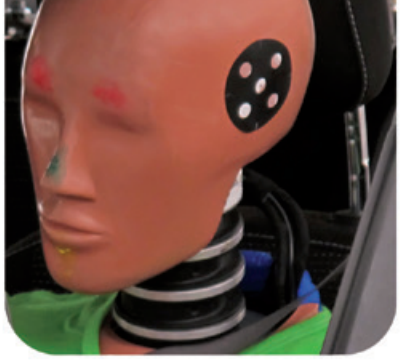
4.3.3 Agency-driven regulatory convergence

Besides market-driven regulatory dispersal, regulations and standards may also be synchronized through the mutual exchange and dissemination of information between regulatory agencies in different countries. Improved means of communication support the sharing of regulatory methodologies and solutions applied among foreign regulatory agencies. Many questions and queries that regulators face are of a cross-national nature and might be subject to studies and scrutiny elsewhere. This may involve basic regulatory areas, like consumer safety and health, or new regulatory areas, such as nanotechnology, additive manufacturing (3D printing), energy efficiency and data protection. Some regulatory agencies may therefore look at foreign regulatory solutions in terms of finding new and efficient regulatory solutions that correspond to desired performance and overall levels of requirement.

Taking *regulatory inspiration* from foreign agencies is not uncommon between the EU and the US. For example, many European regulatory agencies were influenced by US environmental protection policies such as emission standards and better regulation practices.[73] Now, and in the future, it is not unlikely that similar regulatory dispersal will also increase between agencies in developed and developing countries. Many developing countries, particularly emerging economies, are about to build up product regulatory systems in support of the increasing welfare ambitions of their growing middle-class populations. This may require the type of expertise and experience that regulatory agencies in the EU and US possess.

Regulatory capacity translated into competent and capable agencies that can produce qualitative impact assessments, apply better regulation principles and achieve satisfactory regulatory outcomes is consequently a substantial factor with regard to the dispersal of good regulatory solutions, particularly the ability to extract knowledge and expertise among broadly defined stakeholder groups and support a regulatory environment that fosters innovation and growth. Agencies that are open to informal transnational networking and sharing regulatory ideas are probably in a better position to achieve good regulatory outcomes and reduce costs associated with regulatory differences.[74]

Cooperation between EU and US regulatory agencies through TTIP could, in this regard, foster a benchmark environment where regulatory knowledge and experiences are exchanged for the sake of better and more qualitative regulation – regulation that can better adapt to changing global realities, like for example the emergence of new technologies and new trade patterns, and satisfy legitimate public interests such as human health and environmental protection.

4.4 Summary of the three main arenas

The EU and the US are strong partners that share fundamental views on a rule-based international order. While being partners, they also compete with each other. In various fora of international regulatory cooperation and rule-making, both influence and exert views as a reflection of their own regulatory systems. Different policy projections seem to follow from the fact that the EU and US regulatory systems differ in *how* they achieve certain regulatory outcomes, rather than the outcomes themselves. This report shows that the EU and US divergent views on international standardization and rule-making are reflected in several arenas, such as their participation in international standardization, how they define international standards and how they form FTAs with their trading partners. Both bridge the gap to the international level based on their own stakeholders' interests and overall regulatory state of affairs.

International standardization
Different interpretations of what constitutes an international SDO and an international standard divide the EU and the US when it comes to international level regulatory cooperation. In simple terms, the EU recognizes standards as international ones depending on who developed them, whereas the US emphasizes *how* they were developed. In practice, this implies that the EU only recognizes non-domestic SDOs, while the US also recognizes domestic SDOs, including SDOs established in the US.

These interpretational differences can be explained by the distinct set-ups that exist in the EU and the US. For example, the EU has a regional regulatory system that empowers the EU at international level and strengthens EU policies in the context of international regulatory cooperation. The EU has structural benefits emanating from expanded and externalized policy scopes in the context of regulatory cooperation among countries, within and outside the EU. In comparison, the US has a regulatory system that offers highly efficient and decentralized solutions in its market. At international level, the US may perceive voting disadvantages which do not match its internal market size and regulatory capacity. Where the EU would prefer an international solution based on an international structure that it finds to be globally recognized, the US would widen the meaning of *international* and avoid being bound to an order where it cannot act in accordance with its perceived power.[75]

From a macro perspective, interpretational differences affect the status of international standards and create uncertainties in terms of what significance international standards may have. A common understanding between the EU and US would increase the predictability and reliance of the international standardization system and counteract the emergence of new trade barriers due to non-compatible standards.

Free trade agreements
Both the EU and the US are in the process of negotiating numerous FTAs with third countries. Concluded EU and US FTAs with third countries have taken different forms and have had different pur-

poses. For example, many EU FTAs are essentially accession agreements, or agreements that generally approximate national regulations and standards with European ones. Others, and particularly US FTAs, are more focused on establishing bilateral terms of trade and are directed toward certain areas, like intellectual property protection.

A general trend, as the EU and US are now negotiating new FTAs, is that these are more comprehensive and substantial than previous FTAs. Measures to address NTBs, such as sector provisions, product standards and regulatory cooperation, are becoming increasingly important. In this regard, the EU and the US tend to emphasize different approaches in terms of achieving regulatory convergence with third countries. EU FTAs appear to promote the dispersal of international regulatory solutions which are also applied in the EU. In comparison, the US promotes consultation and transparency procedures within third countries' rule-making procedures and their emphasized definition of international standards.

As both the EU and the US endorse approaches that fit with their regulatory practices – approaches which in some cases are mutually non-compatible – there is an increased need to reach agreement in important areas when new and more comprehensive FTAs are negotiated. This is particular important with regard to so-called mega FTAs like TPP which, alongside TTIP, may bring a large part of global GDP output under FTA regulatory regimes.

Market size and regulatory capacity

A combination of market size and regulatory capacity have affected the ability of the EU and the US to disperse regulatory solutions between themselves and other countries. Large internal markets and strong regulatory institutions tend to influence foreign businesses and national agencies to make regulatory adjustments in compliance with the strictest requirements applied in the largest markets. A self-standing regulatory harmonization seems to be generated when businesses with an international presence avoid multi-regulatory environments and adapt to a single regulatory regime that generates access to the most beneficial markets. The EU has, in this regard, dispersed its regulations and standards in areas where it is perceived as the strictest regulator. This is particularly evident in the area of environmental protection, where REACH and RoHS influence foreign businesses and stakeholders. Regulatory adjustments among businesses also tend to influence regulatory agencies to make corresponding legal adjustments in their domestic markets.

When regulatory solutions are dispersed and achieve international recognition, this can have substantial economic and societal effects. For example, businesses can avoid switching costs and increase their competitiveness if the standard they apply achieves international recognition. Public policy objectives may be better accomplished if a particular interest is incorporated into a globally recognized standard. When EU and US regulatory solutions are mutually incompatible they might negatively affect the other on a global scale. This is particularly true if one side's standards attain worldwide dispersal, but the other's do not. Regulatory distinctions, which are essentially unnecessary, can therefore cause regulatory competition between the EU and the US, which creates unnecessary barriers to trade and hampers the dispersal of good regulatory solutions.

Increased regulatory convergence between the EU and the US has great potential, since the acceptance of mutually compatible requirements would give access to the combined EU and US market. Many businesses around the world would, as a result, be able to benefit from adopting combined EU and US regulatory solutions. Such scenario could have ripple effects, minimize regulatory fragmentation and trigger global regulatory improvements in areas such as environmental protection and human health.

5. Future International Regulatory Convergence and TTIP

The focus of this report has so far been on describing international rule-making, comparing the EU and US product regulatory systems and clarifying how both systems have converged globally. This chapter expands the conclusions drawn from previous sections and puts them into the context of TTIP, as well as future international regulatory convergence.

One of the conclusions drawn is that the product regulatory systems of the EU and the US are built in different ways and abide by distinct principles. The main differences relate to the essential objectives of their internal markets and the role public policy objectives and implementation have in terms of actively facilitating regulatory integration and trade. For example, the EU pursues the fulfilment of its internal market by removing cross-national regulatory differences. Harmonization and strong regulatory alignment lies at the centre of this development. The US does not direct trade engagement as the EU does, but is more inclined to ensure that the market has the best conditions to nourish itself and to define its own way of direction. The US allows for regulatory plurality and competition in achieving commercial outcomes.

The EU has a regional structure and the US has a national one. This affects how the gap to the international level is bridged. Both have promoted international outcomes that fit with their respective product regulatory systems. The EU vests its power in international standardization organizations that acts as harmonizing focal points in specific sector areas and structurally develop regulations and standards for global dispersal. Instead of emphasizing *who* the developer of an international standard is, the US tends to focus more on *how* the standard is developed in order for it to be an international standard. The US thereby opens for several, and potentially conflicting, international standardization organizations, and diverts from an international structure which is cohesive and hierarchical to a more pluralistic and fragmented one.

These fundamentally different approaches split international rule-making into two. The EU promotes what it conceives as international standard bodies, while the US push for international standardization according to its definition.[76] If TTIP can converge EU and US regulatory approaches, the likelihood of bridging that split at the international level would increase – which would improve global rule-making, transparency and be of benefit of trade through the removal of unnecessary cross-national regulatory differences.

The following section provides a proposal of how each side's product regulatory systems can be connected, while at the same time keeping the identity of their systems intact and allowing for other countries to participate in the future. This proposal does not offer a complete solution for TTIP's regulatory pillar, but should instead be understood as an opening for dialog and reflection. Its purpose is to identify elements that may be crucial for future regulatory cooperation between the EU and the US and contribute to an ambitious TTIP that functions as an effective deterrent to unnecessary barriers to trade.

5.1 A Transatlantic Standards Approval Scheme

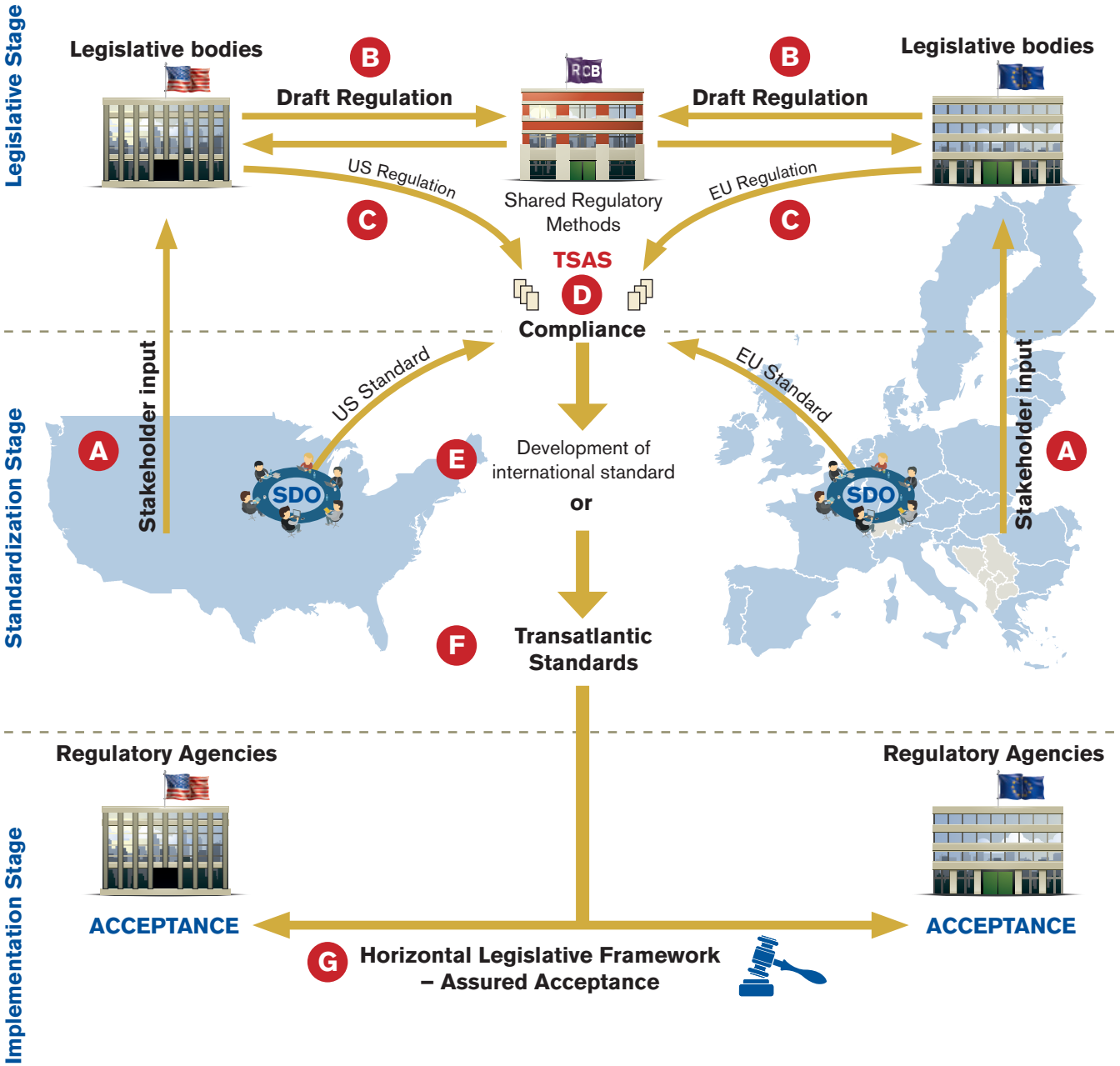
Over the past two decades, a structure for transatlantic regulatory cooperation has gradually been developed. A set of guidelines on regulatory cooperation and transparency, annually adopted road maps intended to implement the guidelines, a high level forum for regulatory cooperation, and a body of political oversight, the *Transatlantic Economic Council* (TEC), are all results of previous regulatory cooperation efforts. If a structure for cooperation has been gradually developed, what has been lacking – with some exceptions – is the actual implementation of the concepts aiming to reach harmonized, equivalent or compatible solutions, and to minimize or eliminate unnecessary regulatory divergence. TTIP now offers an opportunity to address this.

In the area of standards, global efforts to unify various product regulatory systems have so far focused on either placing a specific status on the *body* that develop standards or defining the *procedures* for how standards are to be developed.[77] However, when looking at the peculiarities and differences of the EU and US product regulatory systems there is a need to consider another approach – an approach that can utilize the best features of the two systems, offer flexibility where they are different and reinforce the components that they have in common. A *Transatlantic Standards Approval Scheme* (TSAS) can lay the foundation for this and support the much-needed implementation that has been previously sought.

5.1.1 TSAS Model

The TSAS model outlined below offers a framework that could be explored in TTIP. The model is based on areas where EU and US regulators may cooperate and establish common regulatory requirements through the proposed Regulatory Cooperation Body (RCB). Standardization is thus linked to cooperation among EU and US regulators. Various forms of cooperation that EU and US SDOs may engage in outside the legal sphere is not included in the TSAS model. TSAS offers a starting point for cooperation to take place on standards and may create spillover effects on privately organized cooperation between the EU and US on standards. Note also that the TSAS model, at this stage, only covers EU harmonized areas and US federal level. The flowchart provides an overview of the TSAS model. Each step in the legislative and standardization processes are commented in A, B, C, D, E, F and G.

Figure 12. The Transatlantic Standards Approval Scheme (TSAS) Flowchart



Description of the Transatlantic Standards Approval Scheme (TSAS) Flowchart

A Ordinary law-making processes in the EU and the US. Various stakeholders provide input to legislative initiatives.

B Legislative and regulatory proposals are communicated to the EU-US counterpart for comment. Information exchange takes place via the RCB. Regulatory dialog may result in steps being taken to achieve regulatory convergance between the EU and the US. It may also result in the common identification and adoption of a relevant international standard, or no cooperation at all. EU and US legislative bodies are encouraged to agree on certain essential regulatory requirements that can be supported by standards and conformity assessment procedures.

C If the EU and US can agree on shared regulatory methods that are based on essential requirements and have these essential requirements approved by EU and US legislators, both the EU and the US should submit their respective regulation to the RCB and TSAS. European and American SDOs are then free to send their draft standards to the RCB and to seek compliance to the essential requirements settled in *both* EU and US legislation. If the EU-US essential requirements differ in a way that make transatlantic standardization impossible or make standardization difficult to justify from a cost-benefit perspective, ordinary EU and US standardization procedures take precedence. This makes the TSAS process self-regulated.

D TSAS constitutes the link between legal requirements and standards. TSAS allowes EU and US SDOs to coordinate their activities in the context of a predifined transatlantic structure. EU and US SDOs are encouraged under TSAS to cooperate and develop shared standards. TSAS may also allow non-identical standards if both technically can comply to the essential requirements defined in both EU and US legislation. Compliance between legal requirements and proposed standards could be settled by a specifically appointed board under the RCB. A TSAS Board could for example consist of representatives from EU and US regulatory agencies and SDOs that possess the technical and judicial competences needed.

E TSAS aims to trigger voluntary EU and US cooperation on standards. When SDOs explore the different ways of meeting the essential legislative requirements through a standard, TSAS should encourage them to assess if there is a need to initiate a joint EU-US development of an international standard through ISO, IEC or other relevant international standardization body. The process of developing a transatlantic standard would then be replaced by an international standardization process.

F If there is no need to intiate an international standardization process, approved EU-US standards effectively become transatlantic standards. Transatlantic standards would constitute an intermidiate step between EU and US standards in areas where international standards are absent. Gradual approximation between EU and US standards may facilitate the development of future shared international standards.

G In order for TSAS to be efficient, transatlantic standards need to be assured trust and status in both the EU and the U.S. TSAS must therefore be supplemented with a strong framework that efficiently guarantees acceptance of transatlantic standards on both sides. The shared regulatory methods established in B and C should link conformity assessment to the horizontal framework in D.

5.1.2 Explanatory note

This explanatory note provide a more detailed description of TSAS.

Various pathways

An essential objective for an effective implementation of TTIP is the voluntary development of high-quality standards that can be applied in both the EU and the US. Until now, there have essentially been two alternatives for achieving mutually compatible standards between the EU and US, either integrating the EU and US standardization systems through mutual participation between EU and US SDOs in the standardization processes, thus creating mutually developed standards, or allowing standards developed separately in the EU and the US to be accepted by the other party and run side-by-side. Cooperation between EU and US SDOs has so far been inefficient in terms of eliminating standard induced technical barriers to trade.[78] There seems to be inherent difficulties in agreeing to, and finding the practical means for, mutually developed standard solutions that achieve trustworthy long-term outcomes. An option yet to be explored is an approach that would combine the development and application of shared identical standards, while also allowing for specific EU and US standards to be accepted, under certain conditions (under the TSAS), in each other's markets.

Joint regulatory principles

Despite substantial differences, both the EU and US standardization systems support equivalent outcomes in bringing forward high quality standards. A common feature among EU and US legislators and regulatory agencies is that they provide the legal backing that ensures these outcomes – they ultimately lay the foundation for safe and reliable products. Commonality in terms of regulatory objectives is therefore a key area that should be taken advantage of. The development of standards that correspond to both EU and US legislation would be simplified if regulatory agencies adapted to joint EU-US law-making principles and best practices. Technical specifications in legislation should preferably be modified with essential performance-based requirements that define acceptable methods of showing conformity. This can be done through transatlantic dialog and the proposed RCB when new legislation is drafted or when a legislative act is revised. A shared acceptance standards will require a common methodology of evaluating the standards' performance in relation to the applicable legislation, not unlike the new approach doctrine applied in the EU.

Market access

The US product regulatory system is strongly characterized by a plurality of SDOs and standards. This may very well support the development of innovative standards and generate competitive solutions in the marketplace. However, according to the European experience, competing standards may also create hurdles to market access and hamper economic integration between countries. While recognizing that multiple standards can support

innovative industry solutions, there is also a risk that fragmented standardization leads to country-specific and market-unique solutions that hamper trade and effectively restrict market access. Meanwhile, a system based on standards singularity can have similar effects in relation to a system that do not, or cannot, systematically abide to one accepted standard. It is therefore central that TTIP remove market access barriers created by divergent standards and offer solutions that accept standards based on what they achieve.

Shared standards

One way forward is to accept a process that under certain conditions may allow shared EU and US standards to enter each other's markets and limit legally induced market access restrictions. For example, in areas where compliance to standards is mandatory, it should in principle be possible to accept EU and US standards if relevant regulatory agencies can be assured that these standards comply with the applicable EU and US legal requirements. Regulatory agencies should therefore more easily allow both EU and US standards, if they can be assured that a given standard achieves an adequate outcome in relation to applicable legislation. Market-based competition between standards would then not be essential for market access. Both the EU and US standardization systems include procedures for assessing standards relationship to mandatory requirements – the question is rather about privilege and market status of domestic standards. A middle way is to find a flexible procedure that links the EU and US systems – a procedure that determines if a certain standard fulfils requirements set in both EU and US regulations and whether a standard is compatible with other standards in a given area. This may eliminate the risk of non-compliant EU and US standards and create a threshold that defines lowest acceptable deviation between EU and US standards.

Common approval of standards

In order to ensure standards' compatibility with mandatory requirements, a scheme for approving standards should be considered. Approval of standards could be conducted by a central focal body, with a board of experts from both the EU and the US, or through an accreditation scheme that can ensure competence and independence. The standards approval scheme would allow for, where possible, an approval that the standard confirms the essential requirements set out in EU *and* US legislation. In practice, approved standards may, depending on the essential requirements and the assessment of an independent body, be identical or, where acceptable, equivalent. A product manufactured according to approved standards would then be *granted* market access in the EU and the US. Manufacturers should be able to rely on one standard entry. Access to the transatlantic market would trigger the SDOs to develop standards that can fit both EU and US markets and their regulatory systems.

Mutual trust

When implemented, a standards approval scheme, would allow mutual trust to grow between regulators in the EU and the US. However, the effectiveness of this mechanism is dependent on a joint EU-US implementation of a *horizontal legislative framework* that allow for the necessary legal flexibility and variations between the EU and the US, while at the same time ensuring a certain commonality with regard to how standards are accepted. It is essential that both sides *guarantee* that their regulatory agencies accept approved transatlantic standards. By focusing on the practices of regulatory agencies, promoting the use of general essential requirements and expanding their implementation gradually in certain areas, the integrity of EU and US standardization systems stays intact. The aim of an approval scheme is to allow for two systems to run in parallel, not the identification and exposure of superior or inferior standardization systems.

Conformity assessment

A robust system which creates confidence on both markets requires that the conformity assessment procedures are reliable and predictable. This can be achieved in a number of ways. The conformity assessment procedure to be followed in each regulatory area can be defined in the context of establishing shared regulatory methods via RCB. This would eliminate perceived risk of divergent results of conformity assessment due to divergent choice of procedures. The regulators, within the framework of RCB, would have to agree on procedures for conformity assessment. A way forward is to establish a transatlantic register of conformity assessment bodies. Regulators would then have to commit to registering the CABs which meet the

requirements in both the EU and the US. The adoption of transatlantic standards under TSAS offers an opportunity to link legislative requirements and standards to conformity assessment.

Functionality
Products may often be produced in accordance with a set of mutually compliant standards. Changing one standard in a product could imply that the product becomes inoperable, or could conflict with other standards in the marketplace. These are practical issues that will have to be dealt with under the approval scheme – the TSAS-board will have to assess, based on available technical expertise and documentation, acceptable levels of deviation between standards. This may result in the need for identical standards or, in areas possible, allow for non-identical standards that are mutually compliant and achieve sufficient functional equivalence.
A TSAS assessment may also result in the dismissal of transatlantic standards in areas where the EU and US deviate too much. An initial step would be to implement the approval scheme in sectors that are appropriate for enhanced cooperation and in new regulatory areas. An approval scheme would not create fast improvements, but is more of a long-term mechanism that over time would bring EU and US standards closer to each other by virtue of direct access to a combined EU and US marketplace.

Global potential
A standards approval scheme has the potential to foster and support shared EU and US positions with regard to international standards through ISO, IEC and other relevant bodies.[79] The bilateral approximation of EU and US standards through the TSAS could constitute a step towards identifying mutually pursued international outcomes. Bringing EU and US standards closer to each other may enable a dialog on how the EU and US can cooperate in the development of shared international standards. The recognition and acceptance of international standards, defined as *the* relevant standard, should therefore be a long-term objective of TTIP. Additionally, there is no structural hindrance for TSAS to include foreign standards where appropriate. The scheme would not have to be dependent on the origin of the standard in order to approve standards. It would, however, be necessary for participating countries to implement the legal principles in the horizontal legislative framework mentioned above, so that approved EU and US standards are able to access the other party's market on equal terms. A standards approval scheme has the potential to create shared methods of connecting standards to legislation and developing global regulatory practices in areas where predominantly domestic standards exist and where international standards remain to be developed. The global potential of an approval scheme lies in its scale advantages – it can be widened to include new regulatory areas and new countries. Common means of approving standards could also be elaborated further in the context of the WTO and extend existing global efforts of reducing unnecessary barriers to trade.

Facts

TSAS in brief

1. A structure that supports long-term development of transatlantic standards
2. A process that pursues the formation of shared EU-US international standards with account taken to existing structures
3. A controllable and cohesive process that includes several stages before a transatlantic standard is approved in a given area
4. Preservation of existing EU and US standardization systems and business models
5. Shared EU-US regulatory practices in defining essential legislative requirements that standards can comply to
6. Recognition of the legislators' role in providing appropriate conditions and incentives for the development of trans-atlantic standards
7. Recognition of the SDOs' role in finding shared or mutually convergent transatlantic standards
8. Assurances of an efficient implementation on both sides
9. Acceptance of shared standards developed in accordance with a predefined approval system
10. A starting point for future cooperation between EU and US standardization bodies and identification of commonly shared objectives

5.2 Final Comments

TTIP offers an opportunity to reconcile EU and US perspectives when it comes to regulatory cooperation and convergence. If the EU and the US come closer to each other and match their regulatory preferences, this would strengthen their joint interests in a strong free trade system in accordance with WTO principles and the removal of unnecessary barriers to trade. A *transatlantic* dimension to regulatory practices is therefore not only a way of reaching consensus and agreement on specific regulatory issues, but also something that can have an impact, for the benefit of trade, at a global level. As international standardization activities increase, new free trade agreements are negotiated, and regulations and standards are dispersed when markets integrate – shared EU and US regulatory practices may lay the foundation for future models of regulatory cooperation between countries, the promotion of good regulatory practices and efficient regulatory solutions.

The risks of not agreeing on TTIP could prove damaging not only for transatlantic cooperation and the businesses that are dependent on each other's markets, but also with regard to global regulatory progression. Entrenched EU and US positions may hold back the benefits that regulatory convergence could generate in terms of eliminating unnecessary barriers to trade. It could also lead to the further fragmentation of sector markets that are characterized by competing regulatory regimes that are mutually incompatible (like for motor vehicles). The emergence of new economies that pursue the establishment and externalization of their own regulatory models may also deepen regulatory fragmentation if there is no deepened cooperation model in place that could in the future be transferred to the WTO.

This report has shown how EU and US regulatory disconnection is reflected at international level. The report has, in this regard, put forward a concrete proposal for how regulatory cooperation between the EU and the US, in TTIP, can move regulatory competition towards convergence for the benefit of trade and improved global regulatory frameworks.

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DS 231, EC-Sardines, 2002

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Notes

1 Standards Developing Organizations.

2 The WTO Agreements Series (2014), p. 14.

3 The WTO Agreements Series (2014), p. 14.

4 Büthe, T., Mattli, W. (2011), p. 132-136.

5 Article 2.4.

6 Article 2.5.

7 Dispute settlement cases have confirmed the enforceability of these provisions; see EC-Sardines and US-Tuna.

8 The SPS Agreement defines three organizations as developers of international standards. The Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention.

9 Annex 1, point 4.

10 Büthe, T., Mattli, W. (2011, p. 5.

11 China's Product Quality Law calls, for example, on government agencies to use international standards for certification.

12 Büthe, T., Mattli, W. (2011), p. 137.

13 Drezner, D. W. (2011).

14 Drezner D.. W. (2011).

15 National Board of Trade (2015).

16 It has even been argued by a US SDO that the NBT has been in contact with, that it would be misleading to reference the US standardization system as national as it is in fact a decentralized system.

17 Büthe, T., Witte, J. M. (2004), p. 27-28.

18 Harmonized standards are referenced in the Official Journal of the European Union.

19 Harmonized standards cover fourteen areas: chemicals, conformity assessment and management systems, construction, consumer and worker protection, energy efficiency, electric and electronic engineering, healthcare engineering, measuring technology, mechanical engineering and means of transport, community postal services and sustainability.

20 For more information visit http://ibr.ansi.org/. Note that IBR may require that they be made reasonably available to persons who are affected by the law. Many SDOs have their own means of making standards available. Some standards, primarily standards developed by ISO and IEC and some other SDOs, are made available by ANSI.

21 See for example *National Technology Transfer and Advancement Act* (NTTAA) and OMB Circular A-119.

22 However, Congress has in a few cases instructed regulatory agencies to make reference to a specific standard according to US sources that the NBT has been in contact with.

23 Büthe, T., Mattli, W. (2011), p. 154.

24 Read more about PINS in summary "ANSI PINS Process: An Informative Summary (2013)" at http://ansi.org

25 Büthe, T., Mattli, W. (2011), p. 150.

26 See Regulation 765/2008 "setting out the requirements for accreditation and market surveillance relating to the marketing of products".

27 There is substantial cooperation between national market surveillance authorities, for example through rapid exchange of information on dangers arising from the use of products (RAPEX) and the Information and Communication System for Market Surveillance (ICSMS).

28 There are areas where public authorities may conduct inspection activities, like in the area of occupational safety and health.

29 Note that many national SDOs in the EU are financed through membership fees and sale of standards.

30 Note that this is a non-exhaustive list. ASTM is in parenthesis as its status as an international SDO is contested.

31 ISO in figures published at www.iso.org.

32 Estimates found in Büthe, T., Mattli, W. (2011), p. 140.

33 Büthe, T., Mattli, W. (2011), p. 141-144.

34 Find out more about PSDOs at www.iso.org.

35 Documents which are nationally adopted per ISO/IEC Guide 21.

36 These are the principles expressed in the guideline *"2000 Decision on Principles for the Development of International Standards, Guides and Recommendations (2000 Committee Decision)"*.

37 Decisions and Recommendations Adopted by the WTO Committee on Technical Barriers to Trade. G/TBT/1/Rev.9.

38 Büthe, T., Witte, J. M. (2004), p. 40.

39 Hamilton, D. S. (2015), xi-xii.

40 Under Working Party 29.

41 Formally titled: "Agreement concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions".

42 The US is however party to the less legally binding 1998 Vehicle Regulation, formally titled: "Agreement concerning the Establishing of Global Technical Regulations for Wheeled Vehicles, Equipment and Parts which can be fitted and/or be used on Wheeled Vehicles

43 Vogel, D. (2012), p. 8.

44 Jacoby, W., Meunier, S. (2010), p. 307-308 and Meunier, S., Nicolaidis, K. (2006), p. 910-911.

45 G/TBT/N/USA/518.

46 EC-Sardines ABR, paras 225-227.

47 With regard to EU and US export of regulatory approaches, see Horn, H., Mavroidis, C. P., Sapir, A. (2009).

48 Note that the figure include FTAs, CUs and Partial Scope Agreements. The vast majority (approx. 80 percent) are FTAs.

49 Note that the figures exclude accession agreements to the EU. Likewise, FTAs that countries hold with the EU are considered as agreements with one country instead of twenty-eight. Note that partial scope agreements (PSA) signed under the Enabling Clause are excluded in figure 7.

50 The chart shows the "domestic market access" (national GDP) of the countries added with the expansion of market access created by FTAs, measured by the GDP of the FTA partners (as of April 2015). Note that these figures do not provide information about the quality of the FTAs. Only partner countries with which the country/region has an agreement classified in WTO's regional trade agreements information system as a free trade agreement or a customs union is included. The data includes FTA notified through GATT Article XXIV, GATS Article V or the enabling clause. Partner countries with which the country/region has a single partial scope agreement or a single economic integration agreement are not included in these figures. GDP figures for 2013 were not available for the following partner countries: Andorra, Faroe Islands, Palestinian Authority, Barbados, Taipei, Syria and Myanmar.

51 EFTA includes Iceland, Lichtenstein, Norway and Switzerland. Note however that Switzerland is not a party to the EEA.

52 See CU between the EU and Turkey (articles 8-10).

53 Note that several of these non-EU countries, like EFTA countries and Turkey, are members of European SDOs (CEN and CENELEC). Countries in the Balkans, Eastern Europe and the South Mediterranean are affiliated members of European SDOs.

54 See for example the FTA between the EU and Tunisia (article 40).

55 EU Commission (2014), *MRA Newsletter*, N. 8.

56 Commission staff working paper, Agreements on Conformity Assessment and Acceptance of Industrial Products (ACAAs), SEC (2004)1071.

57 National Board of Trade (2015).

58 Article 906(2) NAFTA.

59 With the exception of Cuba.

60 Cooper, W. H. (2014).

61 United States Trade Representative (2014).

62 For more information: See National Institute for Standards and Technology (NIST), www.nist.gov.

63 With regard to EU and US export of regulatory approaches see; Horn, H., Mavroidis, C. P., Sapir, A. (2009).

64 The EU-Korea FTA implementation after 3 years, EU Commission TPC document, 23 October 2014. The US-Korea FTA was concluded a year later in 2012.

65 These effects are specifically documented by Vogel, D. and Bradford, A., among others. See, for example, Vogel, D., & Kagan, R. A. (2004) and Bradford, A. (2012).

66 Vogel, D. (2012), p. 8.

67 Bradford, A. (2012).

68 For example, California's Safe Drinking Water and Toxic Enforcement Act (Proposition 65).

69 Filipec, O. (2014).

70 Bradford, A. (2012).

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73 Vogel, D. (2012), p. 11-12.

74 Wiener, J. B., Rogers, M. D., Hammitt, J. K., Sand, P. H. (2011).

75 These distinctive EU and US approaches are confirmed by the statistics showed on page XX regarding identicalness to ISO and IEC standards, and the National Board of Trade's own observations from the WTO TBT Committee.

76 An EU Commission civil servant that the NBT has been in contact with pointed out that the US position differs from most other countries' position.

77 See for example, in the context of the WTO, the TBT Agreement and the SPS Agreement.

78 EU Commission report (2015). Most SME's that participated in the survey defined TBTs as the major barrier in transatlantic trade.

79 The joint statement between EU and US industry associations Orgalime and Mena is an example of cooperation with regard to ISO and IEC standards. The document is available at http://www.orgalime.org/position/ttip-joint-statement-eu-and-us-industry-associations-orgalime-and-nema.

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